



EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE SINCE 1994



**EXPRESS
Pharma
World
Expo 2027**

India's First Knowledge-led,
Future Focus Pharma Expo

3 4 5
March 2027

 **BEC Goregaon,
Mumbai**

SEPTEMBER 2026, ₹ 40

PIOMA
chemicals
— Partnering Through Innovation —



Vanderbilt Minerals, LLC
A Wholly Owned Subsidiary of R.I. Vanderbilt Holding Company, Inc.

VEEGUM®
Magnesium Aluminium Silicate



- **Suspension:** permanently prevent caking / sedimentation
- **Toothpaste:** prevents drying up / water separation while giving fine texture
- **Emulsion:** prevents emulsion breaking while giving fine texture
- **Tablets:** Improves dissolution, binding & flow properties
- **IT's NOT A THICKENER BUT A STABILIZER!**



The **right ingredient** can
make all the difference
in your formulations



Talk to us
for more information

502, Natraj Commercial Complex Condominium, 194, Sir M.V. Road, Andheri (East), Mumbai - 400069, Maharashtra, India.
Tel: +91-22-45212000 | Email: products@pioma.net

MIWON

Surfactants, Conditioners & Hair Fixative

- Cetrimonium Chloride (CTAC 29)
- Polyquaternium Chloride (Polyquat 10)
- Stearamidopropyl Dimethylamine (SAPDA)
- Sodium Lauroyl Sarcosinate
- VP / VA Copolymer



The **right ingredient** can
make all the difference
in your formulations

Talk to us
for more information

502, Natraj Commercial Complex Condominium, 194, Sir M.V. Road, Andheri (East), Mumbai - 400069, Maharashtra, India.
Tel: +91-22-45212000 | Email: products@pioma.net



EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE SINCE 1994
SEPTEMBER 2026, ₹40



Post event

FDD Conclave:
Ahmedabad Connect

INDIA'S RACE

— FOR THE —



CDMO CROWN

Global pharma is diversifying its manufacturing base. Can India move beyond cost advantage to win strategic CDMO partnerships on quality, technology, speed and scale?





AXO1000 TUBE FILLING MACHINE

- Output – Up to 5100 Tubes Per Hour
- USFDA Compliant
- High Accuracy Filling
- Tool-less Changeover
- Small Footprint
- Same Machine For Metal/Lami Tubes
- Low Rejection Level
- Zero/Negligible Maintenance Cost
- Low Power Consumption
- Low Air Consumption



Creative packaging built on consistent production performance.

Modern pharmaceutical manufacturing demands equipment that delivers both flexibility and uncompromising performance. INVPack Sachet & Stick Packing Machines enable creative packaging formats that help brands stand apart, while AXO Series Tube Fillers minimise downtime through rapid, intuitive changeovers – every machine engineered to deliver the precision, reliability and scalability required by manufacturers who expect more from every production line.



MVA12 SACHET PACKING MACHINE

- Output – Up to 1200 Packs Per Minute
- USFDA Compliant
- High Accuracy Filling
- Small Footprint
- Low Rejection Level
- Zero/Negligible Maintenance Cost
- Low Power Consumption
- Low Air Consumption



For more information, call +91-22-69010532 or email customer.service@vaxom.in.

V **vaxom**



GANDHI

Automations Pvt Ltd

India's **No.1** Entrance Automation & Loading Bay Equipment Company



Differential Air Pressure



Under Pressure



Over Pressure

Clean Room High Speed Doors (Self-Repairing)

- Heavy duty automatic flexible door featuring special and innovative self-repairing system; should the curtain accidentally get dislodged, it automatically be recovered with a simple opening and closing operation.
- High door efficiency & low permeability values
EN 12426 EN 12427 : $< 12\text{m}^3/\text{m}^2\text{h } \Delta 50 \text{ PA}$.
- Size upto: 4000 mm (W) x 4000 mm (H).
- Operating speed and superior sealing properties improve traffic flows and provide environmental control and savings on energy costs.
- Concept of low air permeability in pressurized rooms with positive and negative air pressure.
- Heavy-duty motor: 230V three phase, opening speed upto 2.0 m/s with inverter system.

Dock Levelers | Dock Shelters | Fire Rated Shutters / Doors | Rolling Shutters | Sectional Overhead Doors

STAR EXPORT HOUSE (Government of India Recognised)



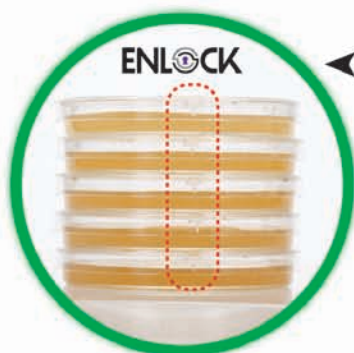
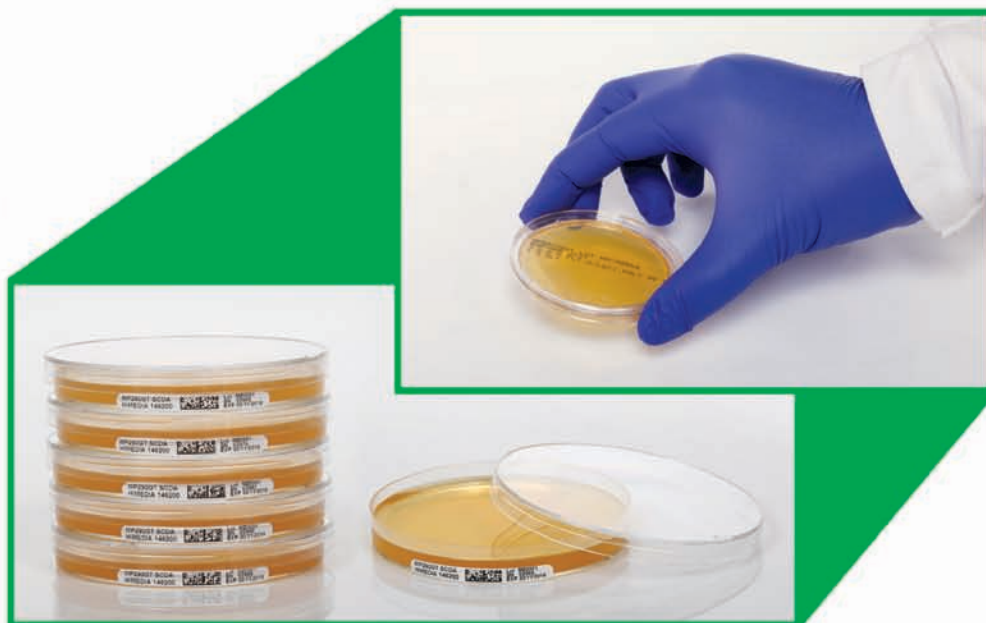
TOLL FREE
1800 209 0200
From Anywhere in India

Corporate Office : Chawda Commercial Centre, Link Road, Malad (W), Mumbai - 400064, India

Tel : +91 22 6672 0200 / 0300 (200 Lines) | Fax : +91 22 6672 0201 | Email : sales@geapl.com | Website : www.geapl.com

Ready Prepared Media

EM-CULT[®]



LOCKABLE PLATES

- New lockability feature incorporated to avoid accidental opening of plates during handling

BARCODED PLATES

- Barcoded format with all the relevant details like Product code, Lot. No. Expiry date, Unique plate number available



STATE OF THE ART MANUFACTURING FACILITY

- Internationally recognised quality
- ISO 9001:2015, ISO 13485:2016 Quality management systems
- WHO GMP compliant clean zones
- Production capacity of 1,50,000 plates/day



Prepared Media Plates, Prepared Liquid Media, Ready Prepared Transport Swabs, Tuberculosis Identification Slants, Rapid UTI Diagnostic Tests, Biochemical Identification Test Kits, HiBio-ID[®] Test Kits, HiDip Slides[®], Multifunctional HiTouch[®] Flexi Plates, HiSafe Blood Culturing System[™].



www.himedialabs.com



info@himedialabs.com



+91-22-6147 1919

... expect only quality from us[™]

Range of HiMedia Products

MICROBIOLOGY

CELL
BIOLOGY

MOLECULAR
BIOLOGY

PLANT TISSUE
CULTURE

HYDROPONICS
SOILLESS FARMING

LAB CONSUMABLES
& INSTRUMENTS

CHEMICALS &
BIOCHEMICALS



who gets it done
with one?

klucel ls™
low-substituted hydroxypropyl
cellulose (hpc)

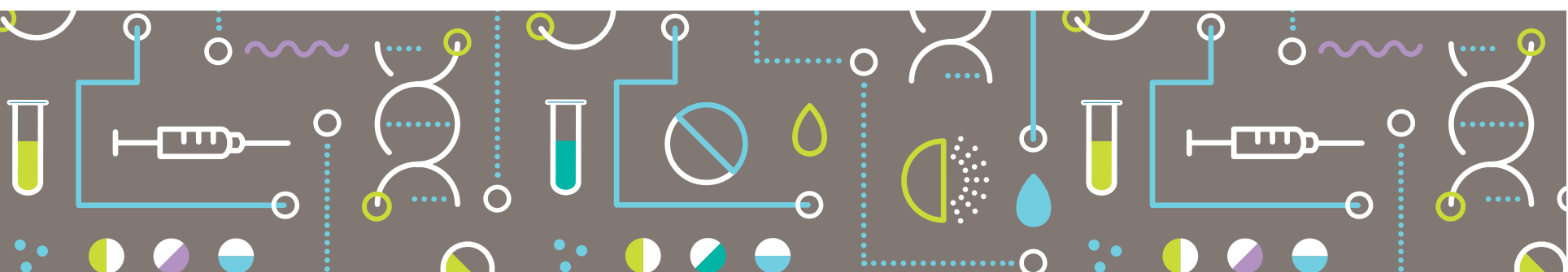
Klucel ls™ low-substituted hpc is a multifunctional binder and disintegrant that has several benefits and applications in oral solid dosage forms.

For more information or sample request, please contact seema.singh@ashland.com

ashland.com / efficacy usability allure integrity profitability™

 **Ashland™**
always solving

® Registered trademark. Ashland or its subsidiaries, registered in various countries ™ Trademark. Ashland or its subsidiaries, registered in various countries ©2025, Ashland PHA25-015



Introducing Rankem GC-Headspace Solvents

High-purity solvents engineered for accurate and reproducible headspace analysis.



Key Advantages

- Each batch tested for GC-HS suitability
- Assay often exceeds 99.95%
- Narrow solvent front enables rapid baseline recovery, minimizing solvent interference
- PTFE Plug to prevent product contamination & degradation
- Available in pack size of 500 ml

Ordering information:

Product	Pack size	Cat. No.
Dimethyl sulphoxide GC-HS	500 ml	RANKD0161
N,N-Dimethylformamide GC-HS	500 ml	RANKD0137
N,N-Dimethylacetamide GC-HS	500 ml	RANKD0774
N-Methyl-2-pyrrolidone GC-HS	500 ml	RANKM0024
Dichloromethane GC-HS	500 ml	RANKD0098

Scan for more information



RANKEM™

Reliable supply worldwide

Global supply disruptions can put pharmaceutical production at risk.

With a globally aligned manufacturing network, SCHOTT produces FIOLEX® clear and amber glass tubing in India and across international sites, applying identical quality standards worldwide.

Consistent global quality supports uninterrupted production, reduces supply risk, and safeguards the integrity of pharmaceutical products worldwide.

One standard. Global assurance. Choose SCHOTT.



[schott.com](https://www.schott.com)



SCHOTT GLASS INDIA PVT. LTD.
santosh.jadhav@schott.com | 00 91 22 4094700

SCHOTT



TRANSCHEM
CORPORATION
PHARMA PVT LTD
EVERYTHING EXCIPIENT

Kolliphor® PS 80

Transchem offers BASF's Kolliphor® PS 80, a colorless or yellow, clear liquid with a faint characteristic odor. Kolliphor® PS 80 is used as a non-ionic surfactant and oil-in-water emulsifier, as plasticizer in a range of solid dispersions and oral dosage forms. It is a non-ionic, hydrophilic emulsifier with broad pH range applicability and good skin tolerance in topical formulations.

Benefits

- Suitable for oral, semi solid and liquid dosage forms as well as softgels
- Plasticizer in a range of solid dispersions and oral dosage forms
- Broad pH range applicability and good skin tolerance in topical formulations
- Solubilizing agent in a variety of pharmaceutical formulations



🏠 Transchem Corporation Pharma Pvt. Ltd.
D421/422, Neelkanth Business Park, Station Road, Vidyavihar (W),
Mumbai - 400086

✉ Email: sales@transchemcorp.com

☎ Phone: +91 022-49711633

🌐 Web: www.transchemcorp.com



Scan to
learn more about
Kolliphor® PS 80



Avantor® ACE® Exclude SEC Column

Reliable, High-Resolution Size Exclusion
Chromatography for Biopharmaceutical Development



INTRODUCING THE NEXT GENERATION OF SEC PERFORMANCE

The Avantor® ACE® Exclude SEC Column delivers robust, cost-effective mAb aggregate analysis with excellent resolution and consistency, offering up to 3× longer lifespan, ~66% fewer replacements and minimal secondary interactions without high-salt buffers.

Built for Biopharmaceutical Workflows

- Clear separation between monomer and dimer/trimer for aggregate identification
- Seamless transitions to new batches
- Extended column lifetime
- Lower salt concentrations can be used in mobile phase
- Good peak shape even at low NaCl concentrations



VWR.COM

Avantor Performance Materials India Pvt. Ltd

19 th Floor, Building No. 5, Tower C, DLF Cyber City
Phase - III | Gurgaon - 122002, Haryana
t +91-1244-65-6700india.sales@avantorsciences.com

Avantor Performance Materials India Private Ltd.

Tiffany, 5th Floor, Hiranandani Business Park
Thane (W), Mumbai - 400607 | t 022-41288100
india.sales@avantorsciences.com



Fibers for Life.

LUBRITAB® -Versatile Excipient From Natural Origin

Hydrogenated Vegetable Oil, NF, BP

Hydrogenated Oil, JP

.....

- Derived from cottonseed oil
- Lubricant for tablets and capsules
- Dry binder
- Controlled release agent
- Viscosity modifier in semisolid formulations, suppositories and soft gelatin capsules
- Compliant with current regulatory requirements



JRS PHARMA



JRS FAMILY

A Member of the JRS Group

- Excipients • Coatings • Biopharma Services
- Technical Services

RETTENMAIER INDIA PVT. LTD.

B/816, Lodha Supremus II, Road No. 22, Wagle Estate, Thane (W)
Maharashtra - 400 604.

Tel: 022 4024 3817-21 | Email: info-india@jrs.de | www.jrspharma.com

Chairman of the Board
Viveck Goenka

Sr. Vice President-BPD
Neil Viegas

Vice President-BPD
Harit Mohanty

Editor
Viveka Roychowdhury*

Editorial Team
Lakshmi Priya Nair
Kalyani Sharma
Neha Aathavale
Swati Rana

DESIGN
Art Director
Pravin Temple

Senior Designer
Rekha Bisht

Senior Artist
Rakesh Sharma

Marketing Team
Rajesh Bhatkal
Ashish Rampure

Production Co-ordinator
Dhananjay Nidre

Scheduling & Coordination
Pushkar Waralikar

CIRCULATION
Mohan Varadkar

CONTENTS



Pg26

INTERVIEWS



P18
SHASHIDHAR KL
CEO,
Pivot Path



P20
VAIBHAVI SHAH
Co-founder and
Director, Invengene



P22
HARI KIRAN CHEREDDI
Founder, Managing
Director and Chief
Executive Officer



P22
SOWJANYA VARMA
Chief Information
Officer,
HRV Pharma



P24
JEEVAN KASARA
Chairman of the Board,
STERIS Healthcare

MARKET

32 | **SIRO CLINTECH**
RELOADED

RESEARCH

35 | **UNCLOGGING**
INDIA'S INNOVA-
TION PIPELINE

TECHNOLOGY

36 | **WHEN THE LAB**
TALKS TO THE
PLANT

Express Pharma®

REGD. WITH RNI NO. MAHENG/2005/21398, POSTAL REGD. NO. MCS/164/2025 - 2027, LICENSE TO POST WITHOUT PREPAYMENT LICENSE NO. MR/TECH/WPP - 368/SOUTH/2025 - 2027, PRINTED AND PUBLISHED BY VAIDEHI THAKAR ON BEHALF OF THE INDIAN EXPRESS (P) LIMITED AND PRINTED AT THE INDIAN EXPRESS PRESS, PLOT NO. EL-208, TTC INDUSTRIAL AREA, MAHAPE, NAVI MUMBAI-400710 AND PUBLISHED AT MAFATLAL CENTRE, 7TH FLOOR, RAMNATH GOENKA MARG, NARIMAN POINT, MUMBAI 400021.

EDITOR: VIVEKA ROYCHOWDHURY.* (EDITORIAL & ADMINISTRATIVE OFFICES: MAFATLAL CENTRE, 7TH FLOOR, RAMNATH GOENKA MARG, NARIMAN POINT, MUMBAI 400021), * RESPONSIBLE FOR SELECTION OF NEWS UNDER THE PRP ACT. COPYRIGHT © 2017. THE INDIAN EXPRESS (P) LTD. ALL RIGHTS RESERVED THROUGHOUT THE WORLD. REPRODUCTION IN ANY MANNER, ELECTRONIC OR OTHERWISE, IN WHOLE OR IN PART, WITHOUT PRIOR WRITTEN PERMISSION IS PROHIBITED.

EXPRESS
Pharma
World
Expo 2027

India's First Knowledge-led,
Future Focus Pharma Expo

**Building tomorrow's
pharma ecosystem,
today.**

3 4 5
March 2027

**BEC Goregaon,
Mumbai**

EXPRESS
PHARMA

The double burden of tighter enforcement, slower implementation

While the Central Drugs Standard Control Organisation (CDSCO) is cracking down on erring industry actors, policy makers are pulling up government departments for slow implementation of schemes.

Thus India's pharma industry, at least the MSME sector, is facing a tough transition to revised GMP norms, hampered by slow implementation of the very schemes that were intended to help them upgrade. This highlights gaps between policy intent and implementation, and the subsequent drag on compliance levels.

The Parliamentary Standing Committee on Chemicals and Fertilisers' 34th Report presented in early August, pointed out that funds set aside under the Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS) for technological upgradation of eligible micro, small and medium pharma enterprises (MSMEs) was underutilised.

The report noted that even though almost the full allocation of Rs. 300.10 crore was approved, implementation was lagging.

In its reply, the DoP submitted that under the Scheme, 301 applications of pharma units for incentives aggregating to approximately Rs. 300.48 crore were approved, which is nearly equivalent to the total outlay of the sub-scheme, as on March 31, 2026.

Of the 301 approved applicants, claims of 64 pharma units amounting to Rs. 45.80 crore were approved, which is just over 20 per cent of the approved applicants. Of this, Rs. 41.70 crore has already been disbursed for 55 pharma units during FY 2025-26.

The DoP's reply stated that the remaining 237 approved pharma units are at various stages, including claims under process, projects completed but yet to submit certificates and projects under implementation.

Given this delay of units going from approval to implementation, the Parliamentary Committee has recommended that the DoP should put in place urgent facilitation mechanisms and hand holding measures.

The Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS) was set up to help drug manufacturing units, specifically MSMEs, upgrade their facilities to meet Revised Schedule-M and WHO-GMP standards. Therefore delayed funds disbursement and implementation means that this segment of the sector will have patchy compliance until the upgradation.

The DoP's submission is that the upgradation process in MSME pharma units, especially smaller units, tended to take longer as it disrupted normal operations.

It is but natural that smaller facilities tend to undertake upgrades in a phased manner over a period of time, while mid-sized firms can upgrade faster as they might have alternate facilities, so that production (and by that extension, revenue streams) are not completely disrupted or at a standstill.

The same report has also asked the DoP for an update on the bulk drug park promotion scheme, under which three



India's pharma MSMEs are facing a tough transition to revised GMP norms, hampered by slow implementation of the very schemes that were intended to help them upgrade. This highlights gaps between policy intent and implementation, and the subsequent drag on compliance levels

bulk drug parks, (in Gujarat, Himachal Pradesh and Andhra Pradesh), were approved, with a grant-in-aid of ₹1000 crore to each park. Here too implementation is lagging. The panel has directed the DoP to submit a detailed status report on the ongoing progress of the three approved bulk drug parks and stressed tracking concrete measures taken to resolve ground-level execution hurdles and deadline slippages.

The Indian Pharmacopoeia Commission (IPC) is also reportedly setting up manufacturing guidelines for semaglutide, given the number of Indian pharma companies releasing generic copies of this complex molecule.

The fact that Dr Reddy's Laboratories, one of India's well respected pharma companies, stumbled on the generic semaglutide front is probably what triggered this inclusion in the forthcoming Indian Pharmacopoeia (IP) Addendum 2028.

DRL reportedly had to recall and pause commercial supplies of some batches of its generic semaglutide as an out-of-specification impurity was detected in the active pharmaceutical ingredient (API) during the production scale-up process.

While the CDSCO has given approval to certain Indian pharma companies to manufacture generic semaglutide for treating type 2 diabetes and managing weight, it has also specified that its use has to be linked to lifestyle changes and strictly under prescription.

CDSCO has also cracked down on illegal online sales, improper prescriptions, deceptive marketing and weight-loss claims, and influencer promotions. The agency has also conducted inspections of locations ranging from pharmacy warehouses, wholesalers, retailers, and slimming clinics, to curb misuse of weight-loss drugs. (<https://www.expresspharma.in/midst-global-headwinds-cdscocracks-down-on-glp-1-gold-rush/>)

Besides cracking down on manufacturing standards, the CDSCO has also turned its gaze on the clinical research segment. In late July, the CDSCO cancelled the registration certificates of seven ethics committees across India, flagging major compliance failures and serious regulatory deficiencies. This is a serious signal to India's clinical research sector that enforcement of the New Drugs and Clinical Trial (NDCT) Rules 2019 and the amendments that followed will be strict.

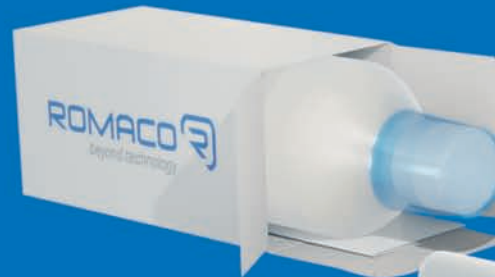
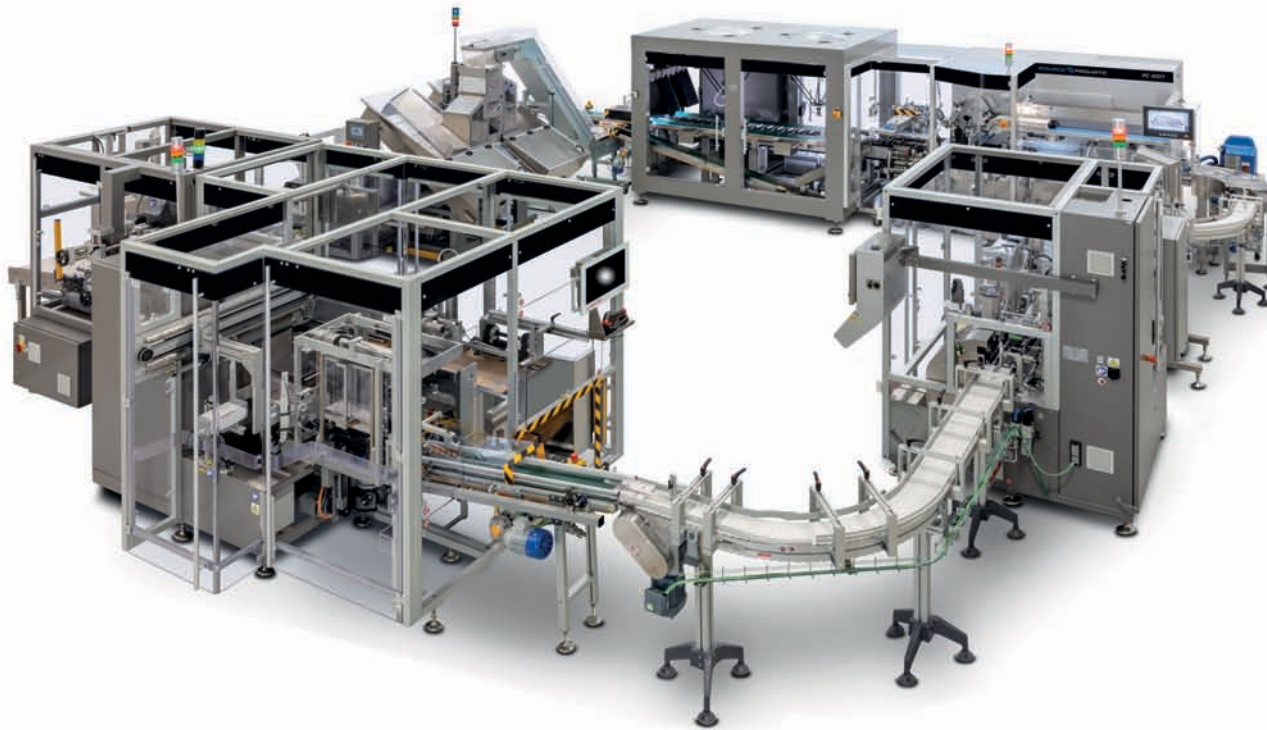
While this is a tough transition period, it's been long overdue. No doubt, there will be some smaller manufacturing units which will decide to call it a day, unable to muster up the funds, or the bandwidth and patience, to upgrade.

This is a necessary clean up of the sector, if we aim to compete to global norms. But these hard learnings will ensure better quality medicines for all. And that is the bottom line.

VIVEKA ROYCHOWDHURY, *Editor*
viveka.r@expressindia.com
viveka.roy3@gmail.com

Tailor-made Packaging Solutions

Complete Lines from Depacker to Palletizer



VERSATILE PACKAGING

Where everybody means business

3
days of
networking**360°**
industry
engagement**12**
months of
visibility**Connect with decision-makers.
Build partnerships that matter.****Stay visible beyond the event floor.****SCAN & JOIN**
Be a part of our community**EPWExpo**
a platform of The Indian Express GroupSECURE YOUR
PARTNERSHIP

Express Pharma World Expo

**Get in touch with our team today!
For Space booking and sponsorships:****Rajesh Bhatkal**
+91 9821313017
rajesh.bhatkal@expressindia.com**Ashish Rampure**
+919664565092
ashish.rampure@expressindia.com

#ExpressPharmaWorldExpo #The nextleap



Driving the world

SEW MOBILE MATERIAL-HANDLING Inspired by Nature, Engineered for Efficiency

At SEW-EURODRIVE, we're inspired by the remarkable engineering in nature and strive to bring the same smart design and efficiency to our products.

Just as expert navigation is in leafcutter ants' DNA, our Mobile Material-Handling solutions synchronise your material flow seamlessly across dynamic factory systems, following optimised paths.

Our Industry 4.0 solutions – Automated Guided Vehicles (AGVs) and Electrified Monorail System (EMS) – are fully customisable and built to German standards. And with expert support across India, we ensure smooth material-handling.

Efficiency: It's in our D.N.A.



Leafcutter ants are nature's expert transporters. These tiny powerhouses carry leaf fragments many times their weight. They navigate obstacles across tough terrains without set routes yet ensure smooth cargo movement.



SEW-EURODRIVE MOBILE MATERIAL-HANDLING SOLUTIONS:

Automated Guided Vehicles (AGVs) | Rail Guided Vehicles (RGVs)
Electrified Monorail System (EMS) | Power Management

+91 96866 24322 | marketing@seweurodriveindia.com
www.seweurodriveindia.com

How Pivot Path is in a sweet spot to address pharma's pressure points

Shashidhar KL, CEO, Pivot Path explains to **Viveka Roychowdhury** Pivot Path's evolution from Strides Pharma's GCC into an independent pharma tech company, bagging INR 100 crore in PE investments, and how speaking the pharma language puts them in a sweet spot to address both regulatory and competitive pressures through efficiency. Excerpts from a free flowing discussion

Pivot Path emerged from Strides Pharma's internal GCC. Are other pharma companies also following the same playbook? And if so, could you name some examples?

Pivot Path, previously known as Arcolab, started in 2019 as a shared services organisation within the Strides Group. At that time, Global Capability Centre (GCC) was not yet the commonly used nomenclature.

The idea was to create a common platform for the group's multiple pharmaceutical entities, which operated across APIs, injectables, oral dosage and biologics. They all had common requirements across IT, digital, clinical, pharmacovigilance, finance and HR, but were operating in silos.

This created inefficiencies in resource allocation and limited knowledge sharing. For example, learnings from an FDA or regulatory audit at one unit were not necessarily reaching another unit. So, the objective was to allocate resources efficiently, build a scalable model and facilitate knowledge sharing.

Many companies today have internal shared services or Centres of Excellence (COEs), but these are largely centralised functions operating within the organisation. We were ahead of the curve in 2019.

A global example is Novo Nordisk. Its IT function eventually spun off as Novo Nordisk IT (NNIT), which now provides services to companies well beyond its former parent. We are taking a similar path,

with a focus on large Indian and mid-sized pharma companies globally.

What are the differentiators?

Six years ago, we were a process- and operations-centric organisation. We consolidated services, negotiated better rates with partners and vendors, and standardised processes. Our philosophy was COSA: consolidation, optimisation, standardisation and automation.

Unlike many multinational GCCs, we did not have the benefit of labour arbitrage. We had the same people, infrastructure and location even as we transitioned into a standalone entity. So, from day one, we had to demonstrate value.

In the third year, we realised that much of our process improvement was coming through technology and digital transformation. We already had deep pharma expertise, but we identified a technology gap. In 2022, we acquired a Bangalore-based technology company and began building pharma-centric solutions.

That is our key differentiator. We combine pharma domain expertise with technology. Technology companies may have solutions, but often need to first understand pharma's nuances and workflows. We already understand the problem.

Our approach is to use technology for business transformation, not the other way around. We combine domain knowledge and



technology to offer integrated solutions.

For mid-sized pharma companies, digital transformation does not have to be overwhelming or highly capital-intensive. We also understand the change-management challenge. Those are the differentiators we bring to the table.

How would Pivot Path approach a mid-sized client? What is the value proposition, and what market trends are driving these companies to approach you?

Every company is experimenting with digital or IT transformation. But mid-sized pharma companies typically have significant legacy manufacturing processes and systems. Many initiatives therefore remain at the process or use-case level. Some POCs

succeed, while others take too long and lose momentum.

Legacy systems also need upgrading, whether in enterprise applications, infrastructure or processes.

Our proposition is to look at digital transformation at the domain level rather than digitising individual processes. Take manufacturing, for example. Instead of digitising one process, we look at the entire manufacturing domain, including manual, offline, hybrid and already-digitised processes.

We can help upgrade infrastructure and networks to the cloud, digitise manufacturing processes, use no-code or low-code platforms for workflows and build a nimble data lake to provide insights for decision-making.

If a company can address all these requirements through one platform, that is the value proposition.

We are now talking to more than 300 unique customers across India and parts of Europe on quality solutions, manufacturing digital transformation, pharmacovigilance and clinical operations. These are our three major solution buckets.

The 70-plus pharmaceutical companies across five continents are our existing customer base, largely through single-line services, particularly PV services. The 300-plus companies represent the new opportunity we are pursuing.

The benchmark for regulatory compliance is

increasing. Geopolitical tensions, tariffs, wars and other crises also affect supply chains. How is your solution relevant to these challenges?

The last 18 months have demonstrated how geopolitical developments can directly affect supply chains. Companies focused on the US market are also dealing with constant regulatory and tariff developments.

At the same time, the generic market is shrinking and price erosion has been happening for several years. This creates margin pressure across both mid-sized and large pharma companies, driving consolidation.

Regulatory expectations are also increasing globally, particularly around manufacturing operations, data management, data integrity and processes. Surprise audits are common, creating additional pressure.

Companies therefore face price pressure while also needing to invest in compliance through technology and solutions.

Our positioning is to address the compliance and regulatory requirements. We help clients assess processes, upgrade technology and undertake transformation. Our solutions can digitise processes, improve efficiency and reduce data-integrity issues. So, we are in a sweet spot to address both regulatory and competitive pressures through efficiency.

Currently, your company generates about INR 147

crore in revenue. What are the projected growth targets for the next few years? What are the growth drivers?

We are targeting around INR 450-500 crore in the next four to five years, with the majority coming from digital transformation and technology solutions.

The opportunity is abundant, and we want to capture it.

You're looking at a global scale, not just India.

India is a major market for us, particularly for our digital transformation solutions. Technology is no longer a differentiator or competitive advantage. Hundreds of startups use the same platforms.

Our differentiator is domain-led solutions. We want to offer them to Indian

companies at a competitive rate so they don't have to depend on global platforms.

We also want to approach Europe and the US with the same rigor. From a revenue perspective, we see India contributing around 40 per cent, Europe 20-25 per cent and the US around 40 per cent.

We are working on our US go-to-market strategy. Having recently become independent and raised capital, our focus now is to build the business.

Are you a pharma company or an IT company?

We are purely a pharma company, but we are in a unique position. We acquired a Bangalore-based deep-tech firm in 2022, with 100-120 people. Our solutions are proprietary and IP-owned.

We want to operate in the

space between large platforms and the needs of mid-sized pharma. We have designed lighter solutions for them. For example, we have our own validation management systems (VMS) and document management systems (DMS) and can build lighter versions of the large enterprise quality platforms using available technology.

We also work with the platform that clients are already running. We help them integrate, customise and run their existing ERP, Quality & Manufacturing environments.

The other challenge is that many startups and AI companies claim to be pharma-centric, but they don't necessarily understand the industry's problems. We have worked with several startups and often ended up teaching

them about pharma.

That was one reason we established our own technology arm. Instead of spending time teaching third-party companies and then seeing them build solutions around that knowledge, we decided to build for pharma ourselves.

The objective is to make digital transformation less difficult and less capital-intensive for mid-sized pharma companies. Change management is equally important. Companies need the confidence that transformation does not mean people losing their jobs or power. It is a process.

We speak the pharma language, and that's where our conversation begins.

What does Ascent Capital's investment in Pivot Path

signal to pharma companies?

Ascent Capital has a strong track record of investing in the life sciences sector and understands the challenges pharma companies face. Their investment in Pivot Path reflects a continued belief in the sector and in the growing need for solutions that address industry-specific operational, regulatory, and transformation challenges.

For pharma companies, it serves as a strong validation of our approach. Ascent's familiarity with the industry gives them a clear perspective on both the challenges and the solutions required, and their investment reinforces confidence in the value we bring to the market.

*viveka.r@expressindia.com
viveka.roy3@gmail.com*



VALEGRO



Recirculating Coolers/chillers

- Working temperature range : -20 to +85 °C
- Temperature stability: ± 0.3 to ± 0.2 °C
- Cooling capacity: 0.35 to 2.5 kW
- Heating Capacity: 2 kW
- Pump flow rate: 15 to 40 lpm
- Pump pressure: 0.5 to 3.5 bar



Scientific Research Instruments Company Private Limited

Website: www.srico-labworld.com | Telephone: +91 9900674407 | Email: info@srico-labworld.com

Bengaluru | Mumbai | Hyderabad | Bhubaneswar | Vadodara | Delhi

Chennai | Goa | Thiruvananthapuram | Pune | Visakhapatnam | Kolkata | Guwahati | Ahmedabad | Chandigarh | Lucknow



The next injectable pharma race will be won on reliability

Vaibhavi Shah, Co-founder and Director, Invengene, discusses how reliability, regulatory predictability, data integrity and co-development will shape the next phase of injectable pharma in an exclusive interview with **Neha Aathavale**

The injectable pharma landscape is becoming increasingly interconnected, with pharma companies, CDMOs, device manufacturers and technology partners working more closely than ever before. What factors are driving this shift towards ecosystem-based collaboration, and how will it reshape competitive advantage over the next decade?

A big shift has been taking place, and three forces are pushing in the same direction at once. The first is the nature of the work itself. Global companies are no longer handing partners discrete tasks to execute at low cost; they are setting up global capability centres and co-development relationships and asking teams to help solve hard development problems. When the work becomes collaborative rather than transactional, the boundaries between pharma company, CDMO, device maker and technology partner naturally dissolve.

The second force is scale that has matured into credibility. India's contract research and development market has roughly doubled in recent years and is growing at almost twice the global rate, while the contract development and manufacturing sector is on a path from around USD 22 billion today toward USD 44 billion by the end of the decade.

The third is intent backed by capital: the patent cliff on biologics - over USD 40 billion of annual revenue losing exclusivity between now and 2029 - has opened a window in biosimilars and complex products, and public policy has moved to meet it. The injectable ecosystem is developing into a network of partners because of the growing alignment of science, demand and policy.



Over the next decade this reshapes competitive advantage in a fundamental way. Capacity is now widely available; what remains scarce is the assurance that a programme handed over will be returned on time, to specification, and able to withstand a regulator's scrutiny. So, advantage will accrue to those who can be trusted inside an ecosystem - who bring regulatory predictability, the integrity of their quality and data systems, and depth of scientific talent. Price was always a borrowed advantage, because anyone can be undercut. The ability to be relied upon as a co-developer is an advantage no one can take away.

As injectable therapies become more complex, particularly with the growth of biologics, GLP-1 therapies, long-acting injectables and drug-device combinations, what operational and organisational capabilities will companies need to prioritise to successfully scale their businesses while

maintaining quality, operational efficiency and regulatory compliance?

In complex injectables - the field in which I have spent most of my career and which Invengene works in - the test is sharper than anywhere else, because the margin for error is smaller. A partner is judged on sterile and aseptic capability, on its grasp of stability and the cold chain, and on whether it can carry a molecule through technology transfer and scale-up without the product quietly changing character. As therapies grow more complex, those capabilities move from being differentiators to being the price of entry.

But the capabilities that actually determine whether a company can scale are organisational, not just technical, and there are three. The first is data integrity as a culture rather than a checkbox - records that are complete, contemporaneous and traceable, and systems built so that the honest result is the only result that can be recorded. This is why the move to digital, paperless

laboratories matters; at Invengene we treated it not as a technology upgrade but as a way to remove ambiguity from the data a partner is asked to rely on.

The second is institutional repeatability. Global partners are wary of organisations that depend on a handful of brilliant individuals, because that talent is mobile and the result is not reproducible. What earns long-term programmes is a professionally governed, process-led organisation that can deliver the same outcome twice. The third is honest project management - realistic timelines, early disclosure of problems, and the discipline to take a molecule from concept to a regulatory-ready dossier. A partner who flags a deviation early is worth far more than one who reports only success. Companies that prioritise these three will scale complexity; those that rely on heroics will not.

As manufacturing technologies continue to evolve and therapeutic pipelines become more diverse, how should organisations balance investments in capacity, flexibility and advanced technologies while managing commercial and regulatory risk?

The instinct is to compete on capacity, but capacity is now the wrong thing to optimise for. What global companies are really buying is confidence, not capacity - and the factors that actually decide where they place their programmes are, in order: regulatory predictability, the integrity of a partner's quality and data systems, the depth of its scientific talent, its speed to clinic and to filing, and only then, cost. Investment should follow that order of priorities rather than the order that is easiest to build.

Practically, that means the teams that win these mandates compete on the total cost of getting a compliant, reliable product to market - not on the lowest unit price. Flexibility matters because pipelines are diversifying toward biologics, long-acting injectables and drug-device combinations, so the ability to reconfigure a line or a technology-transfer process for a new modality protects an organisation against betting on a single therapeutic direction. Advanced technology - particularly digital, paperless quality systems - earns its place not as a showpiece but because it removes ambiguity from data and lowers regulatory risk directly.

On managing risk, the honest lesson is that programmes are usually lost at the compliance and consistency layer, not the scientific one. So the disciplined approach is to invest first in the systems that make quality reproducible and regulatory outcomes predictable, then in flexible capacity matched to real pipeline demand, and to resist the temptation to over-build capacity ahead of the credibility to fill it. Predictability - of quality, of timelines, of behaviour - is the product an organisation is actually selling, and investment should be weighted toward protecting it.

The injectable pharma landscape is evolving beyond the product itself. How are innovations in drug delivery, digital health and supply chain resilience redefining patient value and competitive differentiation?

In injectables, access is very often an engineering problem disguised as a pricing one, and this is where the real opportunity lies. A medicine that must be held between two and eight degrees is effectively

INTERVIEW

unavailable across large parts of Africa, Asia and Latin America however cheaply it is priced, because the cold chain it depends on simply is not there. A vial that must be discarded a few hours after it is opened imposes a quiet, daily tax of waste on every intensive-care unit that uses it. The barrier in both cases is design - and design is precisely what science is built to solve.

Two examples from our own work at Invengene make the point. We re-engineered the formulation of a critical antifungal so that it is stable at room temperature rather than dependent on cold storage, which means it can now travel to, and survive in, places the cold chain never reached. And by changing the preservative system in a fast-acting cardiac injectable, we extended its in-use stability after the vial is punctured from twelve hours to

seventy-two, so a single vial serves longer and far less is thrown away. The active molecule is untouched in both cases; everything around it is rebuilt. Same efficacy, a fundamentally wider reach.

Framed properly, this is not a product story but a public-health one. Reformulating for room-temperature stability and reducing in-use wastage speaks directly to UN Sustainable Development Goal 3 - good health and well-being, and universal access to safe, affordable, essential medicines - and it does so most powerfully for remote and under-served countries, the very places where a broken cold chain or a wasted vial decides whether a patient is treated at all. That is how delivery innovation, digital-quality systems and supply-chain resilience redefine both patient value and competitive differentiation: not

the most expensive science, but the most consequential.

As the injectable pharmaceutical market continues to evolve, what strategic choices made today will determine which companies emerge as industry leaders over the next decade?

The strategic choice that matters most is deciding what you are actually selling. The world does not, in the end, need its medicines made a little cheaper. It needs partners who can make difficult medicines reach difficult places and keep working when they arrive. Companies that choose to compete on that higher standard - designing access into the molecule and being trusted while doing it - will lead. Those that stay in the generics playbook of lowest unit price will keep winning a race that

anyone can undercut.

The second choice is to treat reliability as something built in the laboratory and the quality system, not asserted in a pitch. If programmes are lost, they are usually lost at the compliance and consistency layer. The biggest single source of hesitation remains quality and data-integrity findings, and the damage is never confined to the firm that is cited - a handful of weak actors colours how the whole ecosystem is perceived. The leaders will be those who fix this at the level of governance and culture, and who manage talent volatility so that continuity over a multi-year programme can be taken for granted, because continuity is precisely what co-development demands.

The third choice is continuity itself. Every ecosystem that has successfully

attracted long-term R&D - Boston, Singapore, South Korea, Ireland - did the same unglamorous thing: it made long, consistent bets and stayed with them across political and economic cycles. The building blocks already exist. What determines leadership is execution velocity and consistency: protecting intellectual property visibly, keeping regulatory timelines predictable, and resisting the urge to change direction every few years. Affordability earned India the trust of the world as its pharmacy. Re-engineered science and unwavering reliability, sustained patiently over a decade, will earn something far rarer - a seat at the table where the world's medicines are imagined, not merely manufactured.

neha.aathavale@expressindia.com
nehaaathavale75@gmail.com

GDWaldner

Laboratory Furniture

Our furniture solutions are highly adaptable, flexible and durable, thereby meeting the demands of modern laboratories.

- SEFA 8M compliant cabinets, benches, Lab tables, tall cabinets
- Load bearing capacity - Floor standing cabinets offer upto 900 kg load bearing capacity.
- Aesthetically appealing and attractive
- Superior powder coating
- Built to last - Certified SEFA compliant
- Stainless Steel Hinges
- Choice of Cabinets - Floor Mounted, C-Frame, H-Frame, Suspended, Mobile, Wall, Tall Cabinets, Fume hoods

Fume Hoods

- Manufactured in India with German technology,
- Aerodynamic-centric design with lower air foil and fume hood pillars for superior containment capacity through seamless air flow with minimal turbulence
- High-performance baffle system to rapidly exhaust fumes
- Double cage structure that serves as 'first line of defence' in case of small-scale accidents
- Complete integration with overall lab ventilation system and room controller
- Surpasses DIN EN 14175 and ASHRAE 110 requirements
- Fume Hood Controllers - Waldner smart controllers intelligently manage airflow in fume hoods
- Integrated with IOT Room Controllers and BMS via Modbus or BACnet
- VAV controllers offer up to 50% savings in operating expenses compared to conventional systems.



GD WALDNER India Private Limited
50/A Lamdapura Road, Village Lamdapura, Tal Savli, Vadodara - 391 775
Phone: +91 9974021700 / 650 • E-Mail: salesupport@gdwaldner.com
Regional Offices: Delhi | Bengaluru | Mumbai



www.gdwaldner.com

Why pharma needs smarter decision-making, not just more digital systems

Hari Kiran Chereddi, Founder, Managing Director and Chief Executive Officer, and **Sowjanya Varma**, Chief Information Officer, HRV Pharma, speak to **Kalyani Sharma** about using AI to strengthen pharmaceutical decision-making, predictive compliance and operational intelligence

The pharmaceutical industry has invested heavily in digitisation over the past few years. What gaps in existing digital systems prompted the development of an operating system focused on decision-making rather than workflow automation? Most people in this industry looked at the same landscape and saw a digitisation problem. I saw a different problem entirely. The industry did not lack systems. It lacked reasoning.

Every major digital investment in pharma over the past decade was built to answer one question: what happened? ERP, LIMS, CRM, extraordinary at recording. Built to tell you what occurred after it occurred.

Nobody built something that answers a different question: what should we do next and why?

That gap between recording and reasoning is what we saw. And that is what RIKO™ was built to close. Not because we wanted to build technology. Because we needed it to run the business.

RIKO is introduced as an AI-native pharmaceutical operating system built on operational intelligence. How do you validate the reliability and consistency of its recommendations in regulated environments where human accountability remains critical?

We designed RIKO around one principle from day one, it recommends, humans decide.

Every output RIKO



Hari Kiran Chereddi

produces shows its work. Not just what it recommends but why, with the specific data points and their weights visible to the person making the decision. That person can agree, override, or challenge it. Every override is logged. Every reason is captured.

That audit trail is not a compliance afterthought. It is the point. Over time the pattern of where humans override RIKO tells us exactly where the model needs to improve. The human judgment does not just check RIKO, it trains RIKO.

On validation - we apply the same standard we apply to any analytical method in a GMP environment. You retrospectively test the system against historical outcomes. You document the accuracy. You set thresholds. You review it periodically. The industry has been doing this for computerised systems for decades under GAMP principles. An AI recommendation engine is not fundamentally different. It requires evidence that it

does what it claims to do, consistently, within defined parameters. We treat that as a design requirement, not a burden.

With regulators placing greater emphasis on data integrity, quality risk management and supply chain resilience, how do you see AI-driven decision support changing compliance practices across the pharmaceutical industry over the next five years?

The shift that is coming is from reactive compliance to predictive compliance. And that is significant.

Today compliance in pharma is almost entirely retrospective. An inspection finds something that went wrong months ago. A warning letter documents a pattern that existed for years. A CAPA closes a deviation that already happened. The entire quality management architecture is built around responding to events after they occur.

What changes when you have continuous intelligence when a system is monitoring your supplier's GMP certificate, inspection history, deviation patterns and regulatory alerts in real time is that you stop being surprised. You see the warning letter pattern before the warning letter arrives. You see the GMP risk before the audit.

Over five years I think three specific things happen. Regulators begin recognising continuous monitoring as a quality indicator in its own right. A company that can demonstrate real-time



Sowjanya Varma

supply chain surveillance will be treated differently in an inspection than one relying on periodic audits. Second, data standards will emerge that allow intelligence to flow across company boundaries without compromising confidentiality. Third and this is what most people are not thinking about yet, the definition of a qualified supplier will start to include the supplier's data connectivity. Can they give you what you need to monitor them continuously? If not, they are a higher-risk supplier by definition.

The companies investing in this infrastructure now will not just be better positioned. They will have set the standard everyone else has to catch up to.

Many pharmaceutical companies struggle with fragmented data across manufacturing, quality, regulatory and commercial functions. What are the biggest barriers to creating an integrated decision-making framework, and

how can companies overcome them?

I will tell you what it is not. It is not the technology. The technology to integrate these systems has existed for years. The barriers are entirely human.

The first is data ownership politics. In most pharmaceutical organisations quality owns quality data, commercial owns commercial data, regulatory owns regulatory data. Each function treats its data as institutional territory. An integrated decision framework requires that data to cross those boundaries. That is a culture and governance problem, and it can only be solved from the top. If the CEO does not personally own the integration agenda it does not happen.

The second is what I call the single version of truth problem. When three different teams maintain three slightly different versions of the same product portfolio, different molecule names, different supplier codes, different filing statuses, no AI system can reason coherently across them. You have to fix the data before you can build the intelligence. That work is unglamorous and nobody wants to fund it, but it is the prerequisite for everything else.

The third is specific to regulated industries. People in pharma are conditioned to be conservative about change. An AI system influencing a compliance decision feels riskier than a spreadsheet doing the same thing, even when the AI is

INTERVIEW

more accurate. You overcome that by starting with low-stakes, high-frequency decisions where people can build trust in the system before applying it to anything consequential. Trust is earned incrementally. You cannot shortcut it.

The platform claims to predict quality and compliance risks, including nitrosamine-related concerns, at an early stage. How should the industry balance predictive technologies with established regulatory and quality assurance processes to ensure confidence in such systems?

Predictive tools should trigger the regulatory process, not replace it. That distinction matters

enormously and the industry needs to hold it firmly.

ICH M7 does not change because RIKO exists. What changes is when the risk is caught. Before the route is selected, not after the batch is manufactured. The regulatory process stays intact. It simply starts earlier.

The confidence question is straightforward. A model whose outputs are reviewed by a qualified person before any action is taken is a defensible tool in a regulated environment. What is not defensible is using predictive confidence to skip steps that exist for good reason. Low probability in a model is not the same as tested and confirmed. That line does not move.

As AI becomes more deeply

embedded in pharmaceutical operations, what governance frameworks including transparency, validation, cybersecurity and data ownership do you believe will be essential for wider industry adoption?

Four things. And I will be direct about why each one matters.

Transparency first. Every AI output in a regulated context needs a visible reasoning trail: not a black box recommendation, but a documented chain from input to output with sources and weights visible. If someone asks why a decision was made, the answer cannot be the AI said so. It has to be the AI said so based on these specific inputs, reviewed and approved by this person, on this date. Design for that

from day one.

Validation second. The GAMP principles the industry already uses for computerised system validation apply here. Validation rigor should match the risk of the decision being influenced. A screening tool that identifies molecules for commercial consideration needs different validation than a system influencing batch release. Proportionate, documented, periodically reviewed.

Cybersecurity third and this one is underestimated. Supply chain intelligence, regulatory filing data, commercial pricing: this data is valuable and it is increasingly targeted. The security architecture needs to match the commercial value of what the system knows.

Data ownership fourth and this will be the most contested question in the industry over the next five years. The industry needs to establish those principles now before the systems are sophisticated enough that the answer has large commercial consequences. Write the rules before anyone has broken them.

The principle underneath all four is simple. Governance is not there to restrict what AI can do. It is there to make what AI does trustworthy enough that the industry can rely on it. Restriction without trustworthiness is bureaucracy. Trustworthiness without governance is recklessness. You need both.

*Kalyani.sharma@expressindia.com
journokalyani@gmail.com*



Never Stops Monitoring. Always in Control.

GxP, 21CFR Part 11 of USFDA compliant

testo Saveris 1 delivers reliable, automated and efficient monitoring. With the latest software, stay in control of every process with greater confidence and compliance.

- Multi-level approvals and audit trails for transparency and compliance
- Flexible webhooks to easily activate, pause or reactivate workflows
- Automated actions and schedules for faster, risk-free operations
- Automated workflows to save time and reduce manual effort
- Single sign-on (SSO) for faster and more secure access



Application areas



Warehouse



R&D Units



Laboratories



Production

Testo India Pvt Ltd



+91 20 2592 0000



info@testo.in



India is the hub of our R&D strength, process innovation and regulatory excellence

Jeevan Kasara, Chairman of the Board, STERIS Healthcare, believes India's next pharma growth story will be built on trust, innovation and value, not cost alone. He discusses the China+1 opportunity, the shift towards complex therapies and CDMOs, and how India can grow to become a global hub for pharma innovation, in an exclusive interaction with **Lakshmipriya Nair**

What will fuel the next round of growth, and how can companies stay ahead in this race?

The combination of cost competitiveness and scale has brought India into the fold of the global pharma industry, but what keeps us here now is our ability to be consistent in maintaining the quality of our drugs and our maturity in handling regulations and developing products further up the value chain. It is not the companies that are trying to compete through cost alone that will succeed, but those who invest in their research capability and sophisticated manufacturing processes.

Reshaping the approach to growth in light of diversifying supply chains and heightened regulatory expectations?

The 'China +1' discussion is essentially a discussion about trust. Buyers around the world don't just want another supply source, they want a reliable one. It's time for Indian pharma to view compliance as an investment and not an obligation. Companies that take the proactive approach to incorporate quality by design, upgrade facilities at an early stage, and stay ahead of changing international regulatory requirements will turn their diversification into sustained relationships rather than sporadic purchases. It's also time for the sector to increase backward integration, given its reliance on external sourcing of critical raw materials.

Which of the opportunities – complex generics, specialty, biologics, peptides or CDMO –



has the greatest potential for value creation?

All of them have their own importance, but complex generics and CDMO offer the best opportunity for value creation for the Indian pharmaceutical industry because in both cases our strengths can be used. We are familiar with the regulatory requirements and large scale production, so we can use that for complex generics. CDMO is equally important as Indian companies can collaborate at an advanced stage in the pipeline without taking full responsibility of development. Biologics and specialty products will take more time because of the investment and scientific expertise required.

What has to happen for India to become more than the 'pharmacy of the world'?

The key shift is not just a

function of infrastructure but also a mind-set one. The Indian pharma sector has shown its ability to manufacture consistently on a large scale. But now it must show its ability to innovate. This will require sustained investment in research and development, as well as a policy environment that recognises the risks associated with innovation over the more easily recognised manufacturing efficiencies. Intellectual property security, expedited regulatory approval of new molecules, and availability of research funding are the ingredients needed. But it will also require that Indian firms get used to slower development processes and less certainty in their early stages.

Looking at STERIS Healthcare, where do you see the biggest opportunities for

growth?

Our most promising growth vectors are super specialty therapies in oncology, cardiology and nephrology, paired up with our recently expanded production capacity. We're going full steam on digitising the supply chain so patient access gets better across tier 2 and tier 3 cities, not just the usual metros. Also, the planned IPO plus greenfield expansion in South India puts us in a strong spot to grab both domestic demand and some export upside. STERIS is, honestly, uniquely poised to lead in complex, high margin formulations that hit critical healthcare gaps.

As global pharma companies look for partners that can offer quality, reliability and supply-chain resilience, how is STERIS positioning itself to become a more strategic partner to them?

Because quality is part of everything we do – right from where the raw material begins right up to where the finished product stops. With zero-defect at our ISO-certified & WHO-GMP manufacturing sites, and nimble logistics that neither falter, nor stall. With regulatory intelligence that aligns seamlessly.

The clear communication and bespoke development support we offer for sensitive and complex molecules are just part of the equation.

It is this dependable end-to-end ownership that makes STERIS feel like the vital partner of choice for world leaders seeking enduring global partnerships.

How important is India to

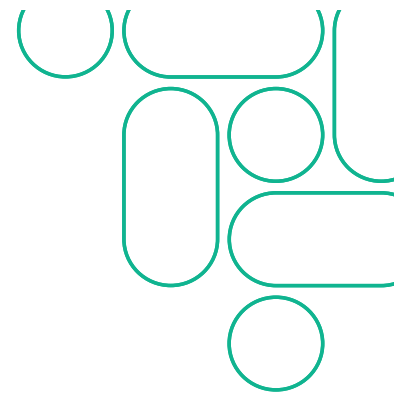
STERIS' global growth plans? Could India become more than a manufacturing base and emerge as a larger global capability hub for the company?

India is not just the hub of our global ambition but rather the hub of our R&D strength, process innovation and regulatory excellence. With an investment of Rs 50 crore in our expansion and the world-class talent that supports us, we will be creating biosimilars and novel drug delivery systems for our regulated markets. The increase in our IP portfolio and robust, audit ready facilities is already transforming India into a strategic capability hub that will drive innovation globally for STERIS.

From a boardroom perspective, what is the one big strategic decision Indian pharma leaders need to make today to build sustainable growth over the next five to ten years?

To India's pharma leaders, my honest advice is: be prepared to do a paradigm shift from volume competition to innovation led value creation. By focusing on differentiated R&D, complex therapies and a strong regulatory science, Indian companies will stand on the threshold of infinite possibilities globally. Rather than dilution in resources everywhere, deploy capital on patent-protected high value-driven and needs-filling portfolio. With such a transition, India will command leadership globally.

lakshmipriya.nair@expressindia.com
lakshmipriyanair@gmail.com



TWO VENUES. ONE SEAMLESS PHARMA EXPERIENCE

From breakthrough ideas to cutting-edge technologies, CPHI & PMEC India brings the pharmaceutical ecosystem together to connect, collaborate and shape what's next.

CPHI India

23–25 Nov 2026

**IICC, Yashobhoomi,
New Delhi**

PMEC India

24–26 Nov 2026

**IEML, Greater Noida,
Delhi NCR**

EXPLORE THE COMPLETE PHARMA ECOSYSTEM



50,000+
Pharma
Professionals



2000+
Exhibitors



120+
Countries
Participating



20+
Expert-Led
Sessions



**ONE PASS.
TWO VENUES.
FOUR DAYS.**



**Discover the people. Explore the innovation.
Experience the future of pharma.**

**Register Now & Be Part of South Asia's Leading Pharma Event.
SCAN THE QR CODE**

#AtTheHeartOfPharma

INDIA'S RACE

— FOR THE —



CDMO CROWN

Global pharma is diversifying its manufacturing base. Can India move beyond cost advantage to win strategic CDMO partnerships on quality, technology, speed and scale?

By **Lakshmipriya Nair**



For years, China+1 has been the big story in India's CDMO opportunity. Now, it is no longer enough. The shift away from China is well underway as global pharma seeks to lessen their exposure to geopolitics, and this clearly benefitted India.

A BCG-IPSO's report titled, *Unleashing the Tiger: Indian CRDMO Sector 2025* estimates that "India's CRDMO industry could grow from around \$3-3.5 billion in 2024 to \$22-25 billion by 2035."

The same report also identifies \$10-15 billion of potential value from global supply-chain realignment, along with opportunities in new modalities and India's emerging innovation ecosystem. Its customer research, a survey of more than 200 CRDMO customers, estimates that around \$5 billion of demand could move to India, while another \$9-10 billion represents unmet demand that India could potentially capture.

The opportunity is significant. But some of the business coming to India today is still risk management, not conviction. Being the alternative is not the same as being the partner of choice.

The harder question is whether India can turn this initial advantage into something more durable such as long-term relationships with global pharma, a deeper position inside development pipelines and a place among the world's preferred CDMO destinations.

As competition intensifies, India will have to earn that position on its own merits.

Beyond China+1

The industry is increasingly questioning whether China+1 can become the foundation of India's long-term CDMO strategy. Dr Chirag Adatia, Partner-Health & Life Sciences and Private Capital Practices, Oliver Wyman, thinks India should stop measuring its CDMO opportunity in terms of business that could move out of China.



For an Indian CDMO, having resilient, global supply networks is a must. Building globally integrated asset platforms with localised hubs that offer the 'best of both worlds' in terms of Eastern and Western advantages can assure the compressed timelines that clients value most

Peter DeYoung
CEO, Piramal Global Pharma



Cost will remain an advantage for India, but it cannot be the only reason customers choose us. The more sustainable proposition is to combine cost competitiveness with scientific depth, quality, and reliable execution

Tuneer Ghosh
President - CMC, Sai Life Sciences



It won't be one modality that defines the next phase - it'll be whichever Indian players can move fastest from 'can we make this' to 'can we make this at GMP scale, reliably, for a global regulator.' That execution question matters as much as the science

Suresh Subramanian
National Lifesciences Leader, EY Parthenon India



The Indian CDMOs who are selected first, rather than being chosen as a backup, will be the ones who stop merely selling capacity and begin selling certainty

Hari Kiran Chereddi
Founder, MD & CEO, HRV Pharma

"China+1 is a door-opener, not a moat," Dr Adatia asserts.

Saurabh Agarwal, Director and CEO, HAB Pharmaceuticals and Research, is direct, "China's CDMO market is roughly double India's and built for volume; India's opportunity, sharpened by BIOSECURE-driven derisking away from Chinese suppliers, is in complexity and trust — hard-to-formulate molecules, drug-device combinations, regulatory transparency — where scale matters less than judgment. India competing on China's terms is a losing game; competing on a different axis is not."

Hari Kiran Chereddi, Founder, MD & CEO, HRV Pharma, arrives at the same conclusion from a different route, "China achieved its position through vertically integrated, large-volume chemical manufacturing on a scale that India won't be able to match in the short term, so if India wants to enter that arena it has to compete against China on her cost structure while also facing China's advantage in infrastructure. India's more sustainable approach is to compete along a different line: by building regulatory trust, through partnership models based on intellectual property, and by offering flexibility when it comes to complex, low-volume, high-value molecules, since global sponsors are looking for a partner who naturally understands FDA and EU-GMP requirements rather than one who is simply focused on volume. Global innovators do not intend to substitute one single-source dependency with another; instead, they are seeking a credible alternative source, either a second or third one with genuinely different risk profiles. That is the opportunity, and it is not about scale."

Aniel Khubchandani, CEO - Development & Manufacturing Solutions, Aragen, frames the opportunity differently. He says, "India does not need to replicate China's CDMO model; it needs to build a differentiated proposition of its own. China has developed significant

scale, infrastructure and deep manufacturing ecosystems over many years. India's opportunity lies in combining its established strengths in chemistry, scientific talent and cost competitiveness with stronger capabilities in integrated drug development, biologics, advanced modalities and high-quality manufacturing."

Tuneer Ghosh, President - CMC at Sai Life Sciences, also shares similar views and looks at the same idea in operational terms. He says "China+1 is an important catalyst. Customers are looking to diversify their supply chains because of geopolitical uncertainty, intellectual property considerations, and the need for greater resilience. But this is not simply about moving work from China to another location. Customers are also looking for partners who can take on more complex programs."

That shift is not just geographical. It is also about the kind of work India is expected to handle.

Cherreddi puts the test more bluntly. He says, "The reason India has made it to the short-list is scale, talent, and cost, but it won't end up at the top of the list. Global innovators are not only moving away from China's low costs but also from concentration risk that is, relying on a single geographical location for critical APIs and intermediates. India's advantage is structural, not merely competitive. Yet having the capacity does not guarantee reliability, and it is reliability that determines a CDMO's decision. The straightforward answer is that India has deserved a place at the table. Whether or not it wins the contract will depend on what happens in the future, specifically on the consistency of its quality systems, the speed of technology transfer, and the predictability of supply, not on cost advantages."

Khubchandani outlines how the role of a CDMO has evolved. "Indian CDMOs are already moving beyond a model defined primarily by cost and manufacturing scale. The next



Developed with India' is a far more valuable proposition than 'made in India' and it's within reach

Dr Chirag Adatia

Partner-Health & Life Sciences and Private Capital Practices, Oliver Wyman



India's opportunity, sharpened by BIOSECURE-driven derisking away from Chinese suppliers, is in complexity and trust — hard-to-formulate molecules, drug-device combinations, regulatory transparency — where scale matters less than judgment

Saurabh Agarwal

Director and CEO, HAB Pharmaceuticals and Research



Global innovators increasingly need partners who can understand the science behind a programme, anticipate challenges and help teams make better decisions earlier

Aniel Khubchandani

CEO - Development & Manufacturing Solutions, Aragen

phase of the industry will be defined by how effectively CDMOs can contribute across the drug development journey, from early discovery and process development to scale-up, regulatory support and commercial manufacturing. Global innovators increasingly need partners who can understand the science behind a programme, anticipate challenges and help teams make better decisions earlier," he points out.

However, he doesn't present the transition as automatic and

points out that it "requires deliberate capability investment, business model evolution, and willingness to own risk alongside clients - things most Indian CDMOs have historically avoided."

That is where the definition of a CDMO partnership starts to change.

Peter DeYoung, CEO, Piramal Global Pharma, says development partnership requires a different level of engagement with the client.

He explains, "Generally

speaking, acting as a development partner requires proactive regulatory (CMC) strategy, scientific and operational problem-solving expertise, and a commitment to project management. Taking a consultative approach to the clients' programs helps innovators optimise molecules long before they hit clinical manufacturing."

He adds, "Evolving from a transactional manufacturing model to a true development partnership requires owning the science from early-stage

discovery and route scouting through to commercialisation. Piramal Pharma Solutions was built with this concept in mind; our cross-functional scientific expertise integrates discovery, development and manufacturing. To eliminate vendor hand-offs, this model requires integrated process development, advanced analytical services, and multi-site tech transfer – all supported by a deep commitment to quality and patient centricity that spans every function."

Ghosh sees that evolution already underway in the kind of work now coming to India. He outlines, "Historically, much of the work coming to India was discovery- and early-phase-oriented, while late-phase and manufacturing work was more tactical. Over the last few years, however, we have seen customers increasingly look to outsource late-phase development and manufacturing work to India. This is an area where we believe Sai Life Sciences is well prepared to take on that challenge."

He predicts, "If we can do that, China+1 can help India evolve from an alternative supplier into a more strategic partner for global pharma."

Where the money moves

The opportunity is also changing at the molecule level.

Dr Adatia breaks it down by segment, "Small molecules will continue to anchor the CDMO value pool — 75%+ of it. Beyond that, the highest-value ground is peptides, ADCs, oligonucleotides and HP-APIs, along with enabling platforms like flow chemistry, biocatalysis and continuous manufacturing. GLP-1 manufacturing alone could be a \$20–25 billion opportunity by 2030, with roughly \$5–6 billion genuinely addressable by CDMOs, that's a category India cannot afford to sit out. Biologics is attractive but capital-hungry, and India is still sub-scale there. Peptides, oligonucleotides and ADCs are where India's synthetic chemistry heritage transfers most directly, and that's where I'd expect the fastest

gains," he predicts.

Suresh Subramanian, National Lifesciences Leader, EY Parthenon India, arrives at a similar shortlist but, in his opinion, "It won't be one modality that defines the next phase - it'll be whichever Indian players can move fastest from 'can we make this' to 'can we make this at GMP scale, reliably, for a global regulator.' That execution question matters as much as the science."

Ghosh also states, "Biologics will continue to be important, while peptides, ADCs, oligonucleotides, and other new modalities are creating new opportunities. And when we talk about peptides, it is important not to think only about GLP-1s. There are a lot of peptides outside of the realm of GLP-1s and hence a very interesting opportunity for us."

He believes that what ties these modalities together isn't the molecule but the capabilities required to develop and manufacture. Citing ADCs as an example, he says, "Supporting an ADC program requires capabilities around payloads, linkers, conjugation, and analytical characterisation, as well as the ability to manufacture the product. Similarly, peptides and oligonucleotides require specialised chemistry, analytics, and manufacturing infrastructure."

He emphasises, "That is why I think the opportunity is increasingly about bringing capabilities together around the molecule, rather than building a business around one modality."

Young also points to complex modalities and bioconjugates as important growth areas.

He states, "It's fair to say that historically, India has been associated with cost as its primary benefit. But in an industry where patients are the end customers, cost does not supersede quality, safety, and functionality. As such, the real focus of partnering with an Indian CDMO should be on value. Value creation must be anchored in flawless compliance records, robust data integrity,

sophisticated technical execution, and delivery."

He adds, "The next wave of growth engines in pharma represents additional opportunities. For example, complex modalities and bioconjugates are a segment where Indian CDMOs are poised to move the needle. Piramal has made investments in capabilities and talent in Antibody-Drug Conjugates (ADCs), highly potent active pharmaceutical ingredients (HPAPIs), and complex peptides for exactly this purpose. Likewise, investing in specialized processing technologies and advanced delivery technologies such as advanced spray-drying suites for poorly soluble molecules and biotherapeutics aligns with where the market is heading."

For an Indian CDMO, however, the opportunity is not only about what it can make. It is also about how reliably it can deliver.

Young says, "For an Indian CDMO, having resilient, global supply networks is a must. Building globally integrated asset platforms with localized hubs that offer the 'best of both worlds' in terms of Eastern and Western advantages can assure the compressed timelines that clients value most."

Dr Adatia concurs, "On large, complex programmes: a handful of Indian players can already run them end to end. For most of the rest, the constraint isn't chemistry — it's scale: reactor capacity, sterile fill-finish and programme-management maturity. That's a solvable problem, but it takes capital and discipline, not just ambition."

The complexity test

The answer from the industry is increasingly yes, but the differentiator is becoming the ability to execute those programmes consistently across development, manufacturing, technology transfer and supply.

Young says, "Leading Indian CDMOs have systematically dismantled the legacy perception that they are suited only for mature, generic APIs or simple

packaging projects. Today's Indian CDMOs feature state-of-the-art facilities and the ability to handle complicated projects across both small and large molecules. Piramal has focused its most recent capex commitments with support of these complex programs in mind, including major investments in the areas of bioconjugates, high potency APIs, and commercial-scale fill finish."

This brings the discussion back to one of India's most important advantages, the capabilities it already has.

What India already has

The case for India does not rest on geopolitics alone. It also has several structural strengths.

Subramanian points out that India already possesses several advantages. He lists them out, "The largest pool of pharma chemistry talent outside the West. One of the highest numbers of USFDA-approved manufacturing sites outside the United States. Deep expertise in process chemistry, scale-up and complex generic development. A growing biotech ecosystem and increasing biologics capabilities."

Cherreddi also says, "When it comes to quality, India is already in competition since the country possesses more US FDA-approved manufacturing sites than any other nation outside the US"

Agarwal agrees, "On core quality systems and USFDA-approved facility counts, India already competes credibly."

Khubchandani also concurs, but distinguishes between the industry's top layer and its average. He says, "Tier 1 Indian CDMOs operate with genuinely embedded quality systems and have clean regulatory track records. Global pharma clients conducting audits are increasingly aware of this bifurcation."

But that bifurcation may be one of the industry's key challenges.

India does not have a capability problem, but it has a consistency problem across the ecosystem.

As Dr Adatia also high-

lights, "Capability depth also remains uneven in biologics, complex peptides, ADCs, high-potency manufacturing, sterile drug product and advanced analytics. India has islands of excellence today. What it doesn't yet have is ecosystem-wide depth, and that's the gap to close."

Cost is no longer the pitch

That also changes the way Indian CDMOs need to sell themselves.

Global pharma companies no longer just want a manufacturer that can execute a defined process. Increasingly, they want a partner that can help move a molecule through development, end to end.

Asked whether India can still win on price, Dr Adatia says, "Yes, but this requires a different business model. Global leaders earn 30%+ EBITDA through technology, reliability and speed, rather than labour arbitrage. Cost is table stakes; it gets you into the conversation, nothing more. In our conversations with pharma CXOs globally, technical capability, dependability, on-time delivery and problem-solving consistently rank above price. That's because a molecule won at Phase I can convert into commercial supply a decade later, customers are choosing a long-term partner, not shopping for a quote," he says.

He cautions, "India needs to retire the '30-50 per cent cheaper' pitch. If a delayed drug launch can destroy hundreds of millions of dollars of value, customers will pay a premium for speed and certainty every time."

Ghosh shares similar views and reiterates, "Cost will remain an advantage for India, but it cannot be the only reason customers choose us. The more sustainable proposition is to combine cost competitiveness with scientific depth, quality, and reliable execution."

He adds, "We are seeing work move beyond simply transferring an established process to India for manufacturing. Customers are increas-

ingly bringing development activities and earlier-stage work, which suggests that they are placing greater confidence in the scientific capabilities available here."

Khubchandani captures the mindset change in a single line and states, "The firms that survive and lead will be those that have moved from execution-for-hire to genuine scientific partnership."

The real gaps

The opportunity is clear. The gaps are becoming clearer too.

Dr Adatia's diagnosis is direct. "India's biggest constraint today is not manufacturing competence, it's consistency of execution. Global customers expect faster RFQ turnaround, shorter technology-transfer timelines, stronger programme management and near-flawless delivery. That bar keeps rising, and India has to rise with it," he says.

Ghosh makes the same point from a delivery standpoint and opines, "I also think we need to be clear about the difference between demonstrating a capability and being able to deliver it consistently at scale. Global innovators expect the same level of quality, reliability and execution whether the program is being run in India or anywhere else in the world."

Cherreddi locates the risk with precision. "Regarding speed and reliability, however, the situation is more uneven, and this unevenness is in fact the main limiting factor, not a lack of technical ability. One warning letter or one missed delivery deadline can nullify years of hard-earned reputation with a global client."

His prescription is operational, not promotional. He advises, "The way to bridge that gap is not through a marketing effort but by adopting operational discipline: by making audit-ready documentation a permanent condition rather than something only done in anticipation of an inspection, by ensuring real-time visibility into a CMO's performance

rather than relying on reports at the end of each quarter, and by treating compliance as a design principle rather than as a mere checkpoint. The Indian companies that are securing repeat business from abroad have made this operational discipline a regular part of their operations rather than something they only do on an ad hoc basis."

The talent bottleneck

Underneath the consistency problem sits a talent problem.

Agarwal names the exact functions India is short on and informs, "Talent depth in the functions that actually decide whether a global innovator signs a multi-year contract — EU-GMP-trained regulatory affairs, quality-by-design formulation science, project management for tech transfer — is where India is genuinely stretched. India adds capacity faster than it adds qualified regulatory and quality professionals, and that gap, not plant count, is what slows conversion from enquiry to contract."

He returns to it in market terms and says, "'Strategic partner' status is earned deal by deal, through demonstrated regulatory judgment during a tech transfer or an FDA query, not through capacity announcements. The industry has the assets; it hasn't yet built enough of that decision-making bench strength across mid-size players, which is where most of India's real capacity actually sits."

Technology remains part of the same equation. "The honest gap is technology adoption in mid-market plants — QMS, LIMS and MES are still inconsistently deployed outside the top-tier players — and that inconsistency is what innovators read as reliability risk. Speed follows the same pattern: the best Indian sites move as fast as anyone; the sector's average doesn't, because digital maturity and regulatory bench strength aren't evenly spread."

Khubchandani's numbers point to progress and a persistent gap sitting side by side. He

THE INDIA CDMO OPPORTUNITY

- **\$3–3.5 bn** — India's CRDMO industry in 2024
- **\$22–25 bn** — projected size by 2035
- **\$10–15 bn** — potential value from global supply-chain realignment
- **\$5 bn** — demand that could move to India
- **\$9–10 bn** — potential unmet demand India could capture
- **75%+** — share of CDMO value pool anchored by small molecules
- **\$20–25 bn** — potential GLP-1 manufacturing opportunity by 2030
- **\$5–6 bn** — potentially addressable by CDMOs

says, "AI-linked skill demand in Indian CDMO grew 180 per cent in last two years — the intent and the talent pipeline are real. Yet continuous manufacturing, where Lonza and Pfizer CentreOne are genuinely ahead, remains India's clearest technology gap in small molecules. We are catching up fast."

Chereddi adds, "Capacity utilisation in Indian API manufacturing is around 30 to 40 per cent, considerably lower than that in China, which shows that the industry has more untapped potential than it is currently bringing to market."

Subramanian identifies three structural gaps.

The first is regulatory agility, where "approval timelines, import clearances for research materials, and multi-agency regulatory processes remain less predictable than competing jurisdictions".

The second is innovation and risk capital, where "India remains underinvested in biotech innovation compared to the US, Europe and China".

The third is talent in emerging technologies, where "the industry needs significantly larger pools of talent in biologics, bioprocess engineering, automation, data integrity, AI-enabled quality systems, and regulatory science."

From vendor to partner

The shift from manufacturing vendor to development partner is perhaps the clearest test of how far India's CDMO industry has moved.

"Developed with India" is a far more valuable proposition than 'made in India' and it's within reach," Dr Adatia says.

"We're already seeing several Indian players move upstream into discovery chemistry, DMPK, process development and clinical supply, with early-stage molecule counts up several-fold over the past two to three years," he adds.

Chereddi is clear about what that transition requires.

In his opinion, "The move from being a vendor to being a partner is not about gaining new capabilities; it's about altering the ownership model. When a vendor receives a specification, they carry out the specification. A strategic partner, on the other hand, shares in the regulatory and technical risks associated with getting a molecule to market, from the DMF filing all the way through to scale-up. This means that Indian companies must make investments upstream, in regulatory intellectual property, in process development, and in having the ability to enter a partnership conversation by owning the filings and the data, not just the factory floor space. The companies that close this gap by developing real development and filing capabilities rather than simply running someone else's process are the ones who will be asked back for the next molecule, not just the current one."

Young's view reinforces that shift. The development partner has to be involved much earlier, own the science and remove handoffs across the development and manufacturing journey.

That is also where BCG-IPSO reports recommendation runs parallel. Move from being a preferred outsourcing desti-

nation to a genuine innovation partner, by building differentiated capability rather than stacking commodity capacity, building end-to-end platforms across the value chain, locking in longer-term relationships instead of leaning on spot business, treating inspection readiness as a daily discipline, and building supply-chain resilience by localising critical starting materials.

The opportunity, then, is no longer simply about attracting work to India. It is about retaining that work through deeper relationships.

Execution, not potential

Dr Adatia gives that ambition a number and a deadline. He says, "My view is that the ambition should be explicit, not implicit: become a top-three global CRDMO geography, and move toward 10–12 per cent of global outsourced work within the next decade. That will take sustained investment in talent, specialist suppliers, world-class quality systems and stronger customer-facing teams. The opportunity is real. Whether India captures it is now a question of execution, not potential."

Ghosh frames the same ambition in terms of complexity. He states, "I think India should aspire to be one of the world's leading CRDMO hubs, but I would measure that ambition by the complexity and value of the work we are able to undertake, rather than simply by the size of the industry."

Capturing the larger opportunity, he explains, "The real ambition should be to build an industry that is globally com-

petitive on science, technology, quality, and execution, while retaining the cost advantage that India has today. If we can make that transition, India can move from being an important outsourcing destination to becoming a strategic development and manufacturing partner for global pharma."

Agarwal and Chereddi reach for almost the same conclusions.

Agarwal says "The CDMOs that get there first won't be the ones with the most capacity; they'll be the ones that closed the talent gap before their competitors noticed it existed."

Chereddi asserts, "The Indian CDMOs who are selected first, rather than being chosen as a backup, will be the ones who stop merely selling capacity and begin selling certainty."

China+1 gave India a strong push. It also delivered a quiet warning: diversification creates options for customers, not loyalty.

India is no longer just competing with China. It is competing with every geography trying to become the next trusted outsourcing destination.

The raw materials for success are already on the table. We have the scale, talent, cost competitiveness, manufacturing experience and a regulatory track record that is gradually maturing.

What's left is unglamorous but unavoidable. Do what was promised, deliver when promised and get it right, consistently.

India's CDMO opportunity was helped along by a geopolitical shift. Its future will be decided by something far more basic, whether global pharma can trust an Indian CDMO with its molecule for the next ten years. That's the real test. And it is how India moves from being the alternative to becoming the choice.

*lakshmi priya.nair@expressindia.com
laxmipriyanair@gmail.com*

*(With inputs from
Kalyani Sharma and
Neha Athavale)*

SIRO Clintech reloaded

As SIRO Clintech completes three decades, founder **Dr Gautam V Daftary** and son **Karan Daftary**, aim to go beyond a traditional CRO's role, as Lifecycle Evidence Partners throughout the product lifecycle, reports **Viveka Roychowdhury**

Corporate history is replete with examples of the 'third generation curse', but the Daftary family seem to be bucking that trend. Sure, they sold Bharat Serums & Vaccines (BSV), founded in 1971 by family patriarch Vinod G Daftary, to Mankind Pharma in 2024.

But the family has ambitious plans for SIRO Clintech, a company founded in 1996, by the second generation, Dr Gautam V Daftary. The third generation, Dr Daftary's sons Akshay and Karan, are firmly in the saddle.

"Divestment of SIRO is not part of the strategic plan", says Founder and Chairman of SIRO Clintech Dr Daftary. Karan Daftary, MD, SIRO Clintech, emphasises that "the focus is much more on growth than on an exit plan. SIRO Clintech is today focused on becoming the largest and most advanced technology-enabled CRO in India."

Divestment increased focus

BSV's divestment to private equity Advent International in 2019 "was an inflection point for the family", reflects Dr Daftary, as it allowed the family "to focus our leadership attention on SIRO in a way that wasn't possible before, and the past decade has been the most focused period of growth in SIRO's history."

He explains that SIRO's independence is deliberate as it allows them to invest with a long-term perspective, something that is difficult in a private equity-owned model. "We are among the very few Indian CROs to make sustained investments in R&D, and SIROai is the result of more than five years of foundational work. That kind of commitment is only possible when you have a long-term vision beyond the next business cycle."

Daftary concurs, saying "We remain open to divestment or



Founder and Chairman of SIRO Clintech Dr. Gautam V. Daftary with his two sons, (left) Akshay Daftary, Board Director, SIRO Clinpharm and Karan Daftary, Managing Director, SIRO Clintech

strategic options over the longer term, but right now the priority is to grow each business, organically or inorganically, rather than pursue an exit plan. Across all businesses, the immediate focus is on infusing safe technology to reduce manual effort, expand the revenue base and grow the client base and service portfolio."

Agreeing with his father, Daftary points out that the demerger two years ago was an important structural change because it gave each business greater focus across its respective markets, clients and positioning. "We are now at a point where we believe the longevity of companies is highly dependent on the technology built into them, as well as on how safely that technology is implemented. That has influenced how we have repositioned the group and how we approach the business."

On the other revenue streams, Daftary says the

medical writing business has moved its focus to the UK and other larger European and US markets because of the opportunities for standardised service offerings. SIRO's staffing business is India-centric in terms of operations, while hiring globally. The demerger therefore created focused businesses that can grow in their own manner.

Making the generational divide work

As much as the two generations are in sync on this aspect, Dr Daftary admits that "the generational difference is real." But the family has made this difference work, as "differences resolve through the discipline of asking each other the harder version of the question, and through mutual respect for what each generation genuinely brings."

As Dr Daftary explains, "I carry the memory of every cycle SIRO has been through over

three decades. Karan carries the read on where the industry is heading next, and the operational tempo the current market demands. Neither view is complete on its own. The way it works in practice is not that one voice wins. It is that we test each other. When Karan pushes for something aggressive on AI or capability build, the question I ask in return is whether we have thought through the downside. When I am cautious on a market move, the question Karan asks is whether the caution reflects the current market or a market that has already changed. Both questions are useful, and neither is decorative."

As Daftary puts it, "I would describe the difference less as 'safe versus aggressive' and more as 'experience versus youth.' Experienced leaders understand not only the opportunities but also the downstream consequences of decisions. The younger generation tends to have a stronger pulse on how quickly technology and market adoption are changing. The combination works well: we can move quickly while still operating in a realistic and safe manner."

He emphasises that they are not trying to build the business around quick profits, but "to build a brand and a legacy over decades. We have seen that model work within the family and want to replicate it. In that sense, the combination of access to AI and technology, together with experienced oversight and guidance around the requirements of drug development and patient care, is a major advantage."

The past three decades

SIRO has ridden both the crests and troughs of global and India's clinical research sector.

Looking back over the past three decades, Dr Daftary agrees, "The last three decades

of Indian CRO business has not been a straight line story. Every five to seven years, the industry has had to reset, and each of those resets pushed SIRO to strengthen a different capability. That is the discipline of an evidence business."

At each reset, SIRO seems to have redefined itself, moving to where the market is.

For instance, as Dr Daftary points out, "When competition grew, SIRO moved up the value chain into strategic services. Medical writing, biometrics, and regulatory science were less commoditised than trial operations, and quality mattered more than headcount. The diversification from medical writing came through a deliberate build over the past decade of what is now the four-pillar architecture: Development clinical trials, Post-approval clinical programs, Real-world evidence, and Evidence platforms and intelligence. Medical writing sits inside the fourth pillar as one capability among several."

Similarly, "when global pharma tightened R&D investment through the 2010s, we deepened the Indian sponsor base and the Post-Approval and RWE offerings, both of which grew as regulators moved to require more local evidence. And on US client over-dependence, geographic and sponsor diversification was a deliberate multi-year shift. US concentration was reduced by design, not by accident, and the Indian sponsor base has become a genuine growth engine over the past decade."

Giving his perspective, Daftary narrates how as India's first CRO in 1996, SIRO was involved in building parts of the Indian CRO ecosystem, including work around ethics committee and site guidelines. Over the early years, the company developed large partnerships with global companies, which made

them one of the prominent players in the Indian clinical research market.

As the clinical trial market in India reached a peak, SIRO opened to private equity investment. 3i Group and Kotak Private Equity became part of the growth story, and a decision was subsequently made to acquire Omega, a large European CRO, in 2008.

In hindsight, Daftary feels that that “was the right decision at the wrong time” as the acquisition coincided with the recession, which led to reduced R&D spending and made the economics and local operations considerably more difficult. Ultimately, SIRO wound down those operations.

Around 2016–2017, the company retained the conviction that clinical research was a business they could scale. With the third generation ready to join the company, SIRO acquired the business back.

The group is now 100 per cent family-owned and completely debt-free, says Daftary, with operations funded through their own cash flows and investments, “which gives us a lean operating model across the group.”

He reveals that SIRO’s clinical research work today is focused primarily on Indian patients. The client roster comprises large Indian pharma companies and Indian affiliates of global companies, as well as FMCG, medical device and vaccine companies. Medical writing has a global footprint, particularly across Europe, the US, APAC and the Middle East, because it can be delivered as a standardised service within larger development programmes, reasons Daftary. The staffing arm is geography-agnostic and works across markets. Overall, the group remains under complete family control.

Revenue wise, across the group, growth was around 40 per cent last year and approximately 15–20 per cent the year before, following some ups and downs in the earlier period. “The momentum over the last two to three years has been strong, and we are looking to build on it further this year. We have also added around 10–12 new clients in the six months since January.



The 5.3 per cent number changes when we stop pitching cost and start pitching evidence quality

Dr. Gautam V. Daftary

Founder and Chairman,
SIRO Clintech



Across all businesses, the immediate focus is on infusing safe technology to reduce manual effort, expand the revenue base and grow the client base and service portfolio. Today, our focus is much more on growth than on an exit plan

Karan Daftary

MD,
SIRO Clintech



Evidence from Phase IV and post-marketing studies is important to understand performance in a broader, real-world population. The shift is from seeing regulatory approval as a milestone to building evidence throughout the product lifecycle

Dr Somesh Bolegave

Head Biometrics, Regulatory & Medical Services,
SIRO Clintech

The key lesson has been that systems, people and processes need to be built first; only then can the business scale. The last two years have provided that launchpad and enabled us to grow well above industry averages,” claims Daftary.

All this has positioned SIRO for the next reset.

From clinical trials to clinical evidence

As Dr Daftary puts it, “The shift from project-based clinical trials to lifecycle evidence partnerships is the single biggest change in the CRO business model in the last decade. It reflects a change in what sponsors actually need. They need evidence at

every stage of the product lifecycle: before approval, immediately after approval, and years into commercialisation.”

While project-based CROs deliver a trial, Lifecycle Evidence Partners deliver a continuous evidence stream across the full commercial life of the product. According to Dr Daftary, “SIRO has architected the business around this shift. The four pillars are the operating structure, not a marketing frame. The tagline that captures this shift is clinical trials to clinical evidence, and it reflects both the direction the industry is moving in and the direction SIRO has already moved to.”

Looking ahead, Dr Daftary

believes that the next chapter is scaling the model. “The shift is not just a business model change; it also reflects a maturing regulatory environment that asks for evidence long after approval, and a maturing scientific standard that asks for evidence from the population the drug will actually treat.”

So, how does a lifecycle evidence partnership look like in practice?

Dr Somesh Bolegave, Head Biometrics, Regulatory & Medical Services, SIRO Clintech explains with an example, citing an oral insulin product that had been approved in the US but faced challenges around integration and adoption in India. The

product represented an important area of formulation science because moving insulin away from injectable delivery has long been an important goal in diabetes care.

The regulatory challenge in India was the absence of sufficient local evidence for the product. Rather than treating approval as the end of the process, the strategy was to develop an India-specific evidence pathway. SIRO Clintech partnered with Cipla to define a route that would satisfy regulatory requirements while also generating confidence in the evidence. SIRO Clintech conducted the Phase III trial, which received approval from the Indian regulator in 2025. The product is now available in the Indian market.

However, Dr Bolegave emphasises that regulatory approval is not the end of the evidence journey. Phase III trials are conducted in selected populations, so evidence from Phase IV and post-marketing studies is important for understanding performance in a broader, real-world population.

He points out that that is the shift from seeing regulatory approval as a milestone to building evidence throughout the product lifecycle. “As AI capabilities expand, patient voice and social media feedback can also be incorporated into the evidence-generation process, so that decision-making is informed not only by developers and companies but also by patient experience and needs.”

He cautions that the challenge is to generate evidence quickly while ensuring that it remains scientifically robust and validated, and reasons that this is where an experienced CRO can combine its knowledge of trial conduct and evidence generation with technology to make the process more efficient.

Policy support

India’s policy framework and regulation seems to have finally caught up with the industry’s evolution, with long awaited policy changes closing gaps.

Both Daftary and Dr Bolegave believe that the New Drugs and Clinical Trial (NDCT) Rules 2019 fundamentally changed the pace and predictability of clinical

cal trial approvals in India.

The measurable difference has been in timelines. Approval cycles that could earlier run six to nine months now sit within defined statutory timelines that regulators have largely honoured. NDCT 2019 delivered defined timelines, expanded scope of oversight, and a formalised SEC review structure, creating the foundation for subsequent reforms.

In their opinion, the 2026 prior intimation pathway is the clearest recent signal of the direction of travel. It compressed review timelines from 90 to 45 working days for eligible studies. They reason that that is a signal that the regulator is willing to move fast when the scientific case is well made and the CRO track record is established.

Going forward, they both believe that the industry would benefit from faster review timelines for standard applications, clearer guidance on Rule 101 country-waiver criteria for cell and gene therapies and rare diseases, stronger SEC composition for emerging modalities, and a risk-based inspection framework for CROs post-registration.

They also point out that infrastructure policy support matters equally: SHAKTI-scale site expansion beyond the first thousand, stronger biomarker testing capacity, patient registry consolidation across therapeutic areas, and continued investment in the digital health infrastructure that decentralised trials depend on.

SIRO has apparently had a good compliance record. Both Daftary and Dr Bolegave emphasise that the company has been inspected and audited by global and national regulatory agencies, including the US FDA, European regulators, the WHO, Indian regulators and Japanese regulators, with no critical observations.

But quality inspections are not limited to regulators. Daftary and Dr Bolegave point out that many global pharma companies operate quality systems that are more stringent than minimum regulatory requirements. They stress that SIRO has been audited more than 250 times by such global

organisations, with no critical observations, which validates the company's quality systems and data integrity.

Thanks to these regulations, they point out that the landscape has evolved on four important fronts. Firstly, mandatory CRO registration under the NDCT Amendment 2024 has raised quality standards. Secondly, CDASH-aligned workflows are now standard rather than optional. Thirdly, risk-based quality management is being formalised in the draft GCP revision. And lastly, AI governance frameworks are becoming part of CRO operating models.

Changing sponsor perceptions

But India's clinical research sector has not made its global mark as expected. Though India's CRO market is expected to reach \$ 4,956.7 million by 2033 at a 9.5 per cent CAGR, India accounted for only 5.3 per cent of the global pharma CRO market in 2025. This clearly points to major issues that still need to be addressed.

As Dr Daftary puts it bluntly, "The 5.3 per cent number changes when we stop pitching cost and start pitching evidence quality."

Taking this further, both Daftary and Dr Bolegave believe that the credibility of that proposition will ultimately depend on whether operational delivery can withstand global regulatory scrutiny and inspection.

They point out that global sponsors are increasingly seeking high-quality evidence: meaningful, publishable, decision-useful insights from every study run in India. India has structural advantages that remain underutilised in the current sponsor narrative, including diverse patient population, a disease burden across therapeutic areas, rapidly evolving digital health infrastructure, and English-language regulatory operations that make audit trails accessible to global reviewers.

They agree that the larger challenge lies in changing sponsor perception. India continues to be viewed as primarily a delivery venue when it should be recognised as a strategic hub for evidence generation. Changing

this narrative will require leadership from Indian CROs supported by an enabling regulatory environment.

The road ahead

Daftary and Dr Bolegave caution that on the regulations front, while the direction is right and the pace has been steady, what the industry needs now is sustained momentum, not new frameworks every year, cautions the duo.

Similarly, the Biopharma SHAKTI programme to establish 1,000-plus clinical trial sites is a step in the right direction, as India has been site-constrained for several years, particularly in therapeutic areas beyond the top three or four, and expanding the site base is therefore a meaningful structural intervention.

But they once again sound a cautionary note, pointing out that this expansion should be matched by quality. Establishing a thousand new sites will be meaningful only if investigator training, ethics committee readiness, and site infrastructure are matched to that pace, and early signals suggest the government recognises this requirement and is investing in supporting this ecosystem.

Operationally, they believe that the impact is likely to show up first in post-approval clinical programmes and post marketing surveillance studies (PMS studies), as these are the categories where India needs greater site density. Development-stage clinical trials are likely to follow as investigator and sponsor confidence at the newer sites increases.

The duo point out that data quality was a legitimate concern in an earlier era, but it is no longer the barrier it once was. Today global sponsors audit the strength of the underlying quality management system, not just the data produced, and Indian CROs that have invested in that system are winning global trials on the strength of their capabilities.

At SIRO, we operate a globally aligned quality management system, supported by ISO-certified diagnostics AI capabilities at the parent group level, a formal AI governance framework, and immutable audit trails for

AI-assisted workflows. These are operational capabilities, embedded in our processes, not simply claims made on paper.

On AI, the generational balance steps into the picture once again.

"AI has a role across the drug and evidence lifecycle, but it is important to separate real capability from industry hype. Our approach is to be clear about what AI can and cannot do," states Dr Daftary.

He agrees that today AI is effective in drafting scientific documents under human review, extracting insights from completed clinical study reports, structuring safety and pharmacovigilance signal detection, and capturing patient voice from digital sources at scale.

But he also points out that AI is not credibly ready for autonomous clinical decisions, independent regulatory submissions, or unsupervised medical writing.

Therefore Dr Daftary believes that AI is a system enhancement, it is not a substitute for clinical governance. "Applied appropriately, AI can materially strengthen informed consent quality through multi-language e-consent, data integrity through real-time query resolution, and evidence generation through capturing patient voice at scale. SIROai is built as an internal capability layer, not a SaaS product sold to sponsors, and that model matters. AI works when it is embedded within a robust quality system, not when it is bolted on top. Our governance principle is simple: AI is a drafting assistant, not a decision-maker. Every AI-assisted output goes through mandatory human scientific review before release, every AI interaction is logged, and audit trails are immutable."

The case for India's clinical research sector

Dr Bolegave is of the firm opinion that India's clinical research industry has matured significantly and become increasingly science driven. The overall trend has been positive, including during COVID-19 when India played a significant role in the global development

and testing of COVID-related products and vaccines, supported by increasingly robust mechanisms and a maturing policy environment.

He points out that another major area of focus is diversity and the need to understand why products may perform differently across populations. It is no longer sufficient to assume that a product developed and approved elsewhere will automatically provide all the evidence required for another population. Regulators increasingly recognise the importance of generating appropriate India-specific evidence while also avoiding unnecessary duplication where robust global evidence already exists. This represents a more mature regulatory approach. Regulators are better able to distinguish between situations where India-specific trials are essential and situations where existing global evidence can be leveraged, complemented by focused local evidence, analyses Dr Bolegave.

Both generations of the Daftary family agree on the strategy going forward. To attract more global trials, they believe that India must keep investing in quality across the CRO ecosystem, educate sponsors that Indian data quality has evolved, and increase participation of Indian organisations in global multi-country trials.

While the systems are largely in place, they reiterate that the bigger challenge now is changing global perception, and that requires India's CRO industry to communicate its capabilities more effectively.

Can SIRO Clintech navigate scaling up with the same quality? Will regulatory oversight continue to keep pace with the deployment of new technologies like AI in clinical research and trials? And when will sponsor perception change to view India as more than a delivery venue but a strategic hub for evidence generation? India's clinical research sector needs to convert potential into reality and the next few years will be crucial toward this goal.

viveka.r@expressindia.com
viveka.roy3@gmail.com

Unclogging India's innovation pipeline

Srinath Venkatesh, MD, India & South Asia, Thermo Fisher Scientific opines that strengthening STEM talent, research capacity and industry-academia collaboration will be critical to turning India's innovation potential into sustainable global competitiveness

Innovation is often measured through rankings, patents and startup success stories. While these are important indicators, they capture only a part of the picture. A truly innovation-led economy is built on a continuous pipeline that connects STEM education, scientific research and industry. When even one part of that pipeline weakens, the country's ability to translate ideas into real-world impact is constrained.

Going by the numbers, India appears to be on the cusp of being considered as an innovation-driven economy. However, that deserves a closer look.

India produces around 2.6 million STEM graduates each year¹, including around 1.5 million engineers². Over the past decade, the country has risen from 66th³ to 38th⁴ rank in the Global Innovation Index, while its startups ecosystem has grown to more than 0.2 million DPIIT-recognised startups⁵. These achievements reflect India's growing ambition to become an innovation-led economy, but they also invite a deeper question: are we strengthening every part of the innovation pipeline that makes such progress sustainable?

These are encouraging signs that India's innovation ambitions are gathering momentum. Yet, innovation cannot be measured solely by outputs such as rankings or startup numbers. The strength of any innovation ecosystem lies in its ability to consistently generate, nurture and translate scientific knowledge into meaningful economic and societal outcomes.

But statistics often hide a more important story.

The real question is not whether India is producing talent, but whether it is creating the conditions for that talent to become researchers, innova-

tors and problem-solvers. This is where the country's innovation pipeline begins to narrow. Of the 1.5 million people who graduate with a science degree each year, about half enrol⁶ in post-graduate degrees, and slightly less than half (365,000) graduate, according to AISHE⁶. The funnel narrows further: 7,400 candidates are awarded a PhD in sciences each year⁶.

What emerges is a 'missing middle'- the crucial layer of scientific research that connects education with industrial innovation.

One number presents the culmination of all the data shared above: the number of full-time equivalent (FTE) researchers per million people. That figure is just 255 in India, against a global average of 1,198⁷. This gap is significant because research capacity ultimately determines how quickly ideas move from laboratories into products, technologies and scalable solutions. Countries that consistently lead in innovation invest not only in talent, but also in creating an environment where researchers can thrive.

India's rise to 38th rank in the Global Innovation Index is encouraging. India has been climbing up the list by one rank over the last three years. Sustaining this trajectory will require translating scientific research into globally competitive products, technologies and companies, if the country is to join the world's leading innovation economies.

As experts⁸ have pointed out, cutting-edge research is happening so fast that the country cannot afford to fall too far behind.

The government's ambitions on innovation are clearly laid out as part of Viksit Bharat and Atmanirbhar Bharat. In this year's Union Budget, finance minister Nirmala



Sitharaman announced a Research, Development and Innovation (RDI) fund of Rs 1 trillion (Rs 1 lakh crore), of which Rs 200 billion (or Rs 20,000 crore) will be allocated in this financial year itself. This includes a Deep Tech fund and financial resources targeted at advanced materials, robotics and artificial intelligence (AI).

These policy measures signal an important shift in how India views research and innovation, not as isolated scientific pursuits, but as strategic drivers of economic growth, technological self-reliance and global competitiveness. Funding is undoubtedly essential, but its real value lies in creating an ecosystem where researchers, startups, academia and industry can work together with shared purpose.

In 2023, the government established the Anusandhan National Research Foundation (ANRF) through an Act of Parliament. One of its main objectives was to promote industry-academia collaboration in R&D.

While India's investment in R&D (0.64% of GDP)⁹ remains below that of many innovation-led economies, an equally important challenge is broadening participation beyond government funding. Innovation ecosystems are strongest when public investment is complemented by sustained com-

mitment from industry. Industries are not simply end-users of research; they are partners in shaping research priorities, investing in translational research, accelerating commercialisation and building future-ready capabilities.

India must find ways to address this 'missing middle', and that must start with STEM education. Building research capacity is not simply about increasing the number of PhD programmes or research institutions. It is about creating an environment where curiosity is encouraged, interdisciplinary collaboration is valued and young researchers see long-term opportunities to pursue scientific discovery. A strong innovation ecosystem is built over decades, through consistent investment in people as much as infrastructure.

First, teaching and research must both be strengthened significantly on an accelerated basis, using financing provided for in the Union Budget and the ANRF Fund. Resources from other initiatives and missions sponsored by the government can also play a key role in developing world-class lab infrastructure, shared scientific facilities and faster access to advanced instrumentation. The will exists, and ways must be found.

Second, STEM education and pedagogy must be integrated into skills, built on foundational education, specialised education, opportunities, and innovation. Included in all of this must be ways of translating research outputs into applied science and solutions that meet industrial and technological needs.

Third, drawing from the two steps outlined above, industry-academia collaboration must increase significantly. In healthcare, climate science and energy, and advanced materials sciences, such collaboration

can begin with institutions of national importance like the Indian Institute of Technology, the Indian Institute of Science, and specialised institutions. These are already primed to do this; what is needed is rapid expansion of such activity.

For private sector corporate strategy, the goal of R&D is to create new sources of competitive advantage. Nationwide, companies haven't been doing enough; that can change now. R&D is a layered phenomenon; addressing the layers can help us understand how to go about maximising what companies and the country at large can get out of investing in it. India's aspiration to become an innovation-led economy cannot be achieved by government or academia alone. It requires industry to move from being a consumer of innovation to becoming a co-creator of it.

Sources

- 1 <https://educationforallinindia.com/the-stem-pipeline-in-india-from-science-classrooms-to-stem-degrees/>
- 2 <https://www.pib.gov.in/Press-releaseshare.aspx?PRID=1702450®=48&lang=2>
- 3 https://www.wipo.int/edocs/pubdocs/en/economics/gii/gii_2013.pdf
- 4 <https://www.wipo.int/web-publications/global-innovation-index-2025/en/gii-2025-results.html>
- 5 <https://www.pib.gov.in/Press-ReleasePage.aspx?PRID=2214872®=3&lang=2>
- 6 https://www.education.gov.in/sites/upload_files/mhrd/files/statistics-new/AISHE%20Book_2021-22_4.pdf
- 7 https://dst.gov.in/sites/default/files/S%26T%20Indicators%20Tables%2C%202019-20.pdf?utm_source=chatgpt.com
- 8 <https://www.pib.gov.in/Press-ReleasePage.aspx?PRID=2150817®=48&lang=2>
- 9 <https://www.pib.gov.in/Press-ReleasePage.aspx?PRID=2153547®=3&lang=2>

When the lab talks to the plant

Lab informatics is changing how pharma companies transfer knowledge, control quality and move from development to commercial manufacturing, writes **Swati Rana**

As pharma companies accelerate digital transformation, lab informatics is emerging as a strategic enabler of faster R&D, stronger data integrity, regulatory compliance, technology transfer and operational efficiency. Solutions such as Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELNs), Chromatography Data Systems (CDS), Scientific Data Management Systems (SDMS) and AI-powered analytics are helping labs move from fragmented, paper-based processes towards connected, data-driven operations.

The business case for connected laboratories

The growing focus on lab automation, data integrity, regulatory compliance and AI-driven analytics is translating into strong market momentum. According to Grand View Research¹, the global lab informatics market was valued at approximately \$5.9 billion by 2033, representing a CAGR of 4.9 per cent between 2026 and 2033. LIMS accounted for the largest product segment, while cloud-based solutions represented the largest delivery mode. The life sciences sector was the largest end-use segment in 2025.

India is also emerging as an important growth market. Grand View Research estimates that the Indian lab informatics market will generate \$397.3 million by 2033, growing at a CAGR of 7.8 per cent.

These figures reflect a broader shift in how pharma companies view lab informatics. It is no longer simply an IT system for managing lab records; it is increasingly becoming part of the digital infrastructure supporting R&D, quality, technology transfer and manufacturing.

Linking the lab to the pharma value chain

One of the most significant benefits of lab informatics is the creation of a single, reliable digital environment for lab data. Analytical development laboratories generate vast amounts of information from HPLC, GC, spectroscopy, dissolution, stability and microbiological testing. Historically, this information was often distributed across instruments, spreadsheets, paper records and standalone applications.

Integrated informatics platforms can capture, manage and connect this information, reducing manual transcription, improving traceability and enabling faster retrieval and review. Automated workflows, electronic records, audit trails, electronic signatures and controlled access further strengthen data integrity and support regulatory expectations, including ALCOA+ principles.

The benefits extend well beyond the lab. Technology transfer and scale-up are emerging as important areas where connected informatics can deliver significant value. Transferring a product or process from R&D to manufacturing involves far more than exchanging documents. It requires the transfer of process understanding, analytical knowledge, historical data and often tacit expertise.

Data silos, inconsistent documentation, equipment differences and communication gaps can create delays, deviations and costly rework. Integrated LIMS, ELN, MES and document-management environments can provide a common data ecosystem, ensuring that development, QC, QA, technology-transfer and manufacturing teams work from approved and consistent information.

The interoperability challenge

Despite the benefits, digital transformation is not without challenges. Integration with analytical instruments and legacy systems remains one of the biggest barriers. Pharma laboratories often operate instruments from multiple vendors with different data formats, communication protocols and software versions. Legacy equipment and applications can be particularly difficult to connect to modern platforms.

At the same time, regulatory expectations around data integrity, cybersecurity, electronic records and auditability continue to evolve. Organisations therefore need to balance modernisation with the need to preserve valuable historical data and maintain validated systems.

Industry experts point towards a phased approach to digitalisation, rather than large-scale replacement programmes. Standardising data sources, using open interfaces, establishing robust governance and involving lab, quality, IT and compliance teams from the beginning can help organisations manage integration and validation challenges more effectively.

The rise of the intelligent laboratory

The next phase of lab informatics will increasingly be shaped by AI, automation and advanced analytics. AI can help identify trends in stability data, detect anomalies in analytical results, support method optimisation and potentially predict instrument or process failures before they affect operations.

Automation can reduce routine activities such as sample tracking, data compilation, result verification and report generation, allowing scientists to focus more on scientific in-

terpretation, problem-solving and innovation. Real-time analytics can also enable laboratories and manufacturing teams to move from reactive investigation towards predictive decision-making.

Concepts such as digital twins, AI-powered lab assistants and real-time data review are likely to become increasingly relevant as informatics platforms mature.

However, successful digital transformation will depend on more than technology. Legacy infrastructure, investment constraints, cybersecurity, regulatory requirements, workforce skills and resistance to change can all slow adoption. Organisations that demonstrate value through targeted pilots, secure executive sponsorship, engage end users, invest in training and adopt scalable and interoperable platforms will be better positioned to realise the benefits.

Ultimately, the future-ready pharma lab will be connected, intelligent, standardised and increasingly autonomous. The convergence of lab informatics, AI, automation and advanced analytics can create a continuous flow of trusted data from discovery and development through quality control, technology transfer and manufacturing.

For pharma companies seeking faster development timelines, stronger compliance, improved quality and greater operational agility, lab informatics is increasingly becoming not just a technology investment, but a foundation for digital transformation and the lab of the future.

What the industry is seeing on the ground

The market trends and technology shifts point to a lab environment that is becoming increasingly connected, automated and

data-driven.

- But how are these changes playing out on the ground?
- What are pharma companies prioritising, where are they encountering challenges?
- How do industry leaders see the next phase of lab digitalisation?

To explore these questions, *Express Pharma* spoke with industry experts and technology leaders on how lab informatics is evolving, its growing impact on analytical development and technology transfer, and the challenges of integrating legacy systems. They also share their perspectives on how AI and automation can help build more connected, agile and future-ready laboratories. The interviews that follow bring together their views and insights on this evolving landscape.

What lies ahead

Their perspectives highlight a common theme - while technology is an important enabler, successful digital transformation also depends on data governance, interoperability, regulatory readiness, process understanding, workforce capabilities and change management.

The opportunity for pharma companies lies in moving beyond isolated technology deployments towards an integrated digital ecosystem in which instruments, laboratory systems, manufacturing platforms and enterprise applications can exchange trusted data seamlessly. As AI and automation mature, the value of informatics will increasingly be measured not only by how effectively laboratories store and manage data, but by how quickly they can convert that data into actionable scientific and operational insight.

swati.rana@expressindia.com
swatirana.express@gmail.com

Taking the guesswork out of technology transfer

Narotam Kumar Juneja, Technical Advisor, Uniserum Lifesciences discusses how lab informatics is helping organisations create a connected data environment, strengthen technology transfer and improve consistency across manufacturing sites

How is lab informatics improving the efficiency and reliability of technology transfer across development and manufacturing sites?

Data management systems play a crucial role in the pharma industry where the stakes are high and the need for accurate and efficient data management systems is paramount. In an industry that deals with sensitive patient information, complex clinical trial data, and stringent regulatory requirements, having a robust data management system is essential for ensuring compliance, efficiency, and ultimately the success of drug development and patient care.

Lab informatics systems improve data reliability, streamline workflows, and ensure compliance across R&D and manufacturing by centralising information and eliminating manual errors. These digital tools connect instruments, tracking systems, and secure data from early discovery through manufacturing. Their positive impact extends well beyond the lab bench.

Shorter development life cycles mean drug candidates progress more efficiently. Consistent and accurate data management strengthens regulatory submissions and reduces the risk of delays or rework. Enhanced collaboration between R&D and manufacturing accelerates technology transfer, which is critical during scale-up and commercialisation.

By capturing all data from connected labs in a centralised system, lab informatics significantly improve reliability and efficiency during technology transfer. There are no typing errors, and verified results can be shared instantly among cross-functional teams across all sites, simplifying

reviews and preventing last-minute issues.

Lab informatics also eliminate traceability and data-integrity concerns through digital audit trails that record every change made during an experiment. No information is captured in paper notebooks; all data resides securely in one unified platform.

These benefits extend to manufacturing as well. Real-time process monitoring, automated alerts, and centralised data control improve reliability, efficiency, and process robustness. Early detection of test failures prevents batch-release issues and strengthens overall regulatory compliance. Data analytics further enhances this framework by predicting and preventing potential issues before they occur, resulting in a more reliable and consistent manufacturing process.

Standardising data formats and terminology across systems ensures data quality, consistency, and interoperability. Decentralised and connected data environments also facilitate seamless data sharing and collaboration among researchers, clinicians, regulators, and patients—an essential requirement for advancing scientific research and improving patient care.

Overall, data analytics has had a transformative impact on pharma manufacturing, driving greater efficiency, quality, and safety in the production of pharma products.

What are the biggest challenges in ensuring seamless knowledge and data transfer between R&D and manufacturing, and how can digital technologies help?

Tech transfer represents a critical bridge between development and commercial



manufacturing. The complex process of transferring product and process knowledge between development teams and manufacturing sites requires precision at every stage. It is far more than a handover of documents or equipment; it is the migration of institutional knowledge, process understanding, expertise, and tacit know-how needed to reliably replicate and scale manufacturing.

However, data silos, fragmented documentation, and variability across sites often turn this essential step into a bottleneck that strains both timelines and budgets. Typical hurdles include incomplete documentation, unrecorded tacit knowledge, raw-material variability, regulatory complexities, and communication gaps between R&D and plant teams.

Traditionally, R&D teams handed over a static package of documents to manufacturing. These packages often lacked essential context—historical insights, minor operational nuances, and the rationale behind key decisions. Many steps were based on unwritten habits rather than accurately documented procedures. As a result, manufacturing teams faced missing batch records,

incomplete method validations, unclear cleaning procedures, and difficulties in analytical method transfer. This frequently forced receiving sites to reverse-engineer processes, leading to deviations, investigations, product delays, and financial losses from rejected batches.

To move beyond these limitations, organisations must migrate from static documentation to an integrated, data-driven approach. A unified digital data environment transforms scattered information into complete, traceable, and audit-ready records. However, even with digital systems, the biggest challenge in tech transfer remains ensuring process robustness and predictability.

Applying Quality by Design (QbD) principles is key. QbD establishes the design space—the relationship between raw materials, process parameters, and critical quality attributes. Without this deep understanding, a new manufacturing site may struggle to remain in a state of control, replicate consistent process parameters, and build a sustainable quality culture.

Historically, process control has relied on reactive quality management—waiting for deviations and then investigating them. Today, AI-driven predictive analytics and real-time data integration allow teams to anticipate deviations before they occur. This gives receiving sites a continuous monitoring system that ensures operations remain within the validated design space.

The result is a more reliable, predictable, and scientifically robust technology-transfer process that reduces quality risks and builds confidence in long-term manufacturing performance.

What role do connected lab informatics systems play in enabling successful technology transfer across multiple manufacturing locations?

Multi-locational technology transfer in the pharma industry involves transferring manufacturing processes and analytical methods across different facilities. These transfers often face challenges such as equipment and facility variations, undocumented critical know-how that remains with R&D staff, fragmented data systems, incomplete batch histories, and communication or cultural barriers. Re-establishing cleaning procedures, analytical methods, and process controls at each site demands significant time and resources.

Multi-country and multi-state facilities also encounter differing regulatory interpretations, pharmacopoeia standards, and audit expectations. These complexities can be effectively addressed through connected laboratory informatics.

Connected lab informatics link laboratory instruments, software systems like LIMS, ELN, CDS, and databases across all locations to create a unified digital ecosystem. This enables seamless data flow from instruments and workflows through analysis and reporting. Instead of functioning as disconnected tools, informatics components operate as an integrated system that reduces cross-functional communication gaps, supports compliance, and enhances reliability.

During technology transfer to any location, a connected informatics platform replaces paper-based systems and outdated, siloed electronic tools with a single, unified

Continued on Page 38

Turning lab data into the next decision

Anurag Chauhan, Assistant GM, Digitalisation, Automation & Analytics (India & Ireland), Amneal Pharmaceuticals discusses how LIMS, ELN, CDS, AI and automation are transforming analytical workflows, while also highlighting the challenges of integrating diverse instruments and legacy systems

Analytical laboratories generate vast amounts of complex scientific data. How has lab informatics changed the way analytical development teams manage data, improve productivity, and ensure data integrity?

Analytical laboratories today generate data from multiple sources including HPLC, GC, dissolution systems, spectrometers, stability studies, and microbial testing platforms. Historically, much of this data was managed through standalone systems and paper-based records, making retrieval, review, and compliance management challenging.

Lab informatics has transformed this landscape by creating a connected digital ecosystem where instrument data, test results, methods, and workflows are managed seamlessly. Systems such as LIMS, ELN, and CDS enable automatic data capture, electronic review workflows, and centralised storage, reducing manual intervention and the risk of transcription errors.

For example, instead of analysts spending hours compiling chromatographic results from multiple instruments and manually preparing reports, data can now be collected, reviewed, and approved digitally within a controlled workflow. This



significantly improves laboratory productivity and shortens turnaround times.

The recent trend is more towards compliance related solutions. New AI solutions focused on audit trail review, controlled user access, and real time alert support regulatory expectations around ALCOA+ principles. Beyond compliance, these systems enable laboratories to shift from simply generating data to extracting meaningful insights that support faster and better decision-making.

What are the key challenges in integrating laboratory

informatics platforms with analytical instruments, legacy systems, and evolving regulatory requirements, and how can organisations overcome them?

While most pharma companies recognize the value of laboratory digitalisation, integration remains one of the biggest challenges.

Laboratories often contain instruments from multiple vendors, each with different communication protocols, data formats, and software versions. In addition to this Legacy equipment that has been in service for more than a decade is very common in the Pharma

landscape. Connecting these diverse systems into a unified digital environment can be complex.

Another challenge is regulatory evolution. Expectations around data integrity, cybersecurity, electronic records, and auditability continue to increase, requiring organisations to continuously review and validate their digital infrastructure.

The most successful organisations address these challenges through a phased digitalisation strategy rather than attempting large-scale replacements. Standardizing data sources, leveraging open interfaces, establishing robust governance, and involving laboratory, quality, IT, and compliance teams right from the beginning of any project are key factors to mitigate integration challenges.

Looking ahead, what capabilities do you believe will define the analytical laboratory of the future, and what role will AI, automation, and digital workflows play in achieving that vision?

The analytical laboratory of the future will be connected, intelligent, and increasingly autonomous. Data from laboratory instruments, manufacturing systems, quality platforms, and enterprise

applications will flow seamlessly across a digital ecosystem, creating a single source of truth.

Artificial Intelligence will help laboratories move from reactive analysis to predictive decision-making. For instance, AI can identify trends in stability data, detect anomalies in chromatographic results, recommend method optimisations, or predict potential instrument failures before they impact operations. The process of review will be completely removed from systems as all systems will be having inbuilt Realtime review mechanism.

Automation will continue to reduce routine manual activities such as sample preparation, data compilation, result verification, and report generation. This will allow scientists to focus more on problem-solving and scientific innovation rather than administrative work.

Looking ahead, concepts such as digital twins, advanced analytics, and AI-powered laboratory assistants will become increasingly relevant.

The laboratories that embrace AI, automation, and integrated digital workflows will be better positioned to accelerate development timelines, strengthen compliance, improve quality, and ultimately enhance accessibility.

Taking the guesswork out...

Continued from Page 37

application environment. Centralised data capture minimises transcription errors and inconsistencies, while

unified platforms ensure complete data lineage, improving reproducibility and audit readiness. Automated workflows reduce manual effort and increase reliability, efficiency, precision, and

accuracy during tech transfer.

As a result, scientists no longer need to spend extended durations at manufacturing sites. Harmonised and streamlined tech-transfer processes significantly

improve productivity, shorten cycle times, and eliminate data-integrity issues and regulatory-compliance risks.

For any organisation aiming to remain competitive globally, implementing connected

laboratory informatics is not optional—it is essential. While the initial implementation may seem costly and time-consuming, the return on investment is rapid and substantial.

Connecting the dots across the laboratory

Dhananjay Dwivedi, Vice President -ARD, Amneal Pharmaceutical examines how connected informatics platforms can improve data management, productivity, collaboration and data integrity, while addressing the integration, regulatory and change-management challenges involved in digital transformation

How does lab informatics transform analytical development laboratories in terms of data management, productivity, data integrity, decision-making, and collaboration?

Analytical development laboratories generate large volumes of complex data from instruments such as HPLC, GC, spectroscopy, dissolution, and stability studies. Lab informatics solutions, including LIMS, ELN, and Scientific Data Management Systems (SDMS), have transformed how this data is managed and utilised.

● Improved data management:

Lab informatics centralises data from multiple instruments and experiments into a single digital platform, making data storage, retrieval, and sharing more efficient. This eliminates data silos and enables researchers to access historical information quickly for method development and investigations.

● Enhanced productivity:

Automation of sample tracking, data capture, calculations, and report generation reduces manual effort and turnaround times. By minimizing administrative tasks, scientists can focus more on data interpretation, problem-solving, and innovation.

● Strengthened data integrity:

Electronic records, audit trails, electronic signatures, and controlled user access ensure that data remain accurate, traceable, and secure. Automated data acquisition also reduces transcription errors and supports compliance with regulatory requirements.

● Better decision-making:

Advanced analytics and real-time monitoring tools help identify trends, deviations, and



potential issues early. Interactive dashboards and data visualisation support faster, evidence-based decision-making and continuous process improvement.

● **Improved collaboration:** Cloud-based and integrated informatics systems facilitate seamless data sharing among analytical, quality, formulation, and regulatory teams, enhancing collaboration and knowledge management across sites.

What are the major challenges organisations face when integrating lab informatics with analytical instruments, legacy systems, data integrity requirements, evolving regulations, growing data volumes, and laboratory workflows—and what strategies can help overcome them?

Laboratory informatics platforms such as LIMS, ELNs, and LES are essential for managing laboratory operations, ensuring data integrity, and supporting regulatory compliance.

However, organisations often face significant challenges when integrating these platforms with analytical instruments, legacy systems, and evolving regulatory requirements.

● Integration with analytical instruments:

Modern laboratories use instruments from multiple vendors, each generating data in different formats and using proprietary software. This often results in manual data transfer, increasing the risk of transcription errors, data loss, and inconsistencies.

Integrating instruments with LIMS or ELN systems can also be technically challenging due

to compatibility and validation requirements. Organisations should implement standardised interfaces, middleware, and automated data capture solutions that enable direct transfer of data from instruments to informatics platforms. This reduces human intervention, improves data accuracy, and enhances traceability.

● Legacy system integration:

Many pharma and life sciences companies continue to rely on older systems that contain valuable historical data but lack modern integration capabilities. These systems often create data silos, limiting visibility across the organisation and complicating data sharing and reporting. A phased modernisation approach should be adopted, using integration middleware and carefully planned data migration strategies. This allows organisations to preserve historical data while gradually transitioning to modern, scalable platforms.

● Maintaining data integrity:

Data integrity is a critical requirement in regulated environments. Laboratory data must remain accurate, complete, consistent, and traceable throughout its lifecycle. Manual data entry and disconnected systems increase the likelihood of errors and regulatory findings during inspections.

Automated workflows, electronic records, audit trails, and strong data governance practices help ensure compliance with ALCOA+ principles and improve confidence in laboratory results.

● Meeting evolving regulatory requirements:

Regulations such as FDA 21 CFR Part 11, EU Annex 11, and GxP guidelines continuously

evolve, placing additional demands on laboratory systems. Every integration, system upgrade, or process change may require validation and compliance assessments. Organisations should implement risk-based validation, establish strong change-control processes, conduct regular audits, and continuously monitor regulatory updates to ensure ongoing compliance.

● Handling large and complex data volumes:

Advances in analytical technologies, genomics, automation, and high-throughput screening have resulted in enormous data generation. Traditional systems often struggle to manage and analyze these growing datasets effectively. Cloud-based informatics platforms, advanced analytics, artificial intelligence, and machine learning tools provide the scalability needed to store, process, and derive insights from large datasets while improving decision-making and research productivity.

● User adoption and change management :

Even technically successful implementations can fail if scientists and laboratory personnel resist adopting new systems. Common barriers include workflow disruption, lack of training, system complexity, and concerns about usability. Successful organisations involve end users early in system selection and design, provide comprehensive training programs, and ensure that new systems align with existing laboratory workflows. Effective change management significantly improves adoption and long-term success.

Connecting development, transfer and manufacturing

Technology transfer is increasingly becoming a data-driven process, with laboratory informatics helping bridge the gap between R&D, quality and manufacturing. **Deepak Shinde**, Sr Executive – R&D (Formulations-TT), FDC explores how connected systems can improve knowledge transfer, standardise processes, strengthen data integrity and accelerate technology transfer across development and manufacturing sites

How does lab informatics enable better control, consistency, and knowledge management throughout the technology-transfer process from development to manufacturing?

Technology transfer is a critical stage in the pharma development lifecycle, where scientific knowledge, analytical methods, process understanding, and quality requirements must be transferred accurately from development to manufacturing. Lab informatics plays an increasingly important role in making this process more structured, transparent, and reliable. By connecting laboratory data, analytical workflows, documentation, and knowledge across sites, informatics solutions help reduce manual effort, improve data integrity, maintain process consistency, and provide greater visibility throughout the transfer lifecycle.

Key contributions include:

● Centralised and standardised data –

Laboratory data, analytical methods, specifications, test results, and stability data can be maintained in integrated systems such as LIMS/ELN, reducing dependence on spreadsheets and manual records.

● **Improved data integrity** – Automated workflows, audit trails, electronic signatures, controlled access, and version control help ensure ALCOA+ principles are maintained throughout the technology-transfer lifecycle.

● **Better method transfer** – Analytical methods, method parameters, system suitability requirements, and validation/verification data



can be transferred in a controlled manner, reducing transcription errors and interpretation differences between sites.

● **Real-time visibility** – Development, QC, QA, manufacturing, and technology-transfer teams can access the same approved information, making it easier to identify gaps and resolve issues before commercial manufacturing.

● **Process consistency** – Standardised electronic workflows and templates help ensure that the same procedures, specifications, sampling plans, and acceptance criteria are followed at both sending and receiving sites.

● **Trend and comparative analysis** – Historical batch, analytical, and stability data can be rapidly compared

between sites. This is particularly useful for identifying differences in assay, dissolution, impurities, process parameters, or other critical quality attributes during site transfer.

● **Reduced transfer timelines** – Automated data capture, approval workflows, document management, and electronic review reduce manual effort and accelerate activities such as batch-document review, analytical transfer, deviation assessment, and change control.

● **Stronger knowledge retention** – ELNs and electronic document repositories preserve development knowledge, experimental data, process understanding, and previous investigation outcomes, making this information

readily available during future site transfers or process improvements.

What are the main barriers to transferring scientific knowledge and data from R&D to manufacturing, and how can digital solutions help overcome them?

The biggest challenges in transferring knowledge and data from R&D to manufacturing are data fragmentation, inconsistent documentation, loss of process knowledge, differences in equipment and processes, manual data entry, and lack of real-time visibility between sites.

Digital technologies can address these challenges in several ways:

● **Data silos and fragmented information** – R&D, QC, QA, and manufacturing may use different systems. Integrated platforms such as LIMS, ELN, MES, and document-management systems can create a common data environment.

● **Inconsistent documentation and version control** – Multiple versions of MFRs, specifications, analytical methods, and development reports can create confusion. Electronic document management with controlled workflows ensures that teams work with the latest approved information.

● **Loss of tacit process knowledge** – Important development knowledge may remain with individual scientists. ELNs and structured knowledge-management systems can capture process rationale, development history, experimental results, and lessons learned.

● **Manual data transfer and**

transcription errors – Re-entering laboratory or process data into different systems increases the risk of errors. System-to-system integration and automated data transfer improve accuracy and reduce manual intervention.

● **Differences between development and manufacturing equipment** – Scale-up may introduce differences in equipment capability and process parameters. Digital tools can support process mapping, historical batch-data analysis, equipment comparison, and data-driven scale-up decisions.

● **Limited visibility during technology transfer** – Teams may not have immediate visibility of transfer activities, deviations, analytical results, or pending actions. Digital dashboards and workflow systems provide real-time status and accountability.

● **Data integrity and traceability** – Maintaining reliable and attributable data throughout the transfer is critical. Audit trails, electronic signatures, role-based access, and automated controls strengthen data integrity and regulatory compliance.

● **Difficulty comparing R&D and manufacturing data** – Analytics and visualisation tools can rapidly compare CPPs, CQAs, assay, dissolution, impurities, yield, and stability trends between development and commercial batches.

How can connected laboratory informatics systems support standardised and efficient technology transfer across

Continued on Page 41

Investing in the lab of the future

Drawing on his extensive industry experience, **Shirish G Belapure**, Sr Technical Advisor, IPA looks at the milestones that have shaped this evolution, the factors slowing adoption, and the strategic investments pharma companies should prioritise to build future-ready laboratories

Based on your industry experience, what have been the biggest milestones in the evolution of laboratory informatics, and what trends are likely to define its next phase of growth?

The field has transformed dramatically over the decades—from manual, paper-based processes to robust digital platforms like LIMS and ELN. Integration across instruments and seamless data exchange have been game-changers, further enhanced by cloud adoption for scalability and collaboration. The rise of AI and advanced analytics has taken laboratory operations to a new level. Going forward, I expect intelligent automation, data standardisation following FAIR principles, support for precision medicine, and heightened cybersecurity will



be key trends.

Despite significant advancements in digital laboratory technologies, adoption remains uneven across the industry. What factors are slowing adoption, and how can organisations accelerate their digital transformation journey?

Despite these advances, digital adoption is uneven across the industry. Legacy infrastructure, budgetary limits, regulatory challenges, and resistance to change are common hurdles. Organisations can accelerate digital transformation by securing executive buy-in, demonstrating ROI through well-designed pilot projects, engaging users with thorough training, and phasing implementation to build

confidence and momentum.

If you were advising pharma companies on building future-ready laboratories, what strategic investments and capabilities would you recommend they prioritize over the next five years?

My recommendation for pharma companies is to invest in scalable cloud platforms, robust AI and analytics capabilities, interoperable systems, advanced cybersecurity, workforce upskilling, and sustainable lab practices. These priorities will help labs stay agile, innovative, and competitive in the fast-evolving landscape.

Drawing on nearly five decades of experience, I'm confident that organisations focusing on these areas will drive operational excellence and industry leadership.

Connecting development...

Continued from Page 40

global manufacturing sites?

As pharma companies expand globally, connected laboratory informatics systems play a critical role in ensuring that the same scientific knowledge, data, methods, and quality standards are consistently applied across multiple manufacturing locations. Key roles include:

- **Global data standardisation** – Connected LIMS, ELN, and other laboratory systems provide standardised formats for analytical methods, specifications, test results, and stability data, making information easier to transfer between sites.
- **Single source of truth** –

Lab informatics plays an increasingly important role in making tech transfer processes more structured, transparent and reliable

Centralised or integrated systems ensure that R&D, QC, QA, and manufacturing sites access the same approved and current information, reducing discrepancies caused by multiple local versions of documents or data.

- **Faster technology transfer** – Analytical methods, specifications, historical results, validation data, and process knowledge can be accessed electronically by receiving sites, reducing reliance on manual document

exchange and accelerating transfer activities.

- **Consistent analytical practices** – Controlled methods, workflows, calculations, system suitability requirements, and specifications help ensure that laboratories at different locations perform testing consistently.
- **Real-time visibility across sites** – Global teams can monitor transfer activities, analytical results, deviations, investigations, and stability

trends remotely. This enables faster identification and resolution of issues.

- **Improved data integrity and compliance** – Electronic audit trails, access controls, electronic signatures, and controlled workflows support ALCOA+ principles and help maintain regulatory compliance across different regions.
- **Cross-site comparison and trending** – Connected systems allow companies to compare analytical and

manufacturing data across locations, helping identify differences in assay, dissolution, impurities, process parameters, yield, and stability performance.

- **Knowledge retention and continuity** – Development history, process understanding, analytical knowledge, and previous investigations remain digitally available even when personnel or manufacturing locations change.
- **Better collaboration and decision-making** – R&D, technology transfer, QC, QA, and manufacturing teams can work from a common data environment, reducing communication gaps and enabling faster, evidence-based decisions.

EXPRESS PHARMA WORLD EXPO

The platform for India Pharma Inc's next leap

Scheduled as a three-day event (**March 3-5, 2027**), the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem

India's pharma industry is at a turning point. Long defined by its scale and cost advantage, the sector is now being reshaped by more complex forces like biologics, stricter regulatory expectations, shifting global supply chains, and the growing importance of innovation-led growth. The next phase will demand not just capacity, but capability.

Recognising this shift, Express Pharma is launching Express Pharma World Expo, a new industry platform designed to bring together the people, ideas and technologies that will define the future of Indian pharma.

Scheduled as a three-day event (March 3-5, 2027, the expo is not just a traditional trade show, but a media-powered business platform built to facilitate high-value conversations, enable partnerships and accelerate decision-making across the pharma ecosystem.

Why this platform, why now

As regulatory scrutiny tightens and global competition intensifies, Indian pharma companies are being pushed to rethink manufacturing quality, compliance readiness, and innovation strategies. At the same time, emerging areas such as biosimilars, specialty pharma and digital transformation are opening new opportunities.

What has been missing is a credible, neutral platform that can bring all stakeholders together, not just to showcase solutions, but to address the sector's most pressing chal-



lenges in a structured, outcome-driven manner.

This is what *Express Pharma* aims to build. A space where industry dialogue translates into business action.

Who will attend

The expo is expected to attract over 10,000 professionals from across India's major pharma hubs, including Mumbai, Hyderabad, Ahmedabad, Pune, Bengaluru, Chennai, and Baddi.

Attendees will include:

- CXOs and business leaders from pharma and biopharma companies
- R&D, manufacturing, plant, and operations heads
- Quality, regulatory, and compliance leaders
- Engineering, technical services, and project heads
- Packaging, validation, and cleanroom specialists
- EHS and sustainability leaders
- Supply chain and procure-

ment strategists

- CDMO and contract manufacturing leaders
- Digital and technology transformation heads

Alongside them will be regulators, policymakers, investors, and solution providers, enabling a cross-functional, decision-making ecosystem under one roof.

The expo floor

The exhibition floor is designed to reflect the full pharma value chain, with participation from:

- API, excipients and KSM manufacturers
- Processing and manufacturing equipment providers
- Packaging solution companies
- Quality, validation, and analytical technology firms
- Engineering, project, and infrastructure specialists
- Cleanroom and controlled environment providers
- Utilities, water, and waste management solution c

ompanies

- EHS and sustainability solution providers
- Digital, automation, and Pharma 4.0 technology companies
- Supply chain and contract service organisations

This breadth ensures that the expo is not limited to one segment, but captures the interconnected nature of modern pharma manufacturing and operations.

Turning presence into progress

The focus here is on structured engagement, ensuring that interactions are relevant and outcome-oriented.

Attendees can expect to:

- Gain insights into regulatory trends, global market access, and emerging technologies
- Discover cutting-edge solutions across manufacturing, packaging, and digital transformation
- Engage directly with decision-makers and industry leaders
- Identify new partnerships and business opportunities
- Benchmark their operations against industry best practices
- Stay ahead of shifts shaping the future of pharma

Conversations that matter

At the heart of the event is a leadership conference curated to address the most critical issues facing the industry.

Key themes include:

- Regulatory intelligence and global compliance readiness
- Strategies for global market access

- Innovation in biosimilars, specialty pharma, and advanced therapies
- Manufacturing excellence and scale-up capabilities
- Pharma 4.0, AI, and digital transformation
- Supply chain resilience and risk management
- Investment, partnerships, and growth opportunities
- The future positioning of Indian pharma on the global stage

These discussions signal a broader shift, from volume-driven growth to quality, innovation and reliability as differentiators.

Beyond an event: Building an ecosystem

Backed by Express Pharma's editorial, digital, and events ecosystem, the platform is designed to enable year-round engagement, extending conversations, insights, and business connections well beyond the event itself.

The launch of this platform is tied to a larger industry question: how can India move from being the 'pharmacy of the world' to becoming a global hub for innovation, quality, and advanced manufacturing?

By convening the right stakeholders and focusing on actionable outcomes, Express Pharma World Expo seeks to play a catalytic role in that transition.

In an industry where the next leap will be defined by collaboration as much as competition, the value of such a platform lies not just in who attends, but in what emerges from the conversations it enables.

AHMEDABAD FDD CONCLAVE 2026

From scale to science: Ahmedabad's pharma ecosystem at crossroads

FR&D leaders in Ahmedabad came together to examine how the function is evolving from development and delivery to digitalisation, differentiation and the next phase of pharma growth at the FDD Conclave: Ahmedabad Connect, reports **Lakshmipriya Nair**

The Formulation Development and Drug Delivery (FDD) Conclave has become a meeting ground for India's formulation R&D community. Scientists, innovators, and industry leaders gather to exchange ideas and tackle real challenges in formulation science and drug delivery.

However, FR&D is no longer just about getting a molecule to market. It is about how well that molecule scales and whether the formulation holds up under real manufacturing conditions. It is about whether patients actually benefit.

So, *Express Pharma* decided to take the FDD Conclave beyond a single annual event, and into the country's key pharma hubs.

Ahmedabad was a natural stop. The city brings together formulation R&D, manufacturing excellence, and scientific talent in one ecosystem. It is home to leading pharma companies, research centres, CD-MOs, and CROs. That combination has helped strengthen India's position in global pharma markets.

The FDD Conclave: Ahmedabad Connect built on that strength. Its theme, *Innovation at scale: Advancing FR&D for global markets*, set the frame for everything that followed. Ahmedabad already has scale, manufacturing capacity, cost efficiency, a deep base of generic drug production. But, can it also become a city built on innovation, without giving up what made it strong in the first place was the real focus of the event.

Rethinking success

The conference opened with a



Lamp lighting ceremony: (L-R) Rajesh Bhatkal, Sr GM, Express Pharma; Ravikiran Bhabad, Deputy GM - OSD, FTF Pharma; Vijay Doshi, MD, Pioma Chemicals; Naresh Gaur, Consultant, Pharma Manufacturing Operations; Dr Amarendra Reddy Donthidi, VP and Head of R&D for Injectables and Ophthalmics, Amneal Pharmaceuticals; Dr Ajay Jaysingh Khopade, Site Head R&D and VP, Head of Formulation and Analytical R&D, Sun Pharmaceutical Industries; and Dr Parva Purohit, Sr VP - R&D, Amneal Pharmaceuticals

panel titled, '*Are we measuring FR&D success the right way?*'

Lakshmipriya Nair, Assistant Editor, *Express Pharma*, moderated this panel discussion which included other experts like Dr Parva Purohit, Sr VP - R&D, Amneal Pharmaceuticals. Dr Amarendra Reddy Donthidi, VP and Head of R&D for Injectables and Ophthalmics, Amneal Pharmaceuticals and Ravikiran Bhabad, Deputy GM - OSD, FTF Pharma, a Shilpa Medicare subsidiary.

The conversation moved through several layers of the same question. What actually defines FR&D success today? Is it enough to look at approvals and launches, or does real impact sit somewhere else? Do the KPIs teams actually drive the right behaviours, or do they just reward speed?

The experts agreed that speed still matters, but it cannot come at the cost of quality. R&D teams need agility too. Markets shift, regulations change and teams have to keep up.

The panel's larger point was about scope. Success is not just a launch. It runs from early development through to manufacturing. A weak link anywhere in that chain puts patient safety at risk.

That reframing had a practical implication. If FR&D outcomes are meant to link to business growth, the scorecard used to judge them has to change too. A metric built only around timelines will miss whether a product actually scales, or whether it holds up once it leaves the lab. The panel's conclusion was clear. The FR&D scorecard of the fu-

ture needs to weigh manufacturability, quality, and downstream performance alongside speed, not treat them as separate conversations.

The formulation toolbox

The discussion was followed by a few informative technical sessions.

Jaynil Doshi, Director - Techno Commercial, Pioma Chemicals, gave a session titled *Hydrocel: Multi-functional cellulose technologies for modern formulators*. Hydrocel is a family of six functional cellulose excipients, sold under one brand.

Doshi's point was about control. Hydrocel is built for tighter parameters than standard pharmacopeial ranges allow. That control lowers development risk. It also makes manufacturing more predictable.

Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo, followed with a presentation on '*Drug release modulation through DRUGCOAT RSPO/RLPO*'. He introduced DRUGCOAT RL and RS polymers, used as binding agents to modulate release.

Prajapati explained that drug release depends on polymer concentration. The right RL-to-RS ratio has to match the drug's own solubility and permeability. Every product needs its own answer.

Beyond generics

Dr Ajay Jaysingh Khopade, Site Head R&D and VP, Head of Formulation and Analytical R&D, Sun Pharmaceutical Industries, took the discussion in a different direction with a session titled, '*Beyond generics: Creating a competitive edge through innovation*'.

Volume is no longer enough, he said. India's generics strength built the industry's global position. But the next phase needs more. Complex formulations and specialty products carry stronger margins and a harder-to-copy edge.

Khopade named three things that have to work together, i.e. product innovation, process excellence, and regulatory strategy. He added a caution too. Innovation only counts if it improves patient outcomes. Science for its own sake is not the goal.

Moving beyond generics is a long-term bet and the returns take time.

Proven technology, new roles

Not every advance means replacing what already works.

Dr Abhijit Gothoskar, Tech-

AHMEDABAD FDD CONCLAVE 2026



L-R: Lakshmipriya Nair, Assistant Editor, Express Pharma (MODERATOR); Dr Parva Purohit, Sr VP – R&D, Amneal Pharmaceuticals; Dr Amarender Reddy Donthidi, VP & Head R&D (Injectables and Ophthalmics), Amneal Pharmaceuticals; Ravikiran Bhabad, Deputy GM - OSD, FTF Pharma (Subsidiary of Shilpa Medicare)



Dr Ajay Jaysingh Khopade, Site Head R&D, VP and Head-Formulation and Analytical R&D, Sun Pharmaceutical Industries



Jaynil Doshi, Director – Techo Commercial, Pioma Chemicals



Dr Abhijit Gothoskar, Technical Expert, Sigachi Industries



Krutik Prajapati, Manager (Techno Commercial), Vikram Thermo (India)



Ritu Laddha, Sr VP & Cluster Head, Zydus Lifescience

nical Expert, Sigachi Industries, made that case in *Matrix formulation using Ultramod systems*. Hydrophilic matrix systems, he said, remain a proven, commercially viable route to controlled drug release.

The company's UltraMod system, he said, improves their robustness and predictability.

Gothoskar's session also pointed to a shift in what formulators expect from suppliers. It is no longer just about buying an excipient. Compa-

nies want formulation support and application expertise alongside it. Sigachi is positioning itself as that kind of partner.

Delivery as differentiation

Ritu Laddha, Senior VP and Cluster Head, Zydus Lifesciences, closed the morning's technical sessions with 'Reimagining pain therapy: Oral-to-intranasal product innovation', a case study on drug delivery.

Zydus developed an in-

tranasal version of cyclobenzaprine, a pain medicine usually taken orally. The goal was faster relief.

Preclinical and human studies backed that up. They showed faster absorption and higher drug exposure through the nasal route.

Laddha framed the result on three fronts i.e. efficacy, tolerability, and patent potential. Her presentation showcased how changing the route of administration can create a new proposition around an

existing molecule.

AI in the formulation lab

After the unconference and lunch, the focus moved to artificial intelligence, with a panel titled, 'AI, talent and technology: The new FR&D toolkit'. Dr Tushar N Mehta, VP - Respiratory and Advanced Analytical R&D, Amneal Pharmaceuticals, moderated this session.

Nilesh Malaviya, Head of Formulation Development, Alembic Pharmaceuticals; Dr Sanju Dhawan, Sr Director

GPRD and Site Leader, Baxter Pharmaceuticals India; Dr Dhaval Pethani, Co-Founder and CTO, Cutyx Research; Dr Prabhat Shrivastava, Associate Director and Vertical Head for Formulation and Packaging Development, Piramal Pharma Solutions, Ahmedabad; Dr Vinod Venkatpurwar, Senior GM, Formulation Development, Cadila Pharmaceuticals; Dr Ajay Vairale, Senior GM, Cadila Pharmaceuticals; and Dr Sunny P Desai, Senior Manager and Site Lead for Technology Transfer, Zydus Lifesciences joined him for this discussion.

The panel's central idea was that AI is shifting formulation from trial-and-error toward predict-and-design. It is helping teams shortlist promising formulations faster. It is flagging manufacturing risks earlier and compressing timelines that used to run for months.

The panel pointed to high-impact use cases such as formulation screening, stability prediction, and early risk-flagging as the areas where AI is already paying off.

Digital twins, AI models and electronic lab notebooks came up as the practical tools behind that shift. They can cut scale-up failures, reduce repetitive work and speed up technology transfer.

But there was a condition attached. AI is only as good as the data behind it. Without a strong digital foundation, none of it works. Fragmented systems and disconnected data can foil even a well-built model.

The panel was candid about the barriers still in the way.



L-R: Dr Tushar N Mehta, VP - Respiratory and Advanced Analytical R&D, Amneal Pharmaceuticals (MODERATOR); Nilesh Malaviya, Head - Formulation Development, Alembic Pharmaceuticals; Dr Sanju Dhawan, Sr Director GPRD & Site Leader, Baxter Pharmaceuticals India; Dr Dhaval Pethani, Co-Founder and CTO, Cutyx Research LLP; Dr Prabhat Shrivastava Associate Director and Vertical Head (Formulation and Packaging Development), Piramal Pharma Solutions, Ahmedabad; Dr Vinod Venkatpurwar, Sr GM, Formulation Development, Cadila Pharmaceuticals; Dr Ajay Vairale, Sr GM, Cadila Pharmaceuticals; Dr Sunny P Desai, Sr Manager (Site Lead) - MS&T (Technology Transfer), Zydus Lifescience



L-R: Naresh Kumar Gaur, Consultant, Pharma Manufacturing Operations (MODERATOR); Dr Madhusudhan Bommagani, President - FR&D, Cadila Pharmaceuticals; Dr Mukesh Patel, MD, QualiHeal Pharmaceuticals; Anshu Rathore, AVP-Pharma & Regulatory, Molkem Labs; Gopal Thakur, Sr Manager, Immacule Life Sciences; Abhikumar Turakhiya, Sr GM and Head - Formulation R&D, Avance Research; Dr Kashyap Nagariya, Assistant Division Head, Otsuka Pharmaceutical India

They spoke of legacy systems, siloed data, and teams that have not yet been trained to work alongside these tools. Getting past that is as much an organisational challenge as a technical one, pointed out the panelists.

The panel also opined that AI should augment scientists, not replace them. Human judgement and accountability stay central to every decision. Balancing that human expertise with machine intelligence, rather than choosing between them, was the panel's recurring theme. The panel also emphasised on governance, particularly around ethical use and protecting confidential data.

They opined that emerging model is the AI-enabled scientist. Someone who understands

both what these tools can do and where their limits sit.

Complexity moves closer to the patient

Dr Richa Dayaramani, Scientist Grade F, NIPER Ahmedabad, spoke about injectables and specialty formulations later in the afternoon, in a session titled Injectables and specialty formulations: Driving the next wave of growth.

Biologics and GLP-1 therapies are growing. That growth demands stronger capability in advanced drug delivery and injectable technology, she said.

Formulation itself is becoming the differentiator. The more complex it gets, the more value there is to capture.

Dayaramani also brought the discussion back to the patient.

Future formulations need to support self-administration, through devices like pre-filled syringes and wearable injectors.

That means formulation, device compatibility, and manufacturing all need to work together. None of it succeeds in isolation.

Ahmedabad's own opportunity

The last panel of the day was a session titled Ahmedabad's innovation edge: Where science meets scale.

Naresh Kumar Gaur, Consultant, Pharma Manufacturing Operations, moderated this discussion. The panel included Dr Madhusudhan Bommagani, President - FR&D, Cadila Pharmaceuticals; Dr Mukesh Patel, MD, QualiHeal Pharmaceuti-



Dr Richa Dayaramani, Scientist grade F, NIPER Ahmedabad

cals; Anshu Rathore, AVP - Pharma and Regulatory, Molkem Labs; Gopal Thakur, Senior Manager, Immacule Life Sciences; Abhikumar Turakhiya, Senior GM and Head of Formulation R&D, Avance Research and Dr Kashyap Nagariya, Assistant Division Head, Otsuka Pharmaceutical India.

The discussion opened with Ahmedabad's role in India's broader pharma growth story, then narrowed to specifics.

The city's advantages came up first. A large pool of skilled talent from pharmacy universities across Ahmedabad and Gujarat. Strong local technical and digital support. A growing base of CMOs and CDMOs, which brings opportunities for technology transfer and faster market access. Government-backed skill-development programmes reinforcing all of it.

The panel treated manufacturing strength as a starting point, not an end point. The real question was how to leverage that strength to accelerate innovation. They also discussed how building development capabilities that can compete globally was the next test for the city's pharma ecosystem.

Complex products and specialty therapies came up as the clearest opening. Biologics, advanced delivery systems, and value-added formulations offer margins and differentiation that conventional generics cannot match. The city already has adjacent capability in manufacturing and talent. What it needs is to direct more of that

capability toward development rather than production alone.

The panelists were emphatic that Ahmedabad needs to move beyond conventional generics. Complex products, biologics, and value-added offerings are crucial to the next phase of growth. Manufacturing strength is not enough on its own. Quality has to keep pace. That combination, the panel said, will decide whether Ahmedabad becomes a genuine global pharma hub.

The panel closed on an open question rather than a clear answer. What comes next for Ahmedabad as a pharma innovation hub depends on whether the ecosystem i.e. talent, manufacturers, CDMOs, and regulators, can pull in the same direction.

The panel closed on an open question rather than a clear answer. What comes next for Ahmedabad as a pharma innovation hub depends on whether the ecosystem i.e. talent, manufacturers, CDMOs, and regulators, can pull in the same direction.

What the day added up to

A strong FR&D organisation today has to deliver products that are innovative, manufacturable, scalable and relevant to patients. That takes earlier attention to scale-up, wider use of data and AI, more sophisticated delivery approaches and tighter coordination between R&D, manufacturing and regulatory teams.

For Ahmedabad, the pieces are largely in place. Talent, manufacturing scale, technical capability, a growing ecosystem.

The task now is to connect them.

lakshmipriya.nair@expressindia.com
laxmipriyanair@gmail.com

AHMEDABAD FDD CONCLAVE 2026

PARTNERS IN PROGRESS



AHMEDABAD FDD CONCLAVE 2026

PARTNERS IN PROGRESS



AHMEDABAD FDD CONCLAVE 2026

PARTNERS IN PROGRESS





AHMEDABAD
CONNECT
FDD
CONCLAVE 2026

Expanding the
formulation R&D
ecosystem

POWERED BY



INNOVATION AT SCALE
ADVANCING FR&D FOR
GLOBAL MARKETS

6

August 2026
Crowne Plaza, Ahmedabad



THANK YOU

WE THANK OUR PARTNERS, SPEAKERS AND PARTICIPANTS FOR EXTENDING THEIR SUPPORT IN
MAKING THE FDD CONCLAVE 2026: AHMEDABAD CONNECT A GRAND SUCCESS

PARTNERS



POWERED BY PARTNER



GOLD PARTNER



GOLD PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



SILVER PARTNER



INTERVIEW

SCHOTT charts long-term roadmap for Type I pharmaceutical glass with FIOLEX® Pro

In an exclusive conversation with **Sundeep Prabhu**, Senior Vice President, Sales & Marketing, SCHOTT India, discusses the evolving needs of the pharmaceutical industry, the role of FIOLEX® Pro in addressing future requirements, and what SCHOTT's long-term portfolio strategy means for pharmaceutical manufacturers in India

Pharmaceutical primary packaging is undergoing significant transformation globally. What trends are shaping the future of primary packaging materials?

The pharmaceutical industry is experiencing a period of rapid change. Manufacturers today are expected to ensure the highest levels of patient safety while also improving manufacturing efficiency, meeting increasingly stringent regulatory requirements, and supporting sustainability goals.

As a result, pharmaceutical primary packaging materials are no longer viewed simply as components. They are becoming strategic enablers of product quality, operational excellence, regulatory compliance, and environmental responsibility. We see growing interest from pharmaceutical companies in solutions that can help them future-proof their operations while maintaining the highest quality standards.

In its recent communication, SCHOTT highlighted FIOLEX® Pro as the future standard for Type I pharmaceutical glass tubing within its portfolio. What led SCHOTT to take this direction?

At SCHOTT, continuous innovation has always been part of our commitment to the pharmaceutical industry. As market requirements evolve, we continuously review and



strengthen our portfolio to meet future pharmaceutical glass packaging needs.

FIOLEX® Pro glass tubing is developed to address three fundamental industry requirements – drug safety, manufacturing efficiency, and product carbon footprint reduction with its optional product line FIOLEX® Pro OCF.

The aim is to provide pharmaceutical companies

with a future-ready glass solution that helps address both current and emerging expectations across the value chain.

What makes FIOLEX® Pro different from conventional FIOLEX® clear?

FIOLEX® Pro combines advancements in material composition, manufacturing technology, and quality transparency.

From a safety perspective, it offers a future-proof glass composition with the absence of any heavy metals and supports easy compliance with ICH Q3D requirements. It is designed to deliver minimal drug-container interactions through superior extractables and leachables performance, constant glass composition, and consistently high hydrolytic resistance.

From an operational standpoint, it supports smooth machinability during converting and fill-finish processes through high cosmetic quality and precise dimensional accuracy. Moreover, the transformation temperature of FIOLEX® Pro is quite identical to FIOLEX® clear minimising disruption and simplifying adoption.

Every product delivery is supported by a digital quality data package enabled by SCHOTT's perfeXion® process, providing an unprecedented level of quality transparency.

Sustainability is becoming increasingly important for pharmaceutical manufacturers. How does FIOLEX® Pro address this?

Sustainability is now a strategic priority for many pharmaceutical companies, and this extends to primary packaging materials and supply chains. In fact, nearly top 20 pharma companies have set strategic SBTi climate targets to reduce their carbon footprint drastically in

the upcoming years.

SCHOTT supports these ambitions with the optional FIOLEX® Pro OCF product line, which will be available first quarter of 2027 with an approx. 50 per cent lower product carbon footprint*. This is enabled by a new electric melting tank technology, powered by 100 per cent of electricity in the production process covered by renewable energy Guarantees of Origin; natural gas is now only used in the separate refining unit and working tank part for technical reasons any longer.

We believe innovations like these can help pharmaceutical companies advance their sustainability commitments without compromising quality or performance.

*Calculation of greenhouse gas emissions from cradle-to-gate per kilogram of saleable glass tubing compared to the market average for borosilicate glass tubing [average value according to ecoinvent 3.10; glass tube production, borosilicate // DE. The value currently calculated is based on empirical values and simulation data]. Relevant information about the FIOLEX® Pro OCF product line and the electrical tank can be found in the implementation plan here.

Some pharmaceutical companies are asking how FIOLEX® Pro fits within SCHOTT's broader

FIOLAX® portfolio. Can you clarify?

Certainly. We understand that the right material makes all the difference in pharmaceutical packaging. As industry requirements rise, SCHOTT remains dedicated to advancing innovation and maintaining quality leadership, ensuring we are prepared to meet both current and future needs. Because patient safety starts with us.

The journey of FIOLAX® Pro clearly demonstrates SCHOTT's steadfast commitment. The introduction of FIOLAX® Pro does not change SCHOTT's commitment to providing a reliable supply. Rather, it further develops our current portfolio and paves the way for the future of SCHOTT's Type I glass portfolio.

There is considerable discussion around FIOLAX® Pro in the market. Should pharmaceutical companies view this as a signal that they need to immediately transition away from packaging made out of FIOLAX® clear?

Not at all. The introduction of FIOLAX® Pro should be viewed as the next evolution step of SCHOTT's portfolio

and our continued commitment to innovation in pharmaceutical primary packaging.

FIOLAX® Pro is developed to address emerging industry priorities around drug safety, operational efficiency, quality transparency, and sustainability.

At the same time, FIOLAX® clear remains an established and trusted product used by pharmaceutical manufacturers around the world.

FIOLAX® Pro will be established as the new standard Type I clear glass for all pharmaceutical applications, gradually succeeding FIOLAX® clear in the long term. But we understand that the pharmaceutical industry operates within long product lifecycles, extensive qualification requirements, and is highly regulated. Therefore, this evolution will be managed with utmost care and in close partnership with converters and pharmaceutical companies, ensuring sufficient time for qualification, regulatory alignment, and adaptation. Please be assured that this transition is designed to

unfold over an extended, decade-scale period, ensuring a seamless and well-supported process that prioritises pharma community requirements and the highest industry standards.

During this time, pharmaceutical companies can continue to rely on FIOLAX® clear with confidence. FIOLAX® clear will be available for years to come, and any transition to FIOLAX® Pro would naturally follow global adoption patterns and will occur gradually over an extended period.

Our message to the market is simple – pharmaceutical companies should choose the solution that best fits their business, regulatory requirements, and sustainability objectives. For those interested in the benefits offered by FIOLAX® Pro, SCHOTT is ready to support them with comprehensive material in our Technical Dossier now. For companies continuing with FIOLAX® clear, SCHOTT remains fully committed to ensuring reliable supply and long-term partnership.

How should pharmaceutical companies approach FIOLAX® Pro today?

Like I already mentioned, FIOLAX® Pro should be viewed as an attractive option for companies that are looking to enhance safety, efficiency, or sustainability within their primary packaging strategy all given by a future-proof glass.

Every pharmaceutical company has unique technical, regulatory, and commercial requirements. Therefore, decisions regarding qualification and adoption should be driven by individual business needs and long-term plans.

Our role is to provide pharmaceutical companies with choices on the right basic glass material, technical support by knowledge sharing, and all information necessary to make the best decision for their product needs. We encourage pharmaceutical companies to use the coming years to evaluate FIOLAX® Pro and to define individual qualification and implementation roadmaps. SCHOTT Tubing remains committed to supporting pharmaceutical companies throughout their evaluation and implementation processes.

What assurance would you

like to give pharmaceutical manufacturers in India or what would be the key take aways from this discussion?

India is one of the fastest growing pharmaceutical markets globally, and we see increasing interest from Indian pharmaceutical manufacturers in advanced therapeutic solutions such as GLP-1 therapies, antibody-drug conjugates (ADCs), and biosimilars across various pharmaceutical container formats.

As companies evaluate how to meet rising expectations around product quality, operational performance, regulatory compliance, and sustainability, FIOLAX® Pro pharmaceutical glass offers a compelling path forward.

I would say that the market should see FIOLAX® Pro as an opportunity. It is a future-oriented solution for companies seeking additional benefits in areas such as safety, efficiency and product carbon footprint reduction.

Our commitment is to provide all partners along the pharma value chain with reliable supply, clear communication and access to the best technologies available, today and in the future.

CONTRIBUTOR'S CHECKLIST

- Express Pharma accepts editorial material for regular columns and from pre-approved contributors / columnists.
- Express Pharma has a strict non-tolerance policy of plagiarism and will blacklist all authors found to have used/refered to previously published material in any form, without giving due credit in the industry-accepted format. All authors have to declare that the article/column is an original piece of work and if not, they will bear the onus of taking permission for re-publishing in Express Pharma.
- Express Pharma's prime audience is senior management and pharma professionals in the industry. Editorial material addressing this audience would be given preference.
- The articles should cover technology and policy trends and business related discussions.
- Articles for columns should talk about concepts or trends without being too company or product specific.
- Article length for regular columns: Between 1200 - 1500 words. These should be accompanied by diagrams, illustrations, tables

and photographs, wherever relevant.

- We welcome information on new products and services introduced by your organisation for our various sections: Pharma Ally (News, Products, Value Add), Pharma Packaging and Pharma Technology Review sections. Related photographs and brochures must accompany the information.
- Besides the regular columns, each issue will have a special focus on a specific topic of relevance to the Indian market.
- In e-mail communications, avoid large document attachments (above 1MB) as far as possible.
- Articles may be edited for brevity, style, and relevance.
- Do specify name, designation, company name, department and e-mail address for feedback, in the article.
- We encourage authors to send their photograph. Preferably in colour, postcard size and with a good contrast.



Email your contribution to:
The Editor,
Express Pharma,
Business Publications Division,
The Indian Express (P) Ltd,
Mafatlal Centre, 7th floor,
Ramnath Goenka Marg,
Nariman Point, Mumbai 400021
viveka.r@expressindia.com
viveka.roy3@gmail.com

Geopolitics and pharma packaging: Building greater security across the supply chain

Bhupesh Kumar Mittal, Technical Packaging Program Lead-APAC, Bayer Pharmaceuticals, looks at how geopolitical shifts are reshaping pharma packaging supply chains and why greater visibility, diversification and preparedness are becoming critical to ensure continuity, product integrity and timely access to medicines

India's pharma strength and its new operating reality

The Indian pharmaceutical industry has evolved into one of the most globally significant healthcare sectors. As per the Economic Survey 2025-26, India ranks third globally by volume and eleventh by value in pharmaceuticals, meeting around 20 per cent of global generics demand, with exports to 191 countries in FY25 and sector turnover reaching Rs 4.72 lakh crore. Over 50 per cent of these exports are directed to highly regulated markets such as the United States and Europe. India is also a leading global supplier of low-cost vaccines, including DPT, BCG and measles vaccines.

IBEF further notes that the domestic pharmaceutical market, valued at around \$60 billion in 2026, is projected to grow to \$130 billion by 2030, supported by more than 3,000 companies, 10,500 manufacturing units and government initiatives such as the PLI scheme, Biopharma SHAKTI and the API-push announced in December 2025. According to KPMG's Q1 FY26 pharma sector snapshot, the Indian pharmaceutical packaging market itself is projected to reach around Rs. 259 billion by FY30. India's scale, therefore, is not only industrial; it is deeply linked to global healthcare access.

However, the operating environment around this strength is changing. Geopolitical tensions, shipping disruptions, energy volatility, tariff uncertainties and import dependencies are increasingly influencing daily operations. *Express Pharma's* June 2026 cover story on "Navigating a VUCA World" rightly noted



that geopolitics is reshaping the pharma landscape, and that supply chain disruption has become a structural feature, not a passing crisis.

Recent events around the Red Sea, the Strait of Hormuz and the wider Gulf shipping corridors have made this more visible. Industry reports have highlighted rerouting risks, delays, doubled freight charges and shipment surcharges for Indian pharma exporters. UNCTAD's June 2026 note observed that, even after the reopening process for the Strait of Hormuz, more than 100 days of disruption had already affected energy markets, transport costs and global trade flows, with an uneven recovery for value chains.

For patients, these events are

ultimately about medicine availability. For packaging professionals, they translate into a very practical question: will the right material reach the right site, with the right quality documentation, at the right time, so that a medicine can safely reach the patient?

Key geopolitical risks currently affecting Indian pharma and their implications for packaging

The most visible risk is upstream dependency. The Government of India has reported that in FY2024-25 India imported around \$4.35 billion worth of APIs, bulk drugs and intermediates across 200 categories, with China accounting

for about 73.7 per cent of these imports. The government has identified single-source vulnerability, price volatility and predatory pricing as risks arising from such dependence.

Packaging carries its own dependency map. Even when conversion happens in India, many upstream inputs - aluminium foil, cold-form laminates, PVC, PVDC, high-barrier films, specialty polymers, glass tubing, elastomeric components, desiccants, closures, inks, adhesives, coatings and machine spares - are linked to global energy, chemical and logistics networks.

The Red Sea crisis showed how quickly this can turn operational. Industry reports noted that shipments earlier taking around 25 days began taking 34 days or more as vessels rerouted around the Cape of Good Hope, and that over 65 per cent of India's pharma exports move by sea. Key routes such as the Red Sea, Strait of Hormuz and Gulf shipping corridors have faced risks of rerouting and delays, affecting delivery schedules and increasing logistics costs for Indian pharma exporters.

For packaging operations, such risks appear as delayed inbound materials, extended lead times, supplier allocation, higher freight cost, production rescheduling, artwork implementation delays and pressure to move to alternates that may not yet be fully qualified.

Impact on packaging material availability, sourcing dependencies and operational continuity

Packaging supply chains are often more complex than they appear. A local converter may still depend on imported foil stock,

imported resin, imported coating chemistry or overseas machine spares. This creates hidden dependency, which becomes visible only during disruption.

In primary packaging, the impact is especially critical. Blister films, aluminium lidding foil, cold-form laminates, bottles, closures, glass vials, ampoules, cartridges, stoppers and plungers are not commodity items. They are product-contact and product-protection systems, and any change can affect stability, compatibility, machinability, regulatory documentation and patient safety.

Secondary and tertiary packaging can also become critical. Cartons, labels, leaflets, shippers and serialisation components are closely tied to market release. A missing leaflet, incorrect label stock, delayed artwork or unavailable shipper can hold a batch even when the formulation is ready.

Supplier reliability also becomes a bigger issue in disruption. Suppliers may prioritise larger customers, domestic markets or high-margin segments during global stress, leaving smaller-volume SKUs or niche pack formats more vulnerable. Packaging teams therefore need supplier relationships that go beyond transactional purchasing, with transparency on capacity, upstream inputs and business-continuity plans.

Operational continuity depends equally on planning discipline. Standard lead times cannot be assumed during a crisis. Transit times extend, port operations become uncertain, freight capacity tightens and emergency air freight becomes expensive. Packaging, procurement, planning, quality, logistics

and manufacturing must work together to identify materials that can stop production and markets that are most exposed.

Emerging challenges: timelines, costs, compliance, sustainability and product integrity

The first challenge is timeline uncertainty. Packaging touches multiple time-sensitive steps - component procurement, artwork approval, vendor release, machine trials, batch packing, quality release and dispatch. Even small delays in a critical component can affect packing campaigns, sequencing and market service.

The second is cost escalation. Industry bodies have flagged that freight charges for imports and exports have nearly doubled, with surcharges of \$4,000 to \$8,000 per shipment, while rising logistics costs, crude oil prices and shipping delays continue to affect inventory cycles. For packaging, cost pressure appears through higher raw material prices, increased inbound freight, emergency logistics, currency volatility, inventory carrying cost and additional qualification work - all difficult to pass on in generic markets.

The third is compliance. Pharma cannot simply switch a packaging material because it is available or cheaper. Depending on the market, a change may require change control, stability data, comparability assessment, dossier update, notification or prior variation approval.

The fourth is sustainability. Pharma companies are moving toward lower material intensity, recyclable structures, responsible sourcing and reduced carbon impact. But a sustainable material with only one qualified supplier can become a vulnerability, and a lower-carbon option that cannot protect the product through longer, disrupted routes may create quality risk. The answer is not to slow sustainability, but to design it with resilience built in.

The fifth is product integrity during disturbed logistics. Longer routes, port congestion, temperature and humidity exposure and additional handling can affect moisture-sensitive tablets, cold-chain products, biologics

and injectables. Packaging and distribution systems must be validated for real-world stress, not only for ideal lanes.

Behind each of these challenges is a human dimension. When a medicine is delayed, it is not only a supply chain metric. It can mean a chronic-therapy patient waiting for refills, a hospital managing shortages, or a public health programme facing uncertainty. Resilience must therefore be framed as patient-access protection, not only as cost protection.

Strategies to strengthen resilience across packaging supply chains

The first strategy is meaningful dual sourcing. Alternate suppliers must be technically qualified, quality approved, commercially ready, operationally trialled and regulatory assessed. For critical materials, dual sourcing should be treated as business-continuity insurance, not only as a negotiation lever.

The second is multi-geography and multi-site thinking. If two suppliers depend on the same upstream raw material source or the same shipping corridor, the resilience benefit is limited. Companies should ensure critical materials can be produced from different sites, regions or logistics routes.

The third is Tier 2 and Tier 3 visibility. Packaging teams must know where key inputs originate - foil, resin, paper, glass tubing, elastomers, coatings, adhesives, specialty chemicals - so that hidden single points of failure can be identified.

The fourth is risk-based inventory. Strategic safety stock should be based on business impact, material criticality, lead-time volatility, storage conditions, shelf life, regulatory complexity and patient criticality. The objective is not excess everywhere, but protection where supply can stop.

The fifth is specification harmonisation. Multiple similar carton sizes, bottle families, foil structures and shipper formats increase inventory, reduce flexibility and slow supplier switching. Harmonisation improves buying power, simplifies qualification and enables faster response during disruption.

The sixth is design for supply continuity. Packaging development must balance product protection, patient convenience and sustainability with material availability, supplier base and alternate options. Highly specialised structures should be justified by product need, not by habit.

The seventh is regulatory preparedness. Packaging, quality and regulatory teams should work together before disruption occurs, so that critical alternates are documentation-ready and change categories are pre-assessed.

The eighth is digital visibility. Dashboards connecting supplier performance, inventory cover, lead-time movement, port disruptions, freight changes, artwork status and production priorities help teams act earlier. AI can further support scenario planning by identifying exposed SKUs, materials and markets.

The ninth is closer supplier partnership. Strategic supplier relationships should include capacity planning, business-continuity audits, joint risk reviews, sustainability roadmaps and transparent escalation mechanisms.

The tenth is cross-functional governance. Packaging risk requires procurement, quality, regulatory, manufacturing, planning, logistics, finance and commercial teams working together, with clear escalation pathways and defined decision rights for critical materials.

Long-term measures to future-proof pharma packaging functions

First, build stronger local and regional packaging ecosystems. India's pharma growth is increasingly being shaped by clusters such as Hyderabad Pharma City, Genome Valley, Jawaharlal Nehru Pharma City and Gujarat's bulk drug park at Jamnagar. Packaging must be part of this cluster thinking, with domestic strength in high-barrier films, pharma-grade polymers, glass, elastomers, compliant printing, serialisation, cold-chain packaging and sustainable material platforms.

Second, introduce packaging resilience scorecards. Each critical component should be evalu-

ated for supply risk, supplier concentration, geography exposure, upstream dependency, lead time, regulatory complexity, alternate readiness, cost volatility and business impact.

Third, embed packaging in enterprise risk management. A company may secure API and manufacturing capacity, but if packaging is not available, the product still cannot reach the market. Senior leadership should review packaging risks for critical brands, export markets, tender products and patient-critical therapies.

Fourth, invest in packaging talent. The future packaging leader must understand geopolitics, trade corridors, regulatory pathways, supplier economics, sustainability, digital tools, manufacturing constraints and enterprise risk - moving from execution excellence to strategic resilience thinking.

Fifth, build distribution resilience into packaging validation. Transport simulation, lane qualification, temperature and humidity monitoring and shipper robustness must be revisited for critical products, given how quickly logistics lanes can change.

Sixth, connect sustainability with security of supply. The best sustainable solution for pharma will be one that reduces environmental impact without increasing patient risk or supply fragility.

Seventh, institutionalise scenario planning. Companies should ask: What if a major corridor is disrupted for three months? What if freight doubles? What if a key supplier allocates capacity? What if an imported resin becomes unavailable? Scenario thinking converts uncertainty into preparedness.

The human dimension: why this matters beyond industry metrics

Behind every packaging decision is a patient. A parent seeking a child's antibiotic, a diabetic patient depending on regular therapy, a cancer patient waiting for treatment, a hospital pharmacy planning inventory, or a public health programme managing vaccine supply - each depends on supply continuity. Packaging

supports that continuity quietly, protecting the product from moisture, light, oxygen, contamination, tampering, breakage, temperature variation and handling stress, while carrying information that helps patients and healthcare professionals use the medicine correctly.

When packaging fails or is delayed, even the best-manufactured medicine may not reach the patient on time. In a volatile world, packaging resilience is not a back-office topic. It is a public health enabler, and packaging leaders have a responsibility to make this visible to boards, regulators, suppliers and partners.

Conclusion: Preparedness is the new competitive advantage

Indian pharma has earned global trust through scale, quality, affordability and reliability. The next phase will test whether the sector can protect that trust in a more unstable world. Geopolitical uncertainty is no longer an external event that occasionally interrupts business. It is becoming a design condition for supply chains.

For packaging functions, the message is clear. The future will not be secured only by better materials or lower costs. It will be secured by resilient design, diversified sourcing, regulatory-ready alternates, intelligent inventory, specification harmonisation, digital risk visibility, supplier partnership and strong cross-functional governance.

The way forward is not panic. It is preparedness. Indian pharma packaging must evolve from a downstream operational function to a strategic resilience function - protecting not only the product, but the promise behind the product: that medicines will reach patients safely, reliably and on time, even when the world around the supply chain is uncertain.

In a geopolitical crossfire, packaging becomes more than a container, closure, label or carton. It becomes a strategic shield for the medicine, the business and the patient. The organisations that recognise this early will be better prepared for what comes next.

How pharma is charting a greener path to growth

Pramuch Goel, Head of Corporate Affairs, Syngene International explores how greener energy, water management, supply chains and responsible manufacturing can strengthen India's competitiveness and reshape the industry's path to long-term value creation

The conversation around environmental sustainability in the pharma industry is now expanding beyond the traditional boundaries of the compliance department. For years, the life sciences sector treated sustainability largely as a peripheral function, focusing primarily on meeting local waste management rules, running safety checklists, and fulfilling regulatory mandates. Today, industry leaders are viewing it as a core business strategy that is central to competitiveness, risk management, operational resilience, brand reputation, and long-term value creation.

This changing industry outlook is becoming increasingly important as the sector begins to confront the scale of its environmental footprint. Making medicines is far more resource-intensive than most people realise. Data from a recent study published in The Lancet Planetary Health shows that the pharma sector's direct emissions intensity is around 60 per cent higher than healthcare services, and nearly 80 per cent higher when total emissions are considered. At the same time, the industry's greenhouse gas footprint is growing faster than both healthcare services and the global average.

The urgency around this challenge is only compounding as the industry continues to expand. The global pharma market is on track to cross \$2.8 trillion by 2033, while India's pharma sector alone is projected to surpass \$130 billion by 2030. Therefore, the sector has the responsibility to scale commercial growth in a way that also reduces its environmental footprint and preserves the ecosystems that sustain both manufacturing operations and long-term public health.

Many leading pharma companies and contract research,



development, and manufacturing organisations (CRDMOs) are responding proactively by accelerating the adoption of green technologies to align with changing client and regulatory expectations. Manufacturers are actively seeking greener alternatives for hazardous reagents, solvents, and chemicals. By overcoming traditional technical barriers and embedding the core principles of reducing, reusing, and recycling directly into waste management loops, labs and manufacturing facilities are establishing clear actions for carbon emission reduction. This includes department-level self-assessments of carbon dioxide output and the integration of rigorous environment, occupational health, safety, and sustainability (EHSS) management systems, which builds deeper trust with stakeholders, including governments, communities, partners, and employees.

Beyond materials and chemistry, energy utilisation has emerged as a critical area where sustainability directly dictates

business performance. Because pharma manufacturing plants run on continuous, 24-hour operating cycles, they are acutely vulnerable to rising power tariffs and grid instability. However, by investing in captive power capabilities, particularly green energy assets, companies are securing both supply continuity and cost insulation. This establishes a clear, undeniable business case: sustainability is not merely an exercise in corporate altruism, but a powerful lever for profitability. Across the broader pharma value chain, locking in long-term renewable energy contracts allows manufacturers to mitigate emissions while simultaneously stabilising operating expenditures. This operational predictability is what ultimately protects production timelines, safeguards supply continuity and stabilises pricing.

A similar business impact is playing out in the realm of water management, where resource conservation has rapidly evolved into a high-stakes risk-management issue. High-purity water is the absolute

lifeblood of medicine formulation and sterile equipment cleaning; yet a significant portion of global manufacturing capacity is concentrated in regions already grappling with acute water scarcity. At Syngene, we recognise that resource depletion poses a risk to operational continuity. We are investing in zero-liquid discharge (ZLD) technologies and closed-loop water purification infrastructure to enhance water security and sustainability across our operations. By recycling and reusing industrial wastewater on-site, these systems significantly reduce dependence on municipal freshwater sources, helping ensure uninterrupted manufacturing operations even during periods of water scarcity.

As organisations globally realise that sustainability yields broader business resilience, they are looking beyond their own factory walls to audit their entire value chain. Global pharma innovators are leading this charge, committing to greenhouse gas reductions that explicitly include their supplier networks under Science Based Targets initiative (SBTi) Scope 3 mandates. Because indirect emissions from raw material sourcing, outsourced manufacturing, and logistics often represent the lion's share of a pharma multinational's total carbon footprint, environmental transparency is no longer an optional procurement metric. Instead, sustainability has become a decisive factor in vendor selection, weighted alongside traditional benchmarks like scientific capability, regulatory track records, delivery reliability, and cost. This paradigm shift creates a powerful cascading effect: suppliers must adopt rigorous, sustainable operating models simply to qualify as preferred partners for global drug innovators.

This rigorous corporate

scrutiny is being mirrored closely in the capital markets, where institutional investors have stopped treating environmental reporting as an optional footnote in the annual report. Today, climate risks, resource dependencies, and carbon liabilities are analysed as leading indicators of a company's long-term financial viability. To command premium valuations and optimise their cost of capital, pharma boards are bringing sustainability directly into corporate governance. This capital market pressure is accelerating the adoption of strict, auditable reporting frameworks, ensuring that environmental performance data is processed with the same accuracy, granularity, and trustworthiness as traditional financial accounting.

The Indian pharma sector has been at the forefront of the sustainability transition, adopting best practices to align its production capacity with global eco-standards. This green transition is creating competitive advantage for India's contract manufacturing sector, which has developed a global reputation for scientific talent, scale, and cost efficiencies. By embedding sustainable engineering, transparent life-cycle tracking, and low-emission production into their core value proposition, Indian contract manufacturers are strengthening their positioning, transitioning from service providers to long-term strategic partners for global innovators. Over the coming decade, leadership in the life sciences world will be redefined by the ability to scale responsibly through resilient, circular operations. For India's pharma ecosystem, this transformation offers an opportunity to move beyond its identity as a high-volume manufacturing hub and emerge as a global model for sustainable, high-value pharma production.

India's biotech self-reliance moment

Dr Arun Asaithambi, Founder, CEO and Chief Scientist, Katamaran Industries, outlines how global shifts could help India build a stronger position in oncology innovation

For much of the past two decades, global biotech leadership has clustered around a handful of hubs, each anchored by patient capital, deep research infrastructure and institutions capable of turning early science into approved medicines. That map is being redrawn. Regulators are rethinking what counts as valid preclinical evidence, global supply chains for research services are shifting, and the definition of a valuable biotech asset is expanding to include the data and platforms behind a drug, not only the drug itself.

India sits at the center of this redrawing, with a genuine chance to build real strength in oncology innovation rather than simply supply services to hubs built elsewhere. This opportunity comes at a time when India's bio economy has grown from around US\$10 billion in 2014 to US\$195.3 billion in 2025, contributing nearly 4.8 per cent to the country's GDP, with the government targeting a \$300 billion bio economy by 2030. Oncology, given the scale of unmet need, is where that opportunity is sharpest. Realising it will mean learning deliberately from the hubs that came before while building an approach suited to India's own strengths.

What global biotech leaders have done right

The world's leading biotech ecosystems did not emerge overnight. They were built through sustained investment, supportive regulation, and close collaboration between research institutions, healthcare systems and industry.

For example, the US built its biotech ecosystem through sustained public investment in basic research, supported by institutions such as the NIH, alongside venture capital willing to back science-led companies through long development cycles. Innovation clusters such as Boston-Cambridge illustrate the advantages of bringing universities, hospitals, startups and pharmaceutical

companies together. Regulatory evolution has reinforced this ecosystem, with the FDA increasingly recognising New Approach Methodologies (NAMs) as valid evidence for investigational new drug (IND)-enabling studies.

China followed a different but equally deliberate path. By treating biotechnology as a strategic national priority, it rapidly expanded manufacturing, contract research and translational capabilities while creating an environment that encouraged companies to move beyond service delivery and develop original therapies. Although India cannot replicate either model, both underline the importance of patient capital, regulatory support and sustained collaboration across the innovation ecosystem.

Why this is India's moment

These lessons are becoming particularly relevant as several global developments converge in India's favor: The FDA's growing acceptance of NAMs is encouraging wider adoption of human-relevant preclinical models, while the newly enacted US BIOSECURE Act - signed into law in December 2025 - is prompting pharmaceutical companies to actively reassess portions of their research supply chains across Asia. Together, these shifts are creating demand for trusted research partners capable of delivering compliant, high-quality preclinical evidence.

This evolving landscape presents India with a significant opportunity to strengthen its role in the global preclinical research ecosystem. The country already has many of the essential building blocks in place, including scientific talent, ICMR-compliant ethical frameworks, FDA-aligned quality standards, and an extensive network of hospitals and research institutions capable of generating high-quality, consented biological data at competitive costs. This foundation is further reinforced by a rapidly expanding biotechnology ecosystem, with 11,800 registered



biotech startups in 2025. The continued growth of this ecosystem reflects stronger support from research institutions, incubators and industry partnerships, creating an environment that is increasingly conducive to scientific innovation and commercialisation.

Building indigenous AI-driven oncology innovation

Having the right scientific ecosystem, however, is only the starting point. The next challenge is converting these strengths into differentiated innovation, and artificial intelligence is becoming central to that effort. The quality of AI-driven oncology research depends increasingly on the biological data used to train it. While traditional models such as two-dimensional cell lines, animal studies and archived tumour samples have advanced cancer research significantly, they are increasingly being complemented by more human-relevant evidence that better reflects the complexity of disease.

India has an opportunity to build a differentiated approach centered on fresh human tumour tissue that preserves native tumour architecture and immune interactions. Emerging platforms can generate fresh tissue, three-dimensional tumour models and multi-modal molecular analysis from a single patient sample for around \$950 to \$1,500, compared with \$20,000-30,000 for a comparable package in Western mar-

kets. Combined with India's clinical diversity, scientific expertise and cost-efficient research ecosystem, this creates the potential to build high-quality biological datasets at scale, strengthening both AI-driven drug discovery and global research partnerships.

Translational research and collaboration must go together

Scientific discovery creates value only when it reaches patients. Translational research bridges this gap by connecting laboratory findings with clinical application. India already has important foundations through institutions such as the Centre for Cellular and Molecular Platforms, the National Centre for Biological Sciences and an expanding network of hospitals capable of supporting ethically governed fresh-tissue research.

Scaling this ecosystem will require stronger collaboration across academia, healthcare, industry and government. Shared standards for tissue procurement, chain of custody and data governance, alongside initiatives such as BIRAC's BioE3 Bio-AI Hub, the Government of India's Research, Development and Innovation (RDI) Fund and international collaborations, can accelerate the movement of discoveries from research laboratories to clinical development while strengthening India's long-term innovation capacity. Building these capabilities is not simply a scientific objective. Increasingly, it is also becoming a commercial advantage.

Rewarding innovation platforms

Recent transactions demonstrate that global pharmaceutical companies increasingly value the technologies behind drug discovery as much as the therapies themselves. Deals involving AI foundation models, proprietary datasets and computational discovery platforms, including transactions by GSK, Takeda and

Eli Lilly, show that platform capabilities have become commercially valuable assets in their own right. GSK's January 2026 partnership with Noetik, for example, committed \$50 million upfront plus recurring annual licensing fees to access AI foundation models trained on large-scale human tumour data - a five-year agreement that treats the model itself, rather than any single molecule, as the licensed asset.

For India, this represents an important strategic shift. The opportunity extends beyond discovering individual drug candidates to building proprietary datasets, AI-enabled platforms and translational capabilities that attract global partnerships while supporting home-grown innovation. Equally important, scientific credibility must continue to be built through rigorous validation, transparent reporting and evidence-based progress.

Looking ahead

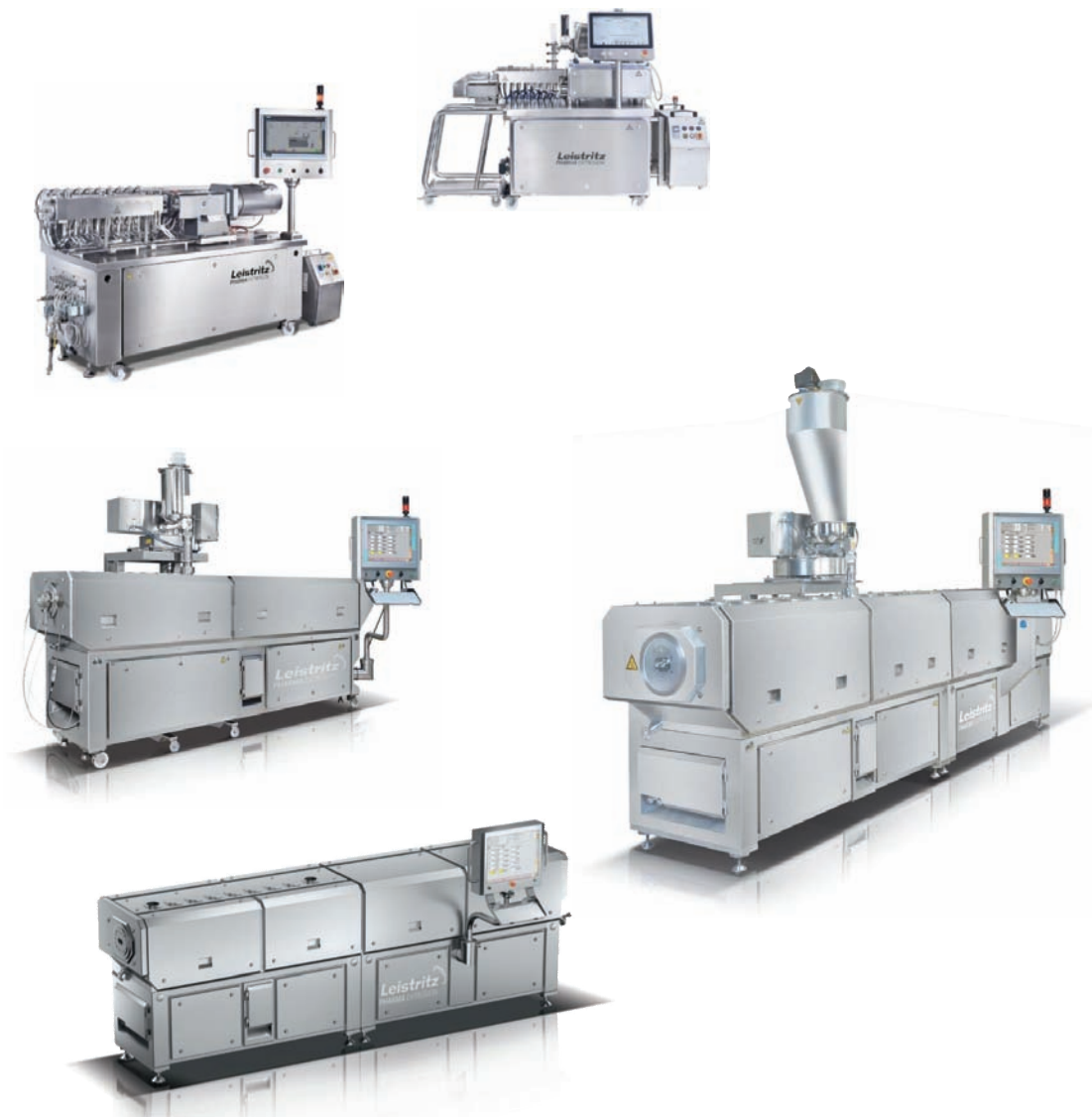
India stands at an important inflection point. Regulatory change, geopolitical realignment and advances in AI are reshaping where oncology innovation can emerge. Combined with India's scientific talent, clinical depth and growing research infrastructure, these developments create an opportunity to move beyond being a global research services provider towards becoming a center for original biomedical innovation.

The path is not without real obstacles. Chronic shortages of patient capital, and still-maturing standards for data governance and tissue chain-of-custody, remain genuine constraints on turning these building blocks into sustained innovation. Realising that ambition will require sustained investment in indigenous R&D, stronger translational research capabilities and deeper alignment between researchers, clinicians, industry and policy-makers. If these elements come together, India will not simply participate in the next generation of oncology innovation but help define it.

Leistritz

Continuous extrusion process for Pharmaceuticals

PHARMACEUTICAL EXTRUSION from 50gm/hour to 100kG/hour



HOT MELT EXTRUSION (HME)



SOLID LIPID EXTRUSION



FILM EXTRUSION



GRANULATION

WET EXTRUSION, WET GRANULATION

MELT GRANULATION

Advantages of twin screw extrusion compared to conventional manufacturing techniques:

integration of several process steps in one machine
excellent mixing capabilities (distributive and dispersive)
scale-up of results from R&D to production machines

reproducibility of process parameters
Inline Process Monitoring via application of Process Analytical Technology (PAT)

small footprint, even for high throughput rates
short processing time
adjustment of process conditions via flexible screw geometry and other process parameters
rapid execution of Design of Experiment (DoE)





Arihant Innochem Offers **MEGGLE** Portfolio of Excipients

Combining German quality with more than 135 years of expertise, **MEGGLE Excipients** provides one of the industry's most comprehensive pharmaceutical-grade lactose portfolios - helping you turn formulations into success.



MEGGLE PHARMACEUTICAL LACTOSE RANGE



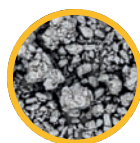
SIEVED LACTOSE

PrismaLac®, CapsuLac®,
SpheroLac®, SacheLac®



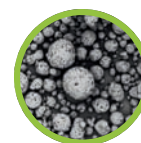
MILLED LACTOSE

GranuLac®,
SorboLac®



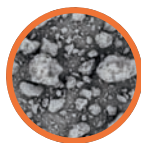
AGGLOMERATED LACTOSE

Tablettose®



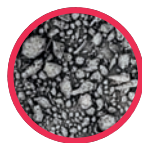
SPRAY-DRIED LACTOSE

FlowLac®



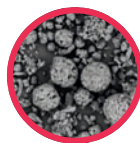
ANHYDROUS LACTOSE

DuraLac® H



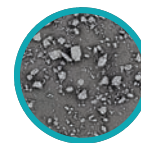
CO-PROCESSED EXCIPIENTS

Cellactose®, MicroceLac®,
CombiLac®



SUSTAINED RELEASE CPE EXCIPIENTS

RetaLac®



DRY POWDER INHALATION (DPI)

InhaLac®



SPECIAL APPLICATION

Lactose Monohydrate LE

WHY CHOOSE MEGGLE?

- Low Nitrite Grades Offered With Nitrite Content Measured For Every Production Lot
- Consistent Batch-To-Batch Quality
- Excellent Flowability And Compactibility

ARIHANTINNOCHEM PVT LTD

YOUR TRUSTED SOURCE FOR
MEGGLE PHARMACEUTICAL
EXCIPIENTS IN INDIA

For More Information, Please Contact

Arihant Innochem Pvt Ltd



+91-22-67674895



enquiry.pharma@arihantinnochem.com



www.arihantinnochem.com



IFB

**WASHES FROM
11 KG TO 130 KG**

Bulk laundry solutions for total peace of mind
———— **COMMERCIAL LAUNDRY SOLUTIONS** ————



-  Impeccable hygiene
-  Water savings
-  Manpower savings
-  Quick turnaround
-  Higher productivity



COMMERCIAL LAUNDRY RANGE		COMMERCIAL DISHWASHING RANGE		24x7 SERVICE ACROSS INDIA	COMMERCIAL ESSENTIALS
 Washer Extractor	 Tumble Dryer	BIS CERTIFIED    Undercounter Glass Washer Undercounter Dishwasher		 IFB CARE Always at your service. Anytime. Anywhere. 24x7 24x7 Support Warranty and post-warranty assistance Nationwide Service Network 110+ trained engineers across India Spare Parts Always Available Inventory maintained at all major towns AMC & CAMC Options Flexible maintenance packages for peace of mind	  Scan here to visit our website
 Flat Work Ironer	 Finishing Equipments	  Hood Type Dish Cum Bottlewasher Rack Conveyor Dishwasher			

☎ 080 45845678 / +91 95139 91116 ✉ query_industrial@ifbglobal.com 🌐 www.ifbappliances.com



Infinity Automation Systems Pvt. Ltd.

— Integrity & Leak Testing Solutions —

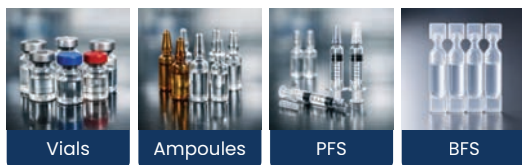
CONTAINER CLOSURE INTEGRITY TESTER

LT-5000 CCIT



- Detects Leaks Up to 1 Micron
- Non-Destructive & Deterministic Testing
- USP <1207> & 21 CFR Part 11 Compliant
- Ultra-Sensitive Pressure/Vacuum Decay Technology
- Compatible with Vials, Ampoules, PFS, BFS & IV Bags
- Remote Connectivity Available

APPLICATIONS



FILTER INTEGRITY TESTER

LT-5000 FLIT



- Bubble Point, Diffusion Flow & Water Intrusion Testing
- Fully Automated & Non-Destructive Testing
- USP <1207>, GMP & 21 CFR Part 11 Compliant
- High-Accuracy (0.075%) Pressure & Flow Measurement
- Compatible with Hydrophobic & Hydrophilic Membrane Filters

APPLICATIONS



SINGLE USE BAG LEAK TESTER

LT-5000 FlexiTest



- Non-Destructive & Deterministic Leak Detection
- Ultra-Sensitive Pressure Decay Technology
- Compatible with 1 L to 5000 L+ Bioprocess Bags
- Compliant with ASTM F2095-01, USP <1207>, GMP & 21 CFR Part 11
- Fast, Reliable Testing with Windows-Based Touch HMI

APPLICATIONS



Infinity Automation Systems Pvt. Ltd.

S No, 80/2A, Mumbai Bangalore Bypass Highway, near JSPM Engg. College, Ashok Nagar, Tathawade, Pune, Pimpri-Chinchwad, Maharashtra 411033

sales@infinityautomations.com

www.infinityautomations.com

+91-74474-24963 / +91-93256-40287



WALK-IN CHAMBERS



The name you can trust



ENHANCED
STORAGE



ROBUST
CONSTRUCTION



CUSTOMIZABLE
SIZES

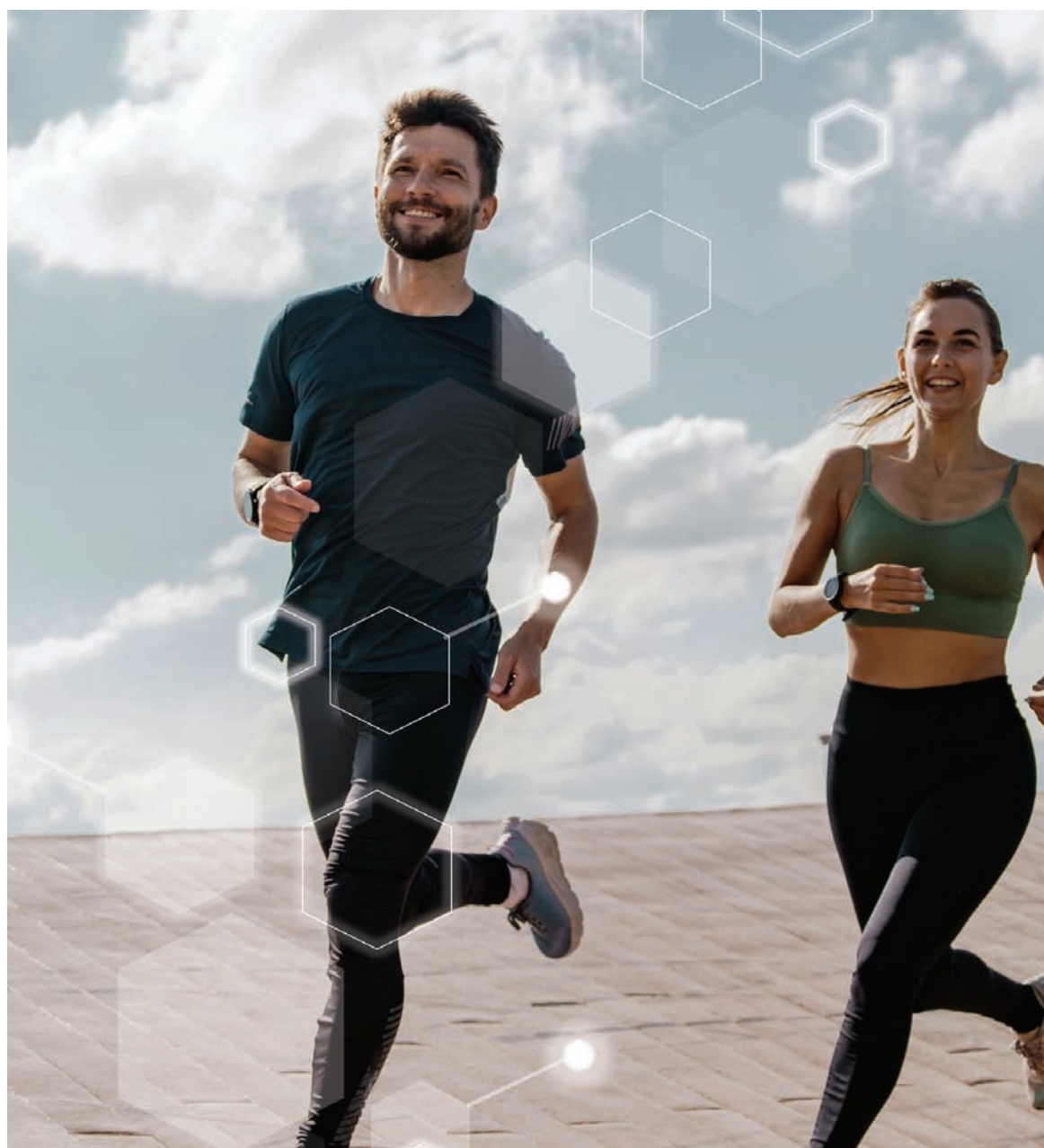


info@newtronic.in

+91 82918 21223

www.newtronic.in

Corporate Office: A/612, Kanakia Wall Street, Chakala, Andheri Kurla Road, Andheri (E), Mumbai-93, India.



HEART



VEINS



**BLOOD
PRESSURE**



**ENDOTHELIAL
FUNCTION**



CHOLESTEROL

Market Expansion
Services by
www.dksh.com



DKSH India Pvt. Ltd.

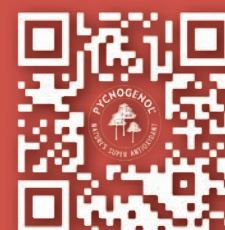
Hiranandani Light Hall Business Park, A-Wing
First Floor, Saki Vihar Road, Andheri East
Mumbai 400 072, India

Mobile +91 82 9187 9774, Phone +91 22 6157 7000
lokesh.karkare@dksh.com, www.dksh.in

PYCNOGENOL®

The One & Only

For Circulation
& Heart Health



www.pycnogenol.com



*For a complete list of scientific research and further information visit our website at www.pycnogenol.com. Pycnogenol®, French maritime pine bark extract, is a registered trademark of Horphag Research and its applications are protected by U.S. patents and other international patents. ©2026 Horphag Research.



PROBIO™

Wellness Begins Within

PROBIO**ZB29P™***Bacillus coagulans*

Gut Health Probiotic

PROBIO**ZB23™***Bacillus subtilis natto*

Bone health Probiotic

PROBIO**ZBOE6™***Bacillus subtilis*

Anti-ageing Probiotic

PROBIO**ZBJDRI™***Bacillus clausii*

Probiotic for Antibiotic-associated diarrhea

PROBIO**ZBRV8™***Bacillus subtilis*

Restores Gut diversity

PROBIO**ZBTM2™***Bacillus subtilis*

Women's Wellness Probiotic

NATTOLIFE™Nattokinase for
Cardiovascular health

Nourish your inner ecosystem.
Discover balanced and natural
health for the whole family
with an advanced probiotic formula.

**Zytex Biotech Pvt. Ltd.**702/B, Polaris, Off Marol Maroshi Road, Marol, Andheri (E),
Mumbai - 400 059. Maharashtra. India.Web : www.zytex.com | Email : info@zytex.com | Tel : +91-22-67723000

Lens  onnect®
SERIES

computar

Industry-First

TELECENTRIC LENS

Focus-driven telecentric lens

Magnification

0.25x, 0.5x, 1x, 2x !!

Customization available

- Can be easily operated remotely from a compatible Camera(I2C)
- Focus can be operated remotely
- Maintain telecentricity even when adjusting focus position
- Support for 2.74μ pixel size
- Two selectable interfaces(I2C/USB)
- Customization available for Magnification

**2/3" Compatible 8MP
and C-mount**



Model	Magnification	WD	F No.
TEC-ML025139U/SC-MPW	0.25 ×	139 ± 20mm	6.5
TEC-ML05132U/SC-MPW	0.5 ×	132 ± 10mm	6.5
TEC-ML10110U/SC-MPW	1.0 ×	110 ± 7.5mm	6.5
TEC-ML2071U/SC-MPW	2.0 ×	71 ± 5mm	6.5



CBC Corporation India Pvt,Ltd.

Phone: 91-22-28579798 | Email: enquiry@cbcindia.com

Website: www.cbcindia.com , www.computar-global.com



KH KILITCH HEALTHCARE INDIA LTD.



Accreditations



9001:2015



14001:2015



Manufacturing Sections

Small Volume
AmpouleSmall Volume
VialThree Piece
Ophthalmic VialTwo Piece Preservative Free
Ophthalmic VialPrefilled Syringes
in Blister packSterile medicated
Swab Sticks

Our Esteemed Clients



Head Office:
Kilitch Healthcare LLP,
 902/B Godrej Colesium, Behind Everad Nagar,
 Near Priyadarshani Circle, Sion (East),
 Mumbai – 400022.
Tel. : 022 6137 2222
Mr. Divya Mehta : +91 9819724957

Factory:
Kilitch Healthcare India Ltd.
 R-905/904, T.T.C. Indl. Area,
 M.I.D.C, Rabale, Navi Mumbai - 400 701.
Tel. : 022 2769 9174, 6516 2146

www.kilitchhealthcare.com | info@kilitchhealthcare.com



**ingredients
& packaging**
S O L U T I O N S

**Trusted for Solutions.
Chosen for Reliability!**



CPHI
India

Visit our
Booth 2G02, Hall 2

IICC, Yashobhoomi,
Dwarka, Delhi

November
23-25, 2026

Our Key Principal Partners

BIOGRUND

Metalco-alupack

NISSO HPC
Hydroxypropyl Cellulose

NKY PHARMA

Tomita



CBC Corporation (India) Pvt. Ltd.

Marwah Centre, Krishanlal Marwah Marg, Andheri East, Mumbai 400 072, India

+91 22 2857 9798

info@cbcindia.com

www.cbcindia.com | www.cbc.co.jp/en/

SUNNY ENTERPRISES

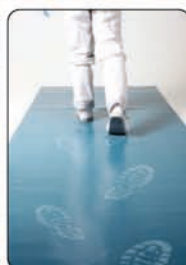
Leaders In Clean Room Contamination Control & Preventive Products



Clean Room Garments



Disposable Garments



Sticky Mats



Clean Room Mopping Systems



Rust Removal System



Clean Room Papers & Markers



Clean Room Pens



Autoclavable Non Autoclavable

Clean Room Shoes



Autoclavable Goggles



Sterile Packaging / Sterile Barrier Systems

Sterile Packaging



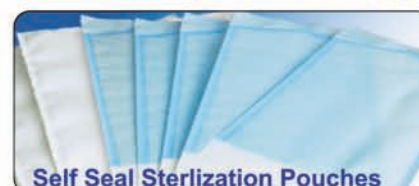
Clean Room Wipes



Fogger for Fumigation



Autoclavable Clean Room Trolley Systems: Plastic & Stainless Steel



Self Seal Sterilization Pouches



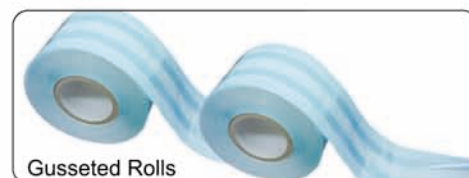
Dupont's Tyvek Rolls



Autoclavable Spray Bottles



Flat Sterilization Rolls



Gusseted Rolls



Autoclavable Tape

Sterilizable / Autoclavable Pouches & Reels with Indicators

Other Products: • Sterilization Rolls • Autoclavable Mop Heads for Floor Cleaning, Autoclavable Wall and Panel Cleaning System • Autoclavable Mop Heads for Wall & Panel Cleaning • Disposable Garments • Autoclavable Lint Free Hand Gloves • Disposable Wipes etc...

“Meeting the Standards, Beating the Prices.”

SUNNY ENTERPRISES

Plot No. 82, Raja Industrial Estate, P. K. Rd., Sarvodaya Nagar, Mulund (West), Mumbai 400 080, Maharashtra, India.

TEL # +91-22-2592 22 45, 25617205 • FAX # +91-22-2591 22 75

CELL # +91 99 87 17 77 32 (Viren) +91- 93 23 58 35 95 (Shirish) +91- 98 92 96 23 25 (Sunny)

Email: sales@sunnyenterprises.in • Website: www.sunnyenterprises.in • www.cleanroomgarments.in



LACTOSE
INDIA LIMITED



Speciality Lactose Grades - Now Made in India
Spray Dried | Anhydrous | Inhalation
Faster Access. Ready Samples.



Trusted Global Manufacturers of Pharma Grade LACTOSE & LACTULOSE | 30 + Years
Consistent • Scalable • Futuristic Pharma Ready

FORMULAC® & **LACTULOSE**
PHARMACEUTICAL EXCIPIENTS API RANGE
LACTOSE (IP/BP/EP/USP-NF) (IP/USP/PH.EUR)



📍 103/104, A Wing, 1st Floor, Navbharat Estate, Zakaria Bunder Road, Sewri (W), Mumbai - 400015, India

☎ +91 22-46644333 ✉ sales@lactoseindialimited.com

www.lactoseindialimited.com





Continuous Coating

Coating, Drying and Laminating - the basic functions of the «KTF-S»

The system is available in a powder-coated steel or full stainless steel version depending on customer requirements

The use of a production machine is not financially viable for research and development purposes

The most economical solution is our continuous coating system of modular design for various materials such as paper, textile, copper, aluminum and plastic foils

Market leaders are using Mathis technology

Mathis
www.mathisag.com



Precision. Quality. Trust.

Engineering Innovation. Delivering Reliability.

Advanced Pharmaceutical Equipment Designed With Precision, Built For Performance And Trusted Worldwide.

High Quality Equipment | Precision Engineering | Custom-Built Solutions | Strict Quality Assurance | Timely Delivery & Installation Support | After Sales Support

Visit Us At
Analytica Lab India 2026.
10 to 12 Sep 2026.
Hitex Exhibition Centre, Hyderabad.
Hall No : **1** | Stall No : **C42.**

enquiry@aureolepharmatech.com | www.aureolegroup.com | +91 86005 22240

Engineering Excellence. Delivering Trust.

We're pleased to inform you that we're
**A Leading Supplier of the following
Spectroscopy & Chromatography Consumables:**



**Hiten Techno Products
Corporation**

1. D2 Lamps

- (i) Hamamatsu Photonics K.K., Japan
- (ii) Mitorika Co., Ltd., Japan
- (iii) Excelitas Noblelight GmbH, Germany

2. HPLC Vials, Caps & Septa

(Cole-Parmer Instrument Company LLC, USA)

3. Spectroscopy Cuvettes

(Starna Scientific Ltd., UK)

4. Certified Reference Materials for Calibrating Spectrophotometers & Spectrofluorometers

(Starna Scientific Ltd., UK)

5. Polystyrene Films for Calibrating FTIRs

(Starna Scientific Ltd., UK)

6. FTIR Cells, Windows & Accessories

(Specac Ltd., UK)

7. Hollow Cathode Lamps

(Mitorika Co., Ltd., Japan)

8. NMR & EPR Sample Tubes

(Norell Inc., USA)

9. Weighing Balances

(Adam Equipment Co. Ltd., UK)

10. Short-Arc Xenon lamps (Ushio Inc., Japan)

11. 96-Well Quartz Microplate

(Starna Scientific Ltd., UK)



**912, The Capital, Adjoining Jio Garden, G Block, Bandra Kurla Complex,
Mumbai - 400 051, India. Tel: +91-22-66268000 (100 lines)
Email: hemang.jhaveri@hitenttechno.com | www.hitenttechno.in**





S.V. SCIENTIFIC PVT. LTD.
Stepping with Science Since 1997

TECHNOLOGY THAT MAKES THE DIFFERENCE



Integrated Wi-Fi functionality
Cross-device App control
Ready for AI-supported monitoring & maintenance via LAUDA.LIVE





Highly efficient cooling technology
100% natural refrigerants
Exceptionally quietly, clean operation and durable



Wide temperature range
Outstanding heating and cooling performance
High precision, dynamics and temperature stability



Modular platform
Customizable configuration
Expandable with a wide range of accessories

THE ALL-NEW DIMENSION OF TEMPERATURE CONTROL
MODULAR, AI-READY, SUSTAINABLE, HIGH-PERFORMANCE

• Intuitive control via Wi-Fi and app • Maximum system integration • Cloud-enabled & AI-ready

REGISTERED & CORPORATE OFFICE :
No. 119, Sylvestra Arcade, 1st Floor, East Park Road, 11th Cross, Malleshwaram, Bengaluru - 560003. BHARATH (INDIA)

Phone : +91-80-2356 7255, 2346 2314
Email : info@svscientific.in
URL : www.svscientific.com



Ami Polymer
Enabling Healthcare



One Connection. Complete Process Control.

ImaLINK™ Manifold - Engineered to connect every critical step in single-use fluid handling.

Designed for modern biopharmaceutical processes, ImaLINK™ Manifold brings multiple fluid pathways together into an integrated single-use solution. Supporting efficient fluid transfer and streamlined process connections, it helps build cleaner, more organized, and more reliable bioprocessing systems.

APPLICATIONS

- **Biopharmaceutical Manufacturing**
Fluid transfer and process integration across critical manufacturing operations.
- **Single-Use Processing Systems**
Connecting multiple fluid pathways within integrated single-use assemblies.
- **Media & Buffer Handling**
Supporting controlled transfer through different stages of media and buffer processing.
- **Cell Culture & Harvest**
Enabling organized fluid flow within upstream bioprocessing applications.
- **Bulk Drug Substance Handling**
Supporting critical fluid movement in sterile containment systems.

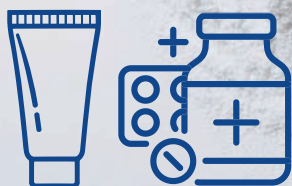


www.amipolymer.com
media@amipolymer.com





FLORITE®



Revolutionize Your Pharma Formulations with Florite®

A Multifunctional Excipient for Superior Drug Delivery

Florite® is a next-generation pharmaceutical excipient designed to overcome complex formulation challenges. With exceptional oil absorbency, excellent API compatibility, and superior compressibility, Florite® enables stable, high-quality solid dosage forms.

Key Features & Benefits

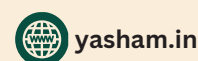
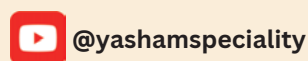
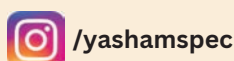
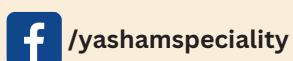
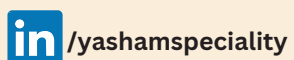
- Superior Liquid Absorption – Absorbs up to 5x its weight (~4.0 ml/g)
- Multifunctional – Acts as diluent, solidifier, stabilizer and binder
- Direct Compression Ready – Excellent flowability and compressibility
- API Stability – Alkaline nature (pH ~8.9) protects acid-sensitive drugs
- Improved Tablet Hardness – High strength at lower compression force
- Excellent Content Uniformity – Ensures precise dosage

Applications

Tablets | Capsules | Solid Dispersions | Dry Syrups | Oily & Hygroscopic Drugs

Compatible APIs

Atorvastatin | Metformin | Telmisartan | Vitamins | Nutraceutical Actives



Head Office:
401, Satya-Dev, A-6, Veera Industrial Estate,
Off. Veera Desai Road, Andheri (West),
Mumbai, Maharashtra – 400053, INDIA

Tel. No.: 022-40639900 **Fax No.:** 022-40639901
Email Id : yasham@yasham.in **Web:** www.yasham.in
Branch Office: New Delhi | **Sales Representatives:**
Ahmedabad, Chandigarh, Hyderabad & Kolkata

M. K. Silicone Products Pvt. Ltd.
SILICONE TRANSPARENT TUBING
for the Quality Conscious....



**An ISO 9001-2015
 Certified Company**

**Quality
 Products
 Since
 1997**

208, Hill View Industrial Premises,
 Amrut Nagar, Ghatkopar (W), Mumbai - 400 086, India.
 Mob.: 9321965968 / 9869412342
 E-mail : sales@mksilicone.com

Blue Heaven

SANITT™
Premium Cleanroom Necessities



SANITT EQUIPMENT & MACHINES PVT. LTD.
 Shed#5, Raj Bucket Factory Compound, Near Ghodbunder Village,
 Ghodbunder Road, Post Mira Road, Dist. Thane-401 104, Maharashtra, India.
 Telephone: 8655530303 / 8655510101 E-mail: cmd@sanitt.net / vipul@sanitt.net / sales@sanitt.net

Agitated Nutsche Filter Dryers

Features

- MOC: SS316/Hastelloy
- Capacity: up to 1 KL
- Metallic multilayered filter media in SS316 or Hastelloy
- Filtration rating: 1 to 150 microns
- Interchangeable filter disc system
- Heatable filter disc for faster drying



**Kumar Process Consultants
 & Chemicals Pvt. Ltd.**

Founded in 1978, we have extensive experience in providing customized microfiltration solutions for the pharmaceutical and chemical industries in India.

Range of products:

- Made-in-India Powder sintered and Multilayered sintered metallic filter media at our sintering facility
- Integrity-tested membrane filters with validation in different materials as per process requirement
- Membrane holders
- Steam filters in SS316
- Capsule filters
- Pre-filters

Mumbai office:
 Plot A-42, Road no. 10,
 MIDC Wagle estate, Thane (W),
 Maharashtra 400604, India

Delhi office:
 920, 9th floor, Westend mall,
 Janakpuri District Centre,
 New Delhi 110018, India



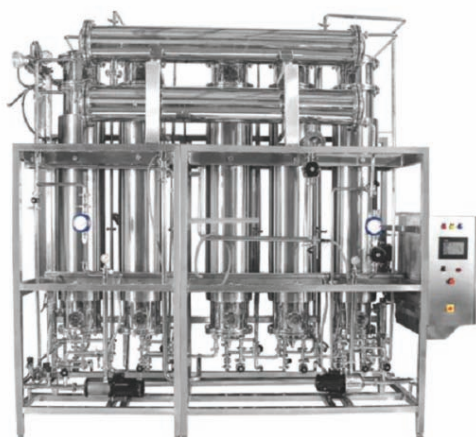
Email us at
info@kumarfilter.com

DPL[®] OFFERS

- PURIFIED WATER / WFI GENERATION SYSTEMS
- PW/WFI DISTRIBUTION SYSTEMS
- MCDP / PSG SYSTEMS
- STORAGE / MIXING TANKS
- WFI TANKS
- HOSES, DRAIN TRAPS
- SANITARY PUMPS

SERVICES

- Electro polishing
- Piping Installation
- Orbital Welding
- Boroscopy
- Instrumentation & Automation



Water Purification



Process Equipments & Spares



DPL[®] DPL VALVES & SYSTEMS PVT. LTD.

+91 93202 11777 info@dplvalves.com purewaterengineers3@gmail.com

www.dairypharmavalve.com

OsmoTECH® XT Single - Sample Micro-Osmometer

Now available!

Best-in-class osmolality performance,
designed with you in mind.



ADVANCED
INSTRUMENTS

HIGHLIGHTED FEATURES:

- Offers the widest range of osmolality testing (0 – 4000 mOsm/kg H₂O)
- Supports 21 CFR part 11, GMP and EU Annex 11 compliance
- Meets Pharmacopeia osmolality testing guidelines
- 3 Level user access and password protection
- Storage: unlimited data storage for access
- Audit trail: Preserve unlimited results and events
- Database backup, protects your data with automatic or manual backup

ROSALINA
INSTRUMENTS

No. 127, Bussa Udyog Bhavan, Tokershi Jivraj Road, Sewri West, Mumbai-400015,
Maharashtra, Landline : +91 022 - 24166630 Mobile : +91 9833286615

**SHREE
GAURAV**

AN ISO 9001:2008
14001:2004

VITON • SILICONE • NEOPRENE • NITRILE • EPDM

**Our Products are Manufactured -
Having Certified Cleanroom of Class 10000**

DMF No 27899 for Braided Silicon Hose
DMF No 27897 for Silicon Tubing Peroxide/platinum Treated

FBD / FBP Inflatable Gasket



Sanitary "O" Rings & Gaskets



Silicone Solid/Sponge Gaskets



Silicone Transparent Tubing

SHREE GAURAV RUBBER PRODUCTS

Factory: 112/B, Marudhar Indl. Estate, Opp. Old Syndicate Bank,
Goddev Road, Bhayandar (E)-401 105.

Telefax: 022 28197355, Mobile: 91 9892414152 / 9820469764

E-mail: sari@mtnl.net.in / gaurav_rubber@rediffmail.com Website: www.gauravrubbers.net

PERSONAL PROTECTION GLOVES & GOGGLES

ISO field®
Protecting Life Science

Sterile
600mm(24")



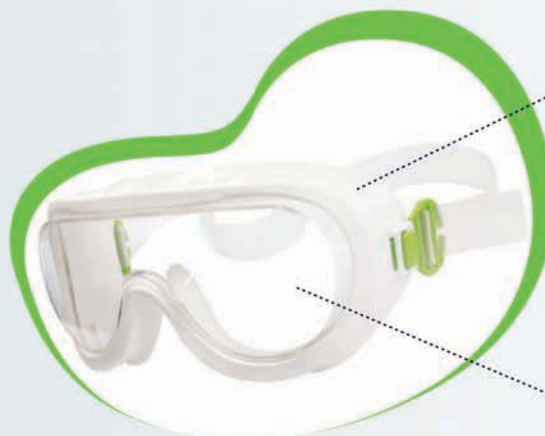
Sterile & Non-Sterile
300mm(12")



Sterile & Non-Sterile
400mm(16")



ISO
Class 4 & 5



Frame: Tested To Withstand
40 Autoclave Cycles

Lens: Tested To Withstand
35 Autoclave Cycles

JUNE®

+91 22 40787979 | +91 9833474859
info@june4gmp.com | www.june4gmp.com

Please Join Us At **analytica Lab India**

HITEX Exhibition Centre, Hyderabad, India.

SAVE THE DATE 10/11/12 September 2026 | Hall No. 5 | Booth No. G31

Swiss
Formula

VIROSIL PHARMA™

A SWISS ECO-FRIENDLY,
CHLORINE-FREE FUMIGANT



available in
5 ltrs &
30 ltrs.



**100%
ELIMINATION
OF AIRBORNE
BACTERIA & FUNGI**

- ✕ **NON TOXIC**
- ✕ **NON IRRITANT**
- ✕ **NON MUTAGENIC**
- ✕ **NON CARCINOGENIC**

AREAS OF APPLICATIONS

Injectable's, Formulations,
Production areas,
QC & QA Labs Storage tank/ CIP
Packaging & Filling Areas,
Research & Life Science,
Tissue culture units,
Microbiological Labs

98202 33200

Microbe
Free In just
60 SECS

ECO-FRIENDLY, ENVIRONMENTAL DISINFECTANT FOR



**AERIAL
FUMIGATION**



**AIR CONDITIONING SYSTEM
DISINFECTION / AHU**



**CLEANING IN PLACE
(CIP)**



**SURFACE
DISINFECTION**



**PIPE LINES
DISINFECTION**

**CUSTOMISED
DISINFECTION
AUDIT™**

Sanosil Biotech's Virosil Pharma is a revolutionary, eco-friendly fumigant a strong replacement to Formalin Fumigation. The tried and tested patented formulation includes a complex compound which kills all forms of bacteria, viruses and spores, rendering spaces perfectly safe and sterile.

Virosil Pharma is a complex combination of H2O2 and silver ions. It neutralizes all forms of bacteria and viruses by attacking their cell membranes and their DNA/RNA structures.

Virosil Pharma effectively disinfects all critical surfaces. We recommended ULV fogger gives a very fine mist which allows the formulation to be suspended in the atmosphere for a longer period of time guaranteeing 100% kill on all air-borne bacteria and fungus.

WE CATER TO THE DISINFECTION DEMANDS OF MAJOR INDUSTRIES LIKE :



Life
Sciences



Vaccine
Manufacturers



Nutraceuticals



R&D Labs



Ayurveda

Sanosil Biotech Pvt. Ltd. 1st Floor Warden House,
Sir P. M. Rd, Fort, Mumbai, Maharashtra 400001

info@virosilbiotech.com
www.virosilbiotech.com



**Vitafoods™
India**



Title Partner
**KSM-66
Ashwagandha®**
WORLD'S BEST ASHWAGANDHA



9-11 February 2027
Pavilion 1-3, JWCC, Mumbai

A complete nutraceutical experience

Explore key event features at the 2027 edition



New Ingredients & Products Zone

Explore innovative ingredients and cutting-edge solutions shaping the future.



Tasting Zone

Discover, taste and experience the latest nutritional products firsthand.



Global Trends Zone

See innovative products from global brands and learn trends and insights from Mintel.



Conference

Engage in expert-led sessions and gain valuable insights into nutraceutical trends.



NEW

Vitafoods India Innovation Awards

Celebrate breakthrough innovations driving the future of health and wellness.

Engage and grow with

10,000+

expected attendees

220+

exhibitors

40+

participating countries

60+

expert speakers

For enquiries contact:

Pranav Navare

M: +91 77383 23257 | E: pranav.navare@informa.com

Scan to register your interest



Beautiful & healthy legs with Pycnogenol®

Achieving beautiful and healthy legs requires a mix of good blood flow, strong muscles, and smooth skin. Key factors for attractive and fit legs include staying active, keeping the skin soft, and improving circulation, to prevent swelling and other unwanted conditions.

Swelling of the legs or ankles can affect everyone, and it is typically increased on hot days, at the end of the day or after long times of reduced mobility, like during flights or prolonged standing. But edema can also be one of the first symptoms of chronic venous insufficiency (CVI) (1). Other symptoms of CVI include heavy or tired legs, visible varicose or spider veins and skin discoloration. Chronic venous disease affects roughly one out of five adults globally, while the prevalence of venous disorders in India varies between 7 and 25% (2). When including early, asymptomatic, or mild clinical signs, like spider veins and varicose veins, up to 84% of the global population is affected by CVI (3).

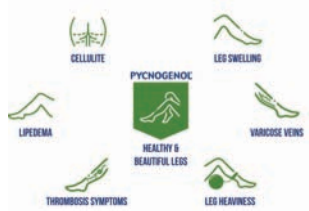
An ever-increasing number of clinical studies demonstrate the efficacy of PycnogenolR French maritime pine bark extract against leg swelling in healthy and particularly in CVI (risk-) patients (4-19). PycnogenolR has been shown to counteract venous insufficiency and prevent thrombosis by improving microcirculation (19-24), blood flow (25-27) and platelet function (28, 29).

A very common cosmetic skin condition of the legs is cellulite, affecting 80-90% of women around the world, including Indian women (30). It is linked to dermal structure and vascular changes, causing subcutaneous fat within connective tissue to push up the skin leading to dimpled and bumpy skin on the thighs, hips, buttocks and abdomen (30). A recent study demonstrated PycnogenolR's beneficial effects on cellulite severity and skin smoothness (31).

Another condition that can affect physical appearance and

general health of the legs immensely is lipedema. Lipedema is a chronic disorder causing an abnormal build-up of subcutaneous fat in the legs that is not caused by obesity and is resistant to traditional diet and exercise (32). The condition can be painful and depending on the severity, can greatly affect mental wellbeing and daily life. A recently published study showed that PycnogenolR supports the reduction of lipedema symptoms (33).

The results of many clinical studies indicate that PycnogenolR as part of a healthy lifestyle can improve the health and appearance of the legs.

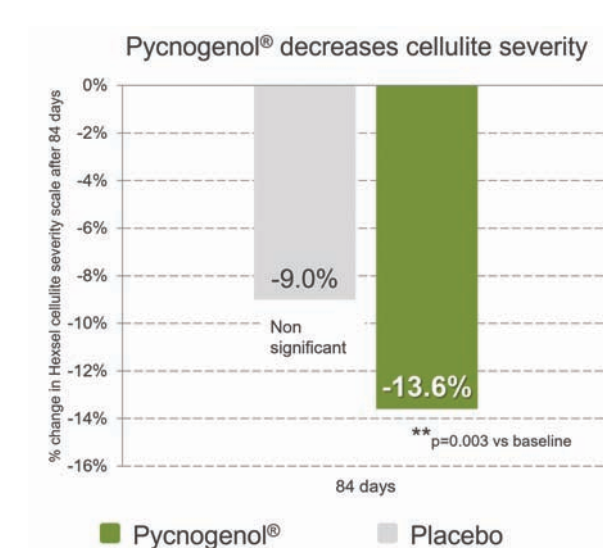


Efficacy for cellulite

A 2025 study revealed that PycnogenolR significantly decreases cellulite severity (31). The double-blind placebo-controlled study included 60 women who took either PycnogenolR or placebo for 3 months. Cellulite severity was significantly reduced by 13.6% in the PycnogenolR group, according to the Hexsel cellulite severity score, a clinically validated tool, assessing five key morphological features of cellulite, such as skin surface alterations or sagging skin. In addition, the study assessed PycnogenolR's effects on skin smoothness and thigh circumference. Upper thigh circumference was significantly reduced by 2.07 cm after the 3 months of PycnogenolR intake compared to a reduction of 0.9 cm in the placebo group. Skin roughness was decreased by 32%, and skin smoothness was increased by 11.2% after PycnogenolR supplementation.

Reduction of Leg Swellings

Venous health is an important prerequisite to avoid leg swelling due to blood pooling and to avoid



Liu, Q., et al. (2025).

further damage to the legs.

PycnogenolR supports venous health by preventing leg and foot swellings in healthy subjects and those suffering from CVI (4-19).

In a clinical study, PycnogenolR reduced leg swelling after 7 to 12-hour flights in subjects with mild to moderate risk for thrombosis, compared to controls. The ankle circumference increased by 11% in the control group and by 6% in the PycnogenolR group (4).

A similar study including healthy and high-risk thrombosis subjects, taking long-haul flights could show that at the end of the flight, the edema score was significantly lower and ankle swelling and leg discomfort were reduced in subjects supplemented with PycnogenolR compared to control subjects and participants, who used compression stockings (5).

A double-blind, placebo-controlled study showed that PycnogenolR supplementation for 2 months significantly relieved heaviness (-54%), swelling (-64%) and discomfort (-64%) in the legs of CVI patients compared to placebo (-3%, -7% and -18%, respectively) (6).

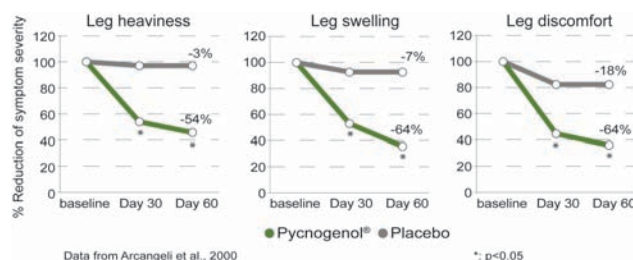
After 8 weeks of regular PycnogenolR supplementation, patients with severe venous hypertension and a history of venous ulcerations showed significant improvements in edema, limb

restlessness, discomfort, swelling, and skin discoloration (7).

The efficacy of PycnogenolR in controlling symptoms of patients with severe, long-lasting venous insufficiency was evaluated in an 8-weeks summer study (8). In this study, compared to compression stockings, PycnogenolR was more effective in decreasing ankle swelling and improving microcirculatory blood flow. The combination of compression stockings and PycnogenolR was most effective against the symptoms of venous disease, leading to a reduction of 38% of ankle swelling and an improvement of microcirculation of 61%.

A recent 2-year study showed that PycnogenolR reduced the progression of venous disease in pre-menopausal women, significantly ameliorating symptoms of CVI, compared to the use of compression stockings (10). This study shows that PycnogenolR's benefits are maintained over time.

Four comparative investiga-



Data from Arcangeli et al., 2000

*: p<0.05

tions demonstrated that PycnogenolR is more efficacious on symptoms of CVI than other products or potentiates the efficacy in combination with them (11-14). PycnogenolR was more effective in the reduction of ankle swelling, edema and the improvement of microcirculation than similar products on the market, like DaflonR and AntistaxR.

Edema is tightly connected to vascular permeability and capillary filtration and contributes to impaired microcirculation. A measure for capillary leaking is the rate of ankle swelling, which was significantly reduced after supplementation with PycnogenolR in subjects with CVI, varicose veins and in diabetic patients with microangiopathy (8, 10, 15, 24).

Improved symptoms of varicose veins

A very common condition that develops during pregnancy are varicose veins, which can occur from weakened or damaged vein walls. A 12-month study with women presenting with varicose veins after their second pregnancy compared the use of compression stockings alone or in combination with PycnogenolR supplementation (17). Signs and symptoms such as heavy legs, discomfort while standing, restless legs and bruises were significantly decreased when co-supplementing with PycnogenolR in comparison to use of compression only.

Amelioration of chronic venous insufficiency symptoms

Once the tissues in the legs receive oxygen and nutrients, the oxygen-depleted blood must be pumped back up to the heart against gravity (1). For this

mechanism to function, one-way valves and muscle contractions are crucial in preventing back-flow and pooling of blood in the legs and feet (1). If the veins are damaged, dilated or there is venous flow obstruction, blood pools in the leg veins, causing high pressure, chronic vessel inflammation, and impaired microcirculation (1, 34). Over time and if left untreated this can develop into chronic venous insufficiency (CVI), including symptoms like edema, itching, heaviness and skin changes, such as skin discoloration, varicose veins or ulcers (1).

Globally, up to 17% of men and up to 40% of women suffer from chronic venous insufficiency with a high number of underdiagnosed cases, especially in early, symptomless stages of the disease (1).

PycnogenolR improves blood perfusion in patients with microangiopathy (impaired microcirculation) resulting from atherosclerosis, diabetes or chronic venous insufficiency (15, 19-24).

A double-blind placebo-controlled study shows that PycnogenolR has beneficial effects on clinical symptoms and microcirculation in women with CVI after sclerotherapy (19). After undergoing sclerotherapy, 50 women with CVI took either PycnogenolR or placebo for three months. Additionally, they wore compression stockings for 30 days following the intervention. PycnogenolR intake significantly improved quality of life and reduced the clinical severity of the symptoms and the score of discomfort compared to placebo. Using a transcutaneous microscope, the researchers measured the patients' microcirculation parameters, assessing health and functionality of the small micro vessels directly under the skin that are responsible for supplying oxygen and nutrients. After 3 months of PycnogenolR supplementation, CVI patients exhibited a significant increase in functional micro vessels in their legs compared to before the study. In addition, significantly less altered or non-functional micro vessels were detected compared to baseline and the study participants in the PycnogenolR group had significantly less leg edema

(-26%) compared to those in the placebo group (-10%).

PycnogenolR supplementation in combination with local application was shown to support microcirculation and the healing of venous ulcers in CVI patients (22). Oxygenation and nutrient supply were improved after taking PycnogenolR, leading to reduced ulcer size by 88% in 6 weeks, compared to a reduction of 69% in control patients.

In a 12-month comparative study, PycnogenolR was shown to significantly improve microcirculation by 43%, decrease the edema score by 53% and improve oxygen (+13%) and carbon dioxide levels (-10%) in patients with moderate to severe signs and symptoms of CVI, outperforming seven other venotonic products (15).

A recently published study confirmed these results, showing that PycnogenolR reduced water and fluid accumulation in CVI limbs, as seen by significantly reduced limb volume by improving microcirculation parameters, such as transcutaneous oxygen and carbon dioxide levels (18).

Decreasing vein thrombosis symptoms

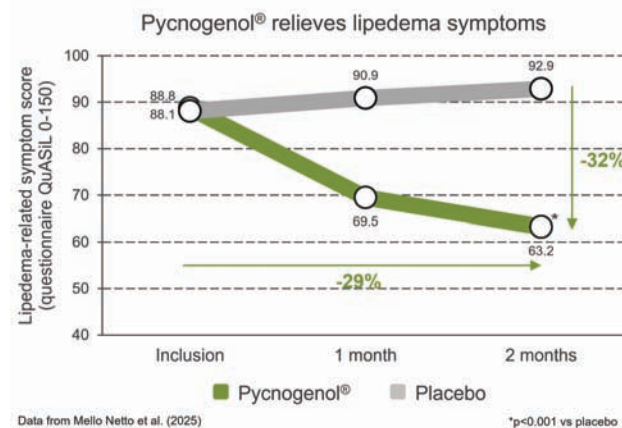
Venous impairment can result from vein wall damage, dilation or can occur as a consequence of deep vein thrombosis, which is caused by a blood clot obstructing blood flow in a vein (35). The leading risk factors for venous insufficiency and thrombosis include age above 50 years, obesity, family history of venous diseases (CVDs), smoking, physical inactivity, long periods of standing or sitting as well as female gender, combined with the number of child births, hormonal contraception and menopause (1).

PycnogenolR supplementation was shown to significantly decrease the occurrence of recurrent deep vein thrombosis and post-thrombotic syndrome (25, 26, 36). PycnogenolR was found to provide relief of edema in the legs and thrombosis-related symptoms (discomfort, restless limbs, subjective swelling, skin alterations). The results of the studies point to an additional improvement of symptom relief when combining

compression stockings with PycnogenolR intake.

PycnogenolR fs effects on lipedema

A new placebo-controlled study published in 2025 shows that the intake of PycnogenolR relieves the main symptoms of lipedema (33).



In the study, one hundred women in their thirties with diagnosed lipedema took PycnogenolR or placebo for 2 months (33). The lipedema-related symptom score was reduced by a 29% compared to baseline and was significantly reduced by 32% compared to placebo at the end of the study. In the lipedema-specific questionnaire on quality of life that was used, several parameters were significantly reduced, such as swelling of the legs, heavy legs, tenderness and bruising. In addition, an 8% reduction in body fat percentage and a significant improvement in quality of life compared to placebo was reported at the end of the study.

PycnogenolR benefits lipedema through its antioxidant (37-43) and anti-inflammatory properties (44-46), which help strengthen blood vessel walls (37, 47, 48) and improve microcirculation (19-21). These effects are particularly relevant for lipedema, where impaired circulation contributes to chronic swelling and tissue discomfort.

PycnogenolR French maritime pine bark extract is a safe, natural and evidence-based solution to support healthy-looking legs. PycnogenolR helps to reduce cellulite, leg swellings and varicose veins. By improving

blood flow, platelet activity and its anti-inflammatory efficacy, PycnogenolR effectively reduces symptoms of chronic venous insufficiency (CVI) and thrombosis. PycnogenolR intake reduces symptoms of lipedema. For more information on how PycnogenolR helps support venous health and beautiful legs, please

visit www.pycnogenol.com.

Article written by Dr. Franziska Weichmann, Manager of Scientific Communications and Product Development at Horphag Research.

References:

1. Azar J, et al. *J Wound Care*. 2022;31(6):510-9.
2. Pillai AR, et al. *Journal of medical sciences*. 2025;28(1):4-9.
3. Salim S, et al. *Ann Surg*. 2021;274(6):971-6.
4. Cesarone MR, et al. *Clin Appl Thrombosis/Hemostasis*. 2005;11(3):289-94.
5. Belcaro G, et al. *Minerva Cardioangiol*. 2018;66(2):152-9.
6. Arcangeli P. *Fitoterapia*. 2000;71:236-44.
7. Cesarone MR, et al. *Angiology*. 2006;57(5):569-76.
8. Cesarone MR, et al. *Minerva Cardioangiol*. 2019;67(4):280-7.
9. Cesarone MR, et al. *Phytomedicine*. 2010;17(11):835-9.
10. Cesarone MR, et al. *Panminerva Med*. 2022;64(4):564-6.
11. Riccioni C, et al. *Eur Bull Drug Res*. 2004;12(1):7-12.
12. Koch R. *Phytother Res*. 2002;16 Suppl 1:S1-5.
13. Cesarone MR, et al. *Clin Appl Thromb Hemost*. 2006;12(2):205-12.
14. Belcaro G. *Int J Angiol*. 2015;24(4):268-74.
15. Belcaro G, et al. *Int J Angiol*. 2017;26(3):170-8.
16. Gulati OP. *Phytother Res*. 2014;28(3):348-62.
17. Belcaro G, et al. *Int J Angiol*. 2017;26(1):12-9.
18. Belcaro G, et al. *Minerva Surg*. 2024;79(4):448-54.
19. de Souza Lima Hara WY. *Rio de Janeiro: State University of Rio de Janeiro*; 2023.
20. Wang S, et al. *European Bulletin of Drug Research*. 1999;7(2):19-25.
21. Belcaro G, et al. *Clin Appl Thromb Hemost*. 2006;12(3):318-23.
22. Belcaro G, et al. *Angiology*. 2005;56(6):699-705.
23. Steigerwalt R, et al. *J Ocul Pharmacol Ther*. 2009;25(6):537-40.
24. Cesarone MR, et al. *Angiology*. 2006;57(4):431-6.
25. Belcaro G, et al. *Minerva Cardioangiol*. 2018;66(3):238-45.
26. Errichi B, et al. *Panminerva Med*. 2011;53(3):21-7.
27. Rodriguez P, et al. *Panminerva Med*. 2015;57:121-5.
28. Araghi-Niknam M, et al. *Integrative Medicine*. 1999;2(2/3).
29. Putter M, et al. *Thrombosis Research*. 1999;55:155-61.
30. Gabriel A, et al. *Aesthetic Surgery Journal Open Forum*. 2023;5:1-13.
31. Liu Q, et al. *Phytomedicine Plus*. 2025;5(3):100821.
32. Kruppa P, et al. *Dtsch Arztebl Int*. 2020;117(22-23):396-403.
33. Seabra De Mello Netto BA, et al. *Cureus*. 2025;17(11).
34. Gschwandtner ME, et al. *Vasc Med*. 2001;6(3):169-79.
35. Youn YJ, et al. *The Korean journal of internal medicine*. 2019;34(2):269-83.
36. Kahn SR. *Hematology Am Soc Hematol Educ Program*. 2016;2016(1):413-8.
37. Enseleit F, et al. *Eur Heart J*. 2012;33(13):1589-97.
38. Ryan J, et al. *J Psychopharmacol*. 2008;22(5):553-62.
39. Chovanova Z, et al. *Free Radic Res*. 2006;40(9):1003-10.
40. Dura.kova Z, et al. *Nutrition Research*. 2003;23(9):1189-98.
41. Devaraj S, et al. *Lipids*. 2002;37(10):931-4.
42. Kolacek M, et al. *Free Radic Res*. 2013;47(8):624-34.
43. Yang HM, et al. *Acta Obstet Gynecol Scand*. 2007;86(8):978-85.
44. Canali R, et al. *Int Immunopharmacol*. 2009;9(10):1145-9.
45. Grimm T, et al. *J Inflamm (Lond)*. 2006;3:1.
46. Schafer A, et al. *Biomed Pharmacother*. 2005;60(1):5-9.
47. Nishioka K, et al. *Hypertens Res*. 2007;30(9):775-80.
48. Zibadi S, et al. *Nutr Res*. 2008;28(5):315-20.

Laser sealing for single-use bioprocessing bags: The next step in sterile fluid containment

Single-use bioprocessing bags have become indispensable in modern biopharmaceutical manufacturing. From media preparation and buffer storage to cell culture, harvest, and final bulk drug substance handling, these systems have transformed manufacturing by reducing cleaning validation, minimizing cross-contamination risk, and improving operational flexibility. Yet, despite advances in film technology, connectors, and automation, one critical manufacturing step has changed very little—the method used to seal thermoplastic films.

For decades, thermal impulse sealing has been the industry standard. While proven and reliable, growing expectations for process precision, automation, and digital manufacturing are prompting manufacturers to evaluate an emerging alternative: laser sealing.

Unlike conventional thermal sealing, laser sealing uses focused, non-contact thermal energy to create highly controlled welds without direct contact between heated tooling and the polymer surface. Although already established in medical device manufacturing, its application in bioprocessing bags is now attracting increasing attention.

Thermal Sealing: a proven industry standard

Most single-use bags are manufactured from multilayer polyolefin-based films using impulse heat sealing. Heated jaws compress the film layers while simultaneously applying heat, allowing the polymer to melt, intermingle, and solidify into a permanent weld. The technology offers several advantages. Equipment is relatively inexpensive, process parameters are well understood, and decades of validation data support regulatory acceptance. Thermal sealing also accommodates a wide range of bag sizes, geometries, and film constructions.

However, it is not without limitations. Because heated bars

physically contact the film, the process depends heavily on pressure uniformity, jaw alignment, dwell time, and temperature control. Tool wear over time can affect seal consistency, while polymer sticking, particulate generation, and cosmetic surface marks occasionally occur. As manufacturers pursue higher automation and tighter process capability, these variables become increasingly important.

Why laser sealing changes the equation

Laser sealing eliminates the heated sealing bars altogether. Instead, a precisely controlled laser beam delivers energy directly into the weld zone. The energy is absorbed at the interface of the polymer layers, generating localized melting while leaving surrounding material largely unaffected. Since no heated tooling contacts the bag, the process is inherently cleaner and more repeatable. The result is an exceptionally narrow heat-affected zone, minimizing thermal distortion and reducing stress on adjacent film layers. For high-value bioprocess bags, where dimensional stability and weld consistency directly influence product integrity, this level of precision offers a significant advantage.

Laser systems also integrate naturally into automated manufacturing cells. Digital control of laser power, scan speed, focal position, and energy density enables closed-loop process monitoring and complete electronic traceability—capabilities increasingly aligned with Industry 4.0 manufacturing.

Advantages beyond precision

The greatest benefit of laser sealing is process consistency. Non-contact energy delivery removes many mechanical variables associated with conventional sealing, reducing dependence on tooling condition and operator adjustment. Narrower weld profiles improve aesthetic appearance while maintaining excellent mechanical

strength. Because only the required region is heated, thermal exposure of surrounding films is minimized. This becomes particularly valuable for multilayer bioprocess films incorporating barrier layers, tie layers, or specialty polymers whose performance may degrade under excessive heat.

Laser sealing also reduces maintenance requirements. Without heated sealing jaws, there is no need for frequent cleaning, replacement of worn tooling, or recalibration caused by mechanical wear. The technology further supports high-speed automated manufacturing, enabling improved throughput and reduced process variability.

Current limitations

Despite its advantages, laser sealing is not a universal replacement for thermal sealing. Capital investment remains substantially higher than conventional impulse sealing equipment. Successful implementation also depends on film design. Many transparent polyolefin films exhibit low laser absorption, often requiring absorber additives, specialized coatings, or optimized multilayer structures to efficiently convert laser energy into heat. Process development is therefore more complex, requiring careful optimization of wavelength, beam profile, laser power, and exposure time for each specific film construction. Furthermore, skilled technical expertise is required to establish and maintain validated laser welding processes.

Regulatory considerations

From a regulatory perspective, laser sealing introduces no fundamentally new compliance pathway, but it does require robust process validation.

Manufacturers must demonstrate that laser-generated welds consistently meet requirements for seal strength, burst pressure, leak integrity, microbial barrier performance, and long-term stability. Validation ex-

pectations remain aligned with established GMP principles and standards such as ISO 13485, ISO 11607 where applicable, and FDA expectations for process validation.

Additional studies should evaluate whether localized laser heating influences extractables and leachables, polymer degradation, or particulate generation. Fortunately, the smaller heat-affected zone often reduces thermal degradation compared with conventional sealing, although this must be demonstrated experimentally rather than assumed.

As with any critical manufacturing process, laser sealing parameters should be treated as Critical Process Parameters (CPPs) within a Quality by Design framework, supported by statistical process capability and ongoing monitoring.

The economics of adoption

The business case for laser sealing extends beyond equipment cost. Although initial capital expenditure may be two to four times higher than conventional thermal sealers, operational economics can become favorable in high-volume production. Improved first-pass yield, reduced scrap, lower maintenance, faster automation, and enhanced process capability collectively reduce total manufacturing cost over the equipment lifecycle.

For manufacturers producing large quantities of high-value single-use bags, even modest reductions in defect rates can offset the higher investment. Conversely, smaller manufacturers or low-volume operations may find conventional thermal sealing remains the more economical choice.

Looking ahead

As biopharmaceutical manufacturing becomes increasingly automated, digitally connected, and quality-driven, the technologies used to fabricate single-use systems must evolve accordingly. Laser sealing represents more than a new welding

method—it reflects a shift toward precision manufacturing with greater process control, traceability, and reproducibility.

Thermal sealing will continue to serve the industry reliably for many applications. However, for next-generation single-use bioprocessing bags demanding tighter tolerances, higher automation, and superior manufacturing consistency, laser sealing is emerging as a compelling technology capable of redefining how sterile fluid containment systems are produced.

References

1. Milewski, J.O. (2017). *Additive Manufacturing of Metals: From Fundamental Technology to Rocket Nozzles, Medical Implants, and Custom Jewelry*. Springer International Publishing.
2. Potente, H., & Becker, F. (2004). *Laser Transmission Welding of Thermoplastics*. Hanser Publishers.
3. ISO 13485:2016. *Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes*. International Organization for Standardization (ISO), Geneva, Switzerland.
4. U.S. Food and Drug Administration (FDA). (2011). *Guidance for Industry: Process Validation—General Principles and Practices*. FDA, Silver Spring, MD, USA.
5. BioPhorum Operations Group (BPOG). (2020). *Extractables Protocol for Polymer Components Used in Single-Use Manufacturing Systems*. BioPhorum, London, UK.
6. Shukla, A.A., Gottschalk, U., & Hubbard, B. (2019). *Single-Use Technology in Biopharmaceutical Manufacture*. In: *Process Scale Purification of Antibodies* (2nd Edition). John Wiley & Sons.



Dr. Priyabrata Pattnaik
Chief Executive Officer
Ami Polymer

testo Saveris 1 to support environmental monitoring in pharmaceutical facilities

The system provides continuous monitoring, data handling, alarm management and documentation for GxP-regulated environments

In the pharma industry, maintaining environmental conditions is linked to product quality, data integrity and regulatory compliance. Research and development laboratories, cleanrooms, production areas, warehouses, cold storage facilities and biobanks require continuous monitoring of parameters such as temperature, humidity and differential pressure.

As pharma processes become more complex and regulatory expectations evolve, manual measurement and documentation methods can create operational challenges. Environmental monitoring systems need to provide continuous monitoring, secure data handling, alarm management and documentation while supporting GxP-regulated environments.

testo Saveris 1 provides an automated solution for environmental monitoring. The system combines measurement technology, data communication, software and services to support pharmaceutical applications. It continuously records environmental parameters, detects deviations and supports users in responding to events.

testo Saveris 1 combines data logger modules, sensors, data communication, software and services in one scalable system. The system uses data loggers and sensors to continuously record environmental parameters. Depending on the application, measurement points can be connected through WLAN, LAN or testo UltraRange communication technology for data transmission across facilities.

The system supports up to 3,000 measurement channels and can be configured for facilities with different monitoring requirements. Data loggers and sensors can be used for laboratories, cleanrooms, production



testo Saveris 1 provides continuous monitoring, secure data handling, intelligent alarm management and documentation for GxP-regulated environments

areas and warehouses, as well as refrigerators, freezers, chillers and controlled chambers.

Digital sensors can be exchanged or calibrated independ-

ently of the data logger. Differential pressure and other parameters can also be integrated into the monitoring system, allowing different environmental conditions to be managed

through a common platform.

The testo Saveris 1 Base collects measurement data from connected monitoring points and supports centralised system management. When pre-

defined limits are exceeded, the system can generate alarms to notify responsible personnel. Depending on the configuration, notifications can be delivered through different channels to support responses to deviations.

The testo Saveris software brings measurement values together for visualisation, analysis and documentation. Electronic records, audit trails, access control and electronic signatures support traceability and compliance requirements in regulated environments.

The system also provides web-based access, allowing authorised users to view measurement data and manage alarms from PCs, tablets or smartphones.

Testo supports customers across the system lifecycle, including site survey, installation and commissioning, qualification, calibration and maintenance. This enables pharmaceutical organisations to work with one technology and service partner for environmental monitoring requirements.

The areas of application include area monitoring in laboratories, production, warehouses and animal houses in pharma; equipment monitoring for QA/QC and microbiology in pharma; cleanroom area monitoring in pharma; refrigeration and deep-freezer applications in pharma; uninterrupted cold chain monitoring and controlled freezing in blood and bio banks; laboratory equipment monitoring from laboratory extractors to water baths; data centre area monitoring; and calibration and testing laboratory area monitoring.

For more details, login to our website www.testo.com or write back to us on info@testo.in

Romaco launches FLEXIJET nozzle for fluid bed granulation

The new nozzle is designed for short granulation processes, with operation, cleaning and maintenance features for frequent product changes

Romaco has developed FLEXIJET, a new generation of nozzles for granulation using the fluid bed process. The nozzle is designed for operation, cleaning and maintenance, and for short granulation processes. Its predecessor, ROTOJET, remains recommended as a nozzle for coating processes that take several hours and use unstable suspensions.

In the fluid bed process, the spray nozzle introduces the spray liquid into the fluidised product to either granulate or coat the powder, depending on the process. Romaco Innojet has developed FLEXIJET for fluid bed granulation, with a focus on handling and nozzle cleaning.

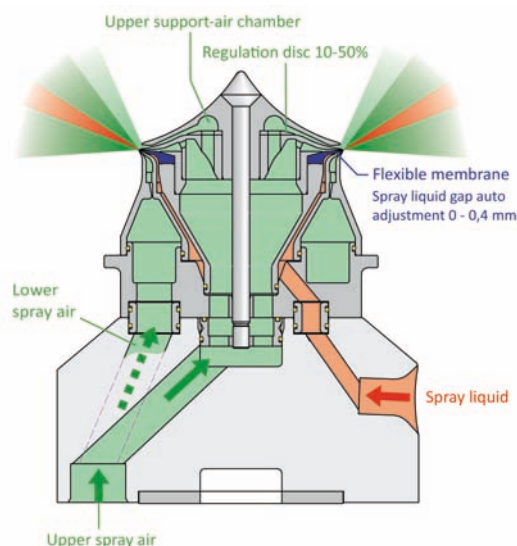
Granulation requires less time than fluid bed coating processes, resulting in more frequent dismantling and cleaning of spray nozzles. FLEXIJET has therefore been designed for short batch processing times and frequent product changes. To remove the nozzle, users need to undo one screw, after which it can be detached and dismantled into ten individual parts. Cleaned components can be refitted without checking and adjusting the spray gaps.

The spray gap uses a flexible plastic membrane to seal the circular gap from above. The flexible cap lifts through the pressure of the incoming liquid and provides distribution at low spray rates. If the process is interrupted, the spray liquid is pumped back, causing the membrane to be sucked in and seal the spray gap. This prevents the gap from drying out and deposits from forming that could block the nozzle when the machinery is restarted.

Maintenance of FLEXIJET



New FLEXIJET® spray nozzle for fluid bed granulation



The FLEXIJET® was specially designed for frequent product changes

is also supported by the availability of all nozzle components and wearing parts for reordering. Users can replace these parts themselves. This differs from ROTOJET, which uses a manufacturing tolerance spanning a chain of more than 20 components. Operation of ROTOJET therefore requires more specialist knowledge than FLEXIJET.

ROTOJET is used for functional coating processes and coating fine starter particles with pharmaceutical ingredi-

ents. Coated micropellets are used to manufacture MUPS tablets, among other applications. The coating process can take several hours, with production times of over 20 hours possible, while the pellets increase in weight and diameter.

This production process requires precision and process control, particularly when working with unstable suspensions that can segregate. To minimise the risk of sedimentation during spraying, ROTOJET uses a rotating



The booster plate and centrally located spray nozzle form one functional unit



The ROTOJET® spray nozzle is a special tool for coating processes taking several hours and using unstable suspensions

nozzle head. The rotation produces relative motion in the spray gap, continuously moving and mixing the spray liq-

uid. This prevents deposits that could block the nozzle and result in unwanted agglomeration.

Romaco Innojet has developed FLEXIJET as an alternative to ROTOJET, allowing users to select the nozzle type according to the process. The two nozzles have compatible mounting dimensions and identical spray geometry. They can therefore be operated with the same process parameters without adapting or converting the machine.

Both spray nozzles are available for all VENTILUS fluid bed processors, from laboratory and pilot scale through to full-scale production. FLEXIJET is also recommended for hot melt coating applications, where no liquid

evaporates and batch processing times are relatively short. The nozzle technology has been patented and is used by pharmaceutical manufacturers in Germany and France, among others.

All sizes of VENTILUS machines use one centrally positioned bottom spray nozzle, whether FLEXIJET or ROTOJET is selected. The nozzle is positioned in the centre of the ORBITER booster plate, which allows process air to enter and provides flow conditions in the cylindrical process container. The booster's circular shape and overlapping vanes cause the

product to move in a donut-type pattern, producing controlled particle motion and enabling product spraying and drying.

Both spray nozzles have three circular spray gaps arranged one above the other. The liquid is sprayed horizontally at a 360° angle through the central gap into the product. Compressed air enters through the upper and lower air supply gaps, atomising the liquid into droplets. Droplet size depends on whether the product is being granulated or coated and is determined by the pressure at which the upper and lower spray jets hit

the spray liquid.

Once the parameters have been defined for a specific process, they remain applicable regardless of the nozzle technology selected. Romaco said the Innojet design, with one nozzle for every scale, supports control of the fluid bed process, while FLEXIJET reduces the complexity of the spray gun. Romaco said the design results in lower maintenance costs, stable processes and high yields.

Romaco will present the FLEXIJET nozzle at POWTECH TECHNOPHARM 2026, taking place from September 29

to October 1 in Nuremberg, Germany, in Hall 9, Stand 9-241. The company will also present its processing solutions, including the VENTILUS Lab fluid bed processor and the KTP 1X compaction simulator.

Company contact

*Romaco India
Thane, Maharashtra
Phone: +91 22 69207600
E-Mail: india@romaco.com*

Laboratory contact

*Experience Centre
Hyderabad, Telangana
Phone: +91 22 69207613
E-Mail: india.service@romaco.com*

Gandhi Automations presents the multi-composites, high-performance door PRIME NEO for clean environments

PRIME NEO is designed for pharmaceutical facilities and laboratories, with washable construction, sealing and resistance to pressure differences

Gandhi Automations presents PRIME NEO, a multi-composite, high-performance door for clean environments. The door is designed to provide sealing and resistance to pressure differences for clean rooms and is washable.

PRIME NEO uses reinforced polymer material with a smooth, joint-free surface. Its door structure allows full accessibility for water cleaning, minimising contamination risks and meeting the requirements of clean environments.

The door's smart design and German technology enable its opening and closing cycle to operate without delay. Its opening and closing cycle reduces exposure time, resulting in a reduction in energy costs and the risk of airborne contamination.

The door has a flexible curtain with horizontal FRP stiffeners guided by vertical guides. Pressure is distributed across the curtain, pushing it against



the guides to provide a seal. The design allows the door to operate under pressure differences

of up to 50 Pa in a controlled room environment.

PRIME NEO also incorpo-

rates safety features designed to reduce the risk of accidents and damage. Its free, flexible

and soft bottom edge minimises hitting impact, while the radar detector and inbuilt photocells reopen the door at the slightest impact.

The door's transparent material allows people to see coming traffic. Long-term transparency is provided by anti-fatigue PVC fabric.

The multi-composite structure includes side guides designed to absorb impact. PRIME NEO is anti-corrosion and paint-free, enabling its use in corrosive and aggressive environments.

The door is equipped with auto-reset technology. In the event of an accidental crash, the curtain sets itself again. The system avoids time loss and reduces the risk of repair costs.

To know more about PRIME NEO, write us at sales@geapl.com or call 022 6672 0200/0300

Eppendorf introduces Research 3 neo pipette value packs

3-pack and 6-pack bundles are now available at a special rate for laboratories worldwide

Eppendorf has introduced a new addition to its Eppendorf Research 3 neo single-channel pipette line, launched in 2025. From today, laboratories worldwide can order 3-pack and 6-pack bundles at a special rate, making it easier and more cost-effective to upgrade to the latest Eppendorf pipetting technology.

The 3-pack bundles are available in three sets, each designed for common laboratory needs. Option 1 includes 10 μ L, 100 μ L and 1000 μ L

The 3-pack bundles are available in three sets, each designed for common laboratory needs. The 6-pack bundle includes 2.5 μ L, 10 μ L, 20 μ L, 100 μ L, 200 μ L and 1000 μ L pipettes, along with a Pipette Carousel 2 for convenient and safe storage

pipettes. Option 2 includes 20 μ L, 200 μ L and 1000 μ L pipettes, while Option 3 includes 1000 μ L, 5 mL and 10 mL pipettes.

The 6-pack bundle includes 2.5 μ L, 10 μ L, 20 μ L, 100 μ L, 200 μ L and 1000 μ L pipettes, along with a Pipette Carousel 2 for convenient and safe storage.

Eppendorf said all multi-packs include an original Eppendorf pipette pen as a bonus item.

The Research 3 neo pipettes address key pain

points for scientists, including faster and easier volume adjustment with a lock to prevent accidental volume changes during pipetting, improved ergonomics with a shorter pipetting button, flexible labelling options, and the reliability and ergonomics Eppendorf is known for.

Further information about the Eppendorf Research 3 neo pipettes and value packs is available at www.eppendorf.link/research3neo



Sanvira Biosciences builds fermentation manufacturing capability in Visakhapatnam

Sanvira Biosciences manufactures fermentation-derived enzymes, probiotic cultures and specialty biological ingredients, alongside contract development and manufacturing services

An established industrial group is applying the discipline of process manufacturing to one of biotechnology's most persistent constraints: the transition from laboratory success to reliable commercial supply.

Sanvira Biosciences manufactures fermentation-derived biological ingredients from a dedicated facility at Visakhapatnam, Andhra Pradesh. Its portfolio spans enzymes, probiotic cultures and specialty biological ingredients supplied to formulators and brand owners, alongside contract development and manufacturing services for organisations taking their own processes to commercial scale. The company is the biotechnology platform of the Sanvira Group, a diversified industrial enterprise with manufacturing operations in India and Oman.

Demand across the sector continues to grow, and the limiting factor is less often the science than the manufacturing. Research institutions and early-stage companies are producing strains, enzymes and biological molecules of real commercial value. Considerably fewer organisations are equipped to produce them consistently, at volume, and to the documentation standards that regulated markets require over sustained periods.

Bringing science and scale together

Commercial fermentation draws on two capabilities that are rarely found in the same organisation.

The first is scientific. It covers strain selection and

cell bank management, media design, control of sterility across long production cycles, and the process development work that determines yield and purity. It extends to scale-up, where oxygen transfer, mixing and heat removal behave differently at every stage between the laboratory and the production vessel. Analytical method development sits alongside this, since a fermentation product is defined by what can be measured and demonstrated in it.

The second is industrial. It covers plant availability, utilities, effluent treatment, cold chain, maintenance regimes and supply systems, all of which determine whether a validated process can be reproduced batch after batch, over years rather than campaigns.

Most difficulties in this sector arise at the junction between the two. A process that performs in the laboratory may not hold at commercial volume, and a plant capable of operating at volume may not hold the control that a regulated product demands. Sanvira Biosciences has been structured to address both, combining a technical team drawn from fermentation science, process engineering and quality assurance with the operating discipline of an established industrial group.

That industrial foundation is substantial. The Sanvira Group is an enterprise of approximately USD 440 million in revenue, with aggregate installed capacity exceeding one million tonnes per annum in its core business and further capacity presently under

construction. It has a demonstrated record in executing capital projects, commissioning facilities to international specifications, and supplying export markets under demanding quality and delivery requirements.

For organisations evaluating a manufacturing partner, this combination matters in a practical way. The primary question is seldom whether a given molecule can be produced. It is whether the partner can hold specification consistently, support the demands of customer audits and regulatory inspection, and sustain supply across the commercial life of the product.

The Visakhapatnam facility

The site is purpose-built for microbial fermentation and constructed to current Good Manufacturing Practices. Effluent treatment, utilities and containment form part of the original engineering design, sized to support sustained operation at commercial volumes.

Upstream fermentation, downstream recovery and purification, analytical laboratories, and packaging and finishing capability are located within a single facility. Its capability extends across biomass and spore-based products, purified fermentation molecules, and finished forms, allowing a range of processes and product formats to be accommodated on the same site.

The facility supports a product through each stage of its development. Customers can undertake process development and pilot-scale production, validate

at intermediate scale, and move into full commercial manufacture within one site, retaining continuity of process, personnel and documentation throughout. This shortens the path from development to qualified commercial supply.

For contract manufacturing, process parameters, train configuration and downstream sequence are established to suit each molecule, with capacity allocated according to the requirements of the programme.

Quality and confidentiality

Manufacturing operations are structured around internationally recognised quality standards, with traceability maintained from incoming raw materials through to finished batch. Standard test procedures, product specifications, change control, deviation management and batch documentation form part of routine production, and the site is equipped to support customer audits and regulatory inspection across domestic and export markets.

Confidentiality carries the same weight. Customer strains, processes and technical information are protected through contractual commitments and segregation of work within the facility, with ownership of customer process knowledge clearly defined from the outset.

Portfolio and markets

The company is building its portfolio across three related areas of microbial fermentation: fermentation-derived enzymes for pharmaceutical, nutraceutical and industrial applications; probiotic

and microbial cultures for human and animal health; and specialty biological ingredients for food, agricultural and industrial use.

These serve customers in human health and nutrition, food ingredients, personal care, agriculture, animal health and nutrition, and biomaterials. The common requirement across these sectors is a fermentation-derived input manufactured to consistent specification, documented to regulatory standard, and delivered reliably. The customer base extends from early-stage innovators seeking a route from validated concept to commercial volume, through to established manufacturers securing or diversifying ingredient supply.

Outlook

Sanvira Biosciences approaches its customer relationships as long-term partnerships, and its build-out reflects that position. Capacity, laboratory capability, technical personnel and quality systems are being developed ahead of demand.

India is well placed in this shift. The country has the scientific base, engineering capability and cost structure to become a significant global supplier of fermentation-derived ingredients. What the sector requires is additional manufacturing capacity built to international standards from inception, and that is the contribution the company intends to make.

Sanvira Biosciences is the biotechnology platform of the Sanvira Group, with fermentation manufacturing operations at Visakhapatnam, Andhra Pradesh.

LUBRITAB® - A versatile excipient from natural origin

Being a solid lipid, LUBRITAB® has various applications pertaining to pharmaceuticals

To design a pharma or nutra formulation, excipients are selected according to their properties, advantages, risks, regulatory status and many more attributes. Due to the benefits of low safety concerns, lipids have become an interesting and promising category of excipients for multiple purposes.^[1]

The term "lipid" describes a family of products with diverse physicochemical properties. Their composition includes oils, fats, waxes, fatty acids and their derivatives, and biosynthetically or functionally-related substances to these compounds.^[1] Naturally occurring lipids are typically triglycerides (triacylglycerols or triglycerides, TAGs), esters of glycerol and three fatty acids.

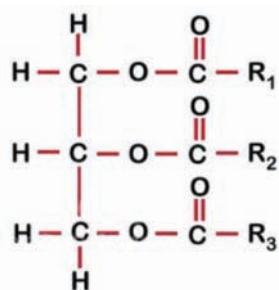


Image 1: Structure of a Triglyceride

The nature and compositions of three fatty acid chains of a TAG molecule, defined as R1, R2 and R3, determine its chemical property. An important characteristic of TAGs is their crystallisation behaviour. The crystallisation behaviour (crystallisation rate, crystal sizes and their network, crystal morphology and crystallinity) of the TAG is directly influenced by polymorphism, and by several external factors such as temperature, pressure, solvent, rate of crystallisation, impurities, etc. Due to the conformation differences, they present different melting points.^[1] This difference helps in identifying particular TAG grade (eg Glycerol mono-stearate and distearate, Hy-

drogenated vegetable oil Type I and Type II, various grades of Polyoxylglycerides). This phenomenon is also important to define applications and process of specific TAG moiety.

In pharmaceuticals, short chain and unsaturated long chain fatty acids (liquids, semisolids and solids) are approved for use in creams, ointments, emulsions, dispersions and suppositories. Long chain triglycerides, which have no practical ability to self-disperse, are digested rapidly in the intestine (lipolysis). Furthermore, their fatty acids and monoglycerides digestion products are solubilised by bile salt - lecithin mixed micelles, which are then absorbed. The lipid excipients used in pharma development are derived predominantly from the food industry where they are used as additives for emulsification, solubilisation, stabilisation and lubrication since long. Besides, lipid excipients have been refined and fine-tuned for the pharma industry to provide solutions to drug delivery challenges including drug solubility, drug dissolution properties and also to resolve manufacturing issues. Over the last four decades, naturally occurring triglycerides have been modified physicochemically to develop excipients suitable for the development of drug delivery systems.^[1]

In like manner, solid lipids became more and more interesting as pharma excipients for solid dosage forms. They are normally crystalline in nature and have melting ranges or melting points determined by their chemical structure (and composition).^[1] They are chemically inert and their properties such as high hydrophobicity, high melting point and low density can be used -

- to lubricate pharma dry powder blends
- as sustained release agent ei-

ther alone or in combination

- to mask bitter-tasting drugs
- to solubilise lipophilic drugs^[1]

Furthermore, solid lipids used as sustained release agents provide different biopharma properties compared to polymers. Fundamentally, the drug release mechanism is different and this provides formulators with broader options for controlling drug release scope to develop innovative dosage forms.^[1] They can be used either alone or in combination with other agents.

Several processing methods could be applied using solid lipids, such as -

- Direct compression
- Dry and wet granulation
- Melt granulation
- Melt pelletization
- Molding
- Spray congealing
- Hot melt coating

Choosing the appropriate TAG for the use in pharma process requires an understanding of their physicochemical properties and its as-

TYPICAL PROPERTIES^[5]

Structure	Refer to Image 1; R ₁ , R ₂ and R ₃ are mainly C ₁₅ and C ₁₇
Acid value	Max. 2.0
Iodine value	Max. 5
Melting range	57° to 70°C
Loss on drying	Max. 0.1 %
Saponification value	175 to 200

sociated effect on lubrication efficiency, API release and taste-masking effect.^[1]

Hydrogenated vegetable oil is a mixture of triglycerides of fatty acids. The two types defined in the USP-NF are characterised by differences in their physicochemical properties like melting range and Iodine value. LUBRITAB® complies with Hydrogenated vegetable oil Type I. It is made from the seeds of varieties of *Gossypium hirsutum* (L) or other *Gossypium* species by refining, and hydrogenation.^{[1][2]}

Applications

LUBRITAB® is used in food products and oral pharma formulations, and is generally regarded as a non-toxic and non-irritant excipient. As discussed in previous section, being a solid lipid, LUBRITAB® has various applications pertaining to pharmaceuticals.

Lubricant: The primary function of lubricants in tableting is to reduce the force required to eject the compressed tablet from the die cavity. In capsule filling, where a plug is formed, lubricants perform essentially the same function by reducing

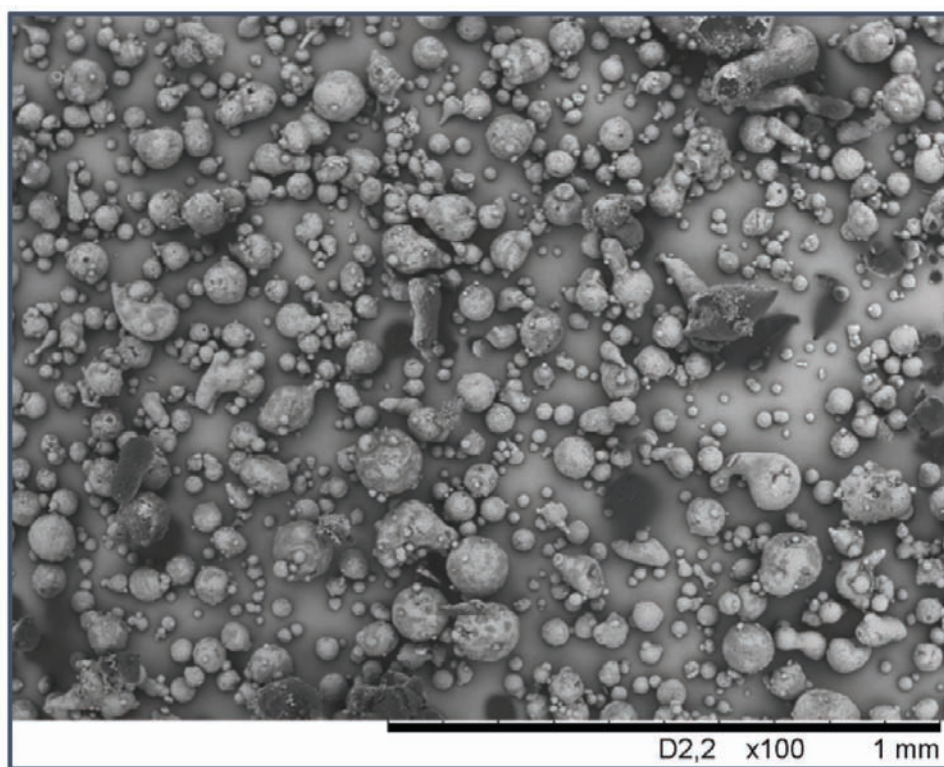


Image 2: SEM image of LUBRITAB®^[4]

the force required to transfer the plug from the dosators into the capsule. Without lubricants, these processes would be difficult or impossible and would result in significantly shorter tooling lifespan. LUBRITAB® is used as a lubricant in oral solid dosage forms at a concentration range of 1 - 6 % w/w. It acts as a liquid film-lubricant. It can be used alone or in combination with other commonly used lubricants.^{[2][3]}

Sustained release matrix: LUBRITAB® is additionally used as the matrix-forming material in lipid-based controlled-release formulations; it may also be used as a coating aid in controlled-release formulations. It has also been investigated in hydrophobic melt agglomeration. This application may find more rele-

vant space, where usage of traditional polymers is restricted or limited due to patent or percentage level (regulatory) constraints.^[2]

Taste masking: Being hydrophobic lipid in nature, LUBRITAB® does not dissolve into oral cavity. Hence, it can be used as a barrier to mask bitter and/or unpleasant taste of APIs by various methods like melt granulation, hot melt coating and spray-congealing where drug particles can be entrapped in wax matrix or covered by wax layer.

Viscosity modifier: Hydrophobic nature and miscibility with various oily materials, its use as a viscosity modifier in the preparation of oil-based liquid and semi-solid formulations is unique. It imparts this useful property during manufacturing of suppositories, to

reduce the sedimentation of suspended components and to improve the solidification process; and in the formulation of liquid and semisolid fills for hard gelatin capsules.^[2]

Wax nature of LUBRITAB® makes it a suitable alternative to hard waxes in cosmetics and topical preparations.^[2]

Binder: LUBRITAB® may be used alone or in combination as a binder in dry and wet granulation processes. It helps to solve capping and lamination during tableting.^[3]

Summary

LUBRITAB® is a plant-derived excipient made by hydrogenation of cottonseed oil. It serves as a lubricant in tablet and capsule formulations. It can also be used as a binder, a taste-masking agent, and in controlled release ma-

trix tablets. It is used in oily liquid and semi-solid dosage forms to alter viscosities.

References

- [1] Petrovick, G.F. (2015) *Orodispersible Tablets Containing Taste-Masked Lipid Pellets with Metformin Hydrochloride for Use by Elderly Patients. The Faculty of Mathematics and Natural Sciences, The Heinrich Heine University in Düsseldorf.*
- [2] Sheskey, P.J., Cook, W.G., Cable, C.G. (2017) *Handbook of Pharmaceutical Excipients, 8th edition, Pharmaceutical Press, 1007-1009.*
- [3] LUBRITAB® | Hydrogenated Vegetable Oil- JRS Pharma (https://www.jrspharma.com/pharma_en/products-services/excipients/lubricants/lubritab.php)
- [4] SEM Images Lubricants-

JRS Pharma (https://www.jrspharma.com/pharma_en/resources/sem-images/lubricants.php)

[5] United States Pharmacopoeia, USP 43-NF 38 (2019).



Krishnakumar Patel
Manager, Technical Services -
Pharma
Rettenmaier India
Krishna.Patel@jrsindia.com



THE FORMULA FOR THOSE WHO FORMULATE THE PHARMA SECTOR.

Express Pharma has been the backbone of this sector since 20 years. It is what the experts look to when the entire industry looks to them. That is because the magazine contains a potent mix of innovative ideas, cutting-edge analyses and expert insights. It's no wonder then that the finest in the field trust the foremost in the field.



COREL PHARMA CHEM
the next generation polymer technologist...

DMF
Available

ACRYPOL[®] FOR SUSTAINED RELEASE FORMULATION



ACRYPOL 971 P | ACRYPOL 971G | ACRYPOL 974P | ACRYPOL 912G

- Enable smaller tablet size in comparison to cellulosic polymers
- High efficiency at low use level
- Cost effective formulation
- Effective in various manufacturing methods viz. direct compression, wet granulation & dry granulation
- Excellent compatability with commonly used tablet excipient
- Unlike linear cellulosic material Acrypol forms the crosslink at low concentration and form the high viscous gels
- No burst effect for highly soluble drugs
- No chance of dose dumping
- Excellent reproducibility
- Pharmacopoeial status available
- Works as efficient binder, no need to use additional binder



Corel House, Opp. Bhagwat Petrol Pump, S.G. highway, Gota, Ahmedabad - 382481 Gujarat, India
Tel: +91 8000880011/ 22/ 33 | E-mail: corel@corelpharmachem.com | marketing@corelpharmachem.com

Website: www.corelpharmachem.com |   

ACRYCOAT[®] | COLORCOAT[®] | ACRYPOL[®] | KYRON[®] T-314 | KYRON[®] | ACRY SOL[®] | ACRYFLOW[®]



**One Smart Solution
for Broad Compatibility**

**Cellulose
Based**



**Universal
Compatibility**



**Multi-Dosage
Flexibility**



**Process
Efficiency**



**Proven
Performance**



 Ideal Cures

 +91 -22-42688700

 www.idealcures.com

 info@idealcures.com



IDEAL CURES