VOL. 20 NO. 8 PAGES 104 www.expresspharma.in

EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE SINCE 1994

JULY 2025, ₹ 40

PIOMA chemicals
Partnering Through Innovation

36 YEARS Since 1989

xaнgel®

Xanthan Gum USP

- Xanthan Gum Transparent
- Xanthan Gum Regular / Opaque
- *Quick Dispersing* Xanthan Gum

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

VOL. 20 NO. 8 PAGES 104
www.expresspharma.in

EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE SINCE 1994
JULY 2025, ₹40

Strategy

Rethinking pharma field force efficiency in developing countries

Interview

Akash Kedia
MD - Healthcare and Lifesciences, Alvarez & Marsal India

Amit Misra
MD - Healthcare and Lifesciences, Alvarez & Marsal India

CILICANT
ACTIVE PACKAGING®
PRESENTS

FDD
CONCLAVE 2025
FORMULATION DEVELOPMENT & DRUG DELIVERY CONCLAVE

POWERED BY
PIRAMA chemicals
Partnering Through Innovation

FROM LAB TO LIFE BRIDGING SCIENCE AND CARE

FDD Conclave 2025 spotlights patient-centric pharma innovation, uniting industry leaders to shape the future of formulation and drug delivery

DADACHANJI GROUP

KAIRISH
Innotech

WHERE TECHNOLOGY MEETS TOMORROW

FROM CONCEPT TO EXECUTION, EVERY SOLUTION IS TAILOR-MADE IN-HOUSE.

A part of **The Dadachanji Group of Companies**, Kairish Innotech is a **future-focused, technology-driven company offering end-to-end solutions across industries.**

We don't offer off-the-shelf. **We build what fits you the best.**

As a key subsidiary, **Kairish Innotech specializes in:**

- Customised Machines & Fabricated Products
- Medical Devices & Sterilisation Solutions
- Tooling, components and parts manufacturing
- Advanced Sterile Processing Technologies

SOLUTIONS AS DIVERSE AS YOUR VISION

From machines to medical devices, from automation to tooling and fabrication—our solutions are as versatile as your needs.

For every unique Product, there is a Custom KAIRISH Solution.

COMPLETE ENGINEERING & MANUFACTURING ECOSYSTEM

Kairish Innotech brings together a robust set of divisions to deliver end-to-end engineering and manufacturing solutions. From precision work in our Tool Room and Fabrication Unit to cutting-edge innovation in Engineering & Analysis, Design, and Automation, each division plays a key role. Our expertise extends to Machine Building, Product R&D, specialized facilities for Medical Device Manufacturing, Sterilization, and Liquid Colourants—ensuring quality, compliance, and innovation at every step.

www.kairishinnotech.com

info@kairishinnotech.com

GANDHI
Automations Pvt Ltd

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

Differential Air Pressure

Washable & Pressure Resistant

High Speed Doors - Prime NEO CR

- Superior sealing to avoid dust entry, maintain asepsis and sterility.
- Easy to clean & disinfect, door is resistant to spray water.
- High door efficiency & low permeability values EN 12426 EN 12427 : < 12m^3/m^2h Δ 50 PA.
- Size upto: 4000 mm (W) x 4000 mm (H).
- The door is pressure resistant while providing smooth operation cycles.
- Structurally designed to be resilient against twisting and denting.
- 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)

World's Safest Door

TÜV AUSTRIA CERTIFIED
TÜV AUSTRIA GMBH
EN ISO 9001 20100233018576
EN ISO 14001 20104233018577
ISO 45001 20116233018578

CE

INDIAN GREEN BUILDING COUNCIL IGBC MEMBER

24X7 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

Soluplus®

For better solubility and bioavailability

TRANSCHEM Since 1989 CORPORATION PHARMA PVT LTD
EVERYTHING EXCIPIENT

Did you know that Soluplus® also solubilizes drugs processed by wet granulation? Try Soluplus® and experience a new dimension in solubility and bioavailability enhancement.

Soluplus® at a glance

- Chemical name: Polyvinyl caprolactampolyvinyl acetate-polyethylene glycol graft co-polymer
- Outstanding solubilization properties, especially for poorly soluble APIs
- Enables bioavailability enhancement
- Ideal for hot melt extrusion and all standard granulation techniques
- Market proven solution for unique formulation challenges
- Amphiphilic structure: polymer and solubilizer perfectly combined in one product
- Molecular weight optimized for superior ASD stability
- Glass transition temperature optimized for easy processing

Clinical safety data available

NOW APPROVED
IN EUROPE

Regulatory Documentation

- US-DMF #23504 (Type IV DMF, containing CMC information)
- Regulatory Information File (RIF) with equivalent content to an Open Part/Applicants Part of a DMF
- US-DMF #23626 (Type V DMF, containing pre-clinical safety data)

Preclinical Safety Data

- Tox Abstract (Summary of the design and results of the pre-clinical studies performed)
- Safety Expert Report (Detailed description of the pre-clinical safety data, as well as two clinical study reports. Available under BASF secrecy agreement)

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

Email: sales@transchemcorp.com

Phone: +91 022-49711633

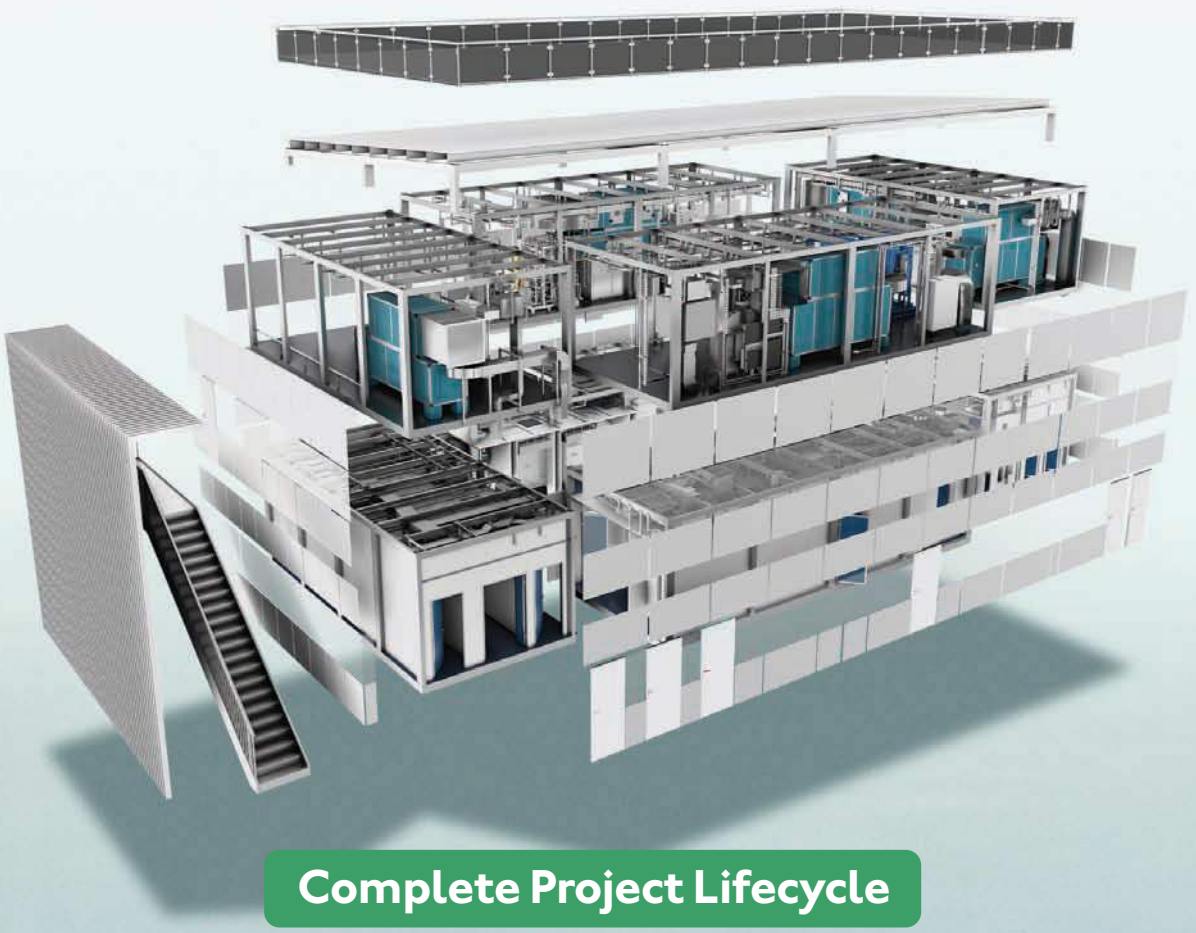
Web: www.transchemcorp.com

MODULAR MOBILE FACILITY
HEALTHCARE RE-ENGINEERED

pharmaaccess
Engineering a Healthier Life

Mobilized. Modernized. Modularized.

From concept to completion, Modular Mobile Facility delivers integrated turnkey solutions that drive cost reduction, enable effortless site installation, and minimize carbon footprint.



Complete Project Lifecycle

Conceptual, Basic & Detailed Designs

Procurement

Manufacturing & Partial Installation

Disassembly & Packing

Shipment & Transportation

Installation & Assembly

CQV

+91 98207 75650 | + 91 22 6819 3888
info@mmfacility.org
www.mmfacility.org
www.pharmaaccess.net

WE ARE ENGICUTION EXPERTS
ADVANCED ENGINEERING
PERCISION EXECUTION

IN-DEPTH. AND WIDE KNOWHOW. THAT'S OUR BRAND OF **EXPERTISE.**

Dear Partner,

Signet is driven by expertise, be that technical or commercial. Nowhere is that more evident than in our partnership with highly reputed companies Dead Sea Periclase, Dead Sea Works Ltd. and Scora, our source of ICL Industrial Products.

Dead Sea Periclase, with its signature 'Aman' process, provides us with the highest quality magnesium oxide, hydroxide and carbonate products. Dead Sea Works Ltd., from whom we source exceptional potassium chloride, is also recognised as the world's top provider. While for all things calcium and magnesium, the specialists at Scora fulfil our every need. So that we can do the same for you.

By associating with expertise, we enhance our own. Making us the foremost name in pharmaceutical excipients.

Signet-ure *expertise*

ICL Specialty Minerals

- MAGNESIUM OXIDE
- MAGNESIUM HYDROXIDE
- MAGNESIUM CARBONATE
- POTASSIUM CHLORIDE, REFINED
- CALCIUM CARBONATE (SCORALITE)
- CALCIUM CARBONATE DC (SCORALITE DC)

Signet

The Complete Excipients Company

TOGETHER

we can make the world

HEALTHIER

together
from lab to production

Quality and efficiency in tablet production do not begin with the actual manufacturing process. Our close cooperation during formulation and process design leads to an end result that exceeds your expectations rather than just fulfilling them. All that improves the quality of the product and the health of your customers.

www.fette-compacting.com

FETTE COMPACTING

IIHMR UNIVERSITY

ADMISSION OPEN 2025

Elevate Your Career With Our Cutting Edge Executive Programs

Two-Year Executive Programs Offered In Blended Mode For Working Professionals

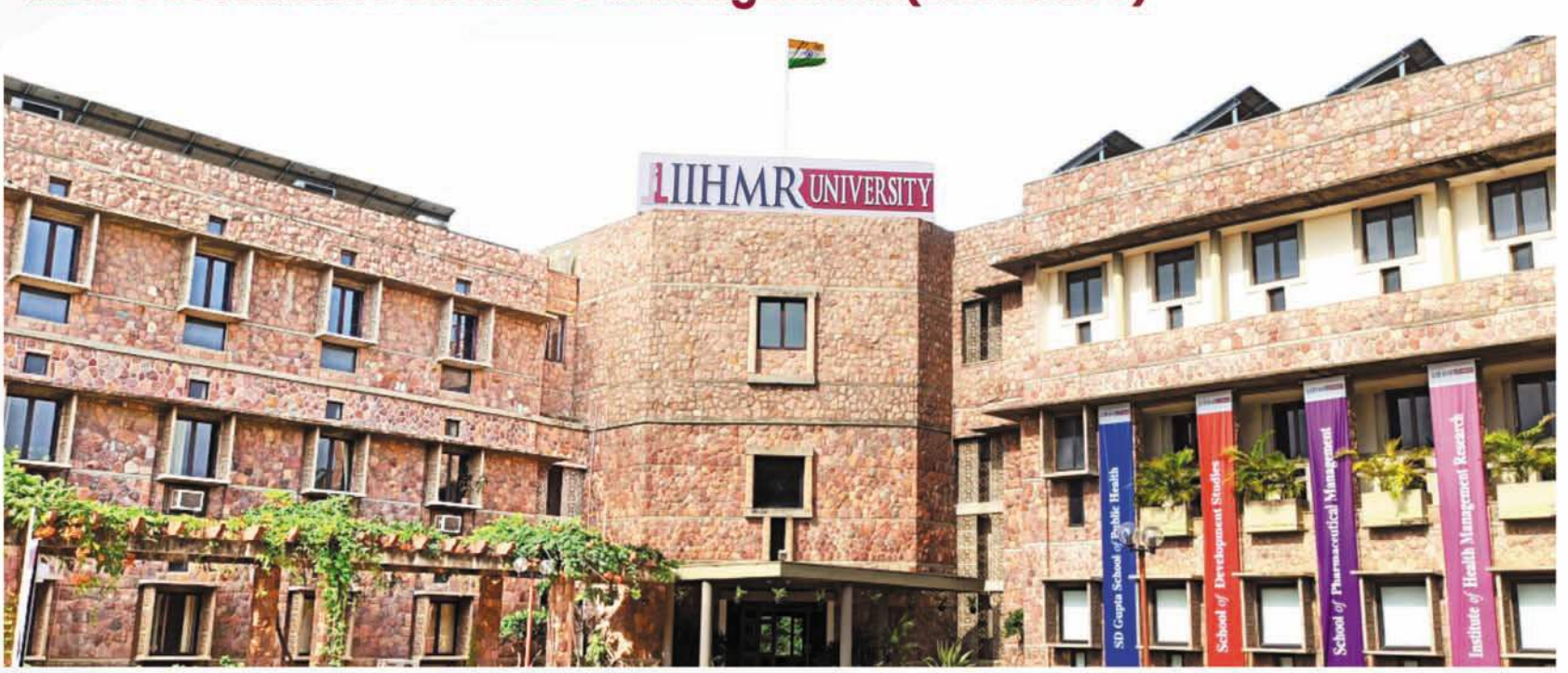
MBA Pharmaceutical Management (Executive)

Master Of Public Health (Executive)

Master Of Hospital Administration (Executive)

MBA CSR & ESG Management(Executive)

MBA Sustainable Business Management(Executive)



#1
HEALTHCARE MANAGEMENT UNIVERSITY IN INDIA BY EDUCATION WORLD 2025

40 YEARS
LEGACY IN HEALTH MANAGEMENT RESEARCH

To Know More About Admissions

1, Prabhu Dayal Marg, Sanganer Airpot, Jaipur- 302029, Rajasthan, India
+91 9275023630 | +91 141-3924700
www.iihmr.edu.in
admissions@iihmr.edu.in

who revs up high-speed tableting for controlled-release?

—

benecel™ **xrf** hpmc

Benecel™ XRF HPMC products have been optimized for controlled-release matrix formulations providing robust products and consistent drug release, especially for high speed tableting operations.

For more information or sample request, please contact our solver.

ashland.com / efficacy usability allure integrity profitability℠

Ashland™
always solving

CPHI India | PMEC India

informa markets

25th – 27th November 2025 | India Expo Center (IEML), Greater Noida, Delhi NCR

South Asia's Largest Pharma Event

Your one-stop shop to source high quality, cost-effective pharma solutions under one roof

50,000+
Attendees

120+
Attendee countries

2,000+
Exhibiting companies

1,20,000+
m^2

FOR STAND BOOKINGS & PARTNERSHIPS

CPHI : KANISHKA AHUJA
E: kanishka.ahuja@informa.com | M: +91 98207 20785

PMEC : DEVENDRA BHOSALE
E: devendra.bhosale@informa.com | M: +91 84335 04446

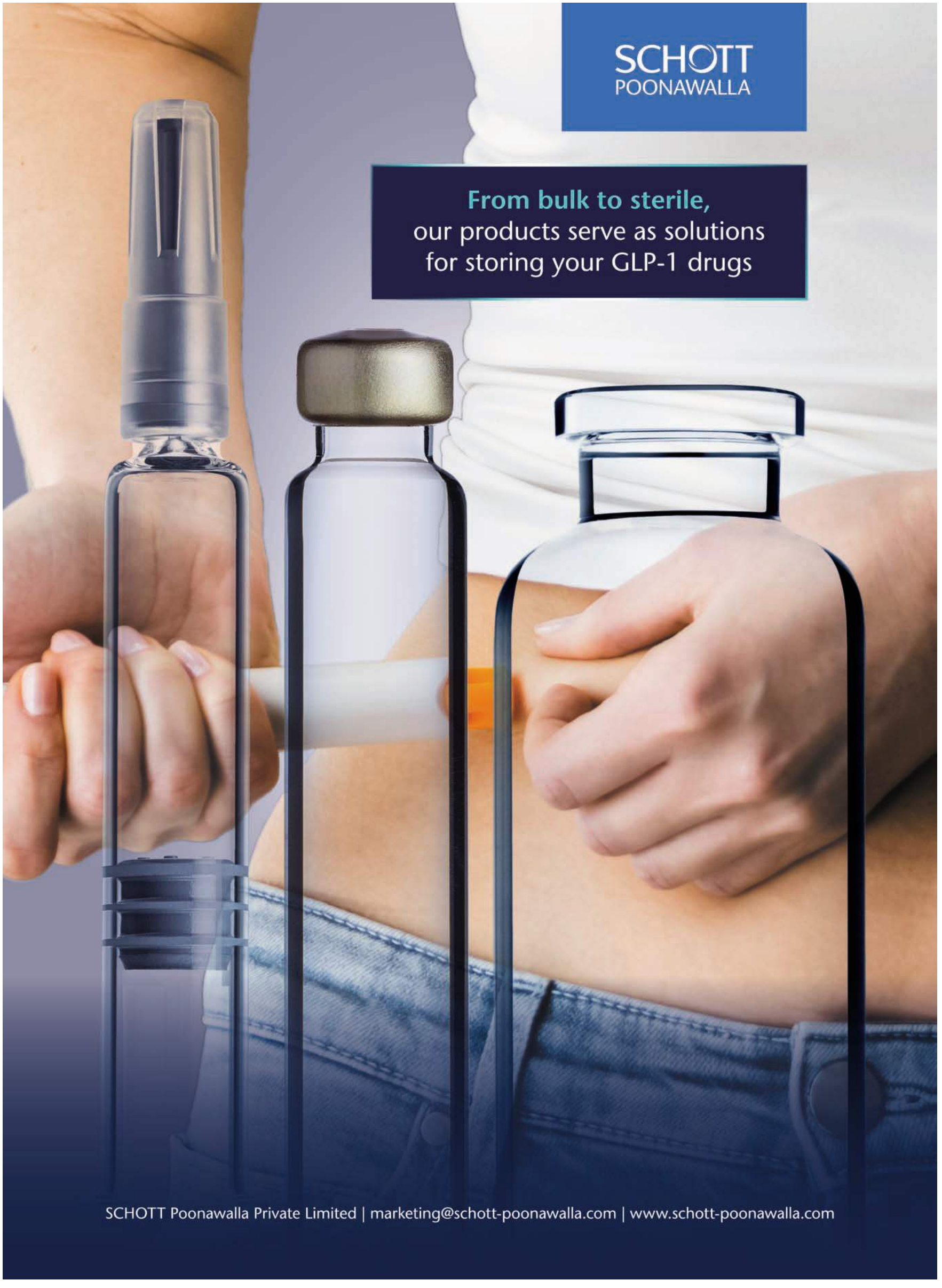
FOR MARKETING & MEDIA PARTNERSHIPS

DHEERESH BANGERA
E: dheeresh.bangera@informa.com | M: +91 90040 21880

MAHESH VERMA
E: mahesh.verma@informa.com | M: +91 74989 67629

CPHI & PMEC India | CPHI & PMEC India | cphi_and_pmec_india | @CPHI_PMEC_India

www.cphi.com/india

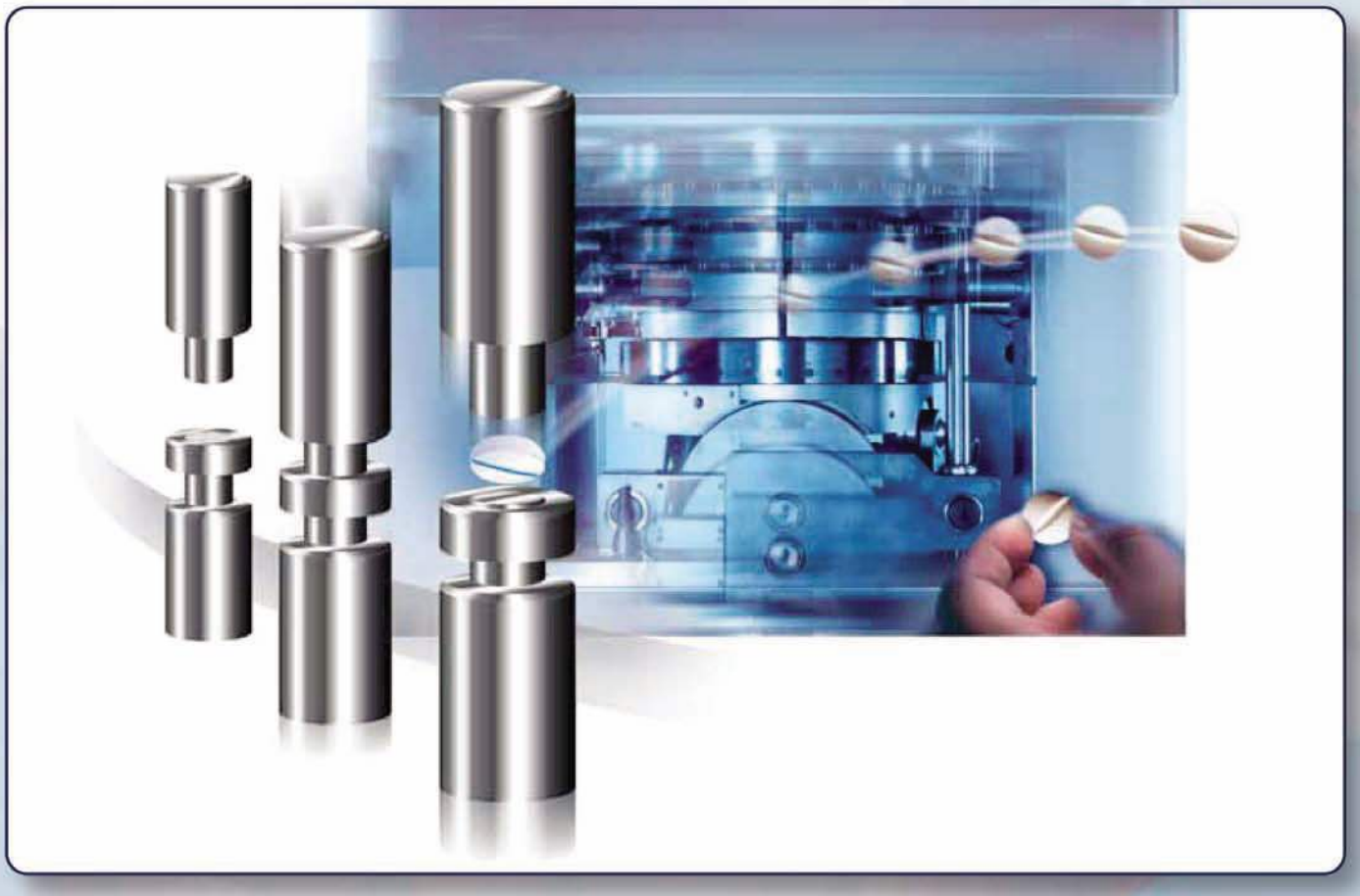

SCHOTT
POONAWALLA
From bulk to sterile,
our products serve as solutions
for storing your GLP-1 drugs
SCHOTT Poonawalla Private Limited | marketing@schott-poonawalla.com | www.schott-poonawalla.com

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

EXPRESS PHARMA

Chairman of the Board
Viveck Goenka

Sr. Vice President-BPD
Neil Viegas

Vice President-BPD
Harit Mohanty

Editor
Viveka Roychowdhury*

Editorial Team
Lakshmipriya Nair
Kalyani Sharma
Kavita Jani
Neha Aathavale

DESIGN
Art Director
Pravin Temble

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

INTERVIEW

Akash Kedia, MD – Healthcare and Lifesciences, Alvarez & Marsal India

Amit Misra, MD – Healthcare and Lifesciences, Alvarez & Marsal India

Dr Vibin B Joseph, ED and CEO, BioZEEN

PRE EVENTS

TECHNOLOGY

STRATEGY

Express Pharma®

Regd. With RNI No.MAHENG/2005/21398. Postal Regd.No.MCS/164/2025 - 27. 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)

The promise and perils of weight loss drugs

Novo Nordisk's much awaited launch of Wegovy on June 24 provides patients in India with one more choice when it comes to weight management solutions. But while Wegovy scores on ease of administration, it remains too pricey for most Indian patients.

There has been some attempt to make Wegovy more price competitive while addressing patient pain points. After all, Novo Nordisk had a few months to observe how the market responded to the launch of Eli Lilly's Mounjaro.

Since its launch this March, Mounjaro has mopped up sales of INR 520 million as of May 2025. As per a company statement, Wegovy comes with an India-specific price, with the first three dosing strengths (0.25 mg, 0.5 mg, 1 mg,) priced at Rs 17345 for four weekly doses, the 1.7 mg dose at Rs 24,280 per month, and the 2.4 mg dose at Rs 26,015 per month. This is apparently to support dosage adjustment in the initial three weeks without additional financial impact.

Novo Nordisk's strategy to offer Wegovy in an easy-to-use pen device across five dosing strengths makes it a self-administered medication, a huge advantage over medication that needs a doctor's visit and possible needle-phobia incidents.

Eli Lilly's Mounjaro starts with the 2.5 mg single dose vial available at Rs 3,500 and the 5 mg single-dose vial at Rs 4,375, taking the monthly cost to between Rs 14,000 to Rs 17,500.

However, the two drugs are not directly comparable in terms of dosage levels. The dosage levels for Mounjaro start at a much higher range, of 2.5mg going up to 15mg, which is significantly higher than the typical dosage for Wegovy which starts at 0.25mg.

Of course, both medications have slightly different indications so it's not an -apples to apples comparison. While Wegovy claims to be the first and only weight management medication indicated for both chronic weight management and risk reduction in major cardiovascular events like stroke, heart attack and cardiovascular disease related death in overweight adults, Mounjaro claims to increase insulin secretion in response to food intake and improve glucose control and weight loss.

Eli Lilly claims that Mounjaro (tirzepatide) showed superior weight loss over Wegovy (semaglutide), citing results from the complete SURMOUNT-5 results published in The New England Journal of Medicine. For the primary endpoint, participants treated with tirzepatide achieved an average weight reduction of 20.2% (an average of 22.8 kg) compared to 13.7% (an average of 15.0 kg) with semaglutide at 72 weeks using treatment-regimen estimand, a 47% greater relative weight loss.

Doctors have warned of the risk of overuse and misuse, cautioning that patients will see such medications as an easy quick fix, without tougher lifestyle changes

Wegovy's principal ingredient semaglutide is set to go off patent in India in March 2026, opening the door to generic semaglutide. Once generic versions hit the market, analysts are predicting up to a 50 per cent crash in prices. Novo Nordisk intends to protect its turf, as observed in the case filed against OneSource Specialty Pharma and Dr Reddy's Laboratories. The latter's patent challenge to one of semaglutide's patents set to expire in March 2026 is being closely watched. The case could set a precedent, with more contenders preparing their legal strategies and ready to launch as soon as the patents expire.

But what's more promising than injectable weight loss drugs are oral tablets in the clinical research pipeline. These oral formulations also hold the promise of being more affordable than injectables, though the latter prove to be more efficient in terms of weight loss.

As pharma companies battle it out for a slice of India's weight management pie, companies will have to choose their strategies: collaborate to increase volumes or remain a premium player, focusing on the top of the pyramid.

While this battle will be an interesting chase, it has serious implications for the millions of Indians who struggle with weight loss and diabetes. Doctors have warned of the risk of overuse and misuse, cautioning that patients will see such medications as an easy quick fix, without tougher lifestyle changes. Eye surgeons are already citing the European Medicines Agency's safety committee warning that up to 1 in 10,000

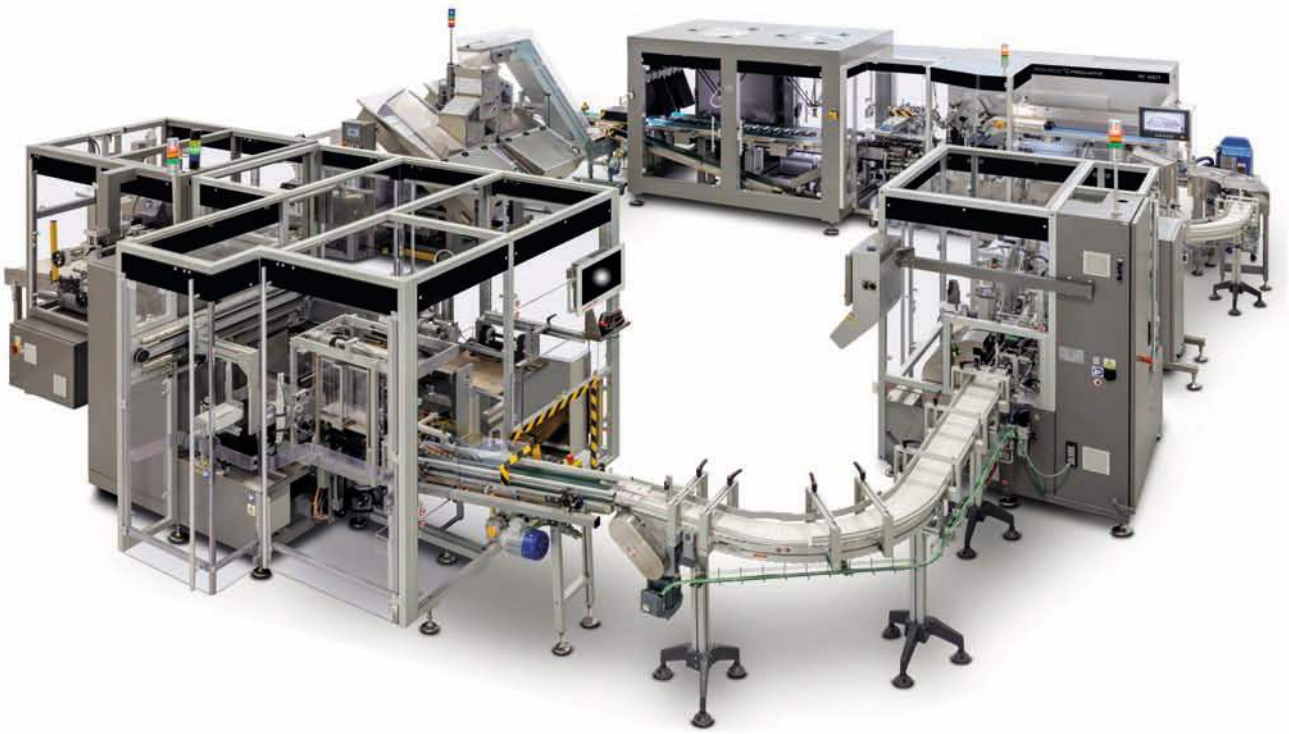
Patients using semaglutide, the active component of Wegovy, Ozempic, andRybelsus, for at least a year may develop non-arteritic anterior ischemic optic neuropathy (NAION). Patient awareness and counselling will be as important as writing a prescription or administering these weight loss shots.

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

ROMACO PROMATIC
beyond technology

Tailor-made Packaging Solutions

Complete Lines from Depacker to Palletizer



VERSATILE PACKAGING

SIGACHI
Experience Excellence..

SIGACHI®

COATING EXCELLENCE

INNOVATION IN EVERY LAYER

PURECOAT®

PureCoat®, a fully formulated ready-mix Film Coating system, adds valuable quality to our portfolio of quality products. PureCoat® comprises meticulously balanced concentrations of polymer, plasticizer, pigments, and opacifiers, ensuring robust and reproducible film coating solutions.

NUTRACEUTICAL COATING

Ready to use Delayed Release/Enteric Film Coating system for Pharmaceutical Dosage forms. .

MOISTURE PROTECTION COATINGS

Ready-to-use film coating system that protects the core tablet or multiarticulate system from direct contact with sensitive Actives and protects the dosage from damage during the initial spray of Functional coatings.

FILM COATING SYSTEMS

Ready-to-use innovative and high productivity range of film coating systems for all of API Segments.

SEAL COATING

Ready-to-use film coating systems for moisture-sensitive and hydrophilic pharmaceutical, nutraceutical, and herbal solid oral formulations.

DELAYED RELEASE COATINGS

Ready-to-use innovative and high productivity range of film coating systems for Nutraceutical products.

www.sigachi.com customercare@sigachi.com

SEW EURODRIVE

Driving the world

SEW MACHINE AUTOMATION

Inspired by Nature, Engineered for Reliability

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

Just as repetitive accuracy is in weaver birds' DNA, our automation components and controllers perform recurring tasks consistently and integrate seamlessly for durable operations.

Our Industry 4.0 solutions – Form, Fill, and Seal Machines, Flow Wrap Machines, and Robotics – are fully customisable and built to German standards. And with expert support across India, we ensure reliable machine automation.

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

popkon.in

Weaver birds are nature's expert builders. These skilful avians construct intricate nests with care and accuracy. They optimise every movement to create durable structures that withstand the elements.

SEW-EURODRIVE MACHINE AUTOMATION SOLUTIONS:

Form, Fill, and Seal Machines | Flow Wrap Machines
Printing Machines | Gantry Cranes | Tripods
Robotics | Palletizers | Cut-to-Length Machines

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

The next decade won't just reward scale — it will reward speed, resilience, and reinvention

Akash Kedia, MD – Healthcare and Lifesciences, Alvarez & Marsal India and **Amit Misra,** MD – Healthcare and Lifesciences, Alvarez & Marsal India, delve into the pivotal trends shaping Indian pharma. They share insights on CDMO valuations, navigating regulatory headwinds, global trade realignments, sector's pivot towards innovation, frontier market strategies, next levers of value creation and more, in an exclusive interview with **Lakshmipriya Nair**

Akash Kedia

Amit Misra

What are the biggest strategic challenges pharma companies in India are grappling with today? How is Alvarez & Marsal helping in tackling them?

India's pharma sector is navigating a perfect storm: intensified USFDA scrutiny (over 40 inspections and multiple warning letters in FY24 alone), continued pricing pressure in US generics, and incomplete backward integration in APIs. Talent shortages in digital, compliance, and regulatory roles are adding to the challenge. Further, as the healthcare ecosystem converges, pharma companies need to focus on building capabilities in broader areas within the human health spectrum like diagnostics and medical technology. At Alvarez & Marsal, we are on the ground helping clients plot growth strategies in core and adjacent businesses, strengthen GTM, modernise operations and diversify globally, all while ensuring speed and execution. For instance, we assisted a large Indian player in integrating its speciality buy out in US and developed growth strategy for its portfolio. We are also assisting mid-sized pharma companies to grow through diversification into newer geographies and product areas.

Which sub-sectors within pharma are currently attracting the most investor interest and why?

Three clear pockets are seeing strong traction:

◆ CDMOs like Aragen and Sai Life, for their tech-driven platforms and export-led growth.

◆ Complex generics and injectables, where players like Gland Pharma offer more attractive margins.

◆ Consumer health & wellness, where D2C brands like ZANDU and HealthKart are benefitting from secular demand.

What investors are chasing is platform quality, differentiated offerings, compliance robustness, and global scalability.

What macro or policy shifts could most influence pharma business strategy over the next three to five years?

Key shifts include the PLI push for API self-sufficiency, US biosecurity legislation (impacting Chinese sourcing), and tightening EU GMP norms. Domestically, the Digital Health Mission is driving investment in compliance tech and health data infrastructure. Companies like Biocon and Dr Reddy's are already adjusting manufacturing strategy and portfolio mix to align with these policy moves. A policy shift towards unbranded generics in the domestic market will also result in significant change in ways of working in the domestic market.

Are Indian pharma companies revising their global expansion strategy in light of regulatory headwinds or trade policy shifts in markets like the US and Europe?

Absolutely. Companies are de-risking US-centric models by expanding in Europe, LATAM, and Southeast Asia. Dr Reddy's is growing in Mexico and Brazil; Sun Pharma has pivoted toward high-margin dermatology and ophthalmology in the US. The focus is shifting toward specialty, complex generics, and biosimilars in defensible markets with better economics. Similarly API companies are focusing on markets such as Japan and Korea to leverage both API and intermediates opportunities.

What trends are you observing in M&A or licensing deals, are clients more cautious or more aggressive now?

It's a mix of selectivity and conviction. Buyers want regulatory clean books, strong leadership, and clear growth levers. But for the right platform, especially in CDMO or digital health, they are

aggressive. Deals like Biocon's Viatris acquisition or Kotak's investment in Tirupati show high competition. Earn-outs and milestone-based deal structures are now standard across transactions.

How do you support clients entering or scaling in frontier markets like Africa, LATAM, or Southeast Asia?
We help clients define tailored market-entry strategies, whether via local partnerships, branded generics, or third-party-led sales. Execution support includes GTM buildout, regulatory playbooks, customer outreach and cost-to-serve optimisation. For instance, Lupin's success in the Philippines and Cipla's scale in Africa show how localization and agile supply chains drive success in these regions.

What's the current valuation outlook in the Indian pharma sector — especially for CDMOs and CRAMS?
High-quality CDMOs and CRAMS are trading at strong multiples, typically 12x to 18x EBITDA, especially when they demonstrate compliance strength, sticky client relationships, and differentiated offerings (e.g., peptides, complex injectables, topical platforms). Recent deals like Carlyle's investment in Viyash or Kotak in Tirupati validate continued investor appetite.

Are Indian companies investing enough in innovative drug platforms (e.g., mRNA, gene therapy, complex generics), or is the market still skewed towards low-cost scale-up strategies?
The ecosystem is slowly shifting. Zydus's ZyCoV-D mRNA vaccine was a bold first, and Dr. Reddy's is scaling complex injectables and ophthalmics. Sun Pharma has acquired specialty players like Concert Pharma. There are companies like Laurus that are making investments in CAR-T therapy. That said, most of the market still focuses on cost-efficient generics. At A&M, we advocate hybrid innovation models — using core cash flows to fund select innovation bets via partnerships or co-development.

What's your take on the growing interest in biologics and cell & gene therapies — is Indian pharma ready for this shift?
Interest is strong, but readiness varies. Biocon Biologics (via Viatris) and Intas are making solid inroads in biosimilars. ImmunoACT's CAR-T launch marked India's CGT debut — a major milestone. Yet broader CGT scale-up will require investments in GMP vector facilities, cryo-infrastructure, and regulatory know-how — areas still maturing. Aurobindo's biologics CDMO unit signals where the market might head next.

To what extent are tech-first pharma companies, those leveraging AI/ML for R&D or blockchain for supply chain, being viewed as higher-value targets or partners by institutional investors?
Very positively. Indegene, with AI-powered commercial and regulatory tools, attracted investment from Carlyle and Brighton Park. Aragen is using ML in discovery workflows, and MSN Labs is piloting blockchain for serialisation. In our M&A work, we've seen that such firms can command valuation premiums of 20–30 per cent over traditional peers. Investors see them as future-ready, asset-light, and defensible.

If you could give one piece of advice to pharma leaders preparing for the next wave of disruption, what would it be?
Invest in adaptability. Whether it's a regulatory jolt, a geopolitical shift, or GenAI-driven transformation — your ability to respond fast will determine success. Build a leadership team that's digitally fluent, globally aware, and execution-focused. The next decade won't just reward scale — it will reward speed, resilience, and reinvention.

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

BiOZEEN is focused on strategic growth through partnerships, diversification, and sustainable innovation

Dr Vibin B Joseph, ED and CEO, BioZEEN shares details about his company's solutions for biopharma manufacturing and talks about changing customer needs, global collaborations, and their future plans for growth, in an interaction with **Lakshmipriya Nair**

The Indian biopharma sector is projected for significant growth. What are the market segments driving growth in the biopharma sector currently? Are you seeing greater traction in vaccine manufacturing, mAbs, or cell and gene therapies?
Multiple converging factors are driving growth in the Indian biopharma sector. A surge in healthcare spending (macro and micro economically), increasing global demand for accessible biologics and India's emerging role as a cost-effective innovation hub are driving growth across the bio-pharma sector.

Vaccines continue to be the primary growth driver in the Indian biopharma sector, with sustained global demand and India's established position with the country supplying over 60 per cent of global vaccine needs. This is followed closely by the expansion of biosimilars and other biologic drugs, where Indian companies are increasingly serving both domestic and international markets. Additionally, there is a growing wave of investment in cell and gene therapies—currently at the R&D stage—which is expected to evolve into a significant growth segment in the coming years as regulatory frameworks mature and clinical successes emerge.

What are the biggest hurdles the industry must navigate to fully realise its full potential?
The industry faces several critical challenges, including increasingly stringent and evolving regulatory requirements, the need to localise sourcing in response to global supply chain disruptions, persistent talent shortages, and high attrition rates. Additionally, there is constant pressure to optimise costs and pricing. However, the most significant hurdle remains the extended timeline from R&D to regulatory approval and commercial production. Navigating the complex and multi-phase development process continues to be a major barrier to accelerating innovation and market access.

How does BiOZEEN define its role in the global biopharma manufacturing ecosystem today, as an equipment provider, a solutions integrator, or a capacity builder? How are you aligning your portfolio to meet emerging biomanufacturing trends?
BiOZEEN defines its role in the global biopharma manufacturing ecosystem as a capacity builder—enabling end-to-end biomanufacturing capabilities through a comprehensive and evolving portfolio.
Our core verticals reflect this commitment:
◆ DBX – Engineered equipment solutions for scalable and compliant biomanufacturing
◆ BioAutomate – Intelligent automation services tailored for bioproduction processes
◆ Bioprocess+ School – Training the next generation of bioproduction professionals through industry-relevant programs
◆ FiltReg – End-to-end filter validation aligned with global regulatory standards
◆ Zeenovis – R&D services focused on bioprocess innovation and scale-up
TurnKX – Turnkey execution services for integrated biomanufacturing facilities
◆ BZ Assure+ – Lifecycle support, maintenance, and smart system upgrades for long-term reliability
With this multi-dimensional offering, BiOZEEN is well-positioned to:
◆ Empower first-time biopharma entrants, especially in high-growth regions such as Asia and Africa
◆ Support expansion and modernisation projects for established manufacturers
◆ Collaborate with global partners to localise and scale biomanufacturing capabilities

What kinds of demands are you seeing from your biopharma clients today that would have been rare or unexpected five years ago? How has the pandemic and post-pandemic landscape altered customer expectations around facility readiness, automation, or local manufacturing?
Over the past five years, particularly in the wake of the COVID-19 pandemic, we've observed a significant shift in client expectations across biopharma manufacturing.
Key changes include:
◆ A move from skilled-labour-dependent operations to systems that can be run by less specialised personnel, with a strong push toward minimal manual intervention. Clients now expect equipment that supports fully autonomous control, even in dynamic and unpredictable process conditions.
◆ A growing demand for lean automation architectures—systems that are modular, flexible, and user-configurable, reducing dependency on vendors for changes or upgrades.
◆ The expectation of real-time digital reporting across all process parameters to enable data-driven decision-making.
◆ Systems that are resilient to frequent software updates, minimising disruption during platform or regulatory upgrades.
◆ An 'audit-ready, always' mindset—driven by the need for real-time data visibility, electronic signatures, and traceable digital records to meet evolving compliance standards.
◆ The transition to paperless e-validation platforms, which streamline validation from design qualification to process performance qualification—accelerating facility readiness and reducing administrative burden.

Post-pandemic, there has also been a marked increase in the preference for local sourcing, both for equipment and services. Clients now expect faster turnaround times from concept design to qualification, with agile partners who can adapt to compressed project timelines.

Dr Joseph, as an Imperial College alumnus, and with Imperial recently launching its global science hub in Bengaluru, India, how do you see such international academic collaborations and initiatives contributing to fostering the innovation and technopreneurship needed to address today's global biotech challenges, particularly within the Indian ecosystem?
Turning challenges into opportunities is woven into Imperial's DNA. World-class research and academic excellence form its core, and entrepreneurship courses through its veins. That's what

defines Imperial to me. As an alumnus, you can imagine my excitement at the endless possibilities to shape a better world. I see immense potential for the global science hub in Bengaluru to accelerate the confluence of industry, academia and entrepreneurship to address global biotech challenges. International collaboration that brings together academia, industry and the innovation community can act as a catalyst in many different ways. For example:

◆ Promote academic knowledge and innovation by providing a platform for local researchers and technopreneurs to engage with global thought leaders, cutting-edge methodologies, and multidisciplinary expertise. Collaborative projects can leverage advanced research and facilitate knowledge transfer of best practices ensuring that Indian biotech remains competitive on a global scale.

◆ Inspire technopreneurship through mentorship networks to early-stage biotech ventures to scale ideas into market-ready solutions, attract venture capital and government funding, and support navigating regulatory pathways, scaling operations, and expanding internationally.

◆ Address global biotech challenges by combining India's manufacturing expertise and cost efficiency with global research insights in localised solutions such as affordable biologics for emerging markets or sustainable bioprocessing methods tailored to India's resource constraints. Collaborative R&D in cell and gene therapies, biosimilars, and other frontier technologies.

◆ Create a thriving ecosystem to upskill talent in emerging fields like AI driven drug discovery, and foster partnerships that align policy and national innovation goal

What are your growth targets or expansion plans for the next five years? Are you looking at M&A, JV models to meet demand? As global biotech investments shift, how is BiOZEEN preparing to stay resilient amid geopolitical tensions, supply chain issues, or shifts in funding models?

Over the next five years, BiOZEEN is focused on strategic growth through partnerships, diversification, and sustainable innovation.

We are actively exploring collaborative models—including joint ventures and strategic alliances—that bring together the complementary strengths of different organisations. Our goal is to deliver integrated, best-in-class solutions by working in synergy with partners, prioritising cooperation over competition to meet the evolving needs of our global clients.

To future-proof our operations and stay resilient amid geopolitical uncertainties, supply chain disruptions, and shifts in funding models, we have redefined our business strategy around the HEATR framework, which aligns with the United Nations Sustainable Development Goals (SDGs 2, 3, 4, 6, 7, 13, 14, and 15)—all aimed at securing life on Earth.

Our expansion will focus on:

Health: Strengthening our portfolio in vaccines, biologics, and biosimilars

Environment: Supporting sustainable agriculture and clean energy through biofuels, bio-pesticides, bio-fertilisers, and bio-disinfectants

Alternatives: Advancing future-ready solutions such as cell-based meat, milk, and honey

Training and Research: Empowering the next generation of biomanufacturing professionals and innovators.

By diversifying our offerings and building mission-aligned partnerships, BiOZEEN is well-positioned to lead in bioproduction while creating positive global impact.

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

Express Pharma to host the maiden edition of Injectable Innovations Conclave in Hyderabad

The event will be held on July 11, 2025 at Le Meridien, Hyderabad, bringing together leaders and experts from across the pharma value chain

India's pharma sector, is now making bold strides in the realm of complex generics and advaced drug delivery. Among the most promising avenues is the injectables segment. Driven by rising chronic disease prevalence, an ageing population, evolving regulatory frameworks, and technological breakthroughs, it is on an accelerated growth path.

Therefore, Express Pharma is organising the Injectable Innovations Conclave, a one-day focused conference dedicated to the latest developments in injectable formulations and drug delivery systems. The event will be held on July 11, 2025 at Le Meridien, Hyderabad, bringing together leaders and pioneers from across the pharma value chain.

This event, under the theme, 'Revolutions in injectables' will explore the many dimensions shaping the future of injectables — from sustainability to smart drug delivery technologies, from circular economy principles to patient-centric design, and from evolving regulatory pathways to affordability challenges.

Key themes and focus areas:

◆ Technological innovations redefining injectable drug delivery systems

◆ Emerging and future trends in formulation and delivery of injectables

◆ Strategies to balance sustainability and affordability

◆ The circular economy in injectables: responsible production, use, and disposal

◆ Navigating the regulatory landscape for compliance and speed-to-market

◆ Smart injectable devices enhancing patient adherence and outcomes

The event will offer a unique opportunity to gain cutting-edge insights, foster collaborations, and understand how innovation is transforming the injectable segment into a key growth engine for Pharma Inc.

Express Pharma to host the third edition of Chandigarh Pharma Summit

To be held on on August 6, 2025, at Taj Chandigarh, it seeks to unite key stakeholders from industry, government, academia, and research to shape a bold new vision for the region and the country. search to shape a bold new vision for the region and the country

After the overwhelming success of the Ahmedabad edition in April, Express Pharma gears up to host the Chandigarh Pharma Summit the Chandigarh Pharma Summit will unite key stakeholders from industry, government, academia, and research to shape a bold new vision for the region and the country.

After the overwhelming success of the Ahmedabad edition in April, Express Pharma gears up to host the Chandigarh Pharma Summit on August 6, 2025, at Taj Chandigarh — the second in its Pharma Summits 2025–26 series under the overarching theme, "Pathways for Global Excellence."

Now in its third edition, the Chandigarh Pharma Summit is poised to spotlight the Tricity region (Chandigarh–Mohali–Panchkula) as a rapidly emerging hub in India's pharma map. Home to over 3,000 registered pharma companies, a strong manufacturing backbone in Baddi, and elite academic institutions like NIPER, the region stands at the crossroads of innovation, infrastructure, and investment opportunity.

As India prepares for its next phase of pharma growth, one that is research-led, digitally enabled, globally compliant, and sustainable, the Chandigarh Pharma Summit will unite key stakeholders from industry, government, academia, and research to shape a bold new vision for the region and the country.

Key themes

◆ Panel Discussion: Building a high-value pharma destination: Making Chandigarh–Baddi investor-ready

◆ Smart pharma manufacturing: Driving digital, green, and scalable solutions

◆ Strengthening quality culture across manufacturing and R&D ecosystems

◆ Biotech & biosimilars: Is Chandigarh ready to become a biopharma innovation hub?

◆ Future pharma workforce: Bridging skill gaps in R&D, digitalisation, and production

◆ Academia-industry collaboration: Tapping into NIPER's innovation potential

◆ Panel Discussion: Pharma 2030: Creating a future-ready, responsible, and resilient sector

Advantage Chandigarh

◆ Strategic location with access to key North Indian markets

◆ Highly skilled workforce from premier institutions

◆ Favorable policies and incentives from local government

◆ Robust infrastructure and seamless logistics

◆ Strong R&D and academic ecosystem with vast collaboration potential

◆ Excellent quality of life for talent attraction and retention

Join us as we collectively chart the next decade of growth, resilience, and leadership for India Pharma Inc.

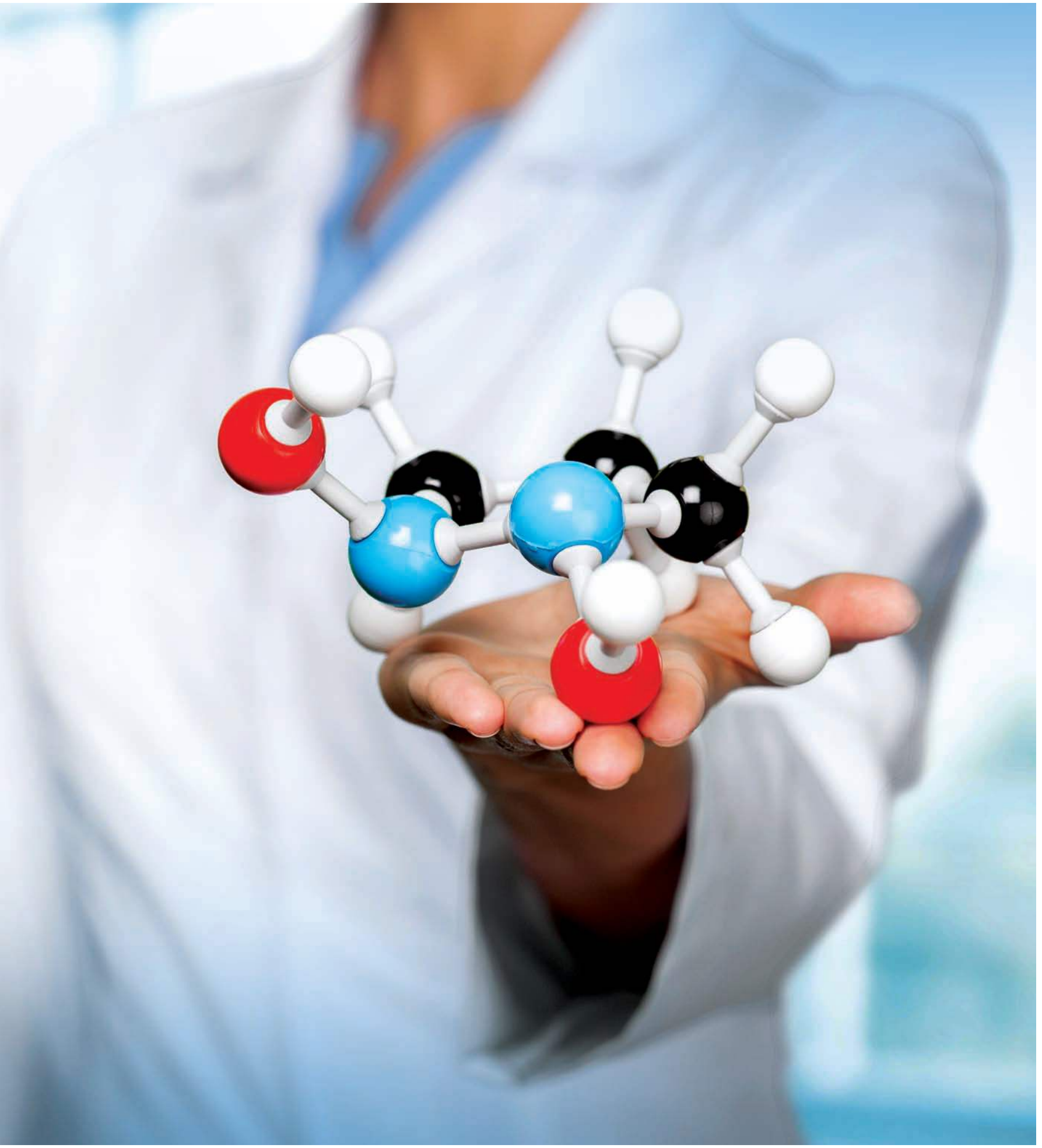
CILICANT
ACTIVE PACKAGING®
PRESENTS

FDD
CONCLAVE 2025
FORMULATION DEVELOPMENT
& DRUG DELIVERY CONCLAVE

POWERED BY
PIDILITE
chemicals
Partnering Through Innovation

FROM LAB TO LIFE BRIDGING SCIENCE AND CARE

FDD Conclave 2025 spotlights patient-centric pharma innovation, uniting industry leaders to shape the future of formulation and drug delivery



Inaugural Session

The inaugural session of FDD Conclave 2025 set a powerful tone for the two-day event that united the industry's brightest minds in FR&D to spur patient-centric innovation. It began with an inaugural address by Viveka Roychowdhury, Editor, Express Pharma and Express Healthcare. Spotlighting the event's central theme — "From lab to life: Bridging science and care", she underscored the need to humanise innovation in drug formulation and delivery. She emphasised that beyond scientific breakthroughs, true success lies in creating solutions that improve patient outcomes and quality of life.

She explained the vision and mission behind setting up the FDD Conclave and thanked the industry for its unwavering support in building the platform and making it successful.

This was followed by a ceremonial lamp lighting, marking the auspicious start of the conclave. Key dignitaries on stage included Roychowdhury, Manish Jain, MD, Cilicant, and Vijay Doshi, MD, Pioma Chemicals, Suresh Pareek, Angel Investor and Rajesh Bhatkal, GM, Express Pharma.

The inaugural session laid the foundation for engaging dialogues and forward-thinking strategies to shape FR&D in India.

L-R: Viveka Roychowdhury, Vijay Doshi, MD, Pioma Chemicals; Manish Jain, MD, Cilicant; and Suresh Pareek, Angel Investor and Rajesh Bhatkal, GM, Express Pharma

Formulation strategies for complex injectables

At the FDD Conclave 2025, Dr. Ajay Jaysingh Khopade, VP FR&D, Sun Pharmaceutical Industries, delivered an insightful presentation that delved into the future roadmap, challenges, and opportunities surrounding formulation strategies for complex injectables.

Dr Khopade highlighted Sun Pharma's initiatives such as leveraging known FDA PSGs for liposomes and long-acting injectables in the near term, to investing in depot R&D platforms, nanosystems, and smart injector biosimilar combinations in the years ahead.

Then, Dr Khopade emphasised how complex generic parenterals are poised for growth as blockbuster injectable products near patent expiry by 2030.

He outlined the need to bridge scientific complexities with robust regulatory planning to optimise this growth potential and spoke on the significance on investing in avanced analytical tools such as Cryo-TEM, PBPK modeling, and stability platforms. Dr Khopade also stressed the growing importance of combination products and backward-compatible device design to drive differentiation and ease of use.

Dr Ajay Khopade, VP FR&D, Sun Pharma

On the regulatory front, Dr Khopade addressed global pathways that could accelerate approvals, such as the EU's hybrid pathway and the US FDA's 505(b)(2) route. He emphasised that proactive regulatory engagement strategies like pre-ANDA meetings and controlled correspondences can de-risk complex product filings.

He also shared case studies such as Nanotecton platform technology – a drug self-assembly system that eliminates the need for toxic excipients and offers enhanced safety and usability. Another highlight was Sun Pharma's innovations in ophthalmics which offer once-daily dosing, BKC-free formulations, and improved patient compliance.

He concluded with strategic recommendations for companies looking to enter this space such as risk-sharing models, platform-based R&D, impurity control strategies, and robust portfolio planning based on market potential.

Panel Discussion: Accelerating OSD innovation: From R&D to market

L-R: Dr Manikandan Ramalingam, Sr VP - Head Formulation R&D, Granules India (MODERATOR); Dr Sajeev Chandran, VP-Pharmaceutical R&D, Lupin; Dr Manish Chawla, VP & Head (R&D), Lotus Pharmaceutical; Dr Sachin Arora, VP & Delivery Manager- Formulation Development Oral Solids - US, EU, CA & Global Markets, Dr Reddy's Laboratories; Dr Sandhya Shenoy, AVP - Formulation R&D, MSN Laboratories; and Dr Khalid Akhter Ansari, Senior Director, Technical Operations, Rising Pharmaceuticals

The first panel discussion at FDD Conclave 2025 was on 'Accelerating OSD innovation: From R&D to Market'. It set the tone for a day focused on transformation, technology and translational impact in the formulation space.

Moderated by Dr Manikandan Ramalingam, Senior VP - Head Formulation R&D at Granules India, the expert panel also included Dr Sajeev Chandran , VP-Pharmaceutical R&D, Lupin India; Dr Manish Chawla, VP & Head (R&D), Lotus Pharmaceutical; Sachin Arora, VP & Delivery Manager- Formulation Development Oral Solids - US, EU, CA & Global Markets, Dr. Reddy's Laboratories; Dr Sandhya Shenoy, AVP - Formulation R&D, MSN Laboratories and Dr Khalid Akhter Ansari, Senior Director, Technical Operations, Rising Pharmaceuticals, each offering insights drawn from global and regional perspectives.

The discussion underscored a central theme: speed-to-market in OSD innovation must be balanced with scientific rigour, regulatory foresight, and patient-centricity. From formulation to commercial rollout, the panellists highlighted the importance of integrating emerging technologies with formulation science to accelerate timelines and elevate outcomes.

A key topic discussed was how Artificial Intelligence (AI) is now being actively leveraged for rapid literature mining, predictive modeling of stability, and compatibility analysis of excipients.

Digital transformation featured prominently in the conversation, with speakers emphasising the role of data structuring, modeling, and automation. Digital tools are not just process enhancers; they're quality enablers, noted the experts and informed that predictive models are helping us foresee impurities and proactively control deviations, reducing the risk of recalls and non-compliance.

The need for cross-functional collaboration also emerged as a vital success factor. Computational modeling, for instance, holds tremendous potential but demands seamless collaboration between formulation experts and data scientists.

- Cost, convenience and compliance should be considered while innovating oral dosage forms
- Efficient and effective of technology and structured data can improve drug efficacy and help reduce timelines from lab to market
- Computational modeling offers value but requires close collaboration between formulation scientists and data experts to ensure reliability
- Digital tools and automation enhance quality systems by predicting impurities, controlling process deviations, and minimising human error
- Early engagement with regulatory authorities supports better alignment and faster development timelines
- Developing the right talent and skill set is critical for successfully integrating digital and scientific approaches in formulation

The panel also called for early engagement with regulatory authorities, especially for complex generics and novel delivery systems. The regulatory landscape is evolving alongside science. Proactive communication and early-stage dialogue can significantly reduce cycle times, pointed out the panelists.

The discussion also addressed cost, convenience, and compliance, the three pillars of patient-centric innovation. Whether it's improving bioavailability, reducing pill burden, or innovating with taste-masking and extended-release formats, patient needs must drive design decisions.

Closing the session, the panelists emphasised the human element of innovation. They pointed out how crucial it is to develop the right talent and skill set is critical for successfully integrating digital and scientific approaches in formulation.

Practical techno-commercial aspects of 'Womb to Tomb' product lifecycle

Dr Jayant Karajgi, COO, Shilpa Medicare, outlined a strategic approach to pharma product development from ideation and execution, till the end of its lifecycle. He emphasised on selecting projects based on company DNA, market data, IP landscape, and regulatory pathways. He also highlighted the importance of clear budgeting, timelines, ROI expectations, and using stage-gate criteria for go/no-go decisions. While ideation may take time, execution must be swift and focused.

In the growth phase of a product, aligning development timelines with business needs is critical. Dr Karajgi stressed building robust products from the outset, noting that shortcuts often have consequences later. He stressed that strong market positioning helps differentiate the product, and smart pricing strategies ensure sustained profitability. He also pointed out how risk mitigation is essential to protect and expand market share.

Dr Jayant Karajgi, COO, Shilpa Medicare

He spoke on how products face challenges such as price erosion, stagnant sales, and increased regulatory scrutiny. Statutory changes or compliance burdens can make products commercially unviable. Moreover, market alternatives often gain ground, further reducing demand. He recommended that at this stage, companies must evaluate whether to revitalise, out-license, or exit, ensuring resources are redirected to more promising opportunities in the portfolio.

Dr Karajgi concluded by emphasising that product development remains more of an art than a science. While data and systems support decisions, human insight is irreplaceable. He advised being financially prepared for 'bad debt' projects, as not every venture yields returns. He opined that success lies in mastering the full lifecycle with clarity, resilience, and a long-term perspective. Those who do, he noted, are the real winners in pharma innovation.

Innovative active packaging: Step towards a more sustainable future

At the FDD Conclave 2025, Dhairy Sharma, Manager - Business Development (Healthcare Division), Cilicant presented a session titled, 'Innovative active packaging: Step towards a more sustainable future.' The session focused on the impact of moisture and oxygen on product degradation and the role of active packaging in addressing this challenge. Sharma began by showcasing the factors that impact product stability-exposure to air and humidity.

To address these challenges, Sharma introduced Cilicant's Accuflip, an equilibrium relative humidity (ERH) regulator which regulates the ERH within a specified range to protect the product. It contains a specialised sorbent which can adsorb and desorb moisture to maintain the specified range of the ERH level according to the requirement of primary packaging.

Dhairy Sharma, Manager - Business Development (Healthcare Division), CILICANT

Sharma also spoke about another active packaging solution from Cilicant that includes desiccant and oxygen absorbers. OXABIDE is an oxygen absorber comprised of iron-based compounds that absorbs oxygen. It helps to create an anaerobic environment by limiting the progression of oxidative degradation by reducing the oxygen present within the primary packaging. It comes in a canister form encasing high-potency compressed tablets. Describing its benefits, Sharma highlighted that its laser-marked canister design offers clean aesthetics, customisable printing options, eliminates ink-related concerns since they don't need labels and therefore has almost zero online rejections due to label peeling.

Concluding the session, Sharma underlined the importance of selecting the right active packaging solutions to maintain product stability and safeguard the product shelf life.

Global excellence in sourcing and distribution of high quality ingredient

Discussing sourcing and distribution practices in the excipients and specialty ingredients sector, Vijay Doshi, MD, Pioma Chemicals, presented the company's approach to raw material supply, adherence to industry standards, and cost considerations in international markets. He also informed that The company's product portfolio supports pharma and personal care industries, reinforcing its position as a supplier of excipients and speciality ingredients in multiple markets.

Pioma Chemicals operates in domestic and international markets. The company maintains strong global partnerships with over 20 international firms, offering a portfolio of more than 2,000 products catering to various industry applications. Doshi highlighted that the company's business model incorporates product development, technical support, and regulatory documentation. The company has expanded its manufacturing and supply chain capabilities through collaborations with external partners, ensuring compliance with global standards.

Vijay Doshi, MD, Pioma Chemicals

He informed that Pioma Chemicals has invested in science and technology to develop new products and manufacturing processes. Its sourcing and distribution networks are structured to meet industry demand while maintaining cost efficiency and regulatory compliance. The company continues to focus on supply chain optimisation and strengthening global partnerships.

Pioma Chemicals has invested in science and technology to develop new products and manufacturing processes

Impurities and excipients

The growing regulatory focus on life-threatening impurities and the evolving role of excipients in formulation took centre stage during a partner session by Sigachi Industries at the FDD Conclave 2025, held on June 13–14, 2025, in Hyderabad. The session, titled, 'Impurities and Excipients', was conducted on Day 1 by Dr Abhijit Gothoskar, Technical Expert at Sigachi Industries.

The presentation opened with a discussion on impurities, particularly nitrosamines. Referencing pivotal 1956 research, it was noted that dimethyl nitrosamine was found to cause liver tumours in rats—a discovery that has since shaped global regulatory standards. Subsequent studies confirmed that nearly 90 per cent of the 300 nitrosamines tested were carcinogenic in various animal models. This has prompted regulatory agencies to closely monitor and mitigate nitrosamine contamination in pharmaceutical products.

Dr Abhijit Gothoskar, Technical Expert, Sigachi Industries

Dr Gothoskar explained that nitrosamine formation depends on several conditions, and approximately 40 per cent of active pharma ingredients (APIs) contain amines that are at risk. Addressing these risks requires not just process control but a strong understanding of excipient behaviour.

The presentation then moved to the role of excipients in formulations, with particular emphasis on their often-underestimated impact. As major components in most oral solid dosages, excipients, especially diluents, play a key role in controlling tablet compression characteristics. Their physico-mechanical properties influence critical factors such as compressibility, tabletability, and compactibility.

Dr Gothoskar presented Microcrystalline cellulose (MCC), specifically Hi-Cel MCC by Sigachi, as a proven multifunctional excipient. His session highlighted MCC's plastic deformation behaviour, hydrogen bond formation, and fibrous particle interlocking, which together enhance tablet strength at low compression forces. Considerations such as blending speed, lubricant interaction, and addition of brittle excipients were also addressed in the context of maintaining optimal tensile strength and performance.

He reinforced Sigachi's position as a dependable formulation partner through this session.

Drug delivery systems - Advances in capsule technology

With drug delivery systems becoming central to improving therapeutic outcomes and patient experience, advancements in capsule technology are paving the way for more precise and efficient formulations. This was the focus of the session titled 'Drug Delivery Systems – Advances in Capsule Technology' at the FDD Conclave 2025.

Conducted by Lekhna Ajgaonkar Kumar, Associate Director – Marketing at Lonza Capsules & Health Ingredients, the session showcased how the company's capsule innovations are helping pharmac partners overcome longstanding formulation challenges while streamlining the path from development to commercialisation.

Lekhna Ajgaonkar Kumar, Associate Director - Marketing, Lonza Capsules & Health Ingredients

The session highlighted Lonza's evolution into a preferred partner for pharma companies globally, offering end-to-end support that spans preclinical research, clinical trials, production, logistics, regulatory guidance, and compliance. This holistic involvement across functions allows Lonza to offer not just products, but integrated solutions tailored to the complex needs of modern drug development.

At the heart of the presentation was Capsugel Enprotect, Lonza's innovative capsule technology designed to address the limitations of traditional enteric-coated systems. Unlike conventional methods that require additional coating steps, Enprotect capsules inherently protect acid-sensitive ingredients from stomach degradation and enable targeted intestinal release. This advancement simplifies manufacturing, enhances reproducibility, and reduces formulation complexity—making it a compelling option for formulators working with challenging APIs.

In addition to its technical merits, Ajgaonkar Kumar also framed capsule innovation as an enabler of patient-centric drug delivery. She also pointed out that by improving stability, bioavailability, and dosing precision, capsule technologies like Enprotect contribute to better adherence and therapeutic success, particularly for sensitive or specialty drugs.

The session underscored how the company's formulation technologies are shaping the future of oral drug delivery and reaffirmed its commitment to supporting pharma innovation across every stage of development.

Enhancing product performance through advanced granulation and coating

As pharma manufacturing grows more complex, advanced granulation and coating technologies are playing a pivotal role in enhancing product performance and process efficiency. This was the central focus of a partner session led by Romaco at the FDD Conclave 2025.

Presented by Shailesh Umakant Parelkar, Senior Manager – Sales, Romaco India, the session titled, 'Enhancing product performance through advanced granulation and coating', gave an in-depth look into how Romaco's engineering innovations are helping pharma manufacturers meet today's evolving formulation and production challenges.

Among the technologies spotlighted was ORBITER, Romaco's advanced air flow bed system that significantly improves the fluidisation of solid particles. This optimisation ensures more uniform granulation and coating, enhancing batch consistency and reducing processing times—key drivers of operational efficiency and product quality.

Shailesh Umakant Parelkar, Sr Manager- Sales, Romaco India

Another standout feature discussed was ROTOJET, an innovative spray system designed with a single 360° nozzle. Its streamlined design not only ensures even distribution but also simplifies maintenance. Since only one nozzle needs to be accessed for cleaning or replacement, manufacturers benefit from reduced downtime and faster turnaround between batches.

The speaker also highlighted the Romaco Innojet platform—a modular, flexible control system that enables step-based recipe management and advanced process automation. This system empowers manufacturers with greater precision and adaptability, ensuring consistent quality while supporting the demands of modern, scalable production environments.

Through this focused presentation, Parelkar emphasised on Romaco's continued commitment to supporting pharma innovation with intelligent, user-centric technologies.

mPredict: Accelerate your drug development journey

The accelerating demand for faster, more efficient drug development has brought digital predictive tools into sharper focus. At the FDD Conclave 2025, Merck Lifescience hosted a partner session on Day 1 titled 'mPredict: Accelerate your drug development journey'. The session was led by Dr Pratik Kakade, Technical Application Expert at Merck Lifescience, and introduced attendees to one of the company's latest digital offerings.

The session introduced attendees to mPredict, a digital tool designed to transform how pharma companies approach formulation and preclinical development. By integrating data-driven intelligence into early formulation workflows, mPredict promises a more streamlined and reliable path from molecule to market.

One of the core advantages of mPredict lies in its ability to recommend promising API processing strategies quickly and with high accuracy, informed Dr Kakade. The platform is significantly faster than both random digital screening methods and traditional experimental screening, reportedly reducing screening time by up to 96 per cent. This time-saving potential could be a game changer for formulators aiming to meet aggressive development timelines without compromising on quality.

Dr Pratik Kakade, Technical Application Expert, Merck Lifescience

He pointed out that beyond speed, the tool offers superior accuracy. mPredict has demonstrated results that are twice as reliable and accurate compared to current industry-standard alternatives. Its predictive capability supports formulators in identifying the most effective processing routes in development, ultimately reducing risk and resource expenditure across the product lifecycle.

Through this session, Dr Kakade emphasised Merck's commitment to enabling smarter, data-driven pharma innovation.

Role of formulations in targeted delivery of m/RNA for vaccines, therapeutics and in vivo gene editing

The expanding scope of mRNA-based therapeutics and vaccines has brought formulation science to the forefront, particularly in enabling targeted, effective, and safe delivery. In a focused session at the FDD Conclave 2025, this critical intersection was explored under the session titled 'Role of formulations in targeted delivery of m/RNA for vaccines, therapeutics and in vivo gene editing.'

Presented by Dr Ramesh Matur, Senior VP and Head of the Vaccines R&D Division at Biological E, the session offered deep insights into how advances in formulation technologies are shaping the future of RNA-based medicine. With an emphasis on both scientific innovation and strategic opportunity, the talk addressed the evolving needs of global healthcare through the lens of delivery platforms.

Dr Ramesh Matur, Sr VP and Head, Vaccines R&D Division, Biological E

Central to the discussion was the role of lipid nanoparticles (LNPs), which have emerged as the preferred non-viral vectors for delivering mRNA. Dr Matur detailed their ability to shield fragile RNA molecules, navigate biological barriers, and enable efficient cellular uptake has made them instrumental in the success of current mRNA vaccines and holds equal promise for gene editing and therapeutic applications. As the demand for precision delivery systems grows, the refinement of LNP-based platforms continues to be a major driver of innovation.

Beyond the science, Dr Matur also highlighted India's potential to play a pivotal role in this space. With a strong foundation in chemistry, biology, and computational sciences, Indian researchers are well-positioned to contribute meaningfully to the global RNA landscape. The integration of these disciplines can accelerate the development of novel delivery systems and biomolecular platforms, while also enabling the creation of intellectual property around rare and unmet disease areas.

Dr Matur concluded the session by underscoring the importance of leveraging India's scientific strengths to not only advance therapeutic possibilities but to also shape the future of personalised, formulation-driven medicine.

Panel Discussion Injectable therapies 2.0: Driving patient-friendly parenteral drug delivery

L-R: Dr Rakesh Bhasin, Head - Generic Formulation R&D, Biocon (MODERATOR); Dr Ravikumar N, EVP, MSN Laboratories; Makarand Avachat, EVP, Lupin; Dr Sukhjeet Singh, Chief Scientific Officer, Acme Formulation; Dr Mallinath S Harwalkar, VP - R&D, Hetero; Dr Amarender Reddy Donthidi, VP & Head - R&D Injectables and Ophthalmics, Amneal Pharmaceuticals; Dr Krishna Bhavanasi, VP- F&D, Torrent Pharmaceuticals

The eighth edition of the FDD Conclave organised by Express Pharma witnessed a very interesting panel discussion on Injectable Therapies 2.0: Driving patient-friendly parenteral drug delivery, which brought together FR&D leaders and scientific experts from across India's pharma landscape. The session focused on the evolving innovations in injectable drug delivery systems and the urgent need to place patient convenience, safety, and adherence at the heart of product development.

Dr Rakesh Bhasin, Head – Generic Formulation R&D, Biocon served as the moderator, setting the tone by underlining how injectable formulations, once viewed purely from an efficacy and stability perspective, must now be reimagined to improve user experience, especially in chronic therapies. He highlighted that the injectables segment is ripe for disruption through thoughtful innovation. Makarand Avachat, EVP, Lupin India; Dr Ravikumar N, EVP, MSN Laboratories; Dr Sukhjeet Singh, Chief Scientific Officer, Acme Formulation; Dr Mallinath S Harwalkar, VP - R&D, Hetero; Dr Amarender Reddy Donthidi, VP & Head - R&D Injectables and Ophthalmics, Amneal Pharmaceuticals and Dr Krishna Bhavanasi, VP-F&D, Torrent Pharmaceuticals were the other esteemed panelists for this discussion.

Among the key innovations discussed were long-acting depot injections, which allow for weekly or monthly dosing intervals, significantly improving patient adherence in therapies requiring sustained drug delivery. These formulations are redefining the treatment paradigm in areas like psychiatry, diabetes, and oncology, informed the panelists, who also emphasised that fewer administrations translate into better compliance and reduced healthcare burden.

They also spoke about the growing relevance of smart injectables and wearable injectors, which are enabling patients to administer drugs at home with minimal risk and greater ease. We are seeing strong momentum in automated, wearable delivery devices that offer precise dosing while enhancing comfort and safety, noted the experts.

The experts added that with the rising popularity of biologics and biosimilars, there's an increasing need for novel delivery mechanisms that can accommodate larger molecules, ensure stability, and maintain efficacy.The trend toward complex injectables necessitates advancements in delivery platforms that are compatible with sensitive molecules and patient-centric in design.

The panel discussion also addressed the innovations in painless injections, an area where the industry has seen only incremental progress, calling for disruptive thinking in drug-device integration.

- Innovations like depot injections are enabling long-acting formulations and improving patient adherance through weekly or monthly dosing
- Smart injectables and wearable injectors are making home administration easier and safer
- Growth in complex injectable biologics is driving the need for novel delivery systems
- Industry is exploring painless injections as part of improving patient experience. Efforts include using bigger needles or higher volume to reduce pain during administration
- There's a growing interest in reusable injection devices, including reusable pens.
- Innovation is limited—current developments mostly involve reworking existing needle technologies rather than introducing new solutions.
- We need to create and incentivise an ecosystem that encourages more innovation

We need to look at injectables from a lifecycle and systems perspective, ensuring they're not just effective but also environmentally responsible and user-friendly, urged the experts.

They stressed the need for a supportive innovation ecosystem. True breakthroughs require aligned incentives — from regulators to investors to academic collaborators. We need platforms that reduce risk, speed up timelines, and reward innovation focused on the patient, opined the panelists.

Unanimously, panellists agreed that while the injectable therapies segment has seen considerable progress, it is still largely driven by incremental enhancements. A bold shift is needed—from improving known delivery systems to developing radically new solutions that meet unmet patient needs.

The discussion closed with a call to action: Indian pharma must leverage its strengths in manufacturing, scientific talent, and market understanding to move beyond 'me-too' products and become global leaders in patient-friendly injectable innovations.

In line with the theme of the conclave, 'From Lab to Life: Bridging Science and Care', the panel underscored that innovation must not stop at the lab bench. It must be designed with the end-user in mind, translating into therapies that are safer, simpler, and more aligned with real-world patient needs.

Transdermal/oral delivery systems and pen/autoinjector assembly machines

At the FDD Conclave 2025, Abhishek Ghongade, Deputy Sales Manager, and Chetan Chennur, Sales & Project Management, from Harro Höfliger gave a detailed presentation on advanced drug delivery formats.

The session focused on process nowhow and related equipment for transdermal and oral delivery systems and offered an overview of cutting-edge technologies shaping the future of patient-centric drug delivery.

Opening the session, the speakers highlighted the company's holistic approach to lifecycle management, from product development to commercialsation, emphasising their expertise in oral dissolvable films (ODF) and transdermal therapeutic systems (TTS).

The presentation cited recent data noting that 16 APIs are currently delivered through FDA/EU-approved transdermal patches, with approximately 80 new systems under clinical trials. Of these, an estimated 16 products could secure FDA approval in the next two to three years.

Chetan Chennur, Sales and Project Manager, Harro Höfliger


Abhishek Ghongade, Deputy Sales Manager, Harro Höfliger

Examples of TTS patches discussed included fentanyl, buprenorphine, lidocaine (for pain relief), nitroglycerin (for post-surgical pain), hormonal contraceptives, nicotine patches for cessation therapy, and others for hypertension and depression. These delivery systems continue to gain traction for their non-invasive nature, consistent drug release, and improved patient adherence.

Switching focus to ODFs, they discussed this innovative dosage form designed to disintegrate or dissolve quickly in the mouth. ODFs are formulated using water-soluble polymers and can incorporate single or multiple APIs. They offer flexible formulation options like taste masking and complex binding. Examples included vitamin strips, melatonin, Ashwagandha, B-complex, and even prescription products like Tadalafil ODF.

The next spotlight was Harro Höfliger's range of equipment, spanning R&D to commercial production. From lab-scale converters to advanced machines, the company offers scalable, modular systems. The experts from Harro informed that the process lifecycle includes reverse engineering, permeation studies, coating, pouching, and technology transfer, underscoring an end-to-end manufacturing commitment.

The session concluded with an overview of their assembly technologies for drug-device combinations, pens, inhalers, diagnostics, and more, coupled with digital systems for traceability, validation, and anti-counterfeiting.

Nitrosamines and excipients: A data-driven approach to safer pharma formulations

Managing nitrosamines that form during manufacturing and storage, due to reactions between nitrites and amine-containing APIs or impurities, remains a significant challenge for the pharmaceutical industry. At the FDD Conclave 2025, Dr Ravleen Singh Khurana, MD, Nitika Pharmaceutical Specialities, addressed this concern by highlighting how the choice of excipients can influence nitrosamine formation in drug products.

Nitrosamine formation is highly influenced by nitrite levels in excipients like microcrystalline cellulose (MCC), lactose, and superdisintegrants. Average nitrite content and batch-to-batch variance differ among excipient types. Therefore, consistency of low nitrite excipients is key. High nitrite levels can increase nitrosamine formation by up to 151 per cent. While changing the supplier of MCC or such critical excipients can reduce risk by ~10x.

Dr Ravleen Singh Khurana, MD, Nitika Pharmaceutical Specialitie

Khurana emphasised the importance of selecting low-nitrite excipients to reduce the risk of nitrosamine formation and improve product safety. He also highlighted the offerings by Nitika, such as MCC, magnesium stearate, and sodium stearyl fumarate with low nitrite levels. These excipients are part of a strategy to mitigate nitrosamine risk and enhance patient safety. This approach can be vital for high-risk formulations and aligns with regulatory guidelines to validate the safety and efficacy of pharma products.

Faster coating technology advantage

At the FDD Conclave 2025, Akil Kadiyavala, GM - Technical Services, Dhara Lifescience presented a compelling case for adopting faster, more efficient tablet film coating technologies. The session showcased Dhara's latest innovations in readymix film coating systems that promise significant process time savings without compromising on quality or performance.

The session started off with an overview of the company. He informed that, founded in 2007 and headquartered in Ahmedabad, Gujarat, Dhara Lifescience has positioned itself as a global provider of pharma coating polymers and film coating systems. The company exports to over 40 countries, including the US, CIS, MENA, and South Korea, and holds certifications such as US FDA registration, GMP, ISO 9001:2015, and EXCiPACT compliance.

During the session, Kadiyawala spotlighted their signature brands, Dharacoat, Readycoat, and Ionex, which cater to a range of applications from taste masking and delayed release to enteric and sustained release coatings.

Akil Kadiyavala, GM - Technical Services, Dhara Lifescience

The highlight of the presentation was Readycoat HS, a film coating system designed to reduce processing time. In a case study involving acetaminophen 500 mg tablets, Readycoat HS was shown to reduce the coating time from 240 minutes to just 110 minutes.

Similarly, Readycoat EZE and Dharacoat MAE 100 P, both methacrylic acid copolymer-based systems, demonstrated accelerated enteric coating advantages.

Kadiyavala also spoke about the kkey factors enabling these improvements such as Dhara's use of fine particle size distribution, co-processed polymer technologies, and advanced manufacturing equipment. He informed that Dhara's fully automated, EXCiPACT-compliant facility ensures high batch-to-batch consistency and stringent quality control.

The session also touched upon how pharma companies can evaluate alternative tablet coating products. The evaluation framework includes supplier assessment, regulatory and technical compliance, and rigorous product-level comparisons. Kadiyavala emphasised the growing need for process efficiency, cost control, and contingency planning in the industry, especially amid rising supply chain complexities.

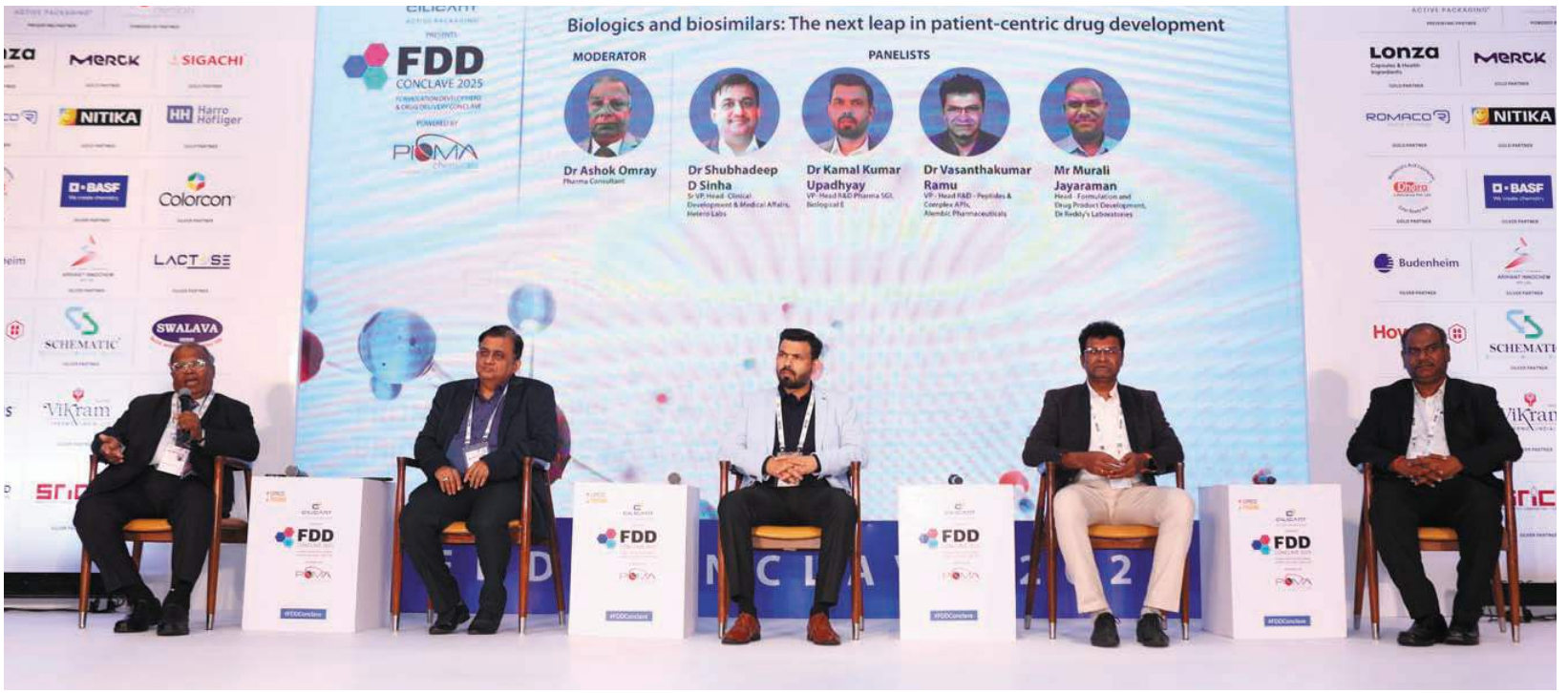
In conclusion, the presentation underlined how smart, ready-to-use coating solutions from Dhara Lifesciences can optimise manufacturing timelines while maintaining regulatory and quality benchmarks.

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

Panel Discussion: Biologics and biosimilars: The next leap in patient-centric drug development



L-R: Dr Ashok Omray, Pharma Consultant (MODERATOR); Dr Shubhadeep D Sinha, Sr VP, Head- Clinical Development & Medical Affairs, Hetero Labs; Dr Kamal Kumar Upadhyay, VP- Head R&D Pharma SGI, Biological E; Dr Vasanthakumar Ramu, VP - Head R&D - Peptides & Complex APIs, Alembic Pharmaceuticals; Dr Murali Jayaraman, Head - Formulation and Drug Product Development, Dr Reddy's Laboratories

The panel discussion titled 'Biologics and Biosimilars: The Next Leap in Patient-Centric Drug Development' at the FDD Conclave 2025 brought together leading minds in pharma R&D to examine how the next wave of innovation can better serve patients. The session addressed a crucial question: how can the future of biologics and biosimilars be shaped to prioritise accessibility, efficacy, and ease of use?

Moderated by Dr Ashok Omray, Pharma Consultant, the panel featured Dr Shubhadeep D Sinha, Sr VP and Head of Clinical Development & Medical Affairs at Hetero Labs; Dr Kamal Kumar Upadhyay, VP and Head of R&D Pharma SGI at Biological E; Dr Vasanthakumar Ramu, VP and Head of R&D - Peptides & Complex APIs at Alembic Pharmaceuticals; and Dr Murali Jayaraman, Head of Formulation and Drug Product Development at Dr Reddy's Laboratories. Together, the experts dissected both the opportunities and challenges surrounding biologics and biosimilars in the context of patient-centric development.

The discussion opened with a focus on peptide-based therapeutics, which have witnessed growing interest for their potential in targeted treatment. The panel stressed that such products must meet rigorous regulatory requirements to ensure consistent safety, efficacy, and quality—an expectation that is non-negotiable in today's pharma landscape. However, meeting these standards is not without challenges. One of the most significant scientific hurdles highlighted was impurity profiling in peptides, a process that demands highly specialised analytical approaches. As the complexity of peptide structures increases, so too does the need for innovative and precise methods to detect and control impurities.

Shifting focus to biosimilars, the panel emphasised that the goal of development must go beyond replication of originator products. Instead, biosimilars should strive to enhance patient outcomes by being not just clinically effective, but also user-friendly. This evolution is critical in a healthcare environment that increasingly values the holistic patient experience. To this end, the ability to self-administer medication at home was cited as a transformative feature in future biologics and biosimilars. Such formats not only reduce the burden on healthcare infrastructure but also empower patients, improve adherence, and support better long-term outcomes.

- Peptide-based products must rigorously adhere to regulations, ensuring safety, efficacy, and quality standards are consistently met.
- Accurate impurity profiling in peptides presents scientific and technical challenges that require innovative analytical strategies.
- The ultimate objective of biosimilar development should be to enhance patient outcomes through accessible, effective, and user-friendly therapies.
- Future biologics and biosimilars should prioritize self-administration capabilities, empowering patients and improving adherence.
- Ensuring the affordability and widespread availability of biosimilars remains a cornerstone for expanding patient access to advanced therapies.

Affordability and access emerged as central concerns as the session drew to a close. The panellists were aligned in their view that widespread adoption of biosimilars hinges on making them economically viable for a broader population. As healthcare systems globally face rising costs and uneven access to therapies, biosimilars hold immense promise in closing these gaps—provided the industry remains committed to their widespread availability.

The panel's insights reflected a common thread: that the future of drug development must be shaped not just in labs or boardrooms, but with the patient at the centre. With the right balance of scientific rigour, and innovation, biologics and biosimilars are poised to lead the next leap in patient-focused care.

FDD Leadership Awards 2025 celebrates the changemakers of FR&D

From promising rising stars to seasoned stalwarts, the awards highlighted those who are shaping the future of FR&D through their passion, vision, and impact

All winners of FDD Conclave 2025 alongwith the presenters and jury members

The seventh edition of the FDD Leadership Awards, and held alongside the FDD Conclave 2025, continued to uphold its legacy of recognising excellence and innovation in Formulation Research and Development (FR&D).

The evening commenced with a warm welcome from from Viveka Roychowdhury, Editor of Express Pharma, Express Healthcare, and Express Nutra. Addressing the gathering, she highlighted the mission behind the awards: to celebrate the individuals who are propelling FR&D towards a more impactful and innovative future.

Next, the jury members, Dr Sumedha Nadkar and Mr Suresh Pareek, who were in attendance for the event were felicitated for their invaluable contributions to the selection process. Roychowdhury thanked them for their discerning judgment. Special mention was made of jury members who couldn't attend – Dr KC Jindal, Dr Veerababu Taduri, and Abha Pant – whose insights were also instrumental behind the scenes.

Subsequently, Manish Jain, MD, Cilicant, and Vijay Doshi, MD, Pioma Chemicals, as the presenting and co-presenting partners of the event, took the stage to give away the awards to this year's recipients. The jury members and Roychowdhury also joined them in this endeavour. *(Check adjacent box for the winners).* Each winner was invited to say a few words, making the evening personal and heartfelt.

The FDD Leadership Awards 2025 closed on a high note with a networking dinner and cocktails, giving attendees a chance to engage, collaborate, and celebrate the spirit of the FR&D community. The event reinforced the importance of recognising talent, nurturing innovation, and building a strong ecosystem for pharma advancement. It also served as a powerful platform to spotlight the evolving priorities of India's pharma sector, from fostering young talent to acknowledging strategic leadership and honouring lifelong contributions.

As the evening drew to a close, one message rang clear: the future of FR&D in India is in capable, visionary hands.

THE AWARDS WERE GIVEN IN THREE KEY CATEGORIES

Stalwarts: This segment recognised the veterans whose contributions are transforming the FR&D landscape

- Dr Ajay Khopade
- Dr Rakesh Bhasin

Leaders: This segment acknowledged achievers demonstrating strategic vision and leadership

- Mr Balvir Singh
- Mr Bijayananda Sahoo
- Dr Pramod Kharwade
- Dr Rahul Hasija
- Dr Vasanthakumar Ramu

Rising Stars: This category celebrated young professionals showing exceptional promise

- Mr Ashok Dewangan
- Mr Kesavalu Purushothaman
- Mr Rakesh Kumar Singh
- Dr Sachin Naik

#FDDConclave

CILICANT
ACTIVE PACKAGING®

PRESENTS

EXPRESS PHARMA

FDD LEADERSHIP AWARDS 2025

POWERED BY

PIDILITE chemicals
Partnering Through Innovation

Congratulations!

Kudos to all the winners of **FDD Leadership Awards 2025**

Keynote Address

Day two at the FDD Conclave 2025 began with a highly insightful and motivating keynote address by Dr Pavan Bhat, CEO, Inventia Healthcare. The presentation set the tone for the day by emphasising the critical role of formulation scientists in addressing global healthcare challenges through innovation, responsibility, and patient-centric thinking.

Dr Bhat reflected on the journey that begins at the lab bench, where formulation starts with literature reviews, patents, de-formulation, and countless trials. At this stage, the focus lies in getting the science right. Dr Bhat emphasised how the field is brimming with opportunities and how rapidly new molecules, markets, and regulations would reshape the landscape.

Dr Pavan Bhat, CEO, Inventia Healthcare

The dosage form does more than deliver the drug; it delivers access. Dr Bhat emphasised its importance by stating that what scientists formulate today defines care tomorrow. He conveyed that formulators must continuously adapt to evolving scientific, regulatory and operational demands and not be deterred by failure. He also explained how speed is now part of innovation. Innovation is not just doing it better. It's doing it faster, with fewer iterations, and fewer regulatory surprises

Dr Bhat reflected on his journey from lab to leadership, highlighting how his scientific focus evolved into a broader business perspective. The shift, he noted, wasn't just technical, but in thinking directionally, aligning science with real-world outcomes and responsibilities.

Finally, sharing insights from his experience, he delivered a message to the future formulators. Future formulators must adapt to scientific, regulatory, and operational forces. They must focus on bridging science and public health by translating global health needs into precise, stable, and accessible formulations.

Panel Discussion: Topical and transdermal drug delivery: The rise of non-invasive therapies

L-R: Suresh Pareek, Angel Investor (Pharma) (MODERATOR); Bijayananda Sahoo, Group Head, R&D - Formulations, Alembic Pharmaceuticals; Dr Sumedha Nadkar, Pharmaceutical Strategy and Technology Consultant, Viridis BioPharma; Mathivanan Rajagopal, VP, Head – R&D, Axxlent Pharma Science; Ashok Dewangan, GM - Transdermal, Encube Ethical

As the push for non-invasive, patient-centric treatment options intensifies, topical and transdermal drug delivery systems are gaining renewed attention. From dermatological treatments to systemic therapies, advances in formulation are expanding the scope and impact of these delivery platforms across therapeutic areas. Addressing these points, our set of panellists delved into the science, technology, and commercial potential behind these routes of drug administration in the first panel at day two of the conclave.

Our esteemed panellists included Suresh Pareek, Angel Investor (Pharma), as the moderator; accompanied by Bijayananda Sahoo, Group Head, R&D - Formulations, Alembic Pharmaceuticals; Dr Sumedha Nadkar, Pharmaceutical Strategy and Technology Consultant; Ashok Dewangan, GM - Transdermal, Encube Ethicals; and Mathivanan Rajagopal, VP, Head – R&D, Axxlent Pharma Science.

The panellists discussed the potential of topical and transdermal drug delivery systems in meeting the growing demand for non-invasive, patient-friendly treatment options. They highlighted key benefits such as the ability to deliver drugs directly to a targeted local site, which can enhance therapeutic efficacy. Additionally, these systems offer controlled and sustained drug release, improving patient compliance and reducing dosing frequency.

However, the panellists agree that, along with its benefits, such drug delivery systems do have their challenges. For topical drug delivery, one of the first hurdles lies in selecting suitable drug candidates. While, repeated application of topical formulations may cause skin irritation or sensitisation, impacting patient adherence and limiting the long-term usability of such therapies.

When it comes to transdermal patches, factors such as patch discomfort, detachment during daily activities, or visible placement on the skin can deter consistent usage, making patient adherence a significant challenge. In the case of microneedle-based drug delivery, while the technology holds considerable promise for pain-free, minimally invasive administration, the panel acknowledged that commercial scalability remains a major hurdle. Manufacturing microneedles with the precision and consistency required for regulatory approval while keeping production cost-effective is a complex task that many developers are still working to overcome.

The discussion also brought attention to regulatory ambiguities, particularly for topical formulations. Unlike oral dosage forms, regulatory guidelines for topical drugs are not always clearly defined across markets. Establishing bioequivalence by demonstrating that a generic topical product performs similarly to its branded counterpart is one of the most critical and unresolved regulatory challenges.

A less explored but highly promising area discussed by the panel was intranasal drug delivery. The panel discussed that one of the most notable applications in this space is inhalable insulin, which has shown encouraging results in offering a non-invasive alternative to injectable insulin for diabetes management. Beyond systemic delivery, the panel also highlighted the exciting, yet still developing, potential of using the nasal route for direct drug delivery to the brain. This could open new therapeutic avenues for treating central nervous system (CNS) disorders such as Alzheimer's. However, challenges such as formulation stability, device design, and targeting efficiency continue to limit widespread adoption, making this a key area for future research and innovation.

In conclusion, advances in formulation science and patch technologies are significantly expanding the possibilities for non-invasive drug delivery.

- Topical and transdermal drug delivery have immense advantages such as targeting drug to a local site, controlled drug delivery and systemic action.
- Challenges for topical drug delivery include selecting suitable drug candidates, limited drug loading capacity and skin irritation.
- For transdermal patches, adherence remains an obstacle. While, for drug delivery involving microneedles, a major hurdle is commercially scaling that product.
- Regulatory guidelines for topical formulations are not clearly defined. Establishing bioequivalence is one of the most critical regulatory challenges for topical formulations.
- A less explored area, intra-nasal drug delivery has a lot of potential. Inhalable insulin is one of the promising therapies under this category, while areas still under exploration are direct drug delivery to the brain.

Panel Discussion: Beyond the needle: Innovations in painless drug delivery

L-R: Dr Jaya Abraham, Head - R&D-India Subcontinent, Haleon (MODERATOR); Satish Chandra Upadhyay, Associate President, Mankind Pharma; Dr Manoj Kumar Singh, Sr VP – Analytical R&D, Micro Labs; Dr Pramod Kharwade, VP-Formulation Development, Intas Pharmaceuticals; Dr Ritu Laddha, Sr VP (F&D), Zydus Lifesciences

- Painless drug delivery systems improve patient adherance, especially in long-term therapies or chronic treatment.
- Nasal drug delivery offers significant promise and potential as it can be used for local delivery as well as systemic delivery. It also offers fast onset of actions, doesn't cause GI disturbances as advantages.
- Organ-on-chips is another drug delivery method which can be painless, safe and effective, reducing the need for invasive trials.
- Cross disciplinary collaborations are essential to spur and encourage innovation in formulation and drug delivery.
- Painless drug delivery systems need to deal with several formulations challenges as well such as solubility, tolerability, absorption. Success depends on designing drugs that can penetrate skin or mucosa without losing efficacy.
- We live in a world driven by technology. We should leverage these advancements to usher more innovation that will help patients in improved ways.

Drug delivery is undergoing a transformation driven by the demand for patient-friendly, pain-free alternatives. As pharma R&D shifts toward improving compliance and therapeutic outcomes, an interesting panel discussion at FDD Conclave 2025 discussed the cutting-edge innovations in pain-less drug delivery methods and technologies.

As the moderator, Dr Jaya Abraham, Head - R&D-India Subcontinent, Haleon, led the panel. Panellists included Satish Chandra Upadhyay, Associate President, Mankind Pharma; Dr Manoj Kumar Singh, Sr VP – Analytical R&D, Micro Labs; Dr Ritu Laddha, Sr VP (F&D), Zydus Lifesciences; and Dr Pramod Kharwade, VP-Formulation Development, Intas Pharmaceuticals.

The panellists began by discussing the advantages of painless drug delivery systems. Such methods are improving patient adherence, particularly in long-term therapies or chronic disease management. The panel highlighted how such systems not only enhance patient comfort but also simplify administration, making them especially valuable for paediatric, geriatric, and needle-phobic populations.

The experts also discussed how nasal drug delivery offers significant promise due to its versatility and unique physiological advantages. It enables both local and systemic delivery. Additionally, nasal delivery reduces the risk of GI disturbances and enhances bioavailability for drugs that are poorly absorbed or degraded when taken orally.

The panel also explored the emerging role of organ-on-chip technologies in the context of drug delivery. By mimicking the structure and function of human organs on a microscale, organ-on-chip platforms can simulate how drugs behave in specific tissues, allowing researchers to optimise formulations and delivery methods without the need for invasive clinical trials. Though still in its early stages for direct drug delivery applications, the technology holds considerable promise in enabling more personalised and precise treatment strategies in the future.

Additionally, the panel emphasised that cross-disciplinary collaborations are essential to drive innovation in formulation and drug delivery. Partnerships can accelerate problem-solving and help translate laboratory breakthroughs into scalable, commercially viable solutions.

While painless drug delivery systems offer clear benefits for patient adherence, they also present several formulation challenges. Key among these are ensuring drug solubility, tolerability, and effective absorption through the skin or mucosal barriers. Unlike injectable routes that deliver drugs directly into the bloodstream, non-invasive systems must overcome the body's natural protective layers. Success in these systems depends on designing drug molecules and corresponding formulations that can penetrate these barriers without compromising efficacy or causing irritation. The panel stressed that achieving this balance is critical to unlocking the full therapeutic potential of painless delivery technologies.

We live in a world increasingly driven by technology, and the pharma sector must harness these advancements to fuel innovation in drug delivery. By embracing these innovations, the industry can create more effective, convenient, and personalised treatment options, ultimately improving patient outcomes and quality of life.

Panel Discussion: Future-ready formulations: Addressing the challenges of special population

L-R: Dr Pirthipal Singh, Head-R&D, Tirupati Group (MODERATOR); Dr Ravindra Agarwal, Sr VP, Mankind Pharma; Elayaraja Natarajan, VP - R&D, Lyrus Life Sciences; Vinod Arora, Principal Advisor, IGMPI; Dr Vaibhav Sihorkar, VP & BU Head- Formulation Solutions, Aragen; Dr Sachin Mundade, Vice President - R&D, Micro Labs; Dr Balasubramaniam Jagdish, VP - Formulation Development (PDU), Recipharm Pharmaservices; Srinivasan Rajaman, GM, Medreich

The final panel discussion on Day 2 of the FDD Conclave 2025 focused on how formulation science can evolve to better serve special populations, including paediatric, geriatric, and immunocompromised patients. The conversation explored the intersection of technology, patient-centricity, and regulatory innovation in developing future-ready drug delivery systems.

The discussion titled, 'Future-Ready Formulations: Addressing the Challenges of Special Populations' was moderated by Dr Pirthipal Singh, Head of R&D at Tirupati Group. Joining him on the panel were Dr Ravindra Agarwal, Sr VP at Mankind Pharma; Elayaraja Natarajan, VP - R&D at Lyrus Life Sciences; Dr Sachin Mundade, VP - R&D at Micro Labs; Vinod Arora, Principal Advisor at IGMPI; Dr Balasubramaniam Jagdish, VP - Formulation Development (PDU) at Recipharm Pharmaservices; Srinivasan Rajaman, GM at Medreich; and Dr Vaibhav Sihorkar, VP & BU Head - Formulation Solutions at Aragen.

The panel opened with an emphasis on the importance of patient-centric design as the foundation of future formulation strategies. For drug products intended for paediatric and geriatric populations in particular, factors such as palatability, swallowability, and ease of administration emerged as non-negotiable attributes that directly influence patient adherence and outcomes.

While patient needs form the heart of development efforts, the panel also highlighted that innovation must be balanced with regulatory compliance and technological scalability. Future-ready formulation strategies, they noted, rely on the convergence of three essential pillars: understanding patient-specific needs, meeting evolving regulatory expectations, and leveraging technology in ways that can be implemented at scale. Within this framework, excipients were identified as both enablers and potential roadblocks. Their selection, compatibility, and impact on the stability and effectiveness of drug products must be managed with precision to avoid downstream formulation challenges.

The conversation then turned to the role of emerging technologies like artificial intelligence and 3D printing. These tools offer exciting possibilities for customising dosage forms for niche patient groups and improving formulation efficiency. However, the panel also acknowledged that there are foundational gaps that must be addressed before these technologies can be fully embedded into routine R&D processes.

As the discussion evolved, the focus briefly expanded to include novel therapeutic frontiers such as cell and gene therapies. These approaches hold transformative potential for the treatment of complex diseases, including cancer, HIV, and genetic disorders, underscoring the need for formulation science to keep pace with advancements in biotechnology.

The session concluded on a note of cautious optimism, with consensus that a future-ready approach to formulation development must blend scientific rigour, emerging technologies, and a deep sensitivity to the needs of vulnerable patient groups.

- Future-ready formulations: Addressing the challenges of special populations.
- Future-ready formulations must prioritise patient centricity, with emerging technologies playing a key role in shaping next-generation solutions.
- Factors like palatability and swallowability play a key role in pediatric and elderly formulations
- The convergence of three critical elements—patient centricity, regulatory-aligned innovation, and scalable technologies—is essential for progress.
- Foundational gaps must be addressed before fully integrating advanced technologies like AI into formulation development.
- Technologies like AI, 3D printing, enable formulation design to tailor dosage forms for specific populations.
- Excipients can be either enablers or obstacles in the journey toward future-ready formulations, depending on how they are selected and managed.
- Liquid formulations hold strong potential, particularly for geriatric and pediatric populations, due to ease of administration and improved patient compliance.
- Cell and gene therapies have great potential to revolutionise treatments of major diseases like cancer, HIV, genetic disorders etc.

STRONGER TOGETHER

CILICANT

PIOMA

LONZA CAPSULES & HEALTH INGREDIENTS

MERCK LIFE SCIENCE

SIGACHI INDUSTRIES

ROMACO INDIA

NITIKA PHARMACEUTICAL SPECIALITIES

HARRO HOEFLIGER PACKAGING SYSTEMS

DHARA LIFESCIENCE

BASF

COLORCON

CHEMISCHE FABRIK BUDENHEIM KG

STRONGER TOGETHER

ARIHANT INNOCHEM

LACTOSE INDIA

HOVIONE HOLDING ASIA

SCHEMATIC ENGINEERING INDUSTRIES

SWALAVA ENTERPRISES

VALGENESIS

VIKRAM THERMO (INDIA)

HUGOPHARM TECHNOLOGIES

AUTOMED SYSTEMS

SRICO

PHARMA TEST INDIA

REGISTRATION

'PARTNERS IN PROGRESS'

'PARTNERS IN PROGRESS'

'PARTNERS IN PROGRESS'

'PARTNERS IN PROGRESS'

'PARTNERS IN PROGRESS'

'PARTNERS IN PROGRESS'

'PARTNERS IN PROGRESS'

EXPRESS PHARMA

CILICANT ACTIVE PACKAGING®

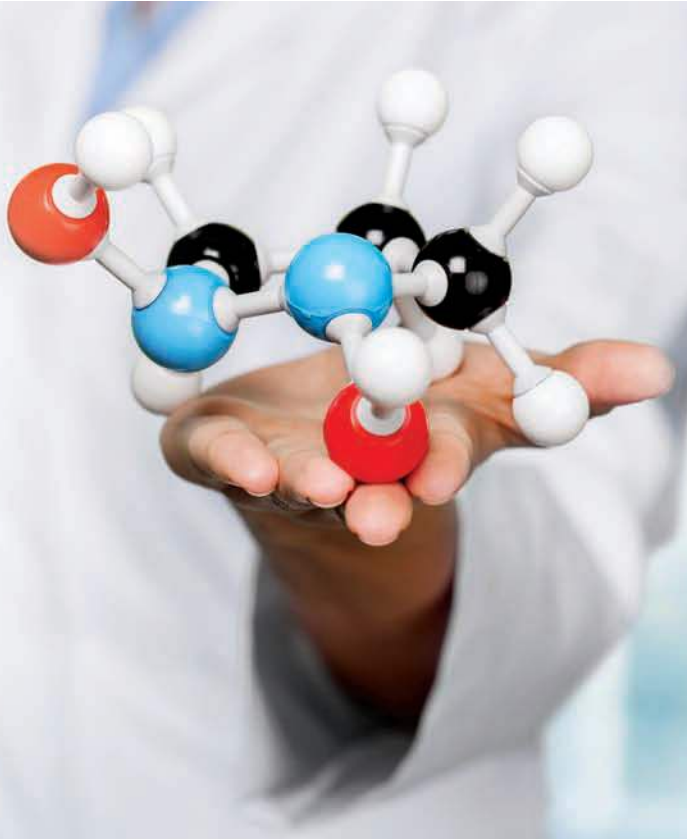
PRESENTS

FDD CONCLAVE 2025

FORMULATION DEVELOPMENT & DRUG DELIVERY CONCLAVE

POWERED BY

PIOMA chemicals
Partnering Through Innovation



13-14 JUNE 2025

LE MERDIEN HYDERABAD

FROM LAB TO LIFE: BRIDGING SCIENCE AND CARE

#FDDConclave

THANK YOU

WE THANK OUR PARTNERS, SPEAKERS AND PARTICIPANTS FOR EXTENDING THEIR SUPPORT IN MAKING THE FDD CONCLAVE 2025 A GRAND SUCCESS

PARTNERS

CILICANT ACTIVE PACKAGING® — PRESENTING PARTNER	PIOMA chemicals — POWERED BY PARTNER	Lonza Capsules & Health Ingredients — GOLD PARTNER	MERCK — GOLD PARTNER	SIGACHI — GOLD PARTNER	ROMACO beyond technology — GOLD PARTNER
NITIKA — GOLD PARTNER	HH Harro Höfliger — GOLD PARTNER	Methacrylic Acid Copolymer Dhara Lifescience Pvt. Ltd. Color Ready mix — GOLD PARTNER	BASF We create chemistry — SILVER PARTNER	Colorcon — SILVER PARTNER	Budenheim — SILVER PARTNER
ARIHANT INNOCHEM PVT. LTD. — SILVER PARTNER	LACTOSE INDIA LIMITED — SILVER PARTNER	Hovione — SILVER PARTNER	SCHEMATIC Containment | Reliability | Flexibility — SILVER PARTNER	SWALAVA स्वलवा Solid solution for better life — SILVER PARTNER	VALGENESIS — SILVER PARTNER
Since 1985 Vikram THERMO (INDIA) LTD. — SILVER PARTNER	HUGOPHARM Systems Engineered with Mind & Spirit — SILVER PARTNER	AUTOMED CONTAINED . ASEPTIC . PROCESS AUTOMATION — SILVER PARTNER	SRICO INNOVATIVE LABORATORY TECHNOLOGY — SILVER PARTNER	PHARMA TEST — SILVER PARTNER	

Laying the digital foundation: How patient suites are reshaping the future of clinical trials

Anthony Mikulaschek, IQVIA, outlines how patient suites are reshaping clinical trials by aligning digital tools around the patient journey to enable faster, more reliable outcomes

Developing a successful clinical trial is like laying a foundation — every brick must be placed with precision. Each tool, workflow and touchpoint must align seamlessly to support a reliable structure. Any misalignment introduces risks that can compromise the trial's integrity and ability to deliver the end points required. In today's increasingly complex research landscape, this foundation is digital.

From patient enrollment to final data capture, each phase of the patient's clinical trial journey generates vast amounts of data. Capturing this data consistently, accurately and efficiently is crucial. According to the National Institutes of Health, an average 12-month trial involving 2,000 patients can generate up to 3 million data points. When handled manually, a trial of the same size has the potential to produce nearly 10 million opportunities for error.

Yet, many trials still rely on fragmented systems, outdated workflows and manual processes. These inefficiencies hinder progress and amplify the risk of data inaccuracies. To overcome these challenges and reduce the potential for costly errors, clinical trials must implement an integrated data strategy utilising a patient suite.

When thoughtfully designed and implemented correctly, a patient suite acts as the digital foundation of a clinical trial, streamlining efficient and accurate data capture, supporting regulatory compliance and enhancing the overall patient experience. In return, this reduces the potential for costly delays and boosts the chances of trial success.

The patient journey as the blueprint

A patient's journey through a clinical trial is more than just a series of check-ins and assessments. It is a continuous stream of critical touchpoints, each generating data that impacts the trial outcome. This data must be captured, analysed, contextualised and readily accessible across the trial's life cycle.

To ensure that trials can operate smoothly, sites and sponsors need systems that not only can capture this data but also reflect a deep understanding of the patient experience behind it. This understanding becomes the blueprint for improving trial efficiency, maintaining regulatory standards and safeguarding patient well-being.

The foundation: What is a patient suite?

A patient suite is not a single platform but a cohesive collection of advanced digital tools that work together to create a seamless experience for sponsors, sites and patients. When integrated, these tools can eliminate data silos, reduce operational friction and improve trial performance.

Think of the patient suite as the digital infrastructure of a clinical trial. When it operates behind the scenes, it remains centered on the patient — streamlining interactions, enhancing clarity and reducing burdens that can contribute to patient dropouts or disengagements.

For sponsors, a well-integrated suite supports the generation of cleaner data and faster timelines. It also enables smarter trial design and ensures compliance at every step. Ultimately, a patient suite isn't just a convenience, it's a strategic imperative for modern clinical trials.

The core components of a patient suite

Each part of a patient suite contributes a different "brick" to the foundation. In total, there are four key bricks, or pillars, that enable the suite to function as an integrated system:

◆ **Electronic clinical outcome assessments:** Patient-reported insights are essential for evaluating a treatment's effectiveness, especially in trials focused on quality of life or symptom relief. Digitally capturing these insights via eCOAs brings significant advantages:

◆ **High-quality data:** Electronic entry reduces transcription errors and produces timestamped, traceable entries.

◆ **Improved compliance:** Mobile-friendly tools and automated reminders help patients complete assessments on time.

◆ **Real-time monitoring:** Sites can quickly gain visibility into patient data, helping identify issues, trends or missed assessments that could impact a trial's outcome.

◆ **Interactive Response Technology:** As clinical trials scale across sites and regions, traditional processes can become a liability. To eliminate these challenges and risks, IRT systems can automate trial logistics, such as patient randomisation, drug supply management and visit tracking. A reliable IRT system forms the operational backbone of a trial, minimising any manual burdens and prioritising smooth workflows.

◆ **eConsent:** Consent is a pivotal moment within the life cycle of a clinical trial. During this phase, both compliance and trust are established between the trial (sponsor and site) and the patient. Modern eConsent tools offer a simpler path for:

◆ **Sites:** Streamlined workflows, single sign-on functionality and easy version control reduce administrative burden and minimise the likelihood of introducing errors.

◆ **Sponsors:** A comprehensive eConsent program ensures global regulatory compliance, boosts recruitment and retention rates and provides data for optimising study design.

◆ **Participants:** The implementation of thoughtful, interactive and accessible content improves understanding and supports informed decision-making. Patients can mark sections for discussion, review on any device and access content tailored to diverse needs, including pediatric or cognitively impaired populations.

◆ **Connected devices:** Accord-

Vitafoods™ India

informa markets

Title Partner

KSM-66 Ashwagandha®

WORLD'S BEST ASHWAGANDHA

Be a part of India's only nutraceutical event that brings the entire supply chain under one roof.

Discover, engage and growth with

10,000+	200+	40+	40+
expected attendees	exhibitors	countires represented	expert speakers

Join us in **2026**

11 - 13 February, 2026

Pavilion 1-3, Jio World Convention Center, Mumbai

Book a stand

ing to a late 2024 report by Deloitte, 43 per cent of consumers now use connected monitoring devices and digital tools for their health. These devices can empower the wearers with actionable insights while enhancing convenience by reducing the need for in-person visits. Additional benefits include:

◆ **Continuous monitoring:** Wearables capture data continuously, offering richer insight into treatment effects.

◆ **Remote engagement:** Patients stay connected without frequent site visits, which is especially valuable for rare diseases or global trials.

◆ **Early detection:** Devices can identify hidden trends in real-time, alerting sites to potential safety issues before they escalate.

Connected devices extend the reach and precision of a clinical trial, transforming how data is acquired, monitored and utilised.

◆ **Real-world benefits:** From workflow to outcomesWhen eCOA, IRT, connected devices and eConsent are part of an integrated suite, the result is a robust digital foundation for clinical trials. Sponsors benefit from a unified stream of high-quality, real-time data that supports agile decision-making. For research sites, less time is spent troubleshooting technology issues and more time can be dedicated to delivering high-quality patient care.

From a participant's point of view, they experience a smoother journey, from enrollment to study completion, with fewer redundancies, clearer instructions and reduced reporting burdens. This increases retention rates, engagement and reliable trial outcomes.

This integrated approach also improves data quality by reducing errors and ensuring protocol adherence. Optimised digital workflows speed up critical phases like enrollment, randomisation and monitoring, leading to faster trial timelines. Finally, from a compliance perspective, built-in audit trails and automated reporting functions ensure that trials are inspection-ready from the outset.

When technology works in harmony across the entire clinical trial ecosystem, everyone benefits, from sponsors to the patients.

◆ **Lessons learned:** Common Pitfalls in Building the Foundation

Despite the benefits of an integrated and comprehensive patient suite, there are common missteps that can derail and hinder the success of a clinical trial. These include:

◆ **Disjointed systems:** When systems are not interoperable, data entry is often duplicated and manual, increasing error rates and nullifying digital efficiencies.

◆ **Poor user experience:** If a patient suite is poorly implemented, it will feel clunky, create frustration and increase the risk of dropout.

◆ **Site exclusion:** Sites, like the patients, are just as deeply engrained with the patient suite. Failing to include their requirements when selecting technology and deployment strategies undermines adoption and effectiveness.

The Future Is Built Brick by BrickConstructing a successful clinical trial, much like building a structure, starts with a solid foundation. Every tool, workflow and interaction with the patient must fit together with precision. When sponsors and sites invest in a fully integrated, patient-centered suite of technologies, they are not just adopting one-time use tools. They are laying the groundwork for expediated timelines, refined and actionable data, and better overall outcomes.

Clinical success no longer hinges on isolated systems or ad hoc solutions. True success is the result of thoughtful design, collaboration and commitment to seamless execution. An integrated patient suite isn't a future luxury — it's a present-day necessity. For trials to thrive in today's complex environment, the digital foundation for clinical trials must be rooted in interconnectivity and built with the patient and site in mind from day one.

Traditional Enteric-Coated Capsules vs a Next-Generation Polymer Capsule

Learn more about the award-winning Capsugel® Enprotect® capsule platform

What are "enteric coated" capsules and why are they used?

Enteric coating refers to a dosage form (e.g. capsule) of an oral medication that is coated with a polymer. Gastro-resistant coating began in 1884 with keratin-coated pills, which failed to withstand gastric digestion. Since then, enteric coating has been widely used in the manufacturing of various drug formulations, including capsules.

The purposes of enteric coating are to promote optimal drug bioavailability by protecting an acid-sensitive active pharmaceutical ingredient (API) from early degradation in the acidic milieu of the stomach and reduce the incidence of gastric side-effects from exposure of gastric mucosa to harmful drugs. Additional benefits of enteric-coated capsules include helping improve product stability, taste, and ease of swallowing, while enabling modified release properties.

How are enteric capsules produced?

There are currently three approaches to the formulation of enteric capsules:

(1) Coating as an add-on, final step in the manufacturing process

(2) Solvent-based coating applied to capsules prior to filling

(3) Capsules made from gastro-resistant polymers that do not require additional coating

Polymers commonly used include cellulose acetate phthalate, methacrylic acid copolymers and hydroxypropyl methylcellulose phthalate.

How do enteric absorption sites differ?

The pH of the small intestine ranges from 6 in the duodenum to around 7.4 in the terminal ileum. Different regions in the intestine have different drug absorptive properties, often specific to a narrow pH range at a specific site. A bi-layered polymer capsule is a suitable option for mid-gut or distal intestinal delivery of acid-labile APIs.

How a bi-layered polymer can protect acid-sensitive API and accelerate drug development

Traditional enteric-coated capsules typically require a post-filling coating, which could expose APIs to heat and/or solvents. Below, we explore the relative benefits of deploying a bi-layered polymer capsule that enables enteric delivery without the need for post-filling coating or sealing. Alongside the potential safeguarding of an active ingredient, removing the need for an additional coating step and associated processes can also expedite manufacturing.

What are enteric "bi-layered polymer" capsules and their advantages?

In bi-layered polymer technology, two polymer layers are seamlessly bonded, providing high levels of gastric protection, targeted API release and delayed dissolution. These polymers are hydroxypropyl methylcellulose (HPMC)—"hypromellose"—and hydroxypropyl methylcellulose acetate succinate, or "HPMC-AS." The more recent polymer blends have several advantages: pharmaceutical compliant dissolution, compatibility with moisture-sensitive drug formulations (HPMC), and pharmaceutical compliant enteric disintegration (HPMC-AS). The HPMC layer is manufactured using a thermogelling process, followed by a second dipping step applying an outer layer of enteric HPMC-AS.

More about HPMC/ HPMC-AS as enteric capsule polymers

HMPC as inner layer

HPMC was introduced as a non-animal alternative to gelatin in the early 2000s. Today's HPMC capsules are regarded as "second-generation"; first-generation HPMC capsules do not dissolve quickly or consistently, potentially rendering the payload ineffective and delaying its release. Such effects are especially problematic when formulating immediate-release drug products. Newer HPMC capsules are engineered to mitigate these issues around dissolution, including thermogelling. Consistent and predictable dissolution performance of the capsule excipient allows formulators to avoid costly and repetitive stability tests, saving time in the drug development process.

HMPC-AS as outer layer

HPMC-AS has various grades that dissolve from pH 5.5 to 7. Therefore, HPMC/HPMC-AS capsules protect an acid-sensitive drug payload, depending on the polymer grade selected; the varying pH of media around HPMC-AS influences its water solubility, thereby allowing a site-specific payload release profile.

Unique Capsugel® Enprotect® Capsule

The Capsugel® Enprotect® capsule comprises a polymer shell with an outer layer of HPMC-AS, which dissolves in pH of ~6, and an inner layer of HPMC interfacing with the API, which dissolves easily at any pH. The capsule is robust and made to very fine tolerances, lending itself to high-speed filling with the minimum of losses.

Conclusion

Coating of capsules as an independent step, with its inherent limitations, was formerly the only option to achieve acid-protection. In seeking to overcome these challenges, Lonza CHI's investment and advances in polymer technology, coupled with a unique patented manufacturing process, have created a new class of capsules for enteric drug delivery.

Without the need for the post-filling enteric coating step, Capsugel® Enprotect® capsules open new possibilities for formulators, overcoming many of the challenges of enteric delivery and the limitations of enteric-coated capsules.

Scan to know more

Faster time to market with Continuous Direct Compression

Development and production using Continuous Manufacturing

The production of medicines and food supplements is experiencing a real innovation boost thanks to Continuous Manufacturing processes. For a long time, manufacturers hesitated in the face of cost-intensive conversions, time-consuming revalidation and complex systems with large space requirements. However, Continuous Manufacturing is now proving that end-to-end production can also be space-saving, uncomplicated and economical. With the FE CPS, Fette Compacting is underlining this development and at the same time positioning itself as an integrated process partner.

In order to make continuous manufacturing more economically attractive, Fette Compacting fundamentally reviewed the concept of continuous direct compression a few years ago. The original approach was still strongly oriented towards established principles of pharmaceutical processing and the combination of existing systems. In order to fully utilize the advantages of continuous direct compression, it was necessary to rethink the entire process and system design.

The resulting processing system FE CPS (Continuous Processing System) establishes a reliable, powerful and highly flexible technology for the continuous production of pharmaceutical and nutraceutical products. The principle of Direct Compression enables the immediate transfer of the powder: it is transferred from the dosing-mixing unit directly to the tablet press via a flexible transport system (Fig. 1). Unlike conventional processes with wet or dry granulation, this eliminates several process steps, significantly reducing space requirements, energy consumption and overall costs. The developers designed the system for a wide range of application scenarios: It processes a wide range of ingredients with a flexible throughput of between five and over 200 kilograms per hour.

Fig. 1: A highly compact Continuous Direct Compression system consisting of the FE CPS Continuous Processing System (right), an FE55 rotary tablet press (left) and a central HMI operating terminal for both systems (center)

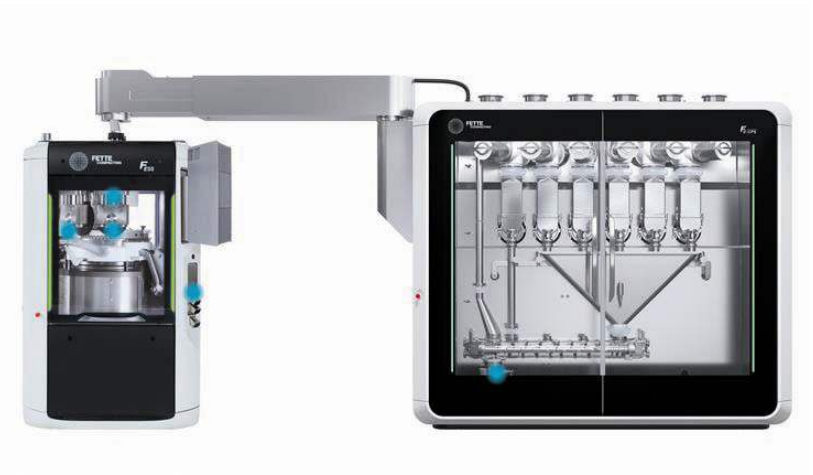


Fig. 2: Possible measuring positions for ePAT NIR sensors (an additional potential measuring point could be set up using an external tablet inspection device with NIR)

Inline quality control

In addition to the optimal interaction of all process steps, quality assurance and efficiency of continuous production depend largely on the integrated analysis technology. With ePAT (embedded process analysis technology), Fette Compacting has developed a solution that is fully integrated into the system: Sophisticated sensors monitor crucial quality attributes at four strategic points (Fig. 2). At the first three measuring positions - at the outlet of the mixer, at the inlet of the tablet press and in the Fill-O-Matic (Fig. 3) - BU (Blend Uniformity) sensors check the homogeneity of the blend. At the fourth position, a TU sensor (Tablet Uniformity) checks each individual finished tablet immediately before it is ejected. These real-time measurements enable immediate detection of quality deviations, allowing operators to react immediately with process adjustments.

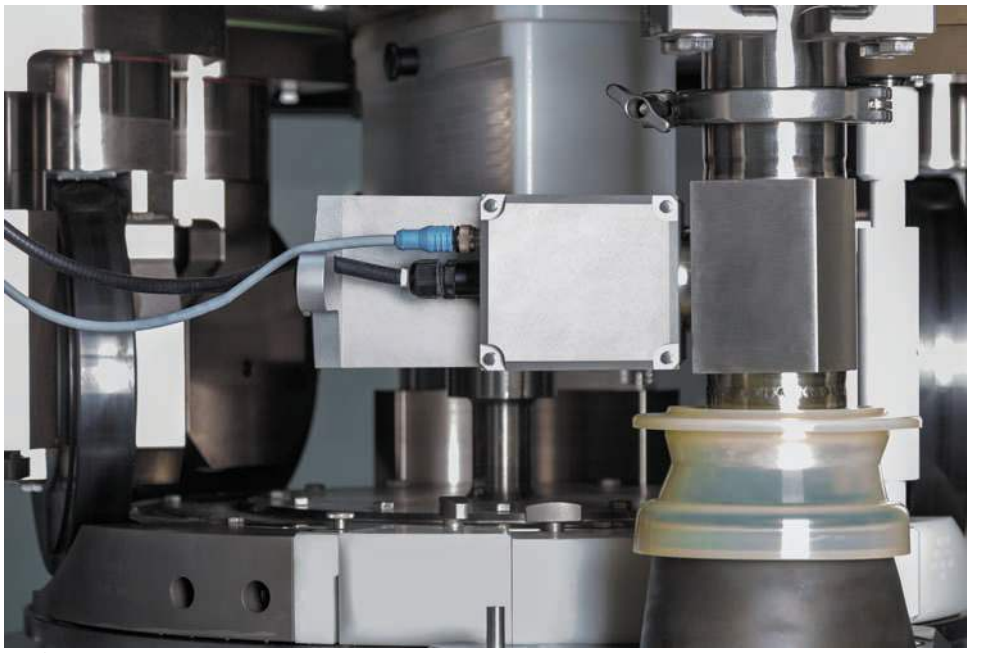


Fig. 3: Near-infrared sensor integrated into the production process in the filling tube of a rotary tablet press (BU measuring head in side view)

This measurement technology creates the basis for real-time release testing. Continuous monitoring is particularly important in product development in order to optimize the mixing process in a targeted manner. The measurements are generally based on near-infrared spectroscopy (NIRS), which has proven to be particularly efficient. In

the spectral range between 750 and 2,200 nanometers, it detects numerous different active ingredients without damaging the products. NIRS enables ultra-fast quality controls and provides information on both the chemical and physical properties of powders and tablets.

The exact use of the measuring points depends on the respective objective: while several sensors plus an optional additional NIR Checkmaster are usually used in development, one or two strategically placed measuring points are usually sufficient for continuous monitoring of critical quality attributes in ongoing production. Alternatively, the BU and TU sensors can also be used in classic batch-to-batch production, both in combination with FE Series tablet presses and with the new i Series from Fette Compacting.

Starting signal for early collaboration

In order to gain a comprehensive understanding of materials and continuous production processes, a multidisciplinary team of experts was put together during the development of the FE CPS. Their expertise played a key role in redesigning continuous manufacturing while supporting customers at every stage of the introduction of this technology - both in development and in production operations.

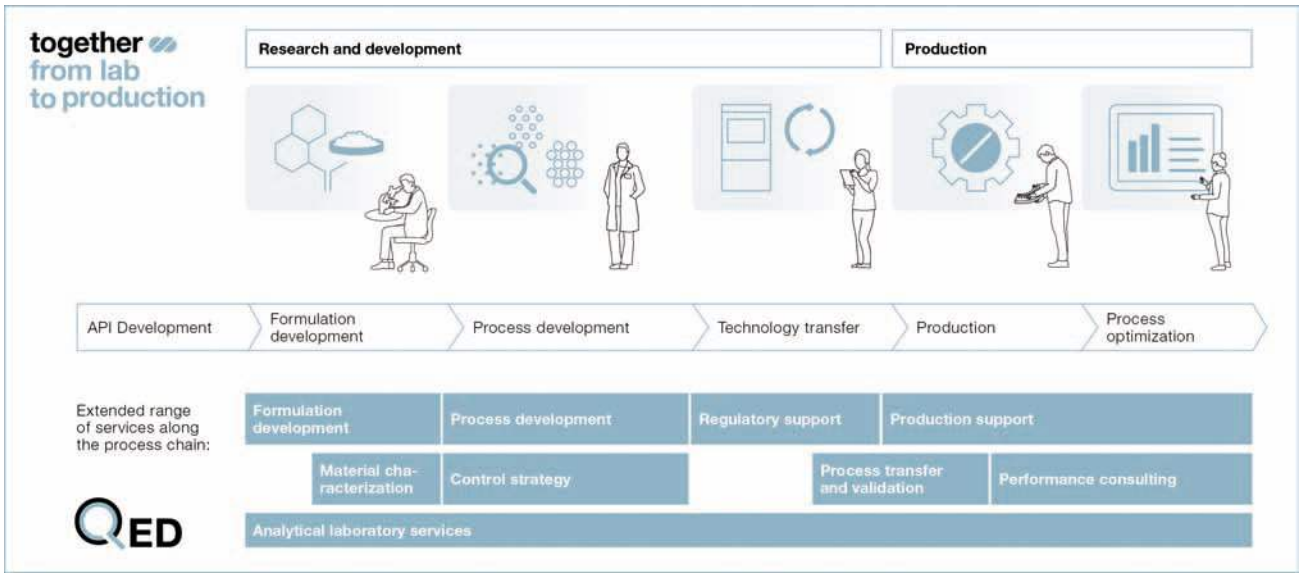


Fig. 4: The holistic process partnership with Fette Compacting begins with early formulation development and extends to process optimization in ongoing production

The innovative understanding of processes and close, early collaboration with customers are now an integral part of Fette Compacting's corporate culture - in line with the new strategic guiding principle "Together - from lab to production" (Fig. 4). FE CPS has thus made a significant contribution to further advancing process development.

Optimizing formulations faster

The efficiency of FE CPS is already evident in the development phase: compared to batch production, the amount of material used is reduced by up to 90 percent, while the test time can be reduced from three months to one day. These advantages are supported by special emulators: Unlike simulators, they allow tests under real production conditions without conversion steps and loss of time, for example for filling and dosing in the FE CPS, which can be emulated with the FE CPS Process Emulator. Users can thus validate their recipes and process parameters at an early stage and identify potential faults as early as the development phase.

Expansion to highly regulated environments

Current successes show that Fette Compacting is further strengthening its role as a reliable partner in early development phases with the FE CPS - even under strict regulatory requirements. An important step in this context is the collaboration with CMIC, a contract manufacturer in the USA, to drive forward continuous manufacturing in a regulated environment. The collaboration between Fette Compacting and CMIC sets new standards in pharmaceutical process and product development by combining innovative technologies with practical applications.

A key element of the partnership is the integration of FE CPS into CMIC's GMP-certified cleanrooms, allowing customers to benefit not only from significant efficiency gains but also from increased regulatory safety. The aim of this partnership is to enable pharmaceutical studies and the development of new and revised formulations. By working closely together, both partners can seamlessly support their customers from the development phase through to production, giving them a decisive competitive advantage. This once again demonstrates how FE CPS ensures an optimal interplay between technological progress and strict quality standards.

Fette Compacting India
Marketing
Contact: +91 86001 24568
marketing-in@fette-compacting.com
www.fette-compacting.com

Rethinking pharma field force efficiency in developing countries

In developing markets like India, where medical representatives remain the cornerstone of pharma sales, field force inefficiency is an expensive blind spot. **Mayuresh Satpute,** Partner at Vector Consulting Group, outlines how a shift from rigid Monthly Tour Plans to dynamic Flexible Journey Plans can unlock significant gains in coverage, compliance, and market share

The global pharma industry thrives on high profit margins, allowing companies to invest heavily in product promotion among healthcare professionals to generate sales. In developing markets, this effort is led by a vast network of Medical Representatives (MRs) who engage directly with doctors to drive prescriptions. In India alone, over 600,000 MRs operate nationwide, with top firms employing over 10,000 MRs each.

Pharma companies often rely on such a large sales force, expecting better doctor coverage, greater brand visibility, and increased sales. While this approach can yield initial gains, its impact diminishes over time as inefficiencies emerge. Sales teams typically operate at only 60-70 per cent efficiency due to poor planning and limited engagement with high-priority doctors. Visit frequency compliance is as low as 30-40 per cent, resulting in suboptimal doctor coverage and weakening the effectiveness of the manpower investment.

To address this, firms invest in digital solutions like CRM systems, automated reporting, and performance monitoring. However, these tools often fail to deliver their core objective: timely, productive, and targeted doctor interactions across regions. With lost sales reaching significant levels, firms are compelled to keep investing in their field force, finding themselves in a dilemma, whether to expand the sales force or run digital initiatives to improve efficiency.

This article examines how pharma companies can improve their field force's potential by addressing operational inefficiencies.

Key hurdles in the pharma field force productivity

1. Gaps in monthly tour plans: Improving field force efficiency is challenging due to execution issues in Monthly Tour Plans (MTPs), which guide MR visits on a daily basis. Despite meticulous planning, various disruptions reduce their effectiveness. Unplanned deviations, such as unexpected leaves, doctors' unavailability, and administrative tasks, often disrupt schedules, leading to cascading adjustments compromising the entire monthly schedule. Missed visits early in the month result in clustered visits later, increasing non-compliance with the plan. Travel inefficiencies further impact productivity, as poorly optimised routes increase commute time, limiting the number of high-priority doctor engagements.

Additionally, disjointed planning arises when future plan fails to consider previous visit data, creating uneven intervals that weaken product recall and relationship-building efforts. Cherry-picking of doctors is another concern, as MRs often focus on accessible or receptive doctors while neglecting others, causing total doctor coverage to fall below 70 per cent despite seemingly high visit numbers. Lastly, administrative and logistical overheads, such as compliance tracking and report submissions, consume valuable time that could otherwise be spent on doctor interactions.

2. Roadblocks for Line Managers (LMs): While MRs struggle with executing MTPs, First Line Managers (FLMs) and Second Line Managers (SLMs) face their own challenges in balancing oversight with on-ground realities. FLMs may focus on certain MRs or regions while neglecting others leading to unequal time distribution. Regularly visiting A-class and B-class doctors is often difficult, leading to engagement gaps. Conflicting schedules further disrupt efficiency, as LM-MR co-visits often prioritise one schedule over another, reducing adherence to visits at the required frequency. Additionally, capacity wastage occurs when LMs spend time on lower-priority tasks, such as co-visiting C-class doctors, instead of focusing on high-value engagements. Strategic misalignment is another concern as SLMs struggle to synchronise long-term objectives with daily field operations, leading to inconsistent execution. Lastly, underutilised high-priority engagements weaken market presence, as key interactions with high-potential doctors and cross-divisional coordination are often overlooked.

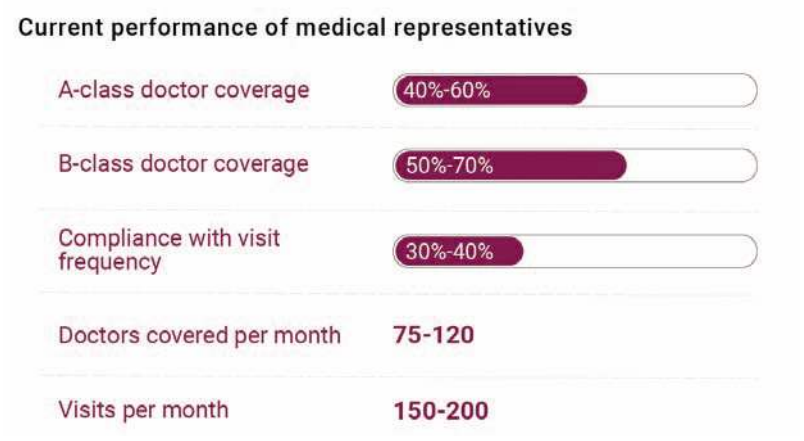
3. Issues in structural planning: Beyond individual field force challenges, systemic inefficiencies further weaken demand generation:

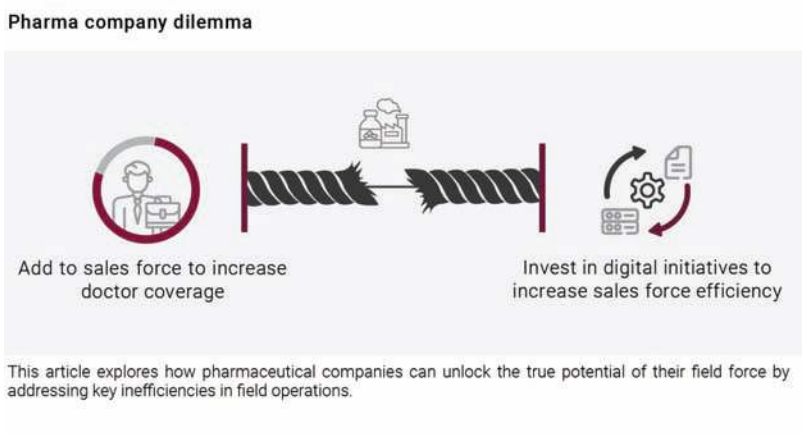
- **Inconsistent coordination:** Misalignment between MRs, FLMs, and SLMs, whether in a top-down or bottom-up approach leads to overlapping visits or neglected doctors.
- **Overloaded or underutilised MTPs:** Overloaded MTPs create unmanageable backlogs when disruptions occur, while underloaded ones leave MR capacity underutilised.
- **Disconnected divisional strategies:** High-priority doctors interact with multiple divisions of the same company, yet poor coordination leads to over-visitation by some teams while leaving others neglected.

Unaddressed, these inefficiencies disrupt doctor engagement, strain MRs with impractical plans, and stall market penetration, ultimately weakening long-term relationships with healthcare providers.

The core issue

The field force aims to maintain timely doctor interactions, en-





suring strong relationships and brand recall. Optimal visit intervals are key, but MRs are frequently forced to deviate from fixed plans due to uncertainties and added tasks, disrupting efficiency. Coordination with managers further adds complexity, making consistency harder to achieve.

A more effective path with Flexible Journey Plans (FJP)

FJP replaces rigid schedules with a dynamic approach, ensuring timely visits and effective engagement. Accessible to all stakeholders, it adapts to real-time conditions to maintain doctor relationships and brand recall.

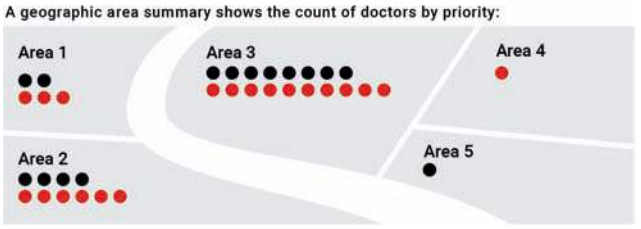
Key principles of FJP

1. Timely visits are based on the gap since the last visit, ensuring optimal recall intervals. A-class doctors should be visited every 10 days (within 8-12 days), B-class every 15 days (13-17 days), and C-class every 30 days (28-32 days). Outstation doctors require visits every 30-60 days, depending on company travel policies.

Their priority-based scheduling will look like this:

2. Priority-based scheduling assigns doctors a colour-coded priority based on the time elapsed since their last visit. For example, in the image below, for A-class doctors, a white status indicates that no visit is required. Green signifies an early window where a visit is not urgent. Yellow represents medium priority, suggesting the need for a visit soon. Red denotes high priority, requiring prompt attention, while black indicates a critical priority, demanding an immediate visit.

A geographic area summary shows the count of doctors by priority:



3. Dynamic planning enables MRs to focus on specific geographical patches with a two to three day planning horizon. A summary of each patch highlights the number of doctors by priority level. MRs prioritise areas with the highest count of black and red doctors, ensuring efficient resource allocation.

4. Streamlined doctor lists are organised in descending order of priority, starting with black, followed by red, yellow, and green. Doctors not due for visits are excluded. Within each priority level, A-class doctors appear first, followed by B-class and then C-class.

5. Visibility of two to three days plan provides MRs with a quick reference to plan for the next two-three days. Based on their visits today and the time elapsed since previous visits, the patch-wise summary for the next day updates automatically.

Key benefits of FJP for MR

1. MR always gets a priority for geographical patch selection, which ensures the highest possible coverage and compliance while utilising maximum available capacity.

2. The need to replan is eliminated as the everyday plan is refreshed based on elapsed days since the last visit. Thus, even in case of disruptions due to other tasks or unforeseen circumstances, MR can still exhibit high coverage and compliance.

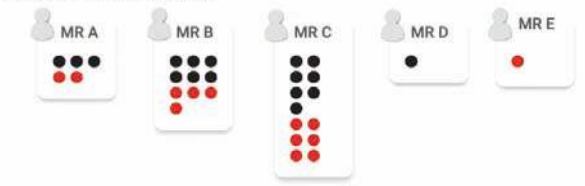
Integrating FLM and SLM planning

FJP can be extended to FLMs and SLMs to align with MR plans. Their visit intervals are calculated similarly but are longer.

For example, an FLM might visit A-class doctors every 60 days and B-class doctors every 90 days. Since FLMs take 30 days to move from Green to Black, they have three opportunities to synchronise with MRs for the same A-class doctor, ensuring common visits.

However, FLMs must still decide which MR, doctor, and geographic patch to visit. FJP guides this by generating reports that highlight high-priority (Red/Black) doctors and their corresponding MRs. The FLM can then select an MR with the highest number of priority doctors, ensuring both schedules remain aligned. This methodology extends to SLMs and higher-level managers by setting visit intervals and selecting relevant doctors.

Black/Red doctor chart of LMs

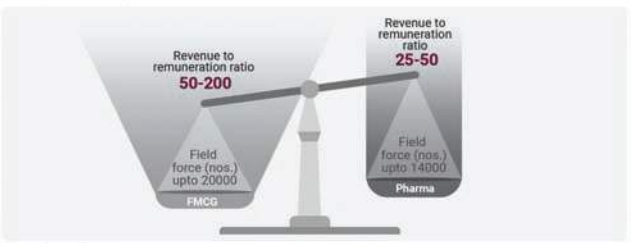


For MRs:	MTP performance	FJP performance
A-class doctor coverage	30%-40%	95%
B-class doctor coverage	40%-60%	95%
Compliance with desired visit frequency	10%-30%	90%
Doctors covered per month	75-120	200
Visits per month	150-200	325+

For FLMs and SLMs:	MTP performance	FJP performance
A-class doctor coverage (60 days)	7%-10%	>80%
A-class doctor coverage (90 days)	10%-12%	>85%
Doctors covered per month	50	200+
Visits per month	70	200+

Sales field force structure of a typical pharmaceutical company

Comparison between the top few companies in FMCG and pharma industry of field force productivity in India



Source: Various

> Implementing FJP in developing markets has significantly improved coverage, compliance, and sales. By expanding doctor reach and ensuring recall, we achieved over 10 per cent delta growth above the market while maintaining the highest market share in the territory

Measurable gains with FJP

Implementing FJP in developing markets has significantly improved coverage, compliance, and sales. By expanding doctor reach and ensuring recall, we achieved over 10 per cent delta growth above the market while maintaining the highest market share in the territory.

Conclusion

Shifting from MTP to FJP enables pharma companies to enhance doctor coverage, drive sales growth, and strengthen healthcare relationships. These strategies boost market penetration, brand recall, and long-term competitiveness. Further optimisation can extend to pharmacy visits, promotions, and other demand-generation efforts, which will be explored in future.

Why smart start-ups are partnering not replacing local pharmacies

Gaurav Lekhrajani, Co-founder and CEO, DavaNinja highlights how instead of marginalising channel partners like pharmacies, some start-ups are forging strong partnerships with local pharmacies that are richer than pharmacy transactions

India's fast evolution of quick commerce is witnessing an understated yet important transformation. Within the lengths of the calendar year that start-up entrepreneurs are sprinting towards the conclusion of, blended with the ratio of speed to scale, there are start-ups dedicated to a healthcare delivery model which favours collaborative partnerships over disruptions. Instead of marginalising channel partners like pharmacies, some start-ups are forging strong partnerships with local pharmacies that are richer than pharmacy transactions

Pharmacies offer familiarity, healthcare guidance, and credibility over other online pharmacy practices. Other channel partners matter and have a greater purpose, and now with strategic technology partnerships, they are transforming into last-mile healthcare enablers. Here is why this partnership-led model is gaining traction.

1. Access to a diverse SKU range: Community pharmacies have a broad and diverse inventory of medication, OTC medicine, wellness products, and other culturally specific products. Utilising this community infrastructure for an inventory source means that start-ups can sell a wide array of products without having to manage a huge central warehouse or large logistical network to handle multi-these types of requests ranging from day-to-day health needs to acute care requests, often times in a matter of hours.

2. On-ground local expertise: Local pharmacists are often cornerstones of their communities. They are familiar faces who know the specific health trends and preferences of their communities. Working with these trusted partners facilitates better patient care and the appropriate dispensing of medications. New start-ups can further this potential by adding verification standards and electronic safety nets to transform a personal experience into a tech-based accuracy experience.

3. Integrated logistics support: Instead of constructing pricey dark stores or urban warehouses, the partner start-ups use the existing pharmacy network to fulfil orders. An intelligent order-routing system and delivery system, in combination, provides a faster dispatch and delivery subsequent to the order, minimises delays in delivery, as well as a shorter distance between the medicine and the customer's doorstep. This model uses logic and logistics.

4. Utilising existing infrastructure: Infrastructure is present. Start-ups will leverage the institutional infrastructure already provided by local pharmacies instead of developing it from scratch. This saves real estate investments, reduces to low operational expenses, and enables quicker market expansion, all while supporting community economic ecosystems.

5. Empowerment over replacement: The aim is not to displace local chemists but to help them. By increasing order volumes, improving digital visibility, and access to logistics and technology assets; these relationships provide an opportunity for pharmacies to thrive as businesses in the digital age. This model upholds their legacy while providing them with the skillset to move forward.

6. Modernisation without losing identity: These partnerships enable pharmacies to provide services like online ordering, live tracking and even digital payments — while keeping all the charm of the community store. Unlike generic fulfilment centres, pharmacies still retain their identity, their name, their signage - and most critically, their sense of community.

7. Real estate and environmental concerns: Dark stores and centralised supply hubs can often add to urban congestion and emissions. A decentralised, pharmacy-led approach decreases distance travelled, carbon emissions, and reliance on additional infrastructure. One small step in a larger movement towards greener, smarter cities.

Start-ups are blending the credibility of local pharmacists and the convenience of digital platforms to create a healthcare model that is more accessible, sustainable, and equitable. And, in tandem, they are demonstrating that innovation does not have to forsake tradition innovation can and should move forward hand in hand with tradition.

Example of a transdermal twin screw extruder and lamination system

KILITCH HEALTHCARE INDIA LTD.

Accrediations

9001:2015 | 14001:2015 | OHSAS 18001 | ASCB(E) | IRQAO | WHO | GLP | GMP | pharmexcil

Manufacturing Sections

Small Volume Ampoule

Small Volume Vial

Three Piece Ophthalmic Vial

Two Piece Preservative Free Ophthalmic Vial

Prefilled Syringes in Blister pack

Sterile medicated Swab Sticks

Our Esteemed Clients

Zydus | FDC | USV | MICRO LABS | ENTOD PHARMACEUTICALS LTD

Head Office:
Kilitch Healthcare LLP,
902/B Godrej Colesium, Behind Everad Nagar,
Near Priyadarshani Cirlce, 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

OsmoTECH® XT Single - Sample Micro-Osmometer

Now available!

Best-in-class osmolality performance, designed with you in mind.

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

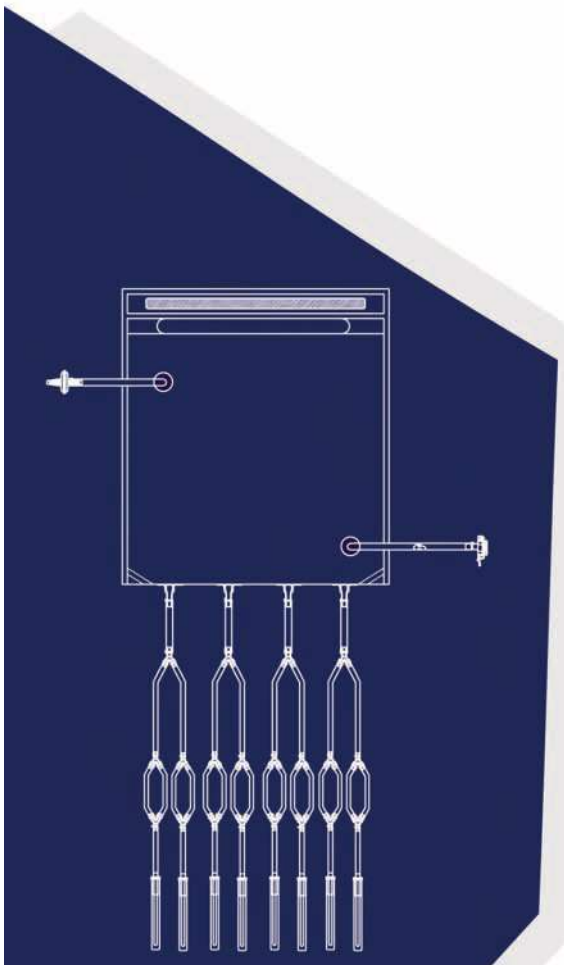
SANITT™

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



www.amipolymer.com
info@amipolymer.com

Ami Polymer®

"Sealing Expert in Silicone"

TUBINGS | HOSES | SINGLE USE ASSEMBLIES | GASKETS | INFLATABLE SEALS

Great Place To Work. Certified APR 2025-APR 2026 INDIA

COMMITTED ecovadis Sustainability Rating MAY 2025

2D Multiline Filling Bags

Revolutionizing Biopharmaceutical Fluid Handling

The 2D multi-line filling bag emerged with single-use technologies in the late 1990s to replace costly, time-consuming stainless steel systems. Its multiple ports enabled simultaneous filling, sampling, and draining—reducing contamination and eliminating cleaning needs.

What is a 2D Multi-Line Filling Bag?

A 2D multi-line filling bag is a flat, sterile, disposable container with multiple ports for fluid transfer, sampling, and storage in biopharma processes.

Key Advantages

- Enhanced Sterility
- Increased Efficiency
- Reduced Human Error
- Customizable Design
- Cost-Effective

Applications in Bioprocessing

- Buffer and media preparation
- Sampling
- Product storage and transfer

Why Ami Polymer?

At Ami Polymer Pvt. Ltd., we manufacture 2D multi-line filling bags entirely in ISO Class 7 cleanrooms to ensure top-tier cleanliness and quality. Our biopharma experts oversee every step to minimize contamination and maintain strict quality control.

We offer fully customizable, cost-effective solutions with fast delivery to support uninterrupted batch production. Since 1998, Ami Polymer has been a trusted leader in single-use systems, specializing in bioprocessing bags and assemblies with world-class manufacturing technology and end-to-end capabilities.

Sodium Hyaluronate

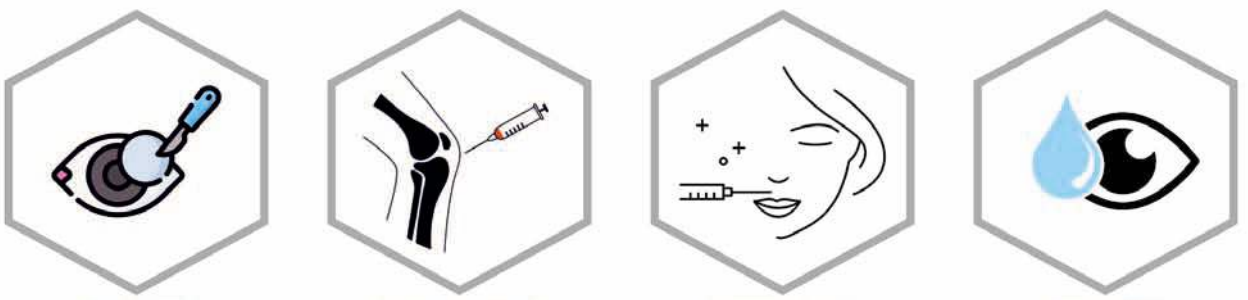
from **Kikkoman Biochemifa Company (Japan)**

YASHAM

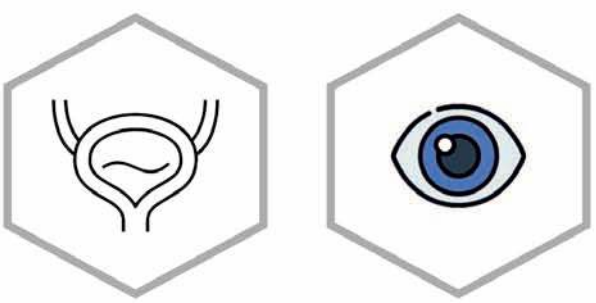
	Grade	Intrinsic viscosity (m^3/Kg)	Molecular weight (M.Dal)
Bioburden	GS-40	0.39 - 0.99	**0.15 to 0.49**
	GS-100	1.00 - 2.49	**0.50 to 1.60**
	GS-200	2.50 - 3.31	**1.61 to 2.31**

Key Specifications :

- Non-Animal origin, produced by Microbial fermentation
- Parenteral grade with BET/ MLT specs
- GMP (ICH-Q7) Controlled
- USP, EP, JP, BP Compliance Grades
- US-DMF, CEP, J-DMF, K-DMF available
- Indian API Registration
- HALAL Certified
- Covers wide range of Intrinsic Viscosity (1.00 to 3.4 m^3/kg) & Molecular Weight (500 – 2200 kDa)
- Customised grade can be offered as per requirement



Cataract | **Knee Injection** | **Dermal Filler** | **Eye Drops**



Interstital Cystis (Inflammation of the Urinary Bladder Wall) | **General Vision Disorders**

YASHAM

Head Office: 401, "Satya Dev", Plot No. A-6, Veera Industrial Estate, Off Veera Desai Road, Andheri (West), Mumbai - 400053
Tel. No. : 022 - 4063 9900 **Fax No. :** 022 - 4063 9901
Email Id : yasham@yasham.in **Website :** http://www.yasham.in

Branch Office: New Delhi
Sales Representative:
Ahmedabad, Bengaluru
Chandigarh, Hyderabad, Pune

HYDROCEL : the Tailor made Hypromellose for OSDs is setting Innovation Standards with Endless Applications from PIOMA CHEMICALS

HYDROCEL - the brand name of the functional excipient Hydroxypropyl Methylcellulose aka HPMC or Hypromellose used progressively for Oral Solid Dosage (OSD) formulations has been subject of a continuous program of development & quality improvement. It is a tailor-made polymer used as a functional excipient in many formulations today across the global pharmaceutical industry.

As we know that the drug properties are the main factor in medicinal formulations, the physical from, the finish & functioning of a preparation is also ever more important with more & more discoveries every day. "Functional excipients have become equally important if not less in ensuring the ideal drug delivery for its maximum effect. Hydrocel – HPMCs are taking a core place in playing these functional roles to perfection" says Mr Jaynil Doshi, Director – Techno Commercial from Pioma Chemicals – a leading organization in Pharmaceutical Industry since over 36 years.

Film coating was developed as undercoating for sugar coating in the 1950's and film-coated tablets were eventually introduced early in the 1970's, Since then, much development work aimed at increasing the production rate of film-coated tablets and reducing the cost has been done in order to improve the efficiency of pharmaceutical manufacturing, as well as the bioavailability of drugs, and film coating is now a well-established and effective technique. Hydrocel is easy to use for film-coating and gives an excellent finish. It is versatile and suitable for many applications in the design of film-coated tablet, drug loading on pellets as well as for manufacturing empty hard veg capsules. In addition, it is effectively used as a binder, since it does not interact with drugs has superior stability & has a non-ionic character.

Its major contribution has been in the field of Controlled Release & Sustained Release Tablets. While most HPMC's currently available are only pharmacopeial compliant which has wider range of specifications, Hydrocel' CR grades of HPMC – which are manufactured from pure wood pulp at a state-of-the-art GMP compliant facility are tailor made to have stringent specifications of specific functional parameters which have direct impact on the performance of the polymer that controls the rate of release of Drug / API from the formulation. Additionally, these are designed & certified to be multi-compendial compliant excipient. Doshi emphasized, "The stringent specification of our Hydrocel – HPMC for controlled release formulations ensures batch to batch consistency for the formulator & research scientist & the multi-compendial compliance makes it a versatile choice of polymer for registration of their formulations in domestic, regulated as well as ROW markets."

To further improve patient compliance, Pioma with their set of polymers spearheaded by Hydrocel – Hypromellose, introduced combinations for specific formulations to research scientists & formulators across the industry with the game changing idea of reducing tablet size & average weight of tablets, this without compromising on the API strength, the release profile desired or set as per pharmacopeial requirement. "With smaller tablets our customers - manufacturers of Tablets, not only found major improvement of patient compliance but it also aided to reduce their inventory management, increase production output & reduce their costs overall", explained Doshi.

The shift to vegan diet for food started picking up pace in the late 90s in several countries especially in America & Europe which gave force to a thought of the same being applied to pharmaceutical products as well. Most capsules back then were made of gelatin capsule shells. With Hydrocel – HPMC, Pioma's team not only unleashed another new application of this versatile polymer but also strongly advocated & contributed to the growth of Veg Capsules or as they say HPMC Capsules across the globe working with many research formulators for the development as well as working on the qualitative improvements across the years on their product to achieve the desired performance, output & efficacy.

Innovation & customer satisfaction remains at the core of Pioma's philosophy whether it is through exploring new applications, developing new products or elevating existing products. The flexibility & advantage that Hydrocel – Hypromellose brings to the table are unmatched & set benchmark standards for the industry on a global level. "While keeping quality, safety & performance in mind, conscious efforts have been taken constantly to keep the costs in check to ensure accessibility of the product to all as this is healthcare we are talking about", said Doshi with pride & satisfaction. With their technical support team, which is available at the behest of the customer, Hydrocel – Hypromellose can provide endless results & resolve issues of existing products for one & all across the Pharmaceutical Industry.

For more information & sample requirement write to products@pioma.net or go on www.pioma.net.

PIOMA chemicals
Partnering Through Innovation

Ensuring Clean Room Integrity with Prime Clean Reset High-Speed Doors: Minimizing Air Permeability and Leakages

High-speed doors for clean rooms are specialized industrial doors essential for maintaining controlled environments. These doors are engineered to be airtight, creating a reliable barrier between different areas of a facility. Their design ensures durability and minimal maintenance, reducing the frequency of repairs and replacements.

High-speed clean room doors offer a range of critical benefits essential for maintaining stringent environmental control. These doors enhance hygiene by providing an airtight seal that effectively isolates clean room environments, preventing the ingress of dust and other contaminants. This capability is especially crucial in sectors such as pharmaceuticals, biotechnology, and food production, where maintaining sterility is non-negotiable.

In the pharmaceutical and life sciences industries, compliance with rigorous regulatory standards necessitates the manufacture of products within controlled clean room environments. A high-performance clean room door is an integral component in ensuring the integrity of these spaces, safeguarding product quality and patient safety.

Beyond contamination control, these doors are engineered with advanced safety mechanisms, including automated sensors and emergency stop functions, which mitigate the risk of operational hazards. Moreover, high-speed clean room doors are designed to maintain precise overpressure or under pressure conditions within the environment. This is vital for preventing cross-contamination and ensuring that the clean room remains in a state of controlled integrity, even under varying operational demands.

Given the critical role these doors play in maintaining the purity and safety of highly specialized environments, selecting the appropriate door system is a decision of strategic importance.

Prime Clean Reset, our high-speed door is designed specifically for clean rooms. This innovative solution is engineered to meet the stringent requirements of controlled environments, ensuring exceptional performance and reliability. Designed with precision to meet the stringent requirements of controlled environments, Prime Clean Reset is the epitome of performance and reliability, ensuring that your clean room operations consistently meet the highest standards of regulatory compliance and product integrity.

Prime Clean Reset is suitable for clean rooms up to ISO Class 5, offering an unparalleled air permeability rate of less than 12 m^3/m^2 h at ? 50 Pa. This ensures that even in the most sensitive environments, the door effectively maintains the critical pressure differentials required to prevent contamination, thereby safeguarding your processes and products.

Engineered with cutting-edge European technology and innovative design principles, Prime Clean Reset offers rapid cycle times for both opening and closing, making it the optimal solution for medium to large entrances in clean room applications. The door's construction is specifically tailored to minimize air leakage and particulate infiltration, ensuring that it supports the rigorous cleanliness standards necessary for applications such as pharmaceutical manufacturing, semiconductor fabrication, food processing, and other highly specialized sectors.

With its robust design and reliable performance, Prime Clean Reset seamlessly integrates into your clean room infrastructure, providing a critical barrier that preserves the integrity of controlled environments. Whether you are operating in a pharmaceutical, biotechnology, electronics, or defence industry, Prime Clean Reset offers the precision, durability, and compliance needed to maintain your competitive edge in highly regulated markets.

Key features of Gandhi Automations' High-Speed Clean Room Doors include:

◆ **Low Air Permeability:** Designed to maintain low air permeability in pressurized rooms with both positive and negative air pressure.

◆ **Compact Design:** The doors are designed to fit inside the columns, with a self-supporting construction that minimizes air leakage.

◆ **Customizable Transparency:** They can be equipped with transparent PVC horizontal sections or vision windows for visibility.

◆ **Specialized Side Guides:** The special side guides ensure a tight integration of the curtain, providing high leak tightness.

◆ **Efficient Operation:** The doors offer high efficiency and low permeability values, compliant with EN 12426 and EN 12427 standards, ensuring < 12 m^3/m^2 h ? 50 PA.

◆ **Durable Control Device Enclosure:** The control device enclosure is made of Stainless-Steel SS 316, ensuring durability and resistance to corrosion.

These high-speed doors are meticulously engineered to minimize air leakage and maintain strict environmental control, making them indispensable for clean room operations. Their rapid opening and closing operation ensure that the internal facility remains isolated from external conditions, effectively upholding the cleanliness and controlled environment essential for maintaining the integrity of clean rooms.

For further information on our high-speed doors offering, contact:

Gandhi Automations Pvt Ltd
Chawda Commercial
CentreLink Road, Malad (W),
Mumbai-400064, India.
Off : +91 22 66720200 /
66720300 (200 lines)
Fax : +91 22 66720201
Email : sales@geapl.com
Website : www.geapl.com

The 'Truth' Syringe

"Truth" Dispense Glass Syringes - 100% inert liquid path instrument for aliquot collection from dissolution test apparatus

◆ The bent glass tube on the Borosilicate Glass syringe allows easy collection of the liquid sample solution from the Dissolution vessels.

◆ The inert borosilicate liquid path ensures that there are no contaminations, particle diffusions, absorptions or reactions from the sampling cannulae or Autosampler of Dissolution test apparatus.

◆ Plastic syringes / tubes, Stainless Steel needles tend to have qualities of absorption which also might react with the sensitive solutions.

◆ These accurate and precise results are the helpful and base for Multimedia Dissolution for bio-equivalence study ahead in the new product development & have to match with reference listed drugs products (RLDs) for the US, EU and other markets

◆ USP <711> recommends the use of glass and inert materials for the apparatus used in the procedure, and for sampling. Drugs which specifically need to be handled by glass include hormonal products as well as non-hormonal products e.g. Levothyroxine sodium tablets etc

◆ Using the Truth syringe eliminates the fear of doubt with respect to contamination during the critical tablet dissolution study.

Top Syringe exports its products to over 40 countries worldwide and counting, keeping a single quality standard for local and export products.

The "Truth" Dispense Glass Syringes is manufactured 100% in India by Top Syringe Mfg Co (P) Ltd. We are fully committed to supporting you with our full product range, spares, and technical assistance.

For more information, Contact:
Top Syringe Compound, W.E. Highway, Pandurangwadi, Mira road (East), Thane 401107 India.
Mob: 81046 82560
Email : sales@topsyringe.com
website: www.topsyringe.com

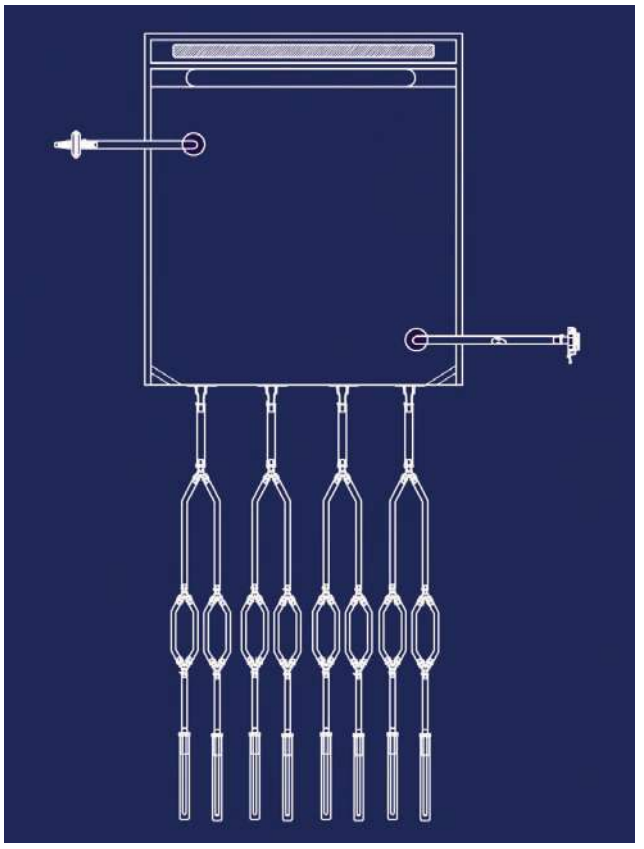
2D Multiline Filling Bags: Revolutionizing Biopharmaceutical Fluid Handling

History of 2D Multiline Filling Bags -

The development of the 2D multi-line filling bag began with the rise of single-use technologies (SUT) in the late 1990s and early 2000s. Before this, bio manufacturers mainly used stainless steel vessels and tubing for fluid handling, which required extensive cleaning and validation, making operations costly and time-consuming. The 2D multi-line filling bag was introduced to solve this issue, with multiple ports and lines allowing for simultaneous processes like filling, sampling, and draining. Early versions were simple but eliminated the need for cleaning, reducing contamination risks.

What is a 2D Multi-Line Filling Bag?

A 2D multi-line filling bag is a flexible, sterile, and disposable container used in biopharmaceutical processes for fluid transfer and storage. "2D" refers to its flat, pillow-like shape, while "multi-line" indicates the multiple ports or tubes that allow fluids to be filled, sampled, or drained simultaneously or in sequence. These bags are often used in processes like buffer and media preparation, and product storage.



Key Advantages:

1.Enhanced Sterility: The 2D bag with a filling needle forms a closed system, greatly reducing contamination risk, crucial for maintaining product quality.

2.Increased Efficiency: The multi-line design allows for multiple processes at once, speeding up operations and reducing downtime.

3.Reduced Human Error: With fewer manual steps, the filling needle and multi-line system minimize the chance of mistakes, making the process safer and more reliable.

4.Customizable Design: These bags can be adapted to specific needs with additional ports or lines, ensuring they fit seamlessly into different processes.

5.Cost-Effective: As single-use bags, they don't require cleaning or validation, saving time and reducing operational costs.

Applications in Bioprocessing:

A. Buffer and media preparation: Efficient filling, storage, and transfer of large volumes of fluids.

B. Sampling: Filling needles allow precise sampling while maintaining sterility.

C. Product storage and transfer: The bags provide a secure, sterile way to handle valuable products.

Why Ami Polymer?

At Ami Polymer Pvt. Ltd., we manufacture all components of our 2D multi-line filling bags exclusively in an ISO Class 7 cleanroom, ensuring the highest standards of cleanliness and quality. Our biopharma experts oversee the entire manufacturing process, guaranteeing zero compromises on quality and minimizing contamination risks.

We provide fully customizable solutions tailored to your specific requirements, with rapid delivery to prevent delays in your batch production. Our products are designed to be cost-effective without sacrificing the quality you expect.

Founded in 1998, Ami Polymer is a leading manufacturer and supplier of single-use systems, specializing in bioprocessing bags and assemblies produced in ISO Class 7 cleanrooms. Our advanced manufacturing technology ensures world-class quality and end-to-end process capabilities to meet the diverse needs of our customers.

As we continue to lead advancements in single-use systems, we invite you to join us on this exciting journey. Discover how Ami Polymer Pvt. Ltd. can support your innovations and contribute to the future of bioprocessing. For more information, reach out to me at chinmaya.p@amipolymer.com.

We look forward to partnering with you and driving progress together!

Chinmaya Ranjan Parida
Senior Executive – Single Use System
Email: chinmaya.p@amipolymer.com
Contact: +91 – 74360 03841

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.

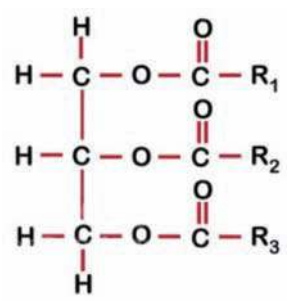


Image 1: Structure of a Triglyceride

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 Glyceryl monostearate and distearate, Hydrogenated 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 pharmaceutics, 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 physicochemicaly 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 either 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 associated effect on lubrication efficiency, API release and taste-masking effect.[1]

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

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 Gossypìum hirsutum (L) or other Gossypium species by refining, and hydrogenation.[1][2]

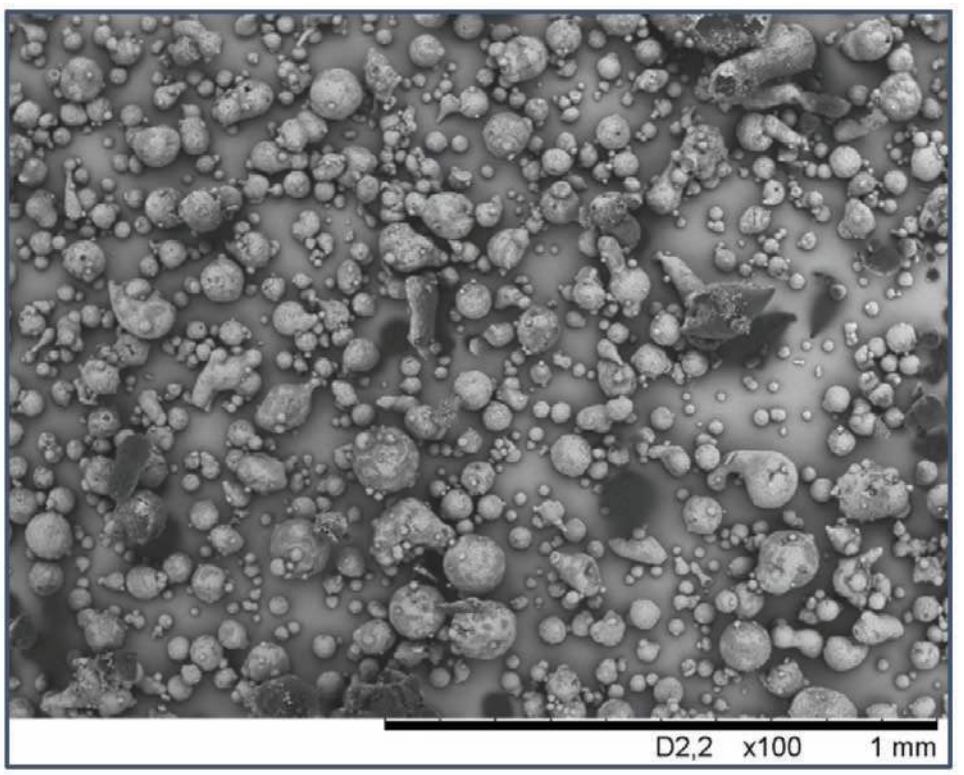


Image 2: SEM image of LUBRITAB® [4]

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

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 relevant 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 matrix 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

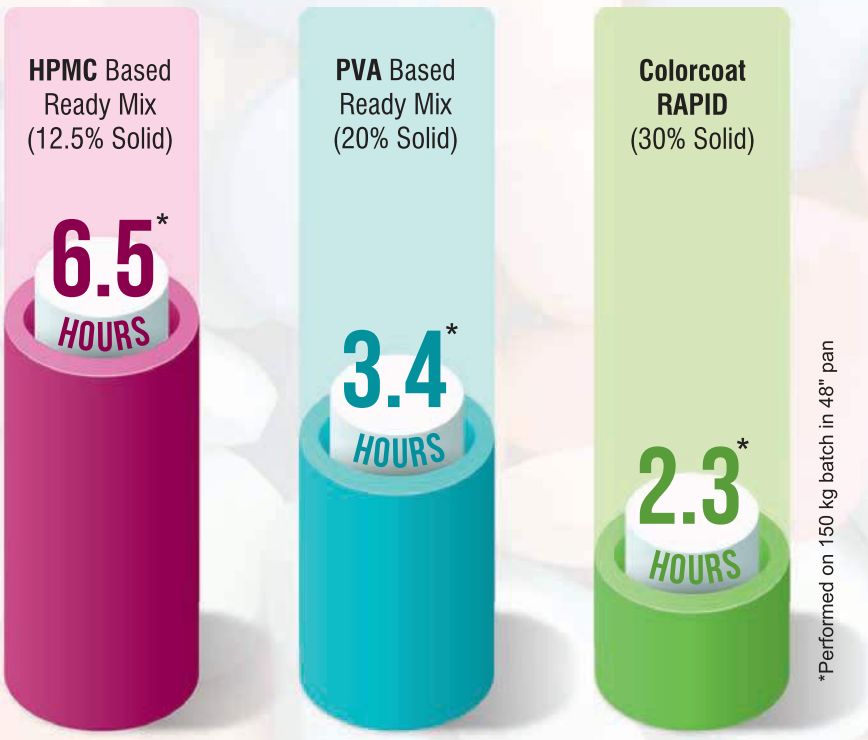
COLORCOAT® RAPID

RAPID IS FUTURE-FUTURE IS RAPID

ACCELERATE COATING EFFICIENCY

BENEFITS

- Solid level up to 30% facilitate rapid coating with high productivity gains
- Saves coating process time up to 40%
- Rapid solution preparation
- Save energy consumption
- Process Adaptability with smooth and glossy appearance
- Easy scale-up in different equipment types or manufacturing sites
- Suitable for batch and continuous processes
- Regulatory support



*Performed on 150 kg batch in 48" pan

COREL PHARMA CHEM

the next generation polymer technologist...

Corel House, Opp. Bhagwat Petrol Pump,
S. G. Highway, Gota,
Ahmedabad - 382 481, Gujarat, INDIA

Tel: +91-8000880011/22/33
E-mail: corel@corelpharmachem.com,
marketing@corelpharmachem.com
Website: www.corelpharmachem.com

ACRYCOAT • COLORCOAT • ACRYPOL • ACRYSOL • KYRON • NUTRACOAT • ACRYFLOW

REGD.WITH RNI NO. MAHENG/2005/21398, POSTAL REGD. NO. MCS/164/2025 – 27, PUBLISHED ON 5TH EVERY MONTH,
POSTED ON 9TH, 10TH, AND 11TH EVERY MONTH POSTED AT MUMBAI PATRIKA CHANNEL SORTING OFFICE, MUMBAI – 400001