VOL. 14 NO. 15 PAGES 80 www.expresspharmaonline.com

EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE
1-15 JUNE 2019, ₹40

+

Interview

Dr Renu Swarup

Secretary, DBT, Ministry of Science and Technology, and Chairperson, BIRAC

A BACKBONE CALLED BIRAC

Nextec Life Sciences, Tergene Biotech, Algalr Nutrapharms, Bugworks Research and Pandorum Technologies are but a few of the many success stories in the making, thanks to BIRAC's blend of industry-academia partnerships

Jaswanti Landmark

LBS Road, Vikhroli (W)

LEASE ONLY

READY FOR FIT-OUTS
WITH OC

2000 to 20000 sq.ft
(Usable Carpet Area)

IDEAL FOR

- Pharma / Labs R & D Application Centres
- Service Industries
- Back Office and Training Centres
- Corporates & Mid Sized Businesses
- Retail, MNCs, BFSI

EASY CONNECTIVITY TO

BKC | POWAI | AIRPORTS
EASTERN EXPRESS HIGHWAY
JVLR | JNPT

Site Address :
Jaswanti Landmark, Mehra Industrial Estate, LBS Marg,
Vikroli (West), Mumbai - 400 079.

Tel : 98210 10765 / 93200 05545 / 022-4003 3338

Email: sales@ashraygroup.com | **Website:** www.ashraygroup.com

A Project by

ASHRAY
No Ceiling on Excellence

GANDHI
Automations Pvt Ltd

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

Inflatable Dock Shelters

- Inflatable Shelters deliver the most versatile seal offered to service the widest diversity of truck and trailer configurations.
- Virtually airtight sealing with inflatable top and side cushions.
- Fast inflation time and deflation time.
- Maximum flexibility for diverse vehicle sizes.
- Ideal shelter for temperature-controlled warehouses and distribution centres to seal against summer heat, winter cold, draught, dust and insects.
- Easy access with no obstruction of the loading opening.
- Sturdy construction with protective curtains.

Dock Levelers | Fire Rated Shutters / Doors | High Speed Doors | Rolling Shutters | Sectional Overhead Doors

World's Safest Dock Shelters

Indian Green Building Council
M E M B E R

ISO 9001 : 2015, ISO 14001 : 2015
BS OHSAS 18001 : 2007

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.co.in | Website : www.geapl.co.in

DRUGCOAT®

METHACRYLIC ACID COPOLYMER BASED BASIC PHARMA POLYMER

DRCOAT
POLYMER EXCELLENCE SIMPLIFIED

CUSTOMIZED READY TO USE PHARMA POLYMER

DRUGCOAT L & S SERIES
Enteric Coating Formulation

AQUEOUS BASE

DRUGCOAT L 30D
DRUGCOAT L 100-55
DRUGCOAT L 100-55D

NON AQUEOUS BASE

DRUGCOAT L 100
DRUGCOAT L 12.5

COLON TARGETED RELEASE

DRUGCOAT S 100
DRUGCOAT S 12.5
DRUGCOAT FS 30D

DRUGCOAT E SERIES
Taste Masking and Protective Formulation

DRUGCOAT E 100
DRUGCOAT E PO
DRUGCOAT E 12.5

DRUGCOAT RL, RS & NE SERIES
Sustain Release Formulation

DRUGCOAT RL 100
DRUGCOAT RL PO
DRUGCOAT RL 12.5

DRUGCOAT RS 100
DRUGCOAT RS PO
DRUGCOAT RS 12.5

DRUGCOAT NE 30D

ENTERIC COATING PRODUCTS

METHACRYLIC ACID COPOLYMER BASED COATING SYSTEM

DRCOAT ECS
DRCOAT ECA
DRCOAT EZ

MOISTURE BARRIER PRODUCTS

HPMC BASED COATING SYSTEM

DRCOAT MB-S
DRCOAT MB-A

PVA BASED COATING SYSTEM

DRCOAT HSP+

IMMEDIATE RELEASE FILM COATING PRODUCTS

HPMC BASED COATING SYSTEM

DRCOAT FCS
DRCOAT FCA
DRCOAT FCA II
DRCOAT FCA III
DRCOAT FCU
DRCOAT SEAL

PVA BASED COATING SYSTEM

DRCOAT HSP

SPECIALTY PRODUCTS

MICA BASED FILM COATING SYSTEM

DRCOAT PEARL
DRCOAT DUO

TRANSPARENT FILM COATING SYSTEM

DRCOAT GLOW
DRCOAT CLR

FLAVOUR/SWEET FILM COATING SYSTEM

DRCOAT FLV

GMP CERTIFIED

EXCIPACT · ISO 9001 SGS · HALAL · US DMF AVAILABLE

For Overseas Enquiries:
M. : +91- 98796 05236
exports1@vikramthermo.com

For Domestic Enquiries:
M. : +91- 99789 39879
marketing@vikramthermo.com

Regd. Off.: 101, Classic Avenue
Opp. Sales India, Ashram Road
Ahmedabad-380 009. Gujarat (India)
Ph. : +91-79-27543745
Fax: +91-79-27540562
E-mail: exports@vikramthermo.com
www.vikramthermo.com

Vikram®
THERMO (INDIA) LTD.
Manufacturer and Exporter, Since 1985

ETEK is a famous brand as Dongguan ETEK Intelligent Equipment Co., Ltd. for PP bottle I.V. Infusion production line, our blowing-washing-filling-sealing production line have been exported to Europe, North America, Africa, South East Asia market. With more than 20 years experience and innovation in this industry, our machine are upgraded with high-speed, Zero-waste, energy-saving, less footprint etc advantages, we have won dozens of authorized patents and awards by China government.

WASHING-FILLING-SEALING MACHINE

BLOWING MACHINE

I.V. INFUSION BOTTLES

DIALYSIS SOLUTION & IRRIGATION SOLUTION

PATENTS & AWARDS

Dongguan ETEK Intelligent Equipment Co. Ltd.
Qiaotao Town, Dongguan City, Guangdong, China.
Mobile / Whatsapp / Wechat: +86-13667331852
Email: cocogan188@163.com • **Website:** www.etekchina.com

EXPRESS PHARMA

SHAPING THE FUTURE OF BRAND INDIA PHARMA

VIZAG PHARMA SUMMIT 2019

THE PORT OF EXCELLENCE

THANK YOU!

To all our delegates, speakers and partners for the support in making Vizag Pharma Summit 2019 a grand success!

PARTNERS

BECKMAN COULTER Life Sciences

Propix Inpection Online

POLMON Measure. Control. Automate.

Since 2001 Smart Scientifically yours...

Ami Polymer Pvt. Ltd. "Sealing Expert in Silicone"

MACK PHARMATECH® MFGRS. PHARMA AND LAB. EQUIPMENTS

AXOMATIC group TUBE FILLING, CARTONING AND PROCESS SOLUTIONS

markem·imaje a DOVER company

Crystal Crystal logistic cool chain ltd

Caliber Deliver More. Deliver Excellence

GANDHI Automations Pvt Ltd

PSA PSA NITROGEN LIMITED Technical Collaboration with Kuroray Co. Ltd. - Japan

Budenheim

Superior excipients meeting your formulation challenges

DI-CAFOS®
TRI-CAFOS®

Budenheim offers a comprehensive range of superior phosphate products ...
covering liquid and solid dosage forms and a wide range of functionalities for pharmaceutical companies.
All **DI-CAFOS®** and **TRI-CAFOS®** grades for direct compression offer several advantages which include excellent flow properties, high tablet hardness and high content uniformity which are essential for high speed tablet manufacturing.

... and extensive global services, including technical and regulatory support
completes the offer to our customers and has made Budenheim a leading player in this segment. Our Tabletting Competence Center enables us to run trials under real production conditions, helps us to understand the requirements of the market and to develop customized solutions for you.

Chemische Fabrik Budenheim KG
Business Unit Performance Materials | 55257 Budenheim | Germany | Phone +49(0)6139 89-0 | pharma@budenheim.com | www.budenheim.com

Signet*ure*

VERSATILITY

From binders and fillers to sweeteners and coating agents, Signet's products cover a diverse range of applications to meet every need; a versatility matched by one of our principal partners, Roquette Frères.

With a highly diversified range of starch-related products and an expert in the field of Polyols, Roquette provides its customers both quality and variety. Emphasizing innovation through research, the company has adopted the concept of 'integrated bio-refining' to transform renewable resources into high quality ingredients suitable for a wide range of applications.

Roquette is the world's leading producer of Starch, Starch derivatives, Polyols and many other speciality products.

ROQUETTE

Native Starches
- Maize Starch
- Potato Starch
- Wheat Starch

Modified Starches
- Pregelatinized Starch
- Sodium Starch Glycolate
- Dextrin

Polyols
- Mannitol
- Maltitol
- Sorbitol
- Xylitol

Speciality Products
- Lycoat
- Pearlitol Flash
- StarLac
- Nutriose

Cyclodextrins
- Betacyclodextrin
- Hydroxypropyl Betacyclodextrin

Sugars and Soluble Fibres
- Dextrose
- Dried Glucose Syrup
- Maltodextrin

METAL

25 leading excipient companies
Over 400 products
Total solutions since 1986

Signet
The Complete Excipients Company

A-801, Crescenzo, C / 38-39, G-Block, Bandra-Kurla Complex, Mumbai - 400 051 I +91 22 61462725 I sales@signetchem.com I www.signetchem.com

EXPRESS PHARMA

Chairman of the Board
Viveck Goenka

Sr. Vice President-BPD
Neil Viegas

Asst. Vice President-BPD
Harit Mohanty

Editor
Viveka Roychowdhury*

BUREAUS
Mumbai
Usha Sharma, Raelene Kambli, Lakshmipriya Nair, Sanjiv Das, Prabhat Prakash, Tarannum Rana

New Delhi
Prathiba Raju, Akanki Sharma

DESIGN
Asst. Art Director
Pravin Temble

Chief Designer
Prasad Tate

Senior Designer
Rekha Bisht

Graphics Designer
Gauri Deorukhkar

Senior Artist
Rakesh Sharma

Digital Team
Viraj Mehta (Head of Internet)

Photo Editor
Sandeep Patil

Marketing Team
Rajesh Bhatkal
Ambuj Kumar
Debnarayan Dutta
Ajanta Sengupta
E Mujahid
Nirav Mistry
Ashish Rampure

PRODUCTION
General Manager
BR Tipnis

Production Co-ordinator
Dhananjay Nidre

Scheduling & Coordination
Arvind Mane

CIRCULATION
Circulation Team
Mohan Varadkar

CONTENTS

From the day it came into existence, the Biotechnology Industry Research Assistance Council (BIRAC) – an institution set up by the Department of Biotechnology (DBT), Government of India, has been backing a number of biotech startups to undertake research and innovation, in turn, strengthening and empowering the biotech industry in the country | P22

MARKET

19 | SMART MANUFACTURING CONCLAVE HELD NEAR MUMBAI

20 | IDMA ORGANISES MARKETING AND SALES CONFERENCE, 2019 IN MUMBAI

21 | PHARMALYTICA 2019 SET FOR AN IMPRESSIVE DEBUT IN MUMBAI

IT@PHARMA

29 | JOSEPH LIM, SALES DIRECTOR APAC, BLUJAY SOLUTIONS

Express Pharma®
Regd. With RNI No.MAHENG/2005/21398. Postal Regd.No.MCS/164/2019-21.
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 Express Towers, Nariman Point, Mumbai 400021. Editor: Viveka Roychowdhury.* (Editorial & Administrative Offices: Express Towers, 1st floor, Nariman Point, Mumbai 400021) * Responsible for selection of news under the PRB Act.

Own up, course correct and move on

With the BJP making another clean sweep at the Centre, the party leader, Narendra Modi has been granted one more term. One hopes that they will make good on their promises for the healthcare and pharma sectors, because without a healthy population, none of the other targets will be achieved. For starters, they could take some pointers from the wish-list of the pharmaceutical industry, which was the cover story of our last edition *(http://www.expressbpd.com/pharma/cover-story/a-report-card-and-a-wishlist/409452/)*

But there is no doubt that the pharma sector too needs to take note of what is expected of them, collectively as well as individually. There have been quite a few examples of the misdeeds of pharma companies. The latest is a civil action suit filed on May 10 by the attorney generals of 44 US states, led by Connecticut, for price fixing of generic drugs. This was a telling indictment of 20 pharma companies, seven of them from India. *(http://www.expressbpd.com/pharma/latest-updates/seven-indian-pharma-companies-among-the-20-sued-by-the-us/409474/)* Some of these companies have already indicated that they will contest the allegations but the 524 page public version of the complaint has painstakingly collected evidence over years, all of which cannot be simply argued away.

If the anti-trust lawsuit focussed on unethical marketing practices, then investigative journalist Katherine Eban's book, *Bottle of Lies: The Inside Story of the Generic Drug Boom* red-flagged shoddy manufacturing practices by pharma companies. Eban's book focusses on two countries, China and India, and on selected companies from India, notably Ranbaxy and Wockhardt. The Twitterati responded predictably. Accolades for Eban outnumbered those who pointed out that the book deals with inspection results and incidences that are a decade old and have reportedly since been fixed. Yet other commentators hint that Eban could have a hidden agenda (For example, this comment from Jack S, New York, May 15, in response to the New York Times review: The choice to make it about the 'Generic Drug Industry' has me wondering if the 'non-fiction' book isn't just a piece of big pharma marketing fiction rather than an accurate portrayal of a massive global industry with hundreds/thousands of factories around the world.)

It is but natural that companies will do anything to protect their turf (brands) and their revenues. So we have come to expect the arguments discrediting generics, playing on the argument that cutting costs equals cutting vital corners and therefore results in less effective treatment outcomes.

But Eban's work spans decades and this is her second book on the malpractices behind generic medicines. The facts speak for themselves. Yes, pharma companies making generics, across nationalities, have defaulted on good manufacturing practices (GMPs) and we have the import alerts and observations to prove this. But brand name pharma companies too run into problems with the US FDA. One writer makes the case that an entire industry or country cannot be judged by the actions of a few bad apples, who are present in all companies and countries. *(https://www.linkedin.com/pulse/american-jugaad-uday-shetty)*

Rather than living in denial and shooting the messenger (Eban in this case), pharma companies have to own up to their mistakes, course correct and move on

Rather than living in denial and shooting the messenger (Eban in this case), pharma companies have to own up to their mistakes, course correct and move on. They will have to toe the line if they want to safeguard their reputations. And export revenues. While some companies have managed to rectify past shortcomings, different slips pop up in current inspections. For instance, take Cadila Healthcare's formulation manufacturing facility at Moraiya, Ahmedabad, which was inspected from from April 22 to May 3. The inspection ended with 14 observations, but the company's note to the stock exchanges emphasised that there were no repeat observations or data integrity related observations.

But the 14 inspectional observations do raise valid concerns. Observations on inadequate cleaning and maintenance of equipment, inadequate validation of the aseptic process, could impact quality of the finished product. Backup data files were not maintained, nor was there a thorough review of unexplained discrepancies. Lab controls did not include the establishment of scientifically sound and appropriate test procedures and in-process specifications were not determined by the application of suitable statistical procedures where appropriate.

Aseptic processing areas were deemed deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions and sterile wipes used during cleaning of equipment in specified aseptic filling lines, intended to remove particles from equipment surfaces, were observed to contain loose fibrous threads. Lastly, the master production and control records lacked complete manufacturing and control instructions.

Ironically, these may seem like measures which pharma companies ought to make as the base level for all production facilities. Often, it is a case of a stitch in time saving nine, i.e. anticipating and fixing things as soon as they go wrong. The problem is when companies refuse to admit that improper cleaning or low air quality in medicine manufacturing facilities will impact quality of the final product. The task of making life-saving medicines puts a great responsibility on the shoulders of these companies and it is time they lived up to this trust. Just as we hope BJP/Modi lives up to theirs.

VIVEKA ROYCHOWDHURY *Editor*
viveka.r@expressindia.com

FUTURISTIC AUTOMATION SOLUTIONS THAT DRIVE YOUR WORLD BEST!

In the ever-changing world of Engineering and Technology, Industrie 4.0 & AI are together poised to bring about unimaginable changes to shop floors and warehouses. Our MAXOLUTION® system solutions for factory and machine automation offer you the most advanced technologies. We can help you master the unique set of challenges and applications in your sector with our extensive product portfolio of motors, gear units, inverters, controllers and software solutions – all of which can be customized for your specific application and used with the interfaces in your application architecture.

From planning to startup, you benefit from our extensive expertise and get everything you need from one place, meaning you can start thinking about tomorrow's processes today.

To know more, do call us or visit our website.

How we drive your world:

- Energy efficient solutions
- Customised training
- Life cycle service
- German design & innovation

LEADER IN DRIVE ENGINEERING
MOTION CONTROL AUTOMATION EXPERT
IN INDIA SINCE 1997 I OPERATING IN 50 COUNTRIES

✆ +91 96866 24322
Email : marketing@seweurodriveindia.com
www.seweurodriveindia.com

SEW EURODRIVE

Driving the world

INTERVIEW

‘Interactive anti-bribery training is an essential element in building a culture of compliance’

The pharmaceutical sector has seen some high profile investigations and settlements concerning bribes given to healthcare providers in various countries, the latest being the anti-trust lawsuit in the US against 18 generic pharma companies, including five Indian companies. **Alexandra Wrage**, President, TRACE, a US-headquartered anti-bribery business organisation, gives **Viveka Roychowdhury** an overview of the risks of transnational business in the pharma industry and outlines what companies can do to increase levels of compliance to local and global anti-bribery laws

While speaking and consulting fees can be legitimate, they have also been used as sham vehicles for improper payments by pharma companies

India is ranked 85 out of 200 countries on the 2018 TRACE Bribery Risk Matrix, which ranks countries based on the assessment of bribery risk. While New Zealand tops as the least risky country, Somalia is the worst. What is the methodology to arrive at this Matrix? What has been India’s comparative rating since it was part of the Matrix?

The TRACE Bribery Risk Matrix assesses the likelihood that companies will be faced with bribe demands in that country. It’s not a generalised perception of levels of corruption, but an in-depth look at what factors make it more likely that a company will be shaken down, either because the opportunity is high (for example, high levels of red tape) or the risk is low (for example, civil society isn’t organised to highlight the problem or enforcement of the laws is weak).

The Matrix aggregates data collected by leading international institutions to derive country-level scores gauging the strength of the various governmental and societal factors that contribute to business bribery risk. The factors are: (1) degree of opportunity for bribery solicitation, defined by contact with government, expectation of bribes and regulatory burden; (2) the strength of deterrence efforts, measured by societal disapproval of bribery and governmental anti-bribery enforcement; (3) governmental transparency of regulatory functions and the health of the civil service sector; and (4) civil society oversight, defined by the quality and freedom of the media, as well as human capital and civic engagement.

How India has fared:

- 2014: 185/197 (score: 80)
- 2016: 178/199 (score: 78)
- 2017: 88/200 (score: 45)
- 2018: 86/200 (score: 50)

Change in these trends over time has in this instance been driven by notable bureaucratic improvements and shifts in societal expectations of bribery. However, because TRACE has made methodological improvements to the Matrix, scores are not strictly comparable from year to year.

What are the key provisions and recent amendments to India’s Prevention of Corruption Act and what do they mean for local and foreign companies? Any specific implications for pharma companies?

The most notable of the amendments is the imposition of criminal liability on the bribe-payer, where it previously fell only upon the public servant for taking a bribe. Individual penalties can go as high as seven-years’ imprisonment and/or a fine. Commercial organisations are also responsible for bribes paid on their behalf under India’s amended law, with possible prison terms of three to seven years for complicit directors and officers. In addition, to avoid penalties and fines, companies should have ‘adequate procedures’ in place to defend against improper conduct. While this approach of ‘adequate procedures’ as a defense is gaining ground internationally, it should be noted that no guidance has been offered to date on what might constitute adequate procedures. At the TRACE Workshop held in Mumbai last May, there was lively discussion on this point and a general sense that the UK guidance on adequate procedures works well until

Indian companies get more clarity.

What is the extent of TRACE International's operations in India? Who are the pharma clients in India as well as global clients dealing with India?
TRACE is headquartered in the US but operates globally, with offices in Canada, Europe, Africa and Asia. We have a partner law firm in India with which we work very closely. Our clients and members include hundreds of multinational companies with operations in India. We also work with hundreds of small and medium local enterprises across industry sectors in India, including pharma. We don't list member companies without first obtaining their approval.

It is a common practice for pharma companies to pay speaking and consulting fees and provide international travel expenses to doctors. What are the latest laws to anti-bribery and transparency laws on such practices? Any examples on how such practices were investigated, detected and dealt with? What were the penalties involved?
Where doctors are employed by the government, they are considered government officials under the Foreign Corrupt Practices Act (FCPA) and would be considered 'public servants' for purposes of India's Prevention of Corruption Act. While speaking and consulting fees can be legitimate, they have also been used as sham vehicles for improper payments by pharma companies to encourage doctors to prescribe their products.
For example (all settled in 2016):
- AstraZeneca ($4.325 million disgorgement plus $822,000 interest and $375,000 civil penalty)
- GlaxoSmithKline ($20 million civil penalty)
- Teva Pharmaceutical Industries (criminal penalty of more than $283 million and disgorgement of approximately $236 million)

What are the most common risks that pharma companies face when engaged in transnational business?
Pharma companies often rely on complex supply and distribution chains, complicating the prevention of third-party bribery. Additionally, extensive government regulation of products can be burdensome, providing temptation to expedite approval through improper means. Under state-run healthcare systems, doctors are considered government officials, which brings into play the FCPA and its significant penalties. Finally, there is a heightened risk of abuse of practices relating to gifts and hospitality within the industry (for example, sponsored conference participation, the funding of research trials, promotional items and activities, etc).

How is the pharma sector different, in terms of the vulnerability to bribery, from other sectors? Any peculiarities, given that we are dealing with lifesaving medicines and doctors who are the decision makers, not the actual consumer, the patient?
The pharma sector is distinctly characterised by a combination of huge markets and vigorous competition among a limited set of players. Other relevant characteristics of the industry are the heavy government involvement in distribution and regulation and the extremely high stakes involved in the development and marketing of new products. As elsewhere, however, bribe-takers are violating a fiduciary responsibility — where professional or civic — with harm generally borne by a public with no direct involvement in the transaction.

What are some of the safeguards that pharma companies can take to mitigate these risks?
The relation between healthcare systems and state or national governments is complex and dynamic. It can vary tremendously from one country to another and within a single country over time. Pharma companies can cultivate a sharpened awareness of these conditions in each market and of the incentives and liabilities to which they give rise. Additionally, requiring rigorous due diligence and prioritising institutional commitment to compliance within the industry is a critical part of fighting corruption.

> Enhanced compliance training is especially important for employees involved in deal-making, such as sales representatives. Companies should also take care to structure incentives in a way that does not encourage wrongdoing

The pharma sector sees many deals, be they mergers, buyouts, etc. What are the red flags that need to be heeded during the due diligence process?
M&A due diligence is a huge topic about which volumes can be written. Perhaps the three most common M&A red flags are (1) ownership by a government official; (2) very obscure corporate structures; and (3) elaborate sales and marketing chains involving agents and sub-agents, the responsibilities for which are not clear. Generally, companies should be thorough and mindful of the scope of successor liability. If there is a problem, the responsible parties will want to know about it before the deal closes, and it must be addressed before additional liability accrues.

What can pharma companies do to increase levels of compliance and ensure their employees adhere to local and global anti-bribery laws?
Interactive anti-bribery training is an essential element in building a culture of compliance, and all multinational companies should require it. Enhanced compliance training is especially important for employees involved in deal-making, such as sales representatives. Companies should also take care to structure incentives in a way that does not encourage wrongdoing. Finally, awareness and understanding of all applicable legal regimes is hugely important for preventing liability.

Tell us about your recent trip to India this May.
I attended the Trade Winds conference in Delhi. It was a great success and a chance for US companies, Indian companies and trade facilitators from the US Department of Commerce to meet in a collegial, but structured manner. The level of interest in the Indian market was clearly very high. From our perspective, it was very encouraging to see the extent to which Indian companies are weaving anti-bribery compliance into their strategy. We come to India regularly and we see the level of sophistication on compliance ramping up very quickly. TRACE provides a public database of pre-vetted business partners in India (and around the world) and we are seeing increasing reliance on this database to find local partners who have been trained on anti-bribery provisions, have adopted a code of conduct and have otherwise committed to a clean and transparent approach to business.

After Trade Winds, we travelled to Mumbai for a TRACE Workshop with about 70 US and Indian companies. The discussion was lively and sophisticated!

viveka.r@expressindia.com

INTERVIEW

'Data science can help in research and development of new drug therapies'

A drug's journey from initial conceptualisation to hitting the market place remains a costly, complex and time-consuming process with no guarantee of success, informs **Swetabh Pathak**, Co-founder and CEO, Elucidata to **Akanki Sharma**, while elaborating more on the process of drug discovery and the role data science plays in making the process easier

What led to the origin of Elucidata and what products and services does it offer?
Advancement in technology coupled with reducing costs, has shifted the focus in drug discovery from data generation to data analysis. With biological data being produced at an unprecedented rate today, pharmaceutical companies require faster data analytics to gather relevant insights in time. This growing need for fast data mining spurred the origin of Elucidata, a data analytics startup that helps in drug discovery.

Our mission is to use data analytics and to transform decision-making processes in R&D labs in biotechnology and pharma companies. We build algorithms and software to process, analyse and visualise large omics datasets across metabolomics, genomics, transcriptomics and proteomics, among others. We build our own products and provide customised solutions for our partners and analyse datasets to answer specific questions. Elucidata has already raised a funding of $1.7 million and is working with some of the leading global pharma companies.

Our products include
- **Polly:** A cloud-based, integrative omics data analytics platform, that can drastically transform the end-to-end drug discovery process and allow for more rapid data turnaround and analysis. Polly can easily adapt to several types of data workflows and features an array of applications that can process, analyse, integrate, and visualise biological data.
- **El-MAVEN:** An LC-MS data-processing engine for large-scale metabolomic experiments that can handle

large datasets (tens of GBs), with an interface built for ease of processing and visualising hundreds of samples.

How important is Elucidata's role in pharma companies? Do you target both domestic as well as international pharma companies?

In the past, researchers and scientists were hesitant in using data science to further advance the development of new pharma drugs and other medical therapies. However, they soon realised that traditional analytical tools were inefficient in analysing large sets of data, and how dependent these two fields are on each other. The need for better data analysis platforms has been felt acutely in recent times.

This is where Elucidata's role becomes crucial. With the use of data science and cloud-based metabolomics data analytics platforms like Polly, the rate at which new medicines are being approved is changing. We are seeing an explosion on data for the pharma industry and the ability to integrate data sets has moved forward massively due to companies like ours, helping in the advancement of drug discovery.

At present, we are working with leading global companies with presence across markets, including India and we hope to expand our presence across both domestic and international pharma companies in the coming years.

> We are keen to work with India biopharma to bring us to the forefront of global drug discovery. We have also been in active conversations with a few labs, hospitals and pharma companies in India

Kindly elaborate on the role of data science in drug discovery.

There are four key areas in pharma where big data can play a crucial role:

- **Omics data management**

The success of genomic sequencing techniques and their affordability has increased their importance in clinical diagnosis and in research. However, analysing them and extracting salient features will help in diagnosis is a job for big data analytics.

- **Clinical trial management**

Conducting large population trials with enough diversity and across multiple study sites is an odious task. Conventional data management and analytical tools may prove insufficient to scale up studies and to make sense of diverse streams of data. Data analytics and management platforms can help by enabling rapid turnaround. Allowing scientists and doctors to respond in real-time should help increase the chances of success of clinical trials.

- **Drug candidate selection and pipeline development**

Using complex algorithms to screen large databases containing biological, chemical and clinical information can help whittle down the right candidates amongst thousands, probable for testing. Advanced analytics is helping analyse clinical data and candidate profiles.

- **Orphan drugs, rare diseases and drug repurposing**

With big data analytics, companies can also identify specific subpopulations for which a 'failed' drug can still be a success. This practice of drug repurposing is especially beneficial to patients suffering from rare diseases that may not be commercially attractive for dedicated product development.

What bottlenecks does the pharma industry face in the drug discovery process in India? How can Elucidata help eliminate them?

As a developing market, India is figuring out the best standards for itself. But there are certain global challenges that everyone, including the Indian pharma industry is grappling with.

Firstly, it usually takes years of effort, money and data mining to bring a drug from bench to bedside. A drug's journey from initial conceptualisation to hitting the marketplace remains a costly, complex and time-consuming process with no guarantee of success. According to a recent report by Pharmaceutical Research and Manufacturers of America, it takes an average at least 10 years for a drug to make the journey from discovery to the marketplace at an average cost of $2.6 billion. Data science aims to thereby streamline the process involved in selecting a candidate drug, developing it, getting it into the clinic and then to the public. Our main goal is to shorten the drug discovery process.

Another challenge in the drug discovery process is the analysis of large sets of data. Traditional analytical tools fall short in analysing huge amounts of data. Here, data science plays a pivotal role. Using data analysis in pharma simplifies comprehensive datasets that are troublesome to understand with conventional programming, equipment and techniques. By finding affiliations and understanding examples and patterns inside these datasets, we can possibly improve care, lower expenses, and spare lives. Data science can help make informed and educated choice in research and development helping in the creation of new drug therapies within the pharma industry.

How does Elucidata aim to enable advancements for pharma brands in India? Can you share a brief about your partners?

We are keen to work with India biopharma to bring us to the forefront of global drug discovery. We have also been in active conversations with a few labs, hospitals and pharma companies in India. We believe our technology will be useful to companies working on India-specific problems as well. For instance, diabetes is an epidemic in India. We have run a lot of analysis related to metabolic diseases. This kind of technology will be useful to any company working on a better cure for diabetes. We are currently working with global brands like Pfizer, Aruon, Yale School of Medicine, Labs at Princeton, and UCLA to name a few. We hope to expand our presence globally in the coming future.

What opportunities do you see for new age start-ups in the healthcare technology space?

Quick advances and innovation in big data and Artificial Intelligence (AI) are effectively changing the life science space — thanks to technology and numerous online healthcare products. There is a lot of information driven by patient profiling, consistency, administrative prerequisites, and logical research. Startups are using this information to support a wide scope of healthcare capacities around clinical choice help, illness observation, and clinical investigation. There is a tremendous opportunity in big data, gene-based studies, omics research and improving patient care via AI. We believe this is just the beginning. We are moving towards a technology-enabled, better-managed future of healthcare and pharma services.

akanki.sharma@expressindia.com

INTERVIEW

‘The global drug development division is the engine that powers the Novartis pipeline’

The Global Drug Development (GDD) centre in Hyderabad, is one of the three major global development sites for Novartis. **Arno Tellmann**, Head, Global Drug Development India, elaborates on the centre's vision, its work towards developing new and innovative drugs, the company’s transforming drug development with new age technology and more, in an exclusive interview with **Lakshmipriya Nair**

What is the vision of Novartis’ Global Drug Development (GDD) centre? What kind of new paradigms do you want to usher into the drug development life cycle?
Novartis Global Drug Development (GDD) centre in Hyderabad, India, is a fully

integrated global centre, which plays a vital role in almost every aspect of drug development. The centre focusses on development programmes to determine and establish the safety and efficacy of a potential new medicine in humans. By bringing together digital revolution and advances in the pharma industry, it is opening up the possibility of treating targets, which were previously deemed 'undruggable'.

How does the centre enable Novartis to lead from the front when it comes to the development of new and innovative drugs with far reaching impact?
The global drug development division is the engine that powers the Novartis pipeline. GDD India supports critical components of the drug development process across all therapy areas and Novartis' pipeline, including innovative medicines (pharma and cancer treatments), and Sandoz (generics and biosimilars) and supports key global functions across clinical development, data management, biostatistics, and data analysis. The centre is playing a critical role in enabling Novartis' strategy to bring life-saving medicines to market including breakthrough products like the heart failure treatment Entresto (sacubitril/valsartan) – known as Vymada in India, Cosentyx (secukinumab, AIN457) – Scapho in India, and Kisqali (ribociclib, LEE011) – Kryxana in India.

What will be the next frontiers in drug development and delivery? How is the GDD centre and Novartis as a company geared to master them?
Developing new medications is an expensive, slow and failure-ridden process. However, data and digital interventions could change that drastically. Novartis is committed to exploring opportunities to leverage new technologies such as artificial intelligence and machine learning that can help accelerate the drug development process. Our efforts are also directed towards fostering a vast ecosystem of partners across the healthcare and technology sectors, an area where the GDD centre in India will play a crucial role. Given the huge talent that we have in the technology sector here, we are looking for avenues to collaborate and innovate.

What are the areas of focus at this centre? Which are the innovative and breakthrough drugs/treatments that are being researched and developed here?
Globally, Novartis as an organisation works in six key therapeutic areas: cancer, cardio-metabolic, respiratory, immunology and dermatology, ophthalmology and neuroscience. India offers a critical mass of industry-leading talent. This enables GDD in India to support critical components of the drug development process across Novartis' broad, integrated pipeline.

For instance, Novartis is developing a digital tool to enable independent early screening of leprosy using AI and deep learning.

Novartis is also in the process of developing some of the most advanced malaria development programmes worldwide. The team in India is extending significant support to this programme. These compounds hold great promise and can go a long way in helping us support the central government's commitment to eliminate malaria by 2030 in India.

How do you choose or shortlist the areas/segments for research and development? What are the parameters?
While our focus is on six therapeutic areas - cardio-metabolic, ophthalmology, respiratory, neuroscience, immunology and dermatology, and cancer, our priority is to identify the unmet needs of underserved populations and integrate these needs into our drug discovery and development strategy. We continue our long-standing commitment to reduce the burden of infectious and tropical diseases. Our innovation process also includes adapting existing products for different types of patients or diseases and for diverse environments. Most often, this work is done with a specific focus on poor and vulnerable patient groups, such as children or the elderly.

GDD centre's webpage claims that it works at making the drug development process simpler, more flexible and efficient. So, what does it entail?
Applied to the drug development process, we are leveraging digital tools to transform the way we develop medicines, and the efficiency with which we do so. We are systematically improving all elements of clinical development by using machine learning to conduct predictive analyses on our operational data resources to facilitate data-driven decision-making in current and future trials.

How are new technologies such as biomolecular platforms, digital technologies and automation driving being deployed at the GDD centre to augment and accelerate R&D breakthroughs?
Digital technologies and data science have incredible potential to unlock the next chapter of medical innovation. Integrating digital into the way we work has enormous benefit for Novartis by improving the way we work with data – one of the most valuable assets we have as a company. Utilising the latest emerging technologies helps us capture better data – making us smarter and more efficient in the ways we approach drug discovery and development.

How would the work being done at this centre enable progress to India's healthcare scenario? What will be its impact?
As an integrated part of Novartis' overall drug development process, GDD India plays a critical role in enabling Novartis' strategy to bring life-saving medicines to patients across the world. It includes addressing India's disease burden, especially when it comes to tropical diseases like malaria and leprosy and non-communicable diseases that have increased owing to changing lifestyles. Our breakthrough products like the heart failure treatment Entresto (sacubitril/valsartan), Cosentyx (secukinumab, AIN457), and Kisqali (ribociclib, LEE011), were supported by teams in GDD India, and all these drugs were also made available to patients in India soon after their global launch.

Does GDD centre have any collaborations with the government, academic institutions or research organisations? If yes, how do these partnerships work? If not, are you looking at any tie-ups in the recent future?
We look for collaborations where we can further existing and new interests in the area of drug development. For example, we collaborate with academic institutes like National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad to provide students an overview of a drug's journey – from concept to clinic to commercialisation in order to help them develop industry-ready skills and capabilities. We have also set up a digital innovation lab in Hyderabad and have been engaging with the start-up ecosystem in Telangana to identify health tech companies passionate about disrupting healthcare to address real world problems. We continue to explore partnerships that will enable us to equip our associates with the skills and capabilities required to bring in efficiencies or explore new technologies such as AI and machine learning that can accelerate the drug development life-cycle.

Do you have similar centres in other countries? If not, why was India chosen to house this center? What makes it the ideal location?
The global drug development centre of Novartis in India is one of the three major global drug development centers for Novartis, the other two being in Switzerland and the US. It plays a key role in Novartis' global vision of combining deep therapeutic area knowledge with advanced, integrated data analytics to drive an agile approach to drug development. This site has integrated development capabilities and the added advantage of housing key drug development functions under one roof resulting in enhanced collaboration internally as well as with Hyderabad's thriving innovation ecosystem.

lakshmipriya.nair@expressindia.com

POST EVENT

Smart Manufacturing Conclave held near Mumbai

More than 100 IT functionaries from manufacturing companies from across India participated at the event where role of IT in pharma was discussed

THE INDIAN Express Group's Express Computer magazine recently organised its maiden Smart Manufacturing Conclave in Khopoli near Mumbai, where more than 100 IT functionaries from manufacturing companies participated from across India. On the sidelines of the conference, the Smart Manufacturing Awards recognised organisations from the manufacturing sector, for their innovative use of new-age technologies.

A panel discussion 'Lessons from digital transformation: The Pharmaceutical Industry Perspective' was held during the event, having panelists Gyan Pandey, CIO, Aurobindo Pharma; Naga Prasad Vaitla, Vice President – IT, Granules India; Suryamohan Surampudi, Sr Director and Head, GxP IT Administration and Assurance, Dr Reddy's Labs; Avadhut Parab, Global CIO, Wockhardt. Parab informed about the initiatives taken in the last one year on the digital front. The idea of making the medical representative (rep) as a super representative was initiated. The rep was empowered with a chatbot, that has a 360-degree view of the doctor. Also, a Zoom software is being

tested, which will lessen the travel time of the rep. The company is exploring to use AI in biotechnology to increase yield by over 20 per cent; and in capacity forecasting too.

Vaitla informed about using technology in the area of training. VR is being used for employees to be trained on various apparatus because all the equipment to be used cannot be bought separately for training. A curriculum has been created for the said purpose.

Aurobindo is also running various projects enabled by IT. In the field of logistics, technology adoption has resulted in efficiency in the movement of goods. The adoption of IT is slow but regulation is kicking in faster technology acceptance and serialisation is an example to demonstrate and so is electronic batch records, because auditors are doubting the integrity of the manual record.

At Dr Reddy's, the company is into its third year of the digital journey, which began in 2016. The senior management was taken into confidence before taking up the digital roadmap. It had three pillars: data availability, centralisation of data and data analysis.

EP News Bureau

IDMA organises Marketing and Sales Conference, 2019 in Mumbai

The theme of this year's conference was "Growing Brands to Level Next"

Tarannum Rana
Mumbai

THE INDIAN Drug Manufacturers' Association (IDMA) recently organised a Marketing and Sales Conference for the year 2019. The theme of the day long conference, which was held in Mumbai, was "Growing Brands to Level Next". The event was attended by business development and marketing professionals from the pharma industry.

Daara B Patel, Secretary-General, IDMA, initiated the conference by welcoming the attendees, and giving them a brief introduction on the conference and its panelists.

Following his welcome address, Sudarshan Jain, Secretary-General, Indian pharmaceutical Alliance, gave a presentation on the topic "Growing Business is Building Brands". Speaking on the need for pharma companies to go back to the basics of brand building, Jain reiterated the significance of a customer-centric business development strategy. He suggested five, simple approaches to enhance a pharma company's branding efforts. These included having a patient-centric approach while developing strategies and minutely customizing a company's brand strategy according to specific areas of interest. He also cited the example of Thyrocare, which revolutionised thyroid disease diagnosis , for presenting a unique business model which complemented other pharma businesses, thereby securing a firm hold in the industry. Referring to Ayushmaan Bharat Yojana, he stated, "If 50 crore people come under the gambit of the scheme, it will significantly open up the market for pharma companies. Ours is not a demand led market, but a supply led market. We need to leverage this demand."

The next speaker, Shrihari Shidhaye, Founder Partner-NextPlan Consulting, talked about some new, emerging concepts that can be implemented in brand building. These included customer micro- segmentation, utilising digital advancements to "leverage and impact customers for better patient outcomes", improving adherence among patients suffering from chronic conditions, journeying from accumulating "lots of data" to converting them into insights. "Most importantly, we need to generate PoD (Point of Differentiation) in a crowded market by focusing on 'what matters' for customers, and 'where do we stand' on such matters," stated Shidhaye.

Speaking on the relationship between brand building and geographical expansion, Abhay Lonkar, Partner, NextPlan Consulting, stated the need for brands to look at a prospective market not in terms of its area, but by the size of its population. "There are many Indias within India. The country needs to be looked at not as a single market, but as hub of many. Different states call for different brand strategies. Several FMCG brands have done this. And it is high time that pharma companies follow."

C. Ashok Kumar, MD, Healthcare 360, talked on the relevance of technology as not only a necessity to bolster a company's foothold in a world that is constantly evolving at a breakneck speed, but also as a brand accelerator. He also talked Kardio Screen by Imedrix, which he claims has the potential to transform cardio disease screening in primary and secondary level healthcare.

Later, Sanjay Bhatia, Partner, NextPlan Consulting talked at length about the concepts that a company can apply to extend brand franchises, asserting on the need a comprehensive situation analysis (both micro and macro). He also said that while weaknesses need to be overcome, strengthening a brand's strength points is even more important.

Salil Kallianpur, Founder and CEO, ARKS Knowledge, who spoke next, spoke on how digitisation has transformed the way brands can connect with their customers. He noted that if digital outreach is done properly, it could easily cut down a sale representative's time that usually goes into explaining the product profile to a customer, making the entire process a lot smoother for both the firm and the customer.

Speaking on brand evaluation and financing, Gawir Baig, Director, O3 Capital, addressed multiple multiple aspects to the subject, including criterion for private equity investment for drug firms. The last speaker, Vinayak Gokhale, Partner-NextPlan Consulting, talked on the topic "Brand Planning to Implementation- SFE Domain".

Vinay Pinto, Chairman, Marketing Committee, IDMA, thanked the speakers. The conference then ended with a Q and A session.

tarannum.rana@expressindia.com

PRE EVENT

PharmaLytica 2019 set for an impressive debut in Mumbai

Over 300 turnkey exhibitors to participate in India's most comprehensive Analytical, Lab, Pharma Machinery & Ingredients Trade Show

UBM INDIA, organisers of CPhI / P-MEC India, the leading global pharma trade show and conference, announced that the 6th edition of the PharmaLytica expo will move to Mumbai from Hyderabad. Formerly a two-day event, Pharmalytica 2019 will be an even more comprehensive three-day show slated to be held between June 10-12, 2019 at the Bombay Exhibition Center, Mumbai. The reputed pharma related expo will seek to leverage the opportunities provided by the impressive pharma hub in West India, while also being in close proximity to the South Indian market.

The expo will enable the pharma community pick up on the latest industry trends, innovations and conduct business with analytical, laboratory, machinery, packaging, pharma ingredients and other allied Industries. The expo is well supported by associations including Pharmexcil, Confederation of Indian Pharmaceutical Industry (CiPi) and Indian Drug Manufacturers' Association (IDMA).

PharmaLytica will witness the participation of over 300 exhibitors from across the country including notable industry players, many of whom are making their maiden showcasing at Pharmalytica. Some of the exhibitors include Elmach Packages, Shimadzu, Dockweiler, Micronclean, Rotarex, Bruker India Scientific, Sartorius, Schott Kaisha, Gattefosse, Perkin Elmer; Thermolab Scientific Equipments, Nicomac Cleanrooms, Mack Pharmatech, Gangwal Chemicals; Kirloskar Pneumatic, Swati Spentose, Borosil Glass Works, Accupack Engineering, NPM Machinery, Toshvin Analytical, Spinco Biotech, Scientific Research Instruments, LP Global, Bitzer India and Anton Paar.

With country participation from Luxembourg, UK, Germany and China, as well as state presence from Maharashtra, Gujarat, Andhra Pradesh, Telangana, Punjab, Haryana, Tamil Nadu, Delhi and Uttarakand, PharmaLytica is well on its way to becoming a truly pan-India congregation that reaches out to all major Industry sectors and Pharma Hubs. This year, there will be special pavilions dedicated to Pharma Machinery & Packaging; Lab Analytical & Cleanroom and API's & Excipients Pavilion.

To enhance the touch-and-feel aspect of the expo, one of the much-anticipated highlights will be the inclusion of Exhibitor Showcase, where visitors can attend featured presentations, hear best of case studies around innovations and technologies trending within the Pharma marketplace. Exclusive B2B Meeting Area and Customer Insight Lounge will also be organised to connect buyers and sellers, enhance the ease of doing business as well as to increase sectoral insights.

EP News Bureau

A BACKBONE CALLED BIRAC

From the day it came into existence, the Biotechnology Industry Research Assistance Council (BIRAC), an institution set up by the Department of Biotechnology (DBT), Government of India, has been backing a number of biotech startups to undertake research and innovation, in turn, strengthening and empowering the biotech industry in the country

BY AKANKI SHARMA

Necessity is the mother of invention and this is what drives every startup that comes up with an innovation to fulfill an underserved need, benefitting the society, and leading to the growth and betterment of an industry. Further, when it comes to biotechnology industry, Biotechnology Industry Research Assistance Council (BIRAC) nurtures and supports these startups by bridging the gap between the industry and academic institutions in order to give a boost to the sector. And, the support offered by BIRAC has led to many success stories.

According to Dr Renu Swarup, Secretary, Department of Biotechnology, Ministry of Science and Technology, and Chairperson, BIRAC, it evaluates the proposal based on unmet need, affordability, societal relevance, novelty and feasibility while considering a project for funding and closely monitors/mentors it for its successful completion. *(See interview: Startups must make sure their idea has a market need).*

Let's look at the case of Dr Ranjana Srivastava, who came up with a startup named Nextec Life Sciences. With a passion for science and a personal commitment to help people suffering from a particular lack of accurate diagnosis across the world, she came up with this biotechnology company, which is based in Lucknow, Uttar Pradesh.

Founded in 2012, Nextec Lifesciences focusses on development of diagnostic assays for infectious diseases, biomarkers and diagnostic/screening assays for lifestyle-related and life-threatening diseases, biosensors, newer screening system solutions for novel antimicrobials, anticancer and more. It also provides consultancy to biotech and non-profits, outreach programmes for villages in healthcare education and screening camps for lifestyle and life-threatening diseases and invites NGOs to form alliances.

RANJANA SRIVASTAVA
Founder, Nextec Life Sciences

- Know your product. Define product in one sentence, value proposition, target market, unique benefit to customers, market competition analysis.
- Get angel investors or business incubators and accelerators for your startup. They can also offer mentoring or advice alongside capital.
- Government programmes that offer startup capital like MUDRA, Startup India, Make in India, BIRAC, Department of Science & Technology — raise funds by winning contests.

SATHYAN KUPPUSAMY
Whole-time Director, Tergene Biotech

- Work on how you can demonstrate your ideas at a small scale and try to establish 'proof of concept' with minimum budget.
- Today, there are quite a number of funding mechanisms available from various agencies like BIRAC, Gates Foundation, Wellcome Trust, Grand Challenges, etc. Keep looking for RFPs and pitch your ideas/work constantly until you succeed.
- Always be ready with a strategic business plan which is crucial for attracting PE/venture capitalists and essential for successful commercialisation of your product.

MOHANRAJ SUBRAMANIAN
CMD, AlgaIR NutraPharms

- Have a clear objective.
- Have a clear business plan, including funding source, strong strategic approach and strong market plan.
- Tolerate and cope-up with any worst situation with patience, as research-driven biotechnological products will take more time than doing any other business.

The inspiration for the company came after one of her family members was diagnosed with primary complex, a form of TB (an infection of lungs) which affects young children. Dr Srivastava recalls, "The boy was not gaining weight and looked pale. After an X-ray of the chest, the doctor suspected primary complex and told us that this infection usually resolves on its own as a child develops immunity over a six- to-10-weeks period but in some cases, it can progress and spread all over the lungs (called progressive tuberculosis). In case it crosses the brain, it could be fatal and thus a combination of drugs was strongly advised. Over the period of his treatment, I observed that he lost his appetite, leading to severe weight loss. His immunity lowered, with a running fear of side effects." She further informs, "Even after the treatment, the point that kept bothering me was how could the infection be confirmed without showing the presence of infectious bacilli. That's when I decided to develop a DNA-based diagnostic test for TB."

Srivastava adds, "We used molecular techniques to identify a stretch of DNA from the genome of Mycobacterium tuberculosis, which was specific to *M. tuberculosis*. The fragment was sequenced and patented in the US (1997, 1998) and India (2006) for its use in the diagnosis of TB. Incidentally, it was the first biological patent from India and a detection system was developed. Central Drug Research Institute (CDRI) then licensed the technology to a Mumbai-based company but this did not work out. So, I decided to start a biotech company and generate funds for developing a TB kit to enable rapid and accurate diagnosis of TB, leading to the birth of Nextec Lifesciences."

Inspiration and motivation

Just like Srivastava, Telangana-based Tergene Biotech was co-founded by Sathyan Kuppusamy, whose father M Kuppusamy has 40 years of experience in the field of vaccines and biopharma products. "We started the company with a vision to develop life-saving vaccines against infectious diseases. There is a huge unmet medical need to cure and treat infectious diseases, for instance, pneumonia. We started working on a 15 valent pneumococcal conjugate vaccine, which should be affordable and at the same time provide a wider protection against prevalent pneumococcal serotypes," informs Sathyan.

However, any new journey comes with its own challenges. While doing something new, one witnesses several ups and downs, but if the passion to achieve something is strong enough, inspiration and support come your way.

So, while on her way to being an entreprenuer, Srivastava was inspired by her husband Dr Brahm S Srivastava, a scientist and Co-partner at Nextec. He became her first guru to teach her molecular biology. Post marriage, she moved to a molecular biology lab in the University of Brussels, Belgium. Thereafter, Dr Nityanand, former Director, CSIR-CDRI and Dr S Ramachandran, former

Secretary, Department of Biotechnology, GoI became the role models in her journey.

"Dr Nityanand gave me a lab and the freedom to work even as a pool officer with all financial support. He made sure that we established gene cloning in CDRI. This was the best scientific challenge responsible for my success. Dr Ramachandran played a great role in my sustainance in recombinant DNA field which was totally new for India and required imported reagents. He personally made sure of the availability of all molecular reagents, restriction enzymes and DNA ligase to all users within the country and established powerful gene cloning technology," she shares.

Apart from it, a Biotechnology Ignition Grant (BIG) from BIRAC, Department of Biotechnology, Government of India (2015-2017) for development of DNA-based diagnostic kit for early and accurate diagnosis of tuberculosis came as another accolade for her. Using DNA as diagnostic marker, the kit detects TB within 20 minutes.

Then, this year in March, Srivastava was also conferred Biotech BIRAC-TiE Winer Award for Entrepreneurial Research 2019 by BIRAC, Department of Biotechnology, GoI.

For Sathyan, his role model was his father who has worked with various organisations, including Ministry of Health and Family Welfare and Indian Council of Medical Research (ICMR). "I draw my inspiration from all his accomplishments and his never-ending quest for research and development of novel vaccines and bio-therapeutics," he apprises.

Handholding startups

Founded in 2008, Tergene has developed platform technologies for novel vaccine candidates and the first product would be the pneumococcal vaccine which is currently in the clinical stage of development. The startup has also supported several biotech companies and research institutions by supplying them with carrier protein, mainly used in conjugate vaccines and cancer research.

Sathyan states, "The research work on pneumococcal vaccine started in the year 2010. In 2011, the Department of Biotechnology (DBT) through their BIPP scheme supported Tergene with a small grant for 'proof-of-concept' work. More than the funding support, it was the encouragement given to a start-up company like us at that point of time and it should be noted that even BIRAC was not in existence during that time. Since then, we have been constantly receiving funding from BIRAC for the pneumococcal vaccine project. Apart from funding, BIRAC appreciates and recognises the advancement in the field of work we do. For instance, in the year 2013, Tergene received BIRAC's Innovator Award in recognition of the technology that has been developed for an indigeneous, Asia-specific pneumococcal conjugate vaccine. They have been handholding us in terms of providing advisory on the regulatory pathway and representing the industry's concerns to the regulatory bodies and appraising the Government of India about the development of much-needed vaccines like the pneumonia vaccine. Most recently, we received a grant funding from BIRAC under the National Biopharma Mission supporting the clinical trials of our pneumo vaccine."

He adds, "BIRAC's support will be there for any product until it sees the light of commercialisation and reaches the common man. The projects are selected on the basis of technical merits and also keeping in mind the country's requirements and unmet medical needs, which are their top most priority."

Tergene's pneumococcal vaccine has completed Phase I clinical trials in India. Phase-II clinical trial of the vaccine is under way and the results are expected in the next two to three months. The company also has plans for global trials, which will be decided in due course of time.

Practices and suggestions

Another startup, AlgalR NutraPharms, that came into existence in July 2014, was founded by Mohanraj Subramanian, who is also the CMD of the company. Based in Tamil Nadu, it provides high-pure algal DHA oil and algal DHA capsules in bulk.

DHA provides significant health benefits to humans, particularly in reducing cardiac diseases, stroke, high blood pressure, depression, arthritis, and brain development in children. In earlier days, fish-derived DHA was popular but had several disadvantages, including fishy odour, fishy taste and heavy metal contaminations. Hence, pure vegetarians do not prefer it. So, Subramanian felt the need of extracting DHA from microalgae, which is 100 per cent vegetarian and came up with these capsules.

He also informs that BIRAC has played a crucial role in his company's growth. "It has first financially supported the new idea, which has a market potential. Based on the proof of concept, BIRAC again supported us and took us to the next level. Now, our company can secure many international orders and we can compete with many Chinese companies on quality, and with the US and European companies on price. The institution assigned us a single mentor Professor Guhan Jayaraman at the initial stage, who later became a collaborator of our project. His guidance and support were productive. Moreover, BIRAC's practices and suggestions in the Technical Expert Committee meetings were all productive and shaped us appropriately."

When the going was tough during his entrepreneurial days, his professors became the role models who inspired him to keep on working towards his goal.

Sathyan even expresses a little disappointment by saying, "Many young brains with the real potential to bring changes in our economy could not reach the target, as they were tired of too many regulatory components and financial setbacks."

ANAND ANANDKUMAR

Co-founder and Chief Executive Officer, Bugworks Research

- Ensure that the founding team has a good mix of science, execution and networking capabilities – many companies from India in the bio space fail because they lack one or more of these vertices.
- Choose a big problem and come up with a differentiated solution. India is an excellent place to do R&D and create Proof of Concept. However, Indian market is brutal and one has to look globally for business opportunities.
- Ethics in everything you do (corporate, financials, science, dealing with fellow-employees) – this is uncompromisable!

TUHIN BHOWMICK AND ARUN CHANDRU

Co-founders, Pandorum Technologies

- "Vasudhaviva Kutumbakam: The world is just one family." So, think global.
- Quoting Mary Shelley, they say, "Of what a strange nature is entrepreneurship! It clings to a mind when it has once seized on it like a lichen on a rock."
- Quoting Swami Vivekanada, they emphasise, "Arise, awake and stop not till the goal is achieved."

Apart from DHA oil and algal DHA capsules, Algalr provides vegan algal DHA powder –FF10, FF20, FF30, and EN 10 (human nutritions); Omega3-226 for animal feed (pet animals); Omega3-Pro for animal feed (Aquaculture); Omega3-lite for animal feed (poultry industries) and Spiromax-PS and Spiromax-DR (for growth and disease resistance in prawn culture), apart from Algal DHA oil and algal DHA capsules.

Fairness and transparency

Moving on to the story of Pandorum Technologies based in Bengaluru, co-founders Arun Chandru and Tuhin Bhowmick came up with their startup in 2011 to bio-engineer functional human tissues and organs suitable for clinical implantation with the support of DBT and Association of Biotechnology Led Enterprises (ABLE).

The duo had won Rs 5 lakh at BEST 2010 organised by the DBT and ABLE at the Indian Institute of Science, which became another motivational factor for them to work for the betterment of the society.

As more and more innovations take place and biotech industry keeps growing in India, it is hoped that BIRAC will keep standing firm and offer its support for a better future of the industry ahead

Describing the role of BIRAC in supporting the journey of Pandorum, Chandru says, “We are recipients of BIG, IGNITE and SBIRI grants and fellowships. BIRAC-supported biotech ecosystem in India has been crucial for deep-tech startups such as Pandorum to sprout and thrive. More importantly, we have been fortunate to be mentored by Dr Renu Swarup, Chairperson, BIRAC. Leaders from academia and industry- Dr G Padmanabhan (ex-Director, Indian Institute of Science, Adviser – BIRAC and Dr Kiran Mazumdar Shaw, CMD, Biocon, have been instrumental in shaping our vision.”

A company with distinct synergy of life science, engineering and clinical competencies, Pandorum Technologies works on design and manufacturing of functional human tissues -- cornea and liver — for medical research and therapeutic applications.

Elaborating on how BIRAC stands as a support during the journey of biotech startups, Anand Anandkumar, Co-founder and Chief Executive Officer, Bugworks Research, says that only a small number of unique scientific ideas get translated into a product, and even a lower number of the products become profitable. Thus, the act to fund novel scientific ideas is a high-risk venture and that too in a country that generally lacks a technical and business finesse to support innovative scientific ideas. “BIRAC has been a clear gamechanger concept and application. It has been a harbinger in the field of biotech and medicine. Multiple seed grants from BIRAC initiated Bugworks’ journey from early 2014. One of the unique aspects of BIRAC is that its grant selection process is fair and transparent. It should be the ‘go-to model’ that might be introduced into other government agencies that deal with science translation in areas such as engineering, physics, and chemistry.”

The massive unmet need in the world owing to lack of any new broad-spectrum antibiotics since the 1960s became the reason Anandkumar thought of coming up with Bugworks Research. He says, “Of the nearly million deaths per year globally, a significant portion comes from India. We realised that neither western pharma companies nor Indian generic companies would invest in a space like antibiotics (that is so complex both from a science and economics space), and therefore started this company to invent a brand new class of broad spectrum antibiotics for the globe, from India.”

His father, who treated TB patients for more than five decades and whom he saw struggling with drug-resistant cases, became the inspiration for him coming up with this company.

Bugworks Research was granted $3-million by Boston-based CARB-X last year for developing next-generation antibiotics for drug resistance. Sharing details about the current status of this project, he notifies, “We have selected a preclinical candidate and are going through late stage preclinical work. The Good Laboratory Practice Toxical (GLP Tox) study is scheduled to be completed by Q4 of this year. If all goes well, we will enter clinical trials during the early part of 2020.”

As more and more innovations take place and biotech industry keeps growing in India, it is hoped that BIRAC will keep standing firm and offer its support for a better future of the industry ahead.

akanki.sharma@expressindia.com

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,
1st Floor, Express Towers,
Nariman Point, Mumbai - 400 021.
Tel: 91-22-2202 2627 / 2285 1964/ 6744 0000
Fax: 91-22-2288 5831
viveka.r@expressindia.com

INTERVIEW

‘Startups must make sure their idea has a market need’

Entrepreneurs’ journey is complex, and with biotechnology, it becomes more complex. However, more than 20 per cent of our start-ups have good success stories, informs **Dr Renu Swarup**, Secretary, Department of Biotechnology, Ministry of Science and Technology, and Chairperson, BIRAC to **Akanki Sharma** in a one-on-one interaction

SEED and LEAP funds are run through our incubators, under which we give them a fixed amount so that startups can invest. Under SEED fund, they can invest upto Rs 30 lakhs and under the LEAP fund, the investment can be up to Rs 1 crore

Since its inception, how has BIRAC been supporting the biotechnology and pharmaceutical industry?
As it shows in the name, Biotechnology Industry Research Assistance Council (BIRAC) was set up seven years back to support the biotechnology industry -- it’s the industry and the assistance which comes in. It was not just a large industry, but our focus was to try and see how we can support the startups and create a strong and vibrant innovation ecosystem. The main areas which we have focussed on after our partnership with the industry is primarily connecting the academia with the industry. Since that was a missing link, our first and foremost action was to connect these and make it into a platform. The second was building capacities -- to facilitate academic researchers to take their ideas and become startups and entrepreneurs and help them to move ahead. The third and most important focus was on how we make our Indian industry globally competitive — to take forward what they are already doing in terms of policy interventions and helping create the correct ecosystem. So, BIRAC has successfully been able to work through all these and it also looks at bringing in strategic partnership – both national and international.

The biotechnology sector is growing exponentially. The target is to reach $100 billion by 2025. Where does India stand in this and how is BIRAC going to accelerate this?
We had put out an action plan in 2016 when the government brought out the Start Up India Action Plan and this number of $100 billion by 2025 was in our 2015 strategy that was announced in December. Our main target is to scale up the number of startups. Thus, we had then said that we will have 2000 startups by 2020. While we directly support 1000, but the ecosystem itself has a large number in it (around 1700-1800), we do say that anything that happens within the biotech sector, somewhere the enabling factor has come from DBT and BIRAC. We have created incubation facilities, mentor groups and more importantly, we have brought investors on the front who can recognise and appreciate the biotech innovations. According to a report, we were somewhere around $45 billion at the bioeconomy as a whole. Going by those numbers, $100 billion seems a doable figure by 2025, and we will have a large number of initiatives that we have proposed -- like facilitating new product development, building capacities and more importantly, focussing on building the infrastructure, and a lot is happening for biopharma through the National Biopharma Mission.

Tell us about the National Biopharma Mission.
In the National Biopharma Mission, we focus on new product development, creating shared infrastructure facilities and building capacities. However, each of these have their own different challenges. Looking at the product vertical, the main objective is to prioritise and decide the importance in terms of disease burden and develop an indigenous product. And, the challenge is to take it quickly to the market, look out for the regulatory policies required to enable to facilitate that, connect what is happening within the country with what is already available globally and ensure

what we are making is not just globally competitive, but is also cost-effective and affordable for our own national needs.

Coming to infrastructure, the challenge is that we do have infrastructure within the country today but it's either within the government system, the public system or in the private sector. Hence, it is not affordable for the startups because there are competitive CROs working on it. So, there our effort is on how we can identify the best groups, partner with them — either create new ones or strengthen existing ones — and make them available and accessible to our startups and researchers. So, we are looking at all— cell line repositories and GLP facilities, among others, and all other facilities required in taking a lead to a product development. We are also looking at new vaccine development in terms of contributing from the research factor.

Any examples for this new vaccine development?
We are looking at various priorities – vaccines for RSV, influenza, cholera and tuberculosis (TB). And, the priorities will keep coming in. We may also look at new technologies which are brought into the country. So, there are various models in which we would function as we cannot have one model looking at all aspects.

BIRAC also has a number of collaborations with UK-based NESTA, Wellcome Trust and IKP Knowledge Park. Please elaborate on that.
The underlined philosophy of BIRAC is that we carry out all our activities through well-defined and well-identified strategic partnerships — be it national or international. Our models of partnership are different but the whole principle behind the partnership is that the partners we choose, add strength to whatever we are doing — be it connecting with larger networks where our startups can get access to larger market, investors, etc or co-funding partners where they bring in their funds and help us to look at co-funding opportunities, or in terms of larger partnerships where they bring in country-to-country partnership.

Our largest co-funding partnership is with the Gates Foundation. We have a project management unit (PMU) which is funded by the Gates Foundation and the WellcomeTrust, and DBT is the main government partner in that, which is responsible for running a large number of Grand Challenges India programmes. Apart form it, we have Grand Challenges Explorations and many more. There is Anti-Microbial Resistance — a four-countries challenge – Brazil, South Africa, Africa and India. We are also developing a partnership now with Grand Challenges Canada to see how we can work on innovations which are in the market place.

How is the partnership with Canada different from Brazil, Africa and South Africa?
Grand Challenges Canada is a funding body. DBT has an MoU with Grand Challenges Canada which we are wanting to take forward as they look at innovations which come from across the world. So, we feel that we will be able to bring in our innovators at a level where they can compete for those global innovations through the Grand Challenges Canada.

Kindly elaborate on the partnerships with WellcomeTrust and NESTA.
We are looking at MedTech Challenge that we will put out with the Gates Foundation and the WellcomeTrust which will look at all medical areas. The other partnerships are also with countries like Sweden and Finland. Recently, BIRAC took a whole delegation of incubators from India to Sweden to see how we can connect the incubated ecosystem. We have sister innovation hubs and C-Camp in Bengaluru is funded by BIRAC. We have signed an agreement with the US for an Indo-US sister innovation hub, and one with with the UK too. The purpose of these sister innovation hubs is to find out how our startups can have an exchange within the ecosystems, how they will have access to those markets, how their startups can look at markets in India and how they can connect with investors.

NESTA is working with Innovate UK, where globally they put out a challenge for AMR to see which group can come up and bid for a large price of eight or 10 million pounds. So, we felt that Indian innovators need to be strengthened to go for it. Thus, we have launched an India Discovery Fund with NESTA, under which we go with their panel of experts and evaluate everything. We have our own evaluators there, but that is for Indian innovators. So, it helps them to improve their research, so that they could be ready to pitch in for that large price. As of now, 11 innovators have been funded in two rounds. We are also considering an assessment now to see which of them have done well and they may need to get a second phase of grant if they are a little closer to submitting their applications for the price.

Tell us about the Sustainable Entrepreneurship and Enterprise Development (SEED) programme.
Sustainable Entrepreneurship and Enterprise Development (SEED) and Launching Entrepreneurial Driven Affordable Products (LEAP) — the new one we have put in — funds are run through our incubators, under which we give them a fixed amount so that startups can invest. Under SEED fund, they can invest upto Rs 30 lakhs and under the LEAP fund, the investment can be up to Rs 1 crore. So, we have created a whole value chain of going from an initial big grant of Rs 50 lakhs to going right upto getting some funding for their project development. Some of it happens through the grants. The next level is where we give them equity funds— SEED, LEAP and ACE. We have now set up a product commercialisation unit in BIRAC. It is when we identify products and technologies which are ready to go to the market, we actually become partners with them and identify what their needs are. If they need any assistance in regulatory matters, there is a committee set up in BIRAC — first hub, which meets every first Friday of the month, where if innovators, researchers, startups and companies cannot connect to the market through the portal, physical meetings or Skype, we have a whole group of DBT, ICMR, DCG(I), BIRAC — all officials sitting in one place and resolve their queries. This is to make sure that we help them to connect with the end-market user, so that the products we identify can be taken to the market.

How is the Bharat Innovation Fund launched by Prime Minister Narendra Modi helping lifesciences and biotechnology?
In 2016, we spoke of the Bharat Innovation Fund, we thought that it would be the only fund that will work but it did not really work the way we had thought it would. The Government of India has launched an equity fund for biotech which is being executed through BIRAC — accelerating entrepreneurs (ACE) fund — to take forward their research and that's fund of funds. We have also invited various other funding institutions to come forward — all those which are SEBI — registered and are into lifesciences and healthsciences sector. We have selected seven different funds as partners and Bharat Innovation fund is one of those partners. Our fund is of Rs 150 crore which we have currently committed to these seven partners — more than 50 per cent of it. We hope to be able to identify more partners, as we move on.

How do you see the future of startups in India?
The startup culture is here to stay and the policies we are putting in for enabling the startup ecosystem will only grow. It will only compliment and identify what is missing and add value to that by bringing new policies. However, our challenge today is looking at the scalability and sustainability of the ecosystem, and we are trying to address that at the moment. Each of these components, bringing in the LEAP and ACE funds, product commercialisation unit, building bilateral cooperations for connecting ecosystems — these are all enablers in that direction.

Even though there are many challenges regarding the sustainability of these start ups, the biggest one is that a start up has to make sure that whatever idea they are taking forward, there is a market need for it. Many a times, there is no proper need assessment and that's where BIRAC and government plays an important role. When we get into investing in them at their ignition grant stage, we do a thorough diligence to see whether their idea has a market potential. If there is no market potential, they don't get funded. The reason is that it is a highly-competitive funding process and it's also to ensure that those who get funded have a correct path to follow. So, they need to be connected with technical and business mentors to take it forward. Even after selecting an idea which has got a market potential, it can still fail because it's all about science. Entrepreneurs' journey is complex, and with biotechnology, it becomes more complex. However, more than 20 per cent of our start-ups have good success stories.

akanki.sharma@expressindia.com

INTERVIEW

‘The biggest barrier to innovation of supply chain is businesses becoming too complacent with the status quo’

Joseph Lim, Sales Director APAC, BluJay Solutions, speaks on how vital it is to transform pharma industry's supply chain systems through value-driven solutions and automation for the industry's progress, and his company's offerings as a logistics and supply chain tech solutions provider, in an exclusive interaction with **Lakshmipriya Nair**

Why is automation the need of the hour in logistics and supply chain systems?
Consumers have come to expect fast, convenient and inexpensive service and delivery options from pharma companies. Add to this, increased global competition from the likes of Amazon and Alibaba and the skills shortage, and supply chains must operate at a scale that can only be achieved with the right technology and automation.

What are the benefits that life sciences companies with minimal supply chain savvy may be overlooking?
Life sciences companies operate in a tough environment, so much so that they spend billions on research to create life-saving and life-changing drugs and other items.

Supply chain managers in the pharma industry have to take many factors into consideration to ensure these products are delivered to the consumer at the right time, in the appropriate condition. Factors such as expiration dates, lot tracking, government regulations and temperature-controlled transportation, along with fluctuating demand and the constant need for granular visibility, make this job difficult.

Managing so many moving parts simply is not possible without some level of automation, whether it be a control tower that automates work-flows and processes, or automated process and robots in a warehouse setting.

As a logistics and supply chain tech solutions company, how are you different from your counterparts? What are the three major differentiators that you have brought to the table?
BluJay’s key point of difference is our Global Trade Network (GTN). Supply chains are becoming more global and more mobile. Our GTN helps customers easily adapt to the complexities of global trade.

1. The GTN allows for real-time visibility while optimising the global movement of pharma companies' products. It provides insight to ensure supply chains are transparent and synchronised. This includes visibility from point of origin through customs, inbound and outbound transportation all the way to the customer's door.

2. A core component of the GTN, Control Tower, provides transparency and synchronisation across an organisation's supply chain and supports work-flow between partners.

3. BluJay unlocks the power of more than 40,000 universally connected partners so companies can achieve greater trade velocity and transform their supply chain economics for disruptive advantage.

How have you expanded your capabilities for the healthcare and pharma sectors? What are the key changes you have introduced and how would it be beneficial in the Indian context?

The Indian pharma industry continues to expand. After growing by 22 per cent in the past decade, Indian exports are expected to capture six to seven per cent of the $760 billion global generics market by 2020.

Growth for India's pharma industry hinges on improving physical capacity, organisational capacity and process capabilities. From a supply chain perspective, the use of automation and technology will be the key. Supply chain maturity needs to evolve and compliance processes need to be enhanced across the value chain.

BluJay's transportation management services enhance planning and shipment visibility to meet pharma and medical industry regulations. It gives logistics and customer service teams a single source for shipment status, with proactive knowledge of expectations, including matching appointment with the expected delivery date, confirming deliveries and quickly reconciling any order that is over, short or damaged.

> Many in the industry take an 'if it isn't broken, don't fix it' attitude toward supply chain management and are missing out on opportunities to improve customer experience and increase business efficiency, ultimately affecting these businesses' bottom lines

Track and trace capabilities for cross-docks, temperature requirements and transport visibility and reporting for medical and pharma products in real-time, to meet regulatory requirements, is crucial. With BluJay's solutions, data is logged at the load planning level for the carrier, which is available for report from the single system.

On-time delivery is essential in a successful retail and healthcare demand chain where dock space is at a premium. The penalties for not meeting scheduled delivery appointments create strained relationships, poor performance reports and result in significant charge-backs for high-value products, such as pharma products. By using the right tools, staff can feel empowered through having supply chain visibility.

What are the most-daunting barriers within the pharma supply chain that you could help surmount?

It sounds simple, but the biggest barrier to innovation of supply chain that we see is businesses becoming too complacent with the status quo. Many in the industry take an "if it isn't broken, don't fix it" attitude toward supply chain management and are missing out on opportunities to improve customer experience and increase business efficiency, ultimately affecting these businesses' bottom lines.

Some of the barriers we see time and time again are:

- Silos between systems and processes
- Outdated IT systems
- Lack of flexibility and innovation of supply chain partners
- Change management hurdles

Which technologies are transforming supply chains? How are they helping to build new digital logistics models to bring in new efficiencies and improved customer experience?

The technologies transforming supply chains are not what most people think.

Despite the hype around emerging technologies like block chain, drones and driver-less trucks, organisations still need to get the basics right by putting customers at the centre of their supply chains. To aid with this, market-leading pharma companies are investing in mobile devices and apps, control tower visibility, warehouse automation and robots to create a competitive advantage. In general, these technologies are further along the maturity curve than block chain, drones and driver-less trucks and have more established records of delivering benefits—both to the business and end consumer.

At the end of the day, it is the technology powering seamless supply chain execution that delivers efficiency, lower cost, and a better customer experience. We are also seeing the power of data in helping companies transform their supply chains. Analytics tools or services that can identify opportunities for cost and time savings based on real data, compared to best practices in the network and/or market benchmarks, provide the kind of actionable data that can transform supply chains.

> It is the technology powering seamless supply chain execution that delivers efficiency, lower cost, and a better customer experience

Can you give us details about your presence in India and what are your plans for this country?

We are a global company and have a strong presence in India, with a deep expertise and knowledge base in the country. One of BluJay's largest offices in the world is located in Hyderabad, with more than 280 employees.

India is an important region for us, and we will continue to invest resources and expand our presence in the market.

lakshmipriya.nair@expressindia.com

INSIGHT

Artificial Intelligence – The future of pharma industry

AI is going to play a critical role in pharmaceutical industry to explore the unmet medical needs of healthcare sector, to meet the pace with which resistance is being developed for molecules and to match the rate at which new diseases are being identified, informs **Pirthi Pal Singh**, Associate Director, Dr Reddy's Laboratories

THE TERM artificial intelligence (AI) was coined somewhere in 1950s, but has become a buzzword in the last few decades, thanks to advanced algorithms and increased volumes of raw data. AI applications have increased exponentially and have become an integral part of our life [1].

Primarily, AI is an information-processing paradigm inspired by the way a mammalian brain processes information. The power of AI is that it learns from the historical data. A variety of mathematical models illustrating the functional aspects of the brain's basic element, the neuron, have been developed. Such mathematical models are termed as artificial neural networks (ANNs), parallel distributed processing (PDP), adaptive systems, connectionist networks, etc.

Role of AI in pharma industry

AI is going to play a critical role in pharma industry to explore the unmet medical needs of healthcare sector, to meet the pace with which resistance is being developed for molecules such as anti-tuberculosis, and to match the rate at which new diseases are being identified. The traditional drug discovery approach can take upto 10 to 15 years and about $2.5 billion investment to bring a molecule from conceptual stage to market [2,3]. In summary, lower success rate in drug discovery phase with huge investment of money and time, is one of the most critical reasons for decline in number of NCEs being discovered. In order to combat these challenges, many pharma companies have already adopted AI in their research programme. Following sections below illustrate how different pharmaceutical companies are engaging AI-based platforms at various stages of their research programme [4,5,6].

AI in drug discovery

Many pharma companies, in collaboration with AI companies, have developed cloud-based AI platforms to accelerate their drug discovery programmes. These platforms look for pattern in data and make use of algorithms that can make accurate predictions about the potential drug molecules based on computational structure analysis, drug target and data from *in-vivo* cell line studies [1]. For instance, Watson Health and Pfizer announced a collaboration to acceler-

ate Pfizer's immuno-oncology discovery programme using cloud-based Watson's machine-learning system. The IBM Watson platform will aid in identification of new drug targets, fixed-dose combinations to be studied and provide assistance in selecting patients for trials [7].

Similarly, UK-based AI drug discovery company Exscientia signed one of the biggest AI drug discovery deal with Celgene to accelerate its small molecule discovery programme in oncology and autoimmunity segment [8]. In addition to it, Exscientia is also supporting drug discovery programme of Sanofi, GlaxoSmithKline, Sumitomo, Evotec, etc, using its artificial intelligence algorithms [9,10].

AI in genomics

Verge Genomics has developed a platform technology that maps genes which are responsible for causing disease and then maps the drug molecule that target them to provide cure. Currently, the platform is being used to discover molecules for treatment of neurological diseases [4].

AI in diagnosis

FDA granted Bayer and Merck & Co with Breakthrough Device Designation for AI pattern recognition software that analyses images from cardiac, lung perfusion and pulmonary vessels [11]. This software will support radiologists by identifying signs of Chronic Thromboembolic Pulmonary Hypertension (CTEPH), a rare form of pulmonary hypertension.

AI in drug repurposing

Drug repurposing is an application of approved drugs for the treatment of a different disease. AI platforms are a boon for drug repurposing, wherein the available data of drug molecules is evaluated to match new targets. HealNet is one of the largest and complex database systems available for existing drugs for rare diseases. This database is developed by Healx and it contains more than billion documented interactions among patients, existing drug molecules and rare diseases. It uses machine learning and AI to repurpose drug molecules for curing rare diseases. Also, Ligand Express, a cloud-based platform from Cyclica, leverages biophysics and AI to identify drug target, mechanism of action, elucidation of adverse effect and repurposing of small molecules [4].

> Many pharma companies, in collaboration with AI companies, have developed cloud-based AI platforms to accelerate their drug discovery programmes. These platforms look for pattern in data and make use of algorithms that can make accurate predictions about the potential drug molecules based on computational structure analysis, drug target and data from *in-vivo* cell line studies

AI in personalised medicine

All individuals are not same with respect to physical structure, rate of metabolism, genetic makeup etc, and therefore the therapy/dose needs to be personalised based on individual requirement. Methods like artificial intelligence and the underlying machine learning can provide the framework to stratify patients, initiate specific tailored treatments and thus increase response rates, reduce adverse effects and medical errors. GNS Healthcare's "Reverse Engineering and Forward Simulation" (REFS), a machine-learning and simulation platform, aids in finding and validating potential new drug candidates based on patient response marker and thus leading to personalised treatments that are better match to individual patients [12].

AI in drug product development

Self-learning AI platforms like Artificial Neural Network (ANN) and Design of Experiment (DoE) helps in understanding inter-parameter interactions and further supports in composition and process optimisation. It helps in developing a multivariate correlation to obtain a quality drug product, based on understanding of cause-effect relationship between formulation ingredients/process parameters and quality target product profile [13].

AI in clinical monitoring

Tencent Holdings, along with Medopad, has developed AI algorithms for patients suffering from Parkinson's disease. AI monitors patient's movement via smartphone camera and determines the severity of the symptoms. Further, it also permits the doctor to monitor patient remotely, adjust dose and fix doctor's appointment.

AI in medical development

Both Alzheimer's and Parkinson's patients are reported to accumulate toxic proteins that results in impaired brain functioning and leads to death of nerve cells. Mission Therapeutics, along with AbbVie, has developed an enzyme platform that enables the degradation of toxic proteins and prevents their accumulation by modulating specific deubiquitylating enzymes [14].

Current challenges of AI application in pharmaceutical industry

AI in the near future is going to play a vital role in pharma industries. It is an effective tool for reducing investment and time to bring molecules from discovery phase to development and finally to market. Its potential to increase the success rate in drug discovery phase has already been established.

However, a majority of the pharma industry still processes the data in a conventional way, although AI and machine-learning platforms are available since decades. There is a need to upgrade IT infrastructure and also a shift is required in the mindset of researchers to believe inthe power of AI. In this regard, an industry-academia collaboration can help to run pilot projects and thereby enhance acceptability of AI.

References

1. Artificial Intelligence What it is and why it matters. https://www.sas.com/en_us/insights/analytics/what-is-artificial-intelligence.html

2. Computer-calculated compounds. Nic Fleming. Nature, Vol 557, 31 May 2018, S55-S57. https://www.nature.com/magazine-assets/d41586-018-05267-x/d41586-018-05267-x.pdf

3. How artificial intelligence is the future of pharma. Jackie Hunter, BenevolentBio. Drug Target review, 5 December, 2016. https://www.drugtargetreview.com/article/15400/artificial-intelligence-drug-discovery/

4. Artificial Intelligence & the Pharma Industry: What's Next. Codrin Arsene. https://www.digitalauthority.me/resources/artificial-intelligence-pharma/

5. AI in Pharmaceuticals. Donna Conroy and Michael Conroy. http://www.pharmexec.com/ai-pharmaceuticals

6. 129 Startups Using Artificial Intelligence in Drug Discovery. Simon Smith. https://blog.benchsci.com/startups-using-artificial-intelligence-in-drug-discovery#step8

7. IBM and Pfizer to Accelerate Immuno-oncology Research with Watson for Drug Discovery. https://www.pfizer.com/news/press-release/press-release-detail/ibm_and_pfizer_to_accelerate_immuno_oncology_research_with_watson_for_drug_discovery

8. AI drug R&D company Exscientia signs deal with Celgene. https://pharmaphorum.com/news/ai-drug-rd-company-exscientia-signs-deal-with-celgene/

9. GlaxoSmithKline signs $43m deal with AI start-up. Rachel Connolly. https://www.theneweconomy.com/technology/glaxosmithkline-signs-43m-deal-with-ai-start-up

10. AI-Based Drug Discovery Biotech is Recruited by Sanofi in €250M Deal. https://labiotech.eu/medical/exscientia-sanofi-ai-deal/

11. FDA Grants Breakthrough Device Designation for CTEPH Pattern Recognition Artificial Intelligence Software from Bayer and Merck. https://www.prnewswire.com/news-releases/fda-grants-breakthrough-device-designation-for-cteph-pattern-recognition-artificial-intelligence-software-from-bayer-and-merck-300758747.html

12. GNS Healthcare Announces Collaboration to Power Cancer Drug Development with REFS™ Causal Machine Learning and Simulation AI Platform. https://www.gnshealthcare.com/gns-healthcare-announces-collaboration-to-power-cancer-drug-development/

13. Quality by Design Approach: Application of Artificial Intelligence Techniques of Tablets Manufactured by Direct Compression. Buket Aksu,corresponding author Anant Paradkar, Marcel de Matas, Özgen Özer, Tamer Güneri, and Peter York. AAPS PharmSciTech. 2012 Dec; 13(4): 1138–1146. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513460/

14. Mission Therapeutics and AbbVie sign DUBs Collaboration in Alzheimer's and Parkinson's Disease. https://missiontherapeutics.com/mission-therapeutics-and-abbvie-sign-dubs-collaboration-in-alzheimers-and-parkinsons-disease/

VIZAG PHARMA SPECIAL

INTERVIEW

Pharma industry gearing up to rapidly changing regulatory norms

By 2020, many branded medicines are going off-patent and there will be an ocean of opportunities for big- and medium-sized pharma companies in India. The rising number of 483s is a big concern. However, Vizag-based pharma manufacturing units have a minimal number of critical observations in nature. **KV Rajendranath Reddy**, Director General, Drug Control Administration, Government of Andhra Pradesh, talks to **Usha Sharma** about the growth potential for pharma companies in the state

Early last year, several top pharma companies faced regulatory compliance issues and received 483s from the US FDA. As a regulator, what steps are you taking to ensure more compliance to the pharma industry?
A majority of the pharma manufacturing sites located in Vizag do comply with current good manufacturing practice (cGMP) norms as per Schedule M of the Drugs and Cosmetics Act, 1940 and most of them are also 'WHO GMP Certified' complying with WHO-TRS guidelines. As many as 20 units are certified by US FDA. Most of the observations by US FDA auditors for the units in the Vizag area are not critical or major in nature. The units concerned submitted their compliance in due course of time, which were again examined by the US FDA and were given certification. Periodical inspections by the inspectorate of this department either individually or jointly with officers of the CDSCO, are being taken up and the review of such reports by both the agencies has brought more depth in specific observations noted during the inspection with respect to the level of compliance to various provisions and the subsequent CAPA by the industry. The pharma industry is gearing up to the rapidly-changing regulatory environment/ norms. The industry has complied with the data integrity issues raised by the US FDA few years ago and the state regulators are working as a facilitator to industry in every possible manner.

What initiatives have been taken and initiated by the state drug controller authority in order to accelerate the growth of pharma exports from Vizag?
The state government, for the past two years, has brought in the concept of issuing of licenses and approvals by various departments concerning the industry, including the drugs control department through single-desk portal only, without the need for physical touch point. The manufacturing licensing services were brought under the Service Delivery Guarantee Act to ensure the speedy/timely processing of the required clearances so that the industry can get the export registrations in a timely manner, wherein the Service Level Agreement (SLA) is a maximum of 15 days for grant of drug licenses and till now 38 units were issued with the grants through the Single Desk Portal and the state of Andhra Pradesh was ranked number one in the ease of doing business.

Inspections pertaining to the issuance of new WHO-GMP certifications or the renewal of the earlier ones, along with the COPP, are being taken up on priority by coordinating with officers of the CDSCO which

will eventually enable their products for export to various destinations.

Give us the update on ADC/drug inspectors appointments at Visakhapatnam air and sea ports. Also, tell us if it will improve the pharma export performance?
Though the matter concerning the appointment of the officers at air/sea ports is not under the purview of the State Drugs Control, it is to mention that officers of the rank of Assistant Drugs Controller and Drugs Inspector from the CDSCO were posted at Vizag port office with other Assistant Drugs Inspectors (keeping in view of the industry needs present in Vizag as against the operation from their Hyderabad office), which will expedite the process of verification, clearances and certification, thereby facilitating the exporters from time to time. It is pertinent to mention that the timely requisite regulatory audits by the officers of the state and the CDSCO necessitating the above certifications are being overseen by an officer of the rank of the Joint Director, Drugs Control Administration from the state, in line with the licensing authority, which are as per the SLAs and will certainly boost the performance of the exports from that part of the state.

The state government is planning to set up three Mini Life Sciences Park within next three years. What is the mandatory procedure to begin with manufacturing process?
The concept of Mini Life Sciences Park and its establishment is still in the nascent stage and the companies trying to establish one, ought to have their clearances ready as envisaged under various other laws through the Single Desk Portal only. Further, as such the manufacturing process with respect to pharma, begins only with erection of the unit with all such infrastructure, instruments and equipment for the manufacture and testing of drugs in place, initially for the test scale and later on pilot and commercial scale. Prospective manufacturers shall take a test license for conducting the product development studies and stability studies and the facility shall comply to the Schedule M of the Drugs and Cosmetics Act, 1940 and Rules, 1945 requirements. As informed earlier, the licenses for commercial scale will be issued within 15 working days after having applied through Single Desk Portal of the Industries Department of Andhra Pradesh and after being satisfied with the compliance level of the provisions of Schedule M under the Drugs and Cosmetics Act, 1940.

As a drug regulator, what is your message to the pharma industry in Vizag?
There is a tremendous opportunity for the pharma industry to look for the those molecules which are going to be off-patented in 2020 and beyond, and the time has come for MSME pharma industry to embrace the latest technological advances in the pharma sector and to upgrade themselves to the international standards. This will give them the edge *vis-à-vis* their peers elsewhere for having all that in place to achieve the regulatory compliance and to access the regulated export markets for long-term sustainability of their industry itself and to ensure the accessibility, availability and affordability of the drugs both in the domestic and international markets.

u.sharma@expressindia.com

POST EVENT

Vizag Pharma Summit deliberates on the future of Brand India Pharma

The theme of the maiden Vizag Pharna Summit was Shaping the future of Brand India Pharma

Usha Sharma
Vizag

AFTER THE successful inaugural editions of Sikkim and Goa Pharma Summit, Express Pharma recently organised the Vizag Pharma Summit. The theme of the maiden Vizag Pharma Summit was 'Shaping the future of Brand India Pharma'. The day-long event was attended by over 80 delegates which included representatives from formulation development, research and development, QA& QC, regulatory affairs, packaging, plant head, supply chain management purchase and decision makers.

Lamplighting ceremony: T Ravi Kumar, Joint Drug Director General, Drug Control Administration, Government of Andhra Pradesh, R Srinivasan, ADC, CDSCO-Vizag Port Office and Srinivas Lanka, Senior Advisor, Pharmexcil

During the event, experts of pharma industry touched upon critical topics like strategies to achieve full compliance, measures to achieve self-sufficiency in APIs, linking talent to value, embracing digital and automation to build next-age capabilities, deploying global best practices, enabling a culture of quality at the shop-floor and sustaining cost-leadership with product excellence.

The event began with the lamp lighting ceremony by T Ravi Kumar, Joint Drug Director General, Drug Control Administration, Government of Andhra Pradesh, who was also the chief guest of the event. He was joined by R Srinivasan, ADC, CDSCO-Vizag Port Office and Srinivas Lanka, Senior Advisor, Pharmexcil.

In his Chief Guest address, Ravi Kumar talked about adoption of technologies to address quality concerns in pharma SMEs. And said that technology adoption is an investment and not an expenditure. He also mentioned about the initiatives been taken by the state government to encourage pharma industry to enhance their performance in the global pharma market. He also stressed on building common effluent treatment plants for small and medium-sized pharma companies, which will assist financially and help them in upgrading to the next level. During his presentation, he also informed about the advantages the state offers to the pharma industry.

The next speaker at Vizag Pharma Summit, Ramanuj Samal, Application Specialist, Beckman Coulter Life Sciences elaborated on the topic of improved compliance, reduced workload and cost with Anatel Online TOC Analysis of pharma waters. He explained the importance of purified water in the pharma segment and mentioned that for pharma use, it is classified as an excipient in the production of non-parenteral preparations, and in specific, for pharma preparations/tests and assays, in which water is indicated, unless otherwise specified. His presentation also touched upon the product portfolio which Beckman Coulter Life Sciences offers in the Indian market.

Anvesh Manne, Director, Polmon Instruments, provided a brief summary of the company's ongoing activities. He delivered a talk on distributed temperature control of laboratory scale reactors. He talked about solutions which the company offers like maximum utilisation of lab space, eliminates clutter in the lab, centralised control and data logging, recipe management, local graphical HMI on the fume hood etc.

The next presenter of the day was Vaibhav Datke, Senior Manager, Business Development, Ami Polymer. Datke gave a presentation on polymer solutions to the pharma industry. He also informed about the company's global distribution channels, product profile and mentioned about pharma tubings in drug processing applications and its key components. He highlighted that all liquid drugs in glass vials are passed through silicone tubing for precise filling and those tubings are used once in a day per batch and it is replaced for every new batch. He also explained how Ami Polymer's products are helping pharma companies impart good solvent resistance and multiple varieties of tubings which have been designed.

Dr Kavita Vengurlekar, Product Manager Data Sciences Group, Caliber Technologies presented on the future of pharma-quality metrics and data analytics. In her presentation, she highlighted the importance of quality metrics and FDA's 21st century vision for pharma engineering. She mentioned that quality metrics are not new to the life sciences industry and are already being used; to continuously monitor quality systems and processes (cGMP), provide information on where improvements can be made, as a part of the annual product review (APQR), as a part of internal audits and to evaluate supplier qualifications. While informing about the modified proposal from FDA on quality metrics she said that the industry should start with three metrics; lot acceptance rate (report by site, differentiated by product), product quality complaints (report by product only) and invalidated OOS (report by site). She also pointed out how artificial intelligence will drive the decision-making process.

The next speaker was Srinivas Lanka, Senior Advisor, Pharmexcil, who talked about steps to minimise India's APIs dependency and increase pharma exports. He said, "Vizag coast has a great strategic advantage to become the health capital of the globe. A mega cluster of eight clusters — API, dosage formulations, biotechnology, fermentation, nanotechnology, herbals/traditional medicine, medical technologies, research linked to MedCity is feasible and will free India from unnecessary import dependence. Universities, scientific talent, social harmony is conducive for rapid growth which will have the potential to generate revenues of over Rs 50000 crores each year."

This was followed by a panel discussion on transforming Vizag into a pharma centre of excellence. The session was moderated by Lanka from Pharmexcil and were joined by Dr Girish Dixit, Senior Vice President and Head CMC, Pharmaceutical Science and Technology, Eisai Pharmaceuticals, India, Suresh Kamath, Vice President Operations, Natco Pharma and KVV Raju, CEO, Granules OmniChem as panelists.

Discussions were held on API import reduction and type of financial reforms needed for

the industry to take up import substitution. Panelists spoke on how industry can reduce operational costs for individual units through shared services andcompete with China with respect to operation costs.

Dixit from Eisai Pharmaceuticals said, "There is no difference in the chemistry skill sets of China and India, only mindset differs. Institutes should get into research for commercial requirements and support industry to overcome innovation challenges. Adoption of new technologies like flow or continuous manufacturing, biocatalysts, enzymatic reactions are need of the day. This can be achieved by creating 'synthesis and solid state cluster' in Vizag. By this, we can make Vizag a centre of excellence."

Kamath from Natco Pharma felt the urge of pharma knowledge sharing platform in Vizag, highlighting the number of pharma units located in the city. He mentioned that there are very limited interaction between industry and regulators. Raju from Granules OmniChem informed about Sagarmala project which is initiated by the government to enhance the performance of the country's logistics sector. Vizag being the hub of pharma manufacturing units, pharma industry can optimise the opportunities, is what he mentioned.

Next, R Srinivasan, ADC, CDSCO-Vizag Port Office spoke on bolstering pharma exports via sea port.

Samal from Beckman Coulter Life Sciences gave another technical rich presentation on hight resolution nano and micron particle characterisation – pharma development to production.

Following his presentation, Prabhas Misra, MD, PSA Nitrogen, highlighted the relevance and importance of nitrogen gas in the pharma industry. In his talk, he said that nitrogen being an inert gas is extensively used in the pharma industry to avoid possibility for fire or explosion. "Usage of nitrogen gas for blanketing purpose in pharma industry for various applications has increased substantially during the last one decade and is likely to increase further in the coming years. We have supplied more than 1400 PSA Nitrogen Plants in the pharma sector alone during the last 35 years," Misra added. He also informed that his company has captured 90 per cent of the business market in India. He talked about the technical collaboration with Kuraray Chemical Co – Japan, and mentioned that the products are supplied in over 20 countries.

(L-R) KVV Raju, Suresh Kamath, Srinivas Lanka and Dr Girish Dixit

(L-R) Shantanu Panda, Bikash Kumar Nayak, Madan Mohan Reddy, Narendira Kumar and Dr Sreeram

Nisha Chowta, Sales Manager, Gandhi Automation, in her speech pointed out the need for pharma warehouse and logistics automation. In her presentation, she gave an overview of the company and how her company's solutions can work as high-performance cleanroom doors with easily disinfected surfaces and meet the most stringent hygienic requirements.

Akash Agarwal, CEO, Director, Crystal Logistic Cool Chain, gave a presentation on the solutions which the company is offering for cold storage. He informed about the company's offering in five brands globally, which has rented/sold more than 12000 units of containers worldwide.

The next speaker at the summit was Satyaprasad Venkata, Managing Director, Smart Labtech. In his presentation, he talked about the industrial weighing solutions. He gave a brief description about the company's product portfolio. Highlighting the relevance of weighing solutions in a laboratory, he said that it is important to test pharma products and their ingredients.

Chidanand BN, National Head Sales & Marketing, Markem- Imaje India, spoke about choosing the right coding solution. His presentation gave an update about different coding technologies which Markem-Imaje India offers in India. He also expressed that his company has capabilities to meet the industry's requirements.

Shantanu Panda, Deputy General Manager, Global Packaging Strategy, Mylan Laboratories, delivered a talk on innovation in pharma packaging - A way forward. He said that in the whole cycle starting from product-pack development to usage by end-user, each design, action and process is gettng digitalised with respective electronic platforms and they are also being integrated for better accountability and coordination. Serialisation, 2D code, QR Code, Mobile authentication are a few of them. Digitalisation will help for easy accessibility /storage / usage of data, which will be more compliant and reliable.

Later on, he joined a panel discussion on 'Strategising for a tech-driven future', which was moderated by Madan Mohan Reddy, Head - India Regional Quality & Regulatory, Eisai Pharmaceuticals. The panelists were Bikash Kumar Nayak, Plant Head, Aurobindo Pharma, Dr Sreeram, Plant Head & Director, Shilpa Medicare and Narendira Kumar, Site Quality Head (QA & QC), Dr Reddy's Laboratories.

The panel discussion touched upon different challenges faced by pharma companies in fulfilling requirements from various regulatory agencies e.g. DGFT (India), serialization (US FDA & EU). Discussions were held on regulatory expectations, dependency on automation, which may lead to some failures, measures for anti-counterfeits. In the beginning of the discussion, Reddy said that patient-centric drug development is the key to future.

Panda cautioned that those who change and adapt will progress and those who resist, will be forgotten. Responding to the moderator's queries, he said that the pharma packaging industry is going through a phase of change towards end-to-end digitalisation and optimisation. Pharma packaging is facing pressure, on reduction in profit margin and growing competition in the generic drug market. Optimisation is key to succeed in this race. So, the focus will be to optimise the packaging design, material and process to make it more cost effective. The rule is to "Increase the convenience", "Cut the excess" and "Stick with compulsory". He also highlighted that the future smart packaging will be more "Optimized-Connected-Compliant-Patient Centric."

Commenting on the regulatory aspects, Kumar pointed out, "Automated solutions in the manufacturing environment (including laboratory) will give more confidence to the regulatory inspectors about management's commitment on GMP compliance and continual improvement."

Sreeram talked about the importance of critical process parameters under the QbD. He said, "I am sure that in next five years, the US FDA will come heavily on pharma R&D centres where the product development takes place. The time has come (if not already late) for the pharma companies to move towards paperless documentation and data-driven product development using the tools such as QbD and PAT. This will bring more transparency, accountability and credibility to product development work."

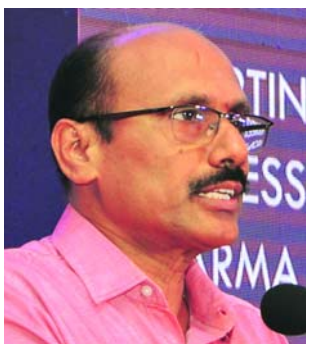
Highlighting that AI will play in the future, Nayak said that the future of Indian pharma industry is completely based on data integrity and automation is going to play a major role in shaping the future of Brand India Pharma.

The participants of the Vizag Pharma Summit lauded Express Pharma for creating such a platform and mentioned that it will help the industry in understanding the problems and suggesting solutions.

u.sharma@expressindia.com

GLIMPSES OF VIZAG PHARMA SUMMIT 2019

EXPERT'S COMMENTS

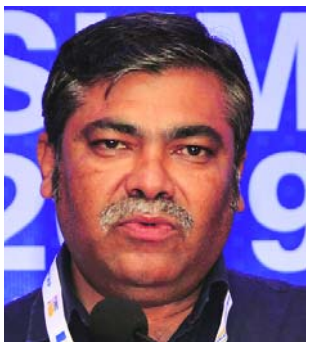


Technology adoption is an investment and not an expenditure

T Ravi Kumar
Joint Drug Director General, Drug Control Administration, Government of Andhra Pradesh

'Sagarmala' project is transforming the nation through port modernisation

KVV Raju
CEO, Granules OmniChem



There are ample opportunities for the pharma sector via the Vishakhapatnam Sea Port

R Srinivasan
ADC, CDSCO-Vizag Port office, Both sea and airports have immense potential for pharma exports

Quality by Design brings down the variability in the processes

Dr Madan Mohan Reddy
Head - India Regional Quality & Regulatory, Eisai Pharmaceuticals, India

Vizag coast has a great strategic advantage to become the health capital of the globe. It has the potential to generate revenues of over Rs 50000 crores each year

Srinivas Lanka
Senior Advisor, Pharmexcil

Force automation in pharma industry is the key mantra to success

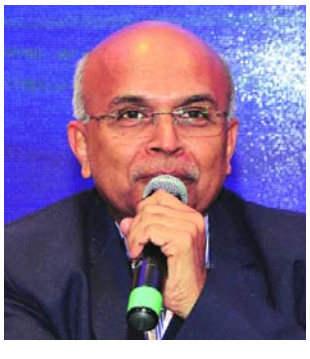
Bikas Kumar Nayak
Plant Head , Aurobindo Pharma

There is no difference in the chemistry skills of China and India, only mindset differs. Institute should perform research to overcome innovation challenge

Girish Dixit
PST, Medicine Development Centre, Eisai Pharmaceuticals India

Automated manufacturing solutions will give confidence to regulators about your commitment on GMP compliance

Narendira Kumar
Site Quality Head (QA& QC), Dr Reddy's Laboratories



Driver for Converting Vizag into Pharma Excellence hub, "Commitment for compliance to Quality"

Suresh Kamath
Vice President Operations, Natco Pharma

The time has come for the pharma companies to move towards paperless documentation and data-driven product development using tools like QbD and PAT

Dr Sreeram
Plant Head & Director, Shilpa Medicare

EXPERT'S COMMENTS

Pharma packaging is facing pressure due to reducing profit margins and growing competition. Optimisation is key to succeed in this race

Shantanu Panda
Deputy General Manager, Packaging Strategy – OSD, Mylan Laboratories

Choosing the right coding solution is very important in the pharma industry

Chidanand BN
National Head Sales & Marketing, Markem- Imaje India

Pharma logistics companies are increasingly focusing on providing sea-based logistics services to reduce transportation costs for their customers

Akash Agarwal
CEO and Director - Crystal Logistic Cool Chain

Data analytics is transforming the pharma lab and beyond

Dr Kavita Vengurlekar
Product Manager Data Sciences group at Caliber Technologies

Synthetic and natural-based polymers have found their way into pharma and biomedical industries and their applications are growing at a fast pace

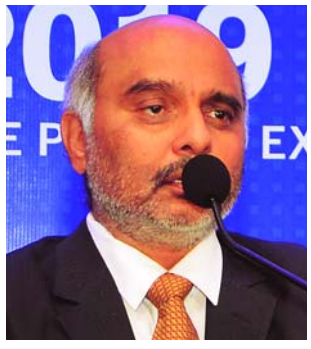
Vaibhav Datke
Sr.Manager-Business Development, Ami Polymer

Quality control is configured to help companies comply with the FDA's expectations on data integrity

Ramanuj Samal
Beckman Coulter Life Sciences

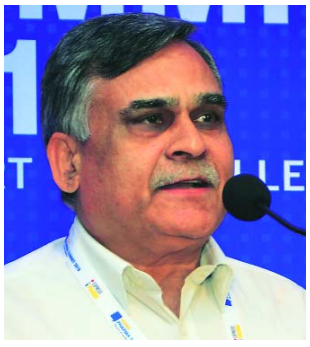
Loading bay and door automation forms are important aspects for greater energy savings and effective maintenance of ambient temperatures

Nisha Chowta
Sales Manager, Gandhi Automation



Weighing solutions in a laboratory is important to test pharma products and their ingredients

Satyaprasad Venkata
Managing Director, Smart Labtech



Usage of nitrogen gas for various applications in the pharma industry has increased substantially during the last decade and is likely to increase in the coming years

Prabhas Misra
Managing Director, PSA Nitrogen

Distributed temperature control of laboratory scale reactors helps in eliminating clutter in the lab

Anvesh Manne
Director Polmon Instruments

Making India Pharma Inc self sufficient

Governments across the world are strategising to ensure accessibility and affordability of drugs with increasing healthcare spends and steps to bring down the cost of medicines without compromising on quality. And, India with its dominance in the generic drugs space, has emerged as a significant partner in achieving these goals. On the domestic front too, the government is encouraging the industry to further its growth as it contributes significantly in the country's total GDP. According to Pharmexcil, India exported pharma products worth of $200.02 million in financial year 2018, with a recorded growth of 37.52 per cent.

However, the irony of the story is that though India surpasses China when it comes to pharma exports, it is largely dependent on China for its raw materials and active pharmaceutical ingredients (APIs). According to Department of Pharmaceuticals, India imports over 60 per cent of APIs from other nations. For some specific APIs, the dependence is more than 80-90 per cent. For example, APIs needed to manufacture Vitamin C, antibiotics-Metronidazole, Ofloxacin, Livofloxacin- all come from China. The dependence is much higher in intermediates than in APIs, and alarmingly there is an increase in this dependence. If we do not take exigent measures to deal with our dependence on certain countries only for a large number of APIs and drug intermediates, it could have an adverse effect on the sector's progress.

Fortunately, the government has taken note of this fact and has been working towards remedying the situation. In 2015, Dr VK Subburaj, the Secretary of Department of Pharmaceuticals at that time, had highlighted the urgent need to bring about self-sufficiency in the field of APIs. And in 2018, the Chemicals and Fertilizers Ministry, along with other ministries, joined hands to draw up a road map for increasing APIs production in the country and reduce India's dependency on China for APIs.

Putting these measures in place and ensuring this smooth implementation will be vital to the success of policy reforms and programmes for the pharma industry. Especially, as the government eyes greater growth and glory through this sector. For instance, Venkaiah Naidu, Vice President of India, had urged the pharma industry to work towards making India an international capital of generic medicines, at the 70th Indian Pharmaceutical Congress, where top pharma CEOs met, in Delhi late last year.

The Prasanta Kumar Ghosh report titled Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018, also says that just 25 companies in India could capture 85 per cent of the market. However, to leverage the true potential of the industry and gear up for fast approaching opportunities such as drugs going off patent, upcoming semi-regulated new markets, focus on special populations, aging populations, pharma companies need to be more self-sufficient and increase their R&D spends.

The report also suggests that the existing policies require to be more 'friendly' to enable development of a stronger local industry for manufacturing APIs that form the core of the industrial strength for India in the global context. It recommends that an exercise can be attempted by the government to select and produce APIs locally by encouraging procurement of key input materials and energies at more 'competitive' prices within the provisions of the WTO from within the country itself.

Incidentally, many of the top pharma companies in India have already set up API manufacturing facilities in Vishakhapatnam due to easy accessibility to sea routes and airports. Therefore, *Express Pharma*, in its Vizag Pharma Special, focussed on how to transform this port city into a centre of excellence for the pharma sector thereby furthering its efforts to become more self-sufficient.

Industry experts and veterans also share their views on minimising API dependency from China, with **Usha Sharma**

China manufactures most of the bulk drugs pharma industry requires

India has exported pharmaceuticals worth $200.02 million in FY18, with a recorded growth of 37.52 per cent.

While we have imported $2251.84 million of APIs and intermediates during the same period, India could try to reduce this trade gap by increasing our exports, which probably is possible by strengthening our bulk drug industry as India's formulation industry (excluding biopharma) is certainly ahead of China and remains our key strength. Bilateral trade talks, though, to an extent help to reduce trade imbalance, it is only our strengths in the sectors that China wants could really bridge it.

China manufactures most of the bulk drugs, including

RAVI UDAY BHASKAR
Director General, Pharmexcil

those involving advanced chemistry skills. They have huge capacities of manufacturing units and also of substantial number, many of them do not meet high regulatory standards prescribed by best of the regulatory agencies across the world. China is now moving towards the best regulatory standards and is already a Pharmaceuticals Inspection Co-operation Scheme (PICS) member as an observatory. It is making efforts to implement PICS guidelines in its pharma manufacturing industry.

As a part of these efforts, many manufacturing units have been notified to upgrade their standards within a stipulated time or leave the stage.

From May 2018, local administrative authorities are also empowered to inspect the manufacturing facilities and impose a fine of $150 per every tonne of non-treated effluents.

All these resulted in shortages of many products, both bulk drugs and formulations which is forcing China to import. This is one of the factors for India's exports to China's growth in FY18.

Pharmexcil activities in promoting exports to China

- Pharmexcil in association with China Chamber of Commerce of Import & Export of Medicines and Health Products (CCCMHPIE) CCCMHPIE organised India-China Pharmaceutical Conference & Business Meet during August 20-21, 2018 at Shanghai, China. It was attended by 27 Indian pharma manufacturers and 100 Chinese companies.
- During the above conference, Pharmexcil signed a Memorandum of Understanding with CCCMHPIE and the objective of this MoU is to set up a long-term partnership and cooperation between CCCMHPIE and Pharmexcil for promoting the exchange, cooperation and trade in pharma products between the member companies of both India and China and to enable greater market access.
- Pharmexcil and CCCMHPIE further to the MoU signing, have designated the focal points. Established Information Desk for greater market access of pharma from India and represent-

ing the issues being faced by India side.

- Pharmexcil extended invitation to MOFCOM and CDE during the Business Meet to host CFDA (NMPA) training programme in India. Closely pursuing with CCCMPHIE and our Embassy at Beijing, China to organise the NMPA training programme this year either in China or in India.
- In December 2018, Pharmexcil in association with China Chinopharma (CSC Corporation), Shanghai, China organised one-day workshop on 'Regulatory Practice and Onsite Audit Requirements from NMPA' in Hyderabad. About 200 members from 120 companies have participated in the workshop.

Pharmexcil, with Department of Commerce, formed a thinktank and brought CSIR labs and industry on one platform for devising strategies to reduce the dependence on China

Import dependence of APIs

Pharmexcil, with support from Department of Commerce, formed a thinktank and brought CSIR labs and industry on one platform for devising strategies to reduce the dependence on China and to make India self-sufficient by developing technology to manufacture intermediates, KSMs indigenously. Convened interactive meetings with CSIR and industry and identified top 30-40 APIS, KSMs and intermediates required to be developed indigenously. Presentation was made to Secretary, Commerce and other departments on the key products (import dependent) and technologies to be developed.

Submitted application for study proposal for developing DPR on import dependence under MAI Scheme.

- The objective of the study is to identify the APIs, KSMs and intermediates that are critical for the nation and the delivery mechanism for R&D, manufacturing and competitiveness
- An indicative roadmap on how to execute this opportunity (suggested partners for technology, R&D, manufacturing, the type of KSM/intermediates/API complex that can be created)

Way forward

- NMPA cooperation is to be solicited for fast-track registration of medicines from India
- CDSCO has to outreach drug regulatory authorities abroad and sign MoUs and mutual agreements for cooperation by overseas FDAs. There is a dire need for CDSCO and NMPA to work closely, exchange information and dialogue regularly, which can yield positive results for Indian companies and facilitate fast-track registration.
- Flexibility in the government procurement of various provinces by China side will facilitate India side for bidding in the tenders.
- Establishing manufacturing units in China and also explore the possibilities of joint ventures.
- Identification of API clusters and manufacturing of largely dependent APIs, intermediates and KSMs in India with support from government and companies manufacturing these products to be given exclusivity rights for few years.

Measures must focus on domestic players

MADAN MOHAN REDDY
Director, Aurobindo Pharma, Hyderabad

The pharma sector in India depends heavily on large-scale imports of Active Pharmaceutical ingredients/intermediate products /basic raw materials from overseas countries for making drugs. The prominent reason for the import of API and others from overseas is certainly business economics.

Of the suggested steps, the Central Government has already announced certain steps to start inspection mechanism and facilities outside India to ensure that only quality APIs are imported. NITI Ayog is also taking several measures as part of Make in India campaign to plan for more API production in India. Though the intent is there, it is equally essential to initiate solid measures in this direction.

India has proven capabilities in the generic drug formulations, but over dependence on a few overseas countries for sourcing raw materials/intermediate products and APIs does not augur well for the Indian pharma sector, as any interruption in supply can badly impact the sector and jeopardise the health of millions of people across the world.

The practical measures in this direction can be envisaged as a multi-pronged approach towards self-reliant India in terms of manufacturing.

India has a competitive advantage of having a deep and broad scientific knowledge coupled with demographic dividend. This can be better deployed to counter the challenges of scale and cost advantages of other countries in the following manner:

To begin with, there should be import-friendly industry policies to register raw materials/intermediate/API facilities in India. This not only multiplies the production volume, but makes it more affordable to the Indian pharma manufacturers as economies of scale accrue to them as well. This, coupled with special incentives for certain families of APIs, can boost up the required momentum of bulk drug manufacturing within India.

Both central and state governments support pharma companies to develop infrastructure and technology trasfer mechanisms, in colloboration with premier engineering and technology institutions.

Support to local manufacturers by issuing licenses on minimum stipulated criteria to keep the competition at level playing field. The government can also improve monitoring the demand situation both from the fresh license issuance perspective, apart from controlling the prices. This will establish desi-level playing situation for companies to operate and thrive.

Rationalise and streamline environmental clearance, taking into account the twin objective of creating a permissive climate for operations to commence and continue, apart from preserving environmental standards

Finally, the government in consultation with professional agencies like Pharmexcil, BDMA, IDMA, CII, etc, to create bulk drug hub linking API value chain such as RM, intermediates and finished bulk drugs with latest technology which act as a catalyst not only to the existing manufacturers for bottlenecking services, but also to the new startup entrpreneurs on the look out for a great opportunity in this arena.

Some of the countries have excelled in bulk drug manufacturing as they have huge trade barriers for export of medicines and APIs. According to industry experts, if India doesn't put in place similar stringent policy and trade barriers, despite having world-class assets and knolwedge resource base, overseas suppliers would dictate price in the future, which will pose a threat to Indian players.

To succinctly put in, short-term measures must focus on domestic players in terms of financial, technology and compliances partnerships. Long-term measures must focus on policy changes by various ministries and administration, in collaboration with professional organisations in the country towards this end.

Indian cos need to explore on putting up facilities in dedicated pockets

Indian pharma companies have a lot of manufacturing sites across the country. However, the economics of scale of units here is different from China which results in high cost of their produce making formulators to depend more on Chinese produce.

Intermediates for the production of final API are sourced from China by major Indian manufacturers. In order to reduce the dependence of these intermediates, Indian companies need to explore on putting up facilities in dedicated pockets across India. The Department of Pharmaceuticals (DoP) shall identify probable states/locations for creating this infrastructure, along with state governments and private developers as collaborators.

India's young manpower, vast areas of land in different

SURESH KAMATH
Vice President- Operations, Natco Pharma

states which are earmarked for pharma clusters shall be utilised for bringing in future facilities. Indian producers shall primary focus on quality and regulatory compliance and better capacities for economics of scale helping for a competitive pricing of their produce. Quality and regulatory compliance is a major issue for Indian pharma sector for both API and formulations for exporting units. Non-compliance to systems and procedures, data integrity and facility maintenance are the major concerns which are being highlighted by international regulatory authorities.

India's thrust on R&D capabilities varies for developing methods of manufacture of intermediates as well as final bulk drug (API). It needs to be strengthened for shorter processes, better yields and safe reactions. During last two decades, India has shown a declining trend in producing good chemistry scientists as majority of people adopted engineering courses due to boom in IT sector.

A major concern for above is with respect to handling of hazardous waste as well as effluents and environmental discharges generated from these units. It is mandatory that the basic infrastructure for the treatment, storage/disposal of the above should be in place, before giving any permissions to start manufacturing activities. Additionally, manufacturers need to have adequate mechanisms that are maintained and complied as per CPCB norms and ISO 45001 and ISO 14001 standards.

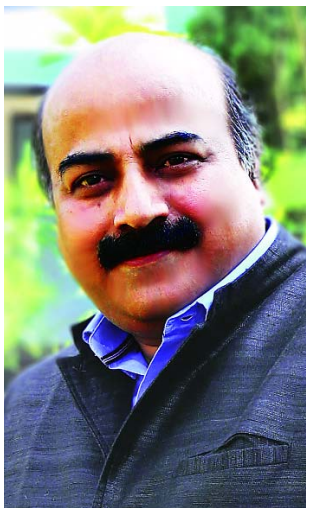
We have educated manpower available across India, but lack skills to meet the industry requirements. We need to make changes in the curriculum for schools/colleges as applicable so that the students undergo skill development, along with regular curriculum. Even special training institutes shall be promoted by government or private players for the above requirement.

In Vizag, a district which was identified and promoted by the Government of Andhra Pradesh (undivided) is a strong foothold for API manufacturing in India. The Andhra Pradesh government had put additional emphasis by introduction of single-window system for approvals, which is a boon for this sector. Private players and government-operated SEZ and non-SEZ zones have come up and started operating, with some of these exclusively for pharma sector. Moreover, power availability is not at all an issue, as there is a common effluent treatment plant and hazardous waste disposal area for handling waste generated by the pharma sector.

How pharma companies can minimise API dependency from China ?

Pharma Companies, over a period of last 25 years, have gradually started depending on China. Many companies started buying APIs. Even many API companies started buying advance intermediates from China.

Initially low cost source availability was the main driver but later, many reasons added to the cause. API industries started buying advance intermediate to reduce their product development cycle, investment in facility for production of intermediate and avoiding the complex chemistry to handle in-house. This has also given short-cut to various product development teams. We, the Indian pharma companies, started filing the DMF's in various regulatory markets with China as a primary source of key starting materials and intermediates, and indirectly locked ourselves for long-term association with Chinese companies. In addition



ANANT BARBADIKAR
MD & COO – India Operations, PharmaZell

to this, there was an outside pressure by various state governments for red category industries. There was an overall reluctance of producing key starting materials and intermediates in-house within India.

Initially, many Indian companies surely benefitted with this approach and worked very well during the last many years. However, gradually Chinese industries started facing the same problems which Indian industries had tried to avoid. Negligence of environment and safety standards started creating serious concerns within China. A recent major explosion was a serious episode in which many industries came under trouble. The immediate threat was the supply — many chemicals started getting delayed — and secondly, Chinese companies started loading the site upgradation / investment cost on the products and the cost of chemicals started increasing exponentially. This has eroded the initial advantage of low-cost source availability.

Another problem which many industries did not anticipate was constant enhancement of regulatory standards, and need for more and more data on key starting materials and intermediates. This has specially became major problem in getting the route of synthesis, impurity profiles, methods of analysis, etc for Europe and the US market.

In short, Indian pharma industries are in trouble from all corners unless they take quick actions during the next three to five years. The important part is to unlearn and unwind some of the strategies. Few important actions that need to be taken are:

- Immediately bring the development team in action to develop the process from basic chemicals and not from advance intermediates.
- Use novel methods of process development to reduce waste and reduce environment pollution to make in-house manufacturing feasible.
- Give impetus on manufacturing in-house or within India.
- Pharma industries need to request the government to dedicate certain zones for chemical industries and give quick environment clearance for taking manufacturing in India.
- Industries need to improve the workforce productivity to make sure that we do not increase cost of production significantly by taking the manufacturing within India.
- Start focussing on the regulatory filings by taking care that Indian source of manufacturing becomes an alternate supplier and slowly replaces the Chinese suppliers, phase wise.

It has become a necessity that every Indian pharma industry makes a long-term strategy, individually or clusterwise, to reduce dependency on Chinese supply of key starting materials and intermediates over the period of next few years. This will not only help in mitigating risk of surprises from China, but it will assure sustainability of Indian pharma's growth story.

Changing the mindset for education can definitely be a game changer

First, it is important to understand the comparison between India and China's economy from a business perspective.

China is now the global factory of the world. All the big countries still prefer China as compared to India. But how did this happen? In 1990, China was producing only 3 per cent of the total global output by value, but now by 2018 it is 25 per cent. In 2017, with $23.25 trillion economy, it became the number one economy of the world. After the US, China is now the most powerful. With $2.2 trillion export, China is the undisputed number one leader in export.

It is not the case that China is producing only low cost or cheap products — 60 per cent of the total luxury items of the world are produced in China. Every year it sees a GDP growth of 8-10 per cent. Hence, the result- 800 million people below poverty line are now above poverty line in last 25 years.

How has it happened?

Lets find out top ten difference between China and India:

Mass production and dumping

China indulges in massive production and hence creates huge scalability. In whichever country it exports, it first checks the prices of the product, and then produces in such massive volume that it brings down the prices even lower than the price of the product in that country (India), and captures the whole market by dumping products at lower prices. If we compare India before 1991, when mostly 'anti large industry policy' existed, focus was more on small scale industries. Small scale was restricted to only small scale, scaling up was an alien concept. The initiative was with a good intention, but did not able to develop the required ecosystem. A business man who cannot scale up the production, cannot reduce the cost and can stick to only option reduction or opting for less manpower. It is actually a misconception that with more manpower, cost will increase, but in reality it decreases. In India, we still do not know how to scale up.

Competitive pricing with reverse manufacturing

Chinese are expert in reverse manufacturing. Big countries focus on innovation of the products, and Chinse take out the knowledge of innovator products. They understand the product deeplyand learn how a copy can be made. With this approach, they save cost of innovation, R&D and IPR. In India, people have less global exposure as they try to restrict limited options and limited space, and so the learning of whos and whys takes a lot of effort. On the other hand, China brings best from the world and develops expertise to create similar product at a lower cost.

Cost-effective labour

Many of us think that Chinese labour is available at lesser cost because its population is more, but that is not the case. Chinese labour is not cheap but highly productive because of China's high focus on skill development. Their government, industries and localities jointly have given the shape to it. Output per person as compared to Indian labour is 20 to 30 times better. Although the Indian government is working on skill enhancement, it still has a lot of ground work needed to do. This is one of the major reasons why we are not able to compete with China.

KV V RAJU
CEO, Granules OmniChem

Experience and expertise

China is now the most popular global manufacturing destination. Practiced and experienced workers ensure that the overall productivity is high. Meanwhile, India still lacks in automated equipment, capacity utilisation, sustainable supply chain and reliable quality control. People in India still don't have the experience and the expertise for that. Although manufacturing set-up and a productive eco system is being developed, still that level of understanding and experience is lacking because of fear and again low scalability and strength. In China, the experience and expertise is in their blood. They can make any thing.

> China indulges in massive production and hence creates huge scalability. In whichever country it exports, it first checks the prices of the product, and then produces in such massive volume that it brings down the prices even lower than the price of the product in that country (India), and captures the whole market by dumping products at lower prices

Stability

Whenever a multi-national client comes to India, at first they feel uncomfortable because of lack of clarity in bureaucracy and government policy. With every new government, policies change. In China, the government is stable, infrastructure is stable, there are no power cuts, no plumbing issue and no flooding issues. To an investor, China looks more stable. There is assurance that work will be done. In India, Make in India is being done forcefully and the actual client are less interested to come because a lot of time , energy and money needs to be put in to manufacture low-cost products.

Education

There is a big difference between China and India's education system. In China, the number of graduates is more than in India. In China, education system provides updated technology, best management practices and global learning practices. Chinese government encourages their students to go for education in the best universities of the world. This is also one of the main reasons that the Chinese are more updated than Indians. Changing the mindset for education can definitely be a game changer for us. Unless there are consistent efforts to improve education and its system, India cannot compete with China.

Industrial network clustering

China has developed cities as supply chain cities. It means whatever is required to produce single focus products or similar products, every resource gets clustered in that city. Government support is paramount to achieve this, in order to provide training, financing, encouragement, infrastructure arrangement. India has also started this,and we can see that each state is promoting itself as a potential industrial hub, but we still have a long way to go. We need to think how this can be done for API specifically.

Cost of power and availability

In China, power is easily available at cheap price, unlike India. In China, per KW cost is Rs 3 but in India it is Rs 8-9. While the former experiences no power cuts, in India there are many industrial areas where power cuts last even up to 10-12 hours and manufacturer have to rely on generators, increasing the overall cost of product.

World class infrastructures

Infrastructures in China — roads, highways, ports,airports, supply chain — is far ahead of India. Any infrastructure project taken up in China is always with long term, planned with 25-30 years in sight, which reduces the total cost in the long terms In India, there are frequently changing policies as governments come and go, which hinders this process.

Government and industry work in partnership

In China, the government and the company work together in partnership. China works with a combination of corporate interest+ political international interest. In India, political instability does not allow these collaboration.

There is a need to focus on skill development

Emerging economies have been struggling with the absence of quality healthcare, and the biggest challenge in healthcare today remains — 'access and affordability of medicines to all.'

It is unexpected that the nation, which enjoys the attractive position of being the one that provides affordable medicines to over 200 countries, vigorously relies upon its neighbour, China, for many essential and extensive volume drugs.

As per the information available, about 84 per cent of APIs of all drugs produced in India are imported. Of these, 65 per cent are from China alone.

DR SANJIT SINGH LAMBA
Managing Director, Eisai Pharmaceuticals

Dependency on China

The principle reason behind the imports of APIs from China is the low cost. Be that as it may, reliance on just one nation for such a large import of APIs, as well as some bulk drugs, is potentially a very risky situation. The API imports from China in value terms are close to Rs 13,853 crore. The industry is relying 100 per cent upon imports of penicillin, vitamins, certain antibiotics and intermediates. China has increased the prices of bulk drugs by 11-fold, or 1,200 per cent, during last two years.

It is critical for India to make drugs which are in the National List of Essential Medicines (NLEM). Most of the active pharmaceutical ingredients are being sourced from China for these basic drugs. On the off chance that China quits providing certain material, there will be challenges both in terms of meeting domestic health needs as well as exports.

Katoch committee

Recently, the Central government expressed concern about Indian pharma company's reliance on China. To lessen India's import reliance, the Katoch Committee in 2015 recommended reforms such as setting up of mega bulk drugs park in five-six states with financial aid from the center and state governments, reviving public sector units and offering tax benefits for R&D spend. Following are some of the recommendations of the committee.

Recommendations

- Setting up of mega parks for API or Bulk drugs manufacturing.
- Innovative ideas and products should be promoted and awards to scientists/industry should be given for contribution to the industry.
- It is necessary to have proper rules and regulations to have a check on the pollution level and the quality of the output.
- There should be provisions for easy soft loans to the Industry through interest subvention.
- Tax free status to cluster developers and cluster participants.
- Incentives should be provided to the manufacturers for setting up large plants and for importing of technology so that they can reduce the cost of production.

Skill development and training

There is a need to focus on skill development and prepare the workforce for the pharma and life sciences industry at different dimensions, such as analytical, GMP and quality management, documentation, regulatory requirements and statistical techniques. Academic syllabus of pharma training institutions may incorporate these regions.

Government encouragement

Pharmaceuticals Export Promotion Council (Pharmexcil) is finding a way to decrease this over-reliance on China.

The council had been conversing with Chinese regulatory authorities and China Chamber of Commerce for Import & Export of Medicines (CCCIEM) to promote exports to China to maintain the trade balance.

The council has submitted a proposal to the Department of Commerce, Ministry of Commerce, Government of India, and created a Task Force comprising of CSIR Labs and industry.

The Task Force has recognised some key basic raw materials that are needed to make active pharma ingredients (bulk drugs) and has proposed creation of industrial clusters to make bulk drugs to combat Chinese companies on the price front.

Import duty

The import duty has been increased from 0 per cent to 7.5 per cent on all pharma imports. India's efforts to reduce reliance on China for drug ingredients are now showing results. In 2017, India imported 354 Active Pharmaceutical Ingredients from China, a 26 per cent plunge compared to 2015.

The Prime Minister's Office (PMO) last year instructed the NITI Aayog and the concerned ministries to plan for APIs production in India. In spite of arranging some meetings and having nearly 300 large and more than 10,000 medium and small companies in the sector, there was very little advancement in this direction.

Conclusion

The suggestions of the Katoch panel such as setting up of mega API clusters, innovative ideas to develop the products, tax free status are commendable, and no doubt these will play an active role in transforming the 'bulk drug' the country. Also, other initiatives, for instance, skill development and training, government encouragement, and import duty structure will enable to reduce the Indian pharma dependency from China.

The government should consider it as national emergency

Self-sufficiency in bulk drugs remains a distant dream as India remains import dependent with over dependence on China, even for essential drugs and many intermediates. Earlier, the government declared 2015 as the year of bulk drugs or Active Pharmaceutical Ingredients (API) in a bid to promote its Make in India initiative. Four years are nearly over but self-sufficiency in bulk drugs remains a distant dream.

In my opinion, the government should consider it as national emergency and allocate enough focus to come out of this situation in the shortest time possible. Business de-risking is of utmost important for sustainability, and this being a healthcare industry, alternate plan B should be in place.

DR B KRISHNA MURTHY
Associate Vice President-FR&D, Natco Pharma- Pharma Division

In order to de-risk, self-sufficiency in all intermediates and starting materials should be ensured by producing locally while maintaining market/commercial viability. One way of achieving this is by government sponsored programmes as they provide conducive environment for the bulk drug industry to develop in India by facilitating necessary infrastructure by building bulk drug manufacturing parks in different corners of the country, facilitate common infrastructure for testing, ETP and STPs run by them and providing facility at affordable costs. Encouraging innovation by rewarding cost-effective process developers, and supporting technocrats to invest and develop process improvement and next century technologies.

On the procedural front, providing single window license, tax incentivisation, power subvention, income tax and GST subvention along with investment subsidies will bolster the industry again, and make India free from single country dependency for manufacture of life saving drugs and their intermediates.

u.sharma@expressindia.com

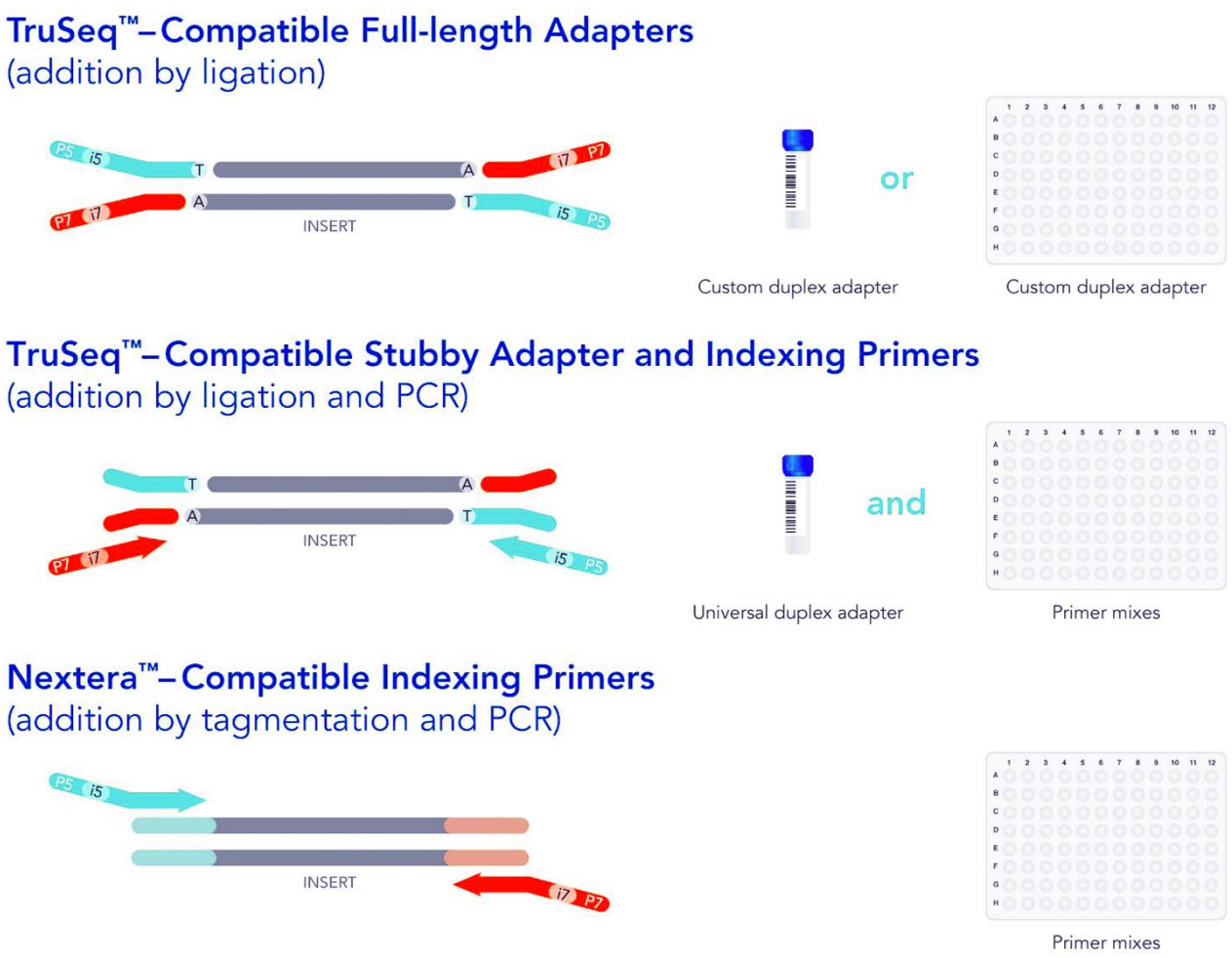
VENDOR NEWS

IDT brings unmatched customisation to NGS

Launch of Custom NGS Adapters and portfolio expansion delivers unprecedented flexibility and ease-of-use

Demonstrating its advocacy for genomics research, Integrated DNA Technologies (IDT) has announced a significant expansion to its NGS portfolio. The company has launched a unique Custom NGS Adapters offering, becoming the only genomics provider to provide an easy and flexible customised adapter solution directly to scientists. The cornerstone of this new offering is a web-based configurator tool, the Custom Adapter Configurator, enabling researchers to effortlessly select exactly the right components for their experiments and immediately order them, thanks to built-in e-commerce function. Completing the lineup is the new Lotus DNA Library Prep Kit, providing a simple, robust, and flexible library preparation to suit every need.

Unlike other array and chip-based manufacturers, IDT adapters and other products are individually synthesised using stringent, proprietary methods that deliver the highest-quality in every single batch – critical for NGS applications. As demonstration of IDT's proficiency, in 2017 the company announced a partnership with Illumina to develop and manufacture a portfolio of indexed NGS adapters for use on Illumina instruments. In order to lower barriers to NGS and provide unmatched flexibility, IDT has now made these adapters easily accessible to users of all levels, enabling researchers to better tailor library preparation to their specific applications. There are three, high-quality configurations available – TruSeq-Compatible Full-length Adapters, TruSeq-Compatible Stubby Adapter and Indexing Primers, and Nextera-Compatible Indexing Primers.



> IDT adapters and other products are individually synthesised using stringent, proprietary methods that deliver the highest-quality in every single batch – critical for NGS applications

Accompanying the adapter selection and key to accessing its unprecedented usability, is the guided Custom Adapter Configurator tool. IDT is well known for its wide range of online tools, helping scientists to reliably design and plan experiments that employ oligos, NGS, CRISPR, genotyping, qPCR, and gene fragments. The tool is the only ecommerce solution available that provides expert guidance, effortlessly walking the user through otherwise complex adapter design and formatting options.

Trey Martin, President, IDT commented, "We are excited about this NGS portfolio expansion. At IDT, we understand that the needs of genomics researchers are not only complex but evolving and unique to the work of the researcher. For NGS customisation options to be seamless, they also need to be simple and time-effective. Understanding these challenges, we wanted to help by providing high-quality custom NGS adapters and our expert guidance. With this, scientists can easily order the best adapter configurations, features, and formats for every project."

With just a 2-hour workflow, the Lotus DNA Library Prep Kit – optimised for use with IDT's custom adapters and xGen capture products – delivers superior coverage and uniformity for sequencing on Illumina platforms. IDT has once again designed the kit with flexibility in mind, enabling it to be compatible with TA-ligation adapters and tailored to almost any application when combined with the new adapter options.

EP News Bureau

LTE appoints India and South-East Asia exports manager

Kolkata-based Ashim Chakravarty, who has 20 years of professional experience in the life sciences industry, has been given the charge

LTE SCIENTIFIC has appointed Ashim Chakravarty as the area export manager for India and South-East Asia, further expanding its global activities. Based in Kolkata, India, he is LTE Scientific's first-ever full-time area manager, specifically employed in the region.

Chakravarty has 20 years of professional experience in the life sciences industry. Before joining LTE Scientific, he spent 13 years with a UK spectrophotometer and chromatography manufacturer.

On his appointment, John Lees, Managing Director, LTE Scientific, said, "Chakravarty is an important and strategic appointment for us and we are delighted to welcome him. He will establish an important full-time presence for us in India and South-East Asia. His appointment will ensure that we are fully represented in the region as our business expands further.

"Chakravarthy will encourage growth through our existing distributor network and also identify new distributors for life science and medical fields. He has a lot of experience and a great ability to respond to clients' needs and new developments.

"We are excited and confident about creating this brand-new position in India. We believe Chakravarty is an excellent addition to LTE's team, as we increase our global activities and our investment in equipment design and manufacturing, customer service and training," he added.

EP News Bureau

Lonza launches dry-powder inhalation capsule portfolio

The product will help to address the specific needs of inhalation drug products manufacturers

LONZA HAS launched Capsugel Zephyr, its new dry-powder inhalation (DPI) capsule portfolio, the most complete portfolio of DPI capsules to meet the growing need for customised solutions for optimal pulmonary drug delivery.

Lonza's Capsule Delivery Solutions team developed Capsugel Zephyr capsules as a portfolio of high-quality, highly customisable DPI capsules of different polymers and compositions, and product customisation services to help address the specific needs of inhalation drug products manufacturers.

> Lonza's Capsule Delivery Solutions team developed Capsugel Zephyr capsules as a portfolio of high-quality, highly customisable DPI capsules of different polymers and compositions

"Capsule-based DPI technology is quickly becoming the preferred DPI drug delivery platform for pulmonary delivery. It provides drug stability advantages, encourages patient compliance and is cost-effective to manufacture with various dose carrying capacity. With more than 20 years of experience in manufacturing DPI- capsules, Lonza offers a uniquely customised portfolio of polymers to meet the growing need of inhalation DPI products for pulmonary drug delivery," stated Stef Vanquickenborne, VP R&D, Lonza Pharma & Biotech.

The Capsugel Zephyr capsule portfolio responds to the marketplace needs for comprehensive inhalation solutions that ensure end-product efficacy with consistent and optimal release performance regardless of formulation characteristics or DPI device principles. With over three billion DPI capsule units delivered worldwide, Lonza offers a full-service inhalation drug-delivery approach based on proven particle engineering platforms, specialised encapsulation technologies as well as customised capsules for use with a large range of DPI devices. The portfolio is further supported by a global integrated supply chain, quality and regulatory support and Lonza's advanced manufacturing network for associated services.

"With the launch of the Capsugel Zephyr capsule portfolio, Lonza will offer full end-to-end solutions for capsule-based DPI products. Our specialised capsule technology provides our customers with the right solution to deliver optimal product performance for the pulmonary route; a testament to how patient-centricity and customer focus are at the heart of Lonza's healthcare continuum," said Fabio Invernizzi, VP Global Sales, Capsule Delivery Solutions, Lonza Pharma & Biotech.

EP News Bureau

Pelican BioThermal bags Asia-Pacific Bioprocessing Excellence Awards

Company celebrates major win at Asia-Pacific Bioprocessing Excellence Awards

PELICAN BIOTHERMAL, which is into temperature-controlled packaging, was announced as a winner at an annual awards ceremony which recognises the excellence of suppliers serving the biologics industry.

Following nomination for the Passive Packaging category award, which was presented at the Biologistics World Asia 2019 conference in Singapore, Pelican BioThermal was announced as the winners. The company was presented with the award following an in-depth judging process whereby more than 30,000 professionals from the biologics industry were invited to vote for Pelican BioThermal and fellow finalists.

As Pelican BioThermal continues to increase its infrastructure and operations in Asia, its key role as a supplier of high performing passive packaging to the biologics industry in the region was rewarded with this coveted award.

Benson Teo, Pelican BioThermal's Senior Director of Sales, Asia, said, "We are excited and humbled to receive this award from the industry in recognition of the high performing products and services we provide. Congratulations to the team at Pelican BioThermal on this latest award. We would especially like to thank all the customers who placed their trust in us to meet their requirements and deliver the expected results. We will continue to innovate while providing the best pioneering products possible for our customers in Asia and worldwide."

EP News Bureau

Watson-Marlow Fluid Technology Group posts sales of over £265 m

The growth is driven by continued growth of key industries

IN THE recently published 2018 annual report, Watson-Marlow Fluid Technology Group (WMFTG), a Spirax-Sarco Engineering Company, reported sales of over £265 million, driven by the continued growth of key industries as well as aggressive overseas expansion.

A significant proportion of business, c.40 per cent of sales, is with the pharmaceutical and biotechnology industry which remained buoyant, supported by record levels of investment. Sales of BioPure, Aflex, FlowSmart and Watson-Marlow Tubing brands, in particular, all contributed strongly to growth. The OEM medical device/clinical diagnostics, and food and beverage industries, two other important markets to the Company, also remained robust.

Watson-Marlow's geographic expansion continued in 2018, with a direct sales presence installed in the Philippines and a company established there that will begin trading in 2019, as well as a new company which began trading in the UAE. This, as well as expansion in the US, Korea and South Africa, all helped to drive significant sales and profit growth.

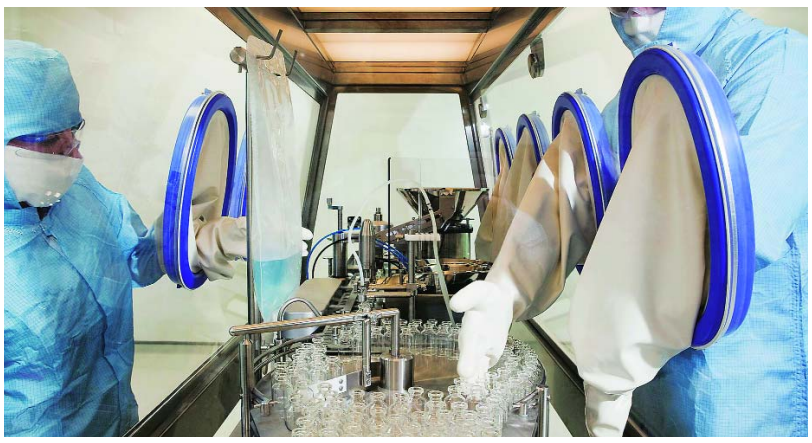
Watson-Marlow Fluid Technology Group (WMFTG) reported organic growth of 9 per cent in 2018, partially offset by exchange headwinds of 2 per cent, delivering sales of £265.2 million. The company increased its adjusted operating profit by 11 per cent and its statutory operating profit from £74.8 million in 2017 to £77.5 million.

Building on this success, the company has recently invested £20m in a new factory for one of its UK-based brands, Aflex Hose, it expects that up to 200 new jobs will be created as a result of the new development over the next 10 years demonstrating a clear commitment to boosting the UK economy in this time of political uncertainty. Watson-Marlow is dedicated to supporting the UK engineering and manufacturing sectors and this year celebrates its 50th anniversary at its headquarters in Falmouth, Cornwall.

The market drivers in Watson-Marlow Fluid Technology Group's key industries, pharma and biotechnology, as well as food and beverage, medical device/clinical diagnostic OEMs and environmental, all remain strong. This positions the company well for continued growth, with further expansion in Southern Europe and Latin America planned for this year.

Jay Whalen, President, Watson-Marlow Fluid Technology Group, "We are pleased to report strong organic sales and profit growth in 2018. Watson-Marlow's fluid management expertise transforms our customers' production processes in biotechnology, pharma, industrial, automotive, mining, food and beverage, original equipment manufacturing and medical device/clinical diagnostic industries. Our strategic investments in our direct sales force, geographical expansion, market-leading new product innovation and manufacturing efficiencies, to name but a few, will enable us to build on this success in 2019 and beyond."

EP News Bureau



9th Edition of PharmaTech Expo 2019 & LabTech Expo 2019 at Chandigarh scales new heights

The event was attended by about 5000 visitors

NORTH INDIA'S dedicated event on pharmaceutical innovation, technology and knowledge was recently held in Chandigarh. The event was the 9th edition of PharmaTech Expo &LabTech Expo 2019 organised by PharmaTechnologyIndex.com.

The event has scaled new heights as over a period, PharmaTech Expo has emerged as a crucial platform for showcasing the latest innovation and technologies throughout all phases of the product lifecycle, focussing on pharma manufacturing and processing technology, pharma systems and services. This year the focus of the three-day expo was on pharma machinery and equipment manufacturing sector and pharma packaging, Lab and Analytical Instruments, pharma formulations and nutraceuticals.

The inauguration function was graced by Dr Dinesh Dua, Chairman, Pharmaceutical Export Promotion Council of India; Prof Raghuram Rao Akkinepally, Director, NIPER Chandigarh; Dr Naresh Sharma, President, Indian Pharmaceutical Association(IPA), Delhi Branch & Deputy Drugs Controller(I) ,CDSCO; Pradeep Kumar Mattu, State Drug Controller, Punjab; NK Ahuja, State Drug Controller, Haryana; GP Malhotra, Assistant Director (North) EEPC India; Dr Rajesh Gupta, President, HDMA; Dr GS Pandey, Director, Kopran and Dr DN Dixit, Ex- Regional QA Head, Sun Pharma.

The exhibition was planned in 7500 square metres, with more than 200 exhibitors who displayed machinery and equipment for producing drugs and pharma products and the event was attended by about 5000 visitors. This year, the exhibition area was up by 22 per cent and there has been 31 per cent increase in number of exhibiting companies and the visitor flow increased by 40 per cent compared to the earlier events.

> This year the focus of the three-day expo was on pharma machinery and equipment manufacturing sector and pharma packaging, Lab and Analytical Instruments, pharma formulations and nutraceuticals

A seminar on 'Recent Developments in Indian Regulations and Needs of Pharma Industry' was organised jointly with Indian Pharmaceutical Association (IPA), Delhi Branch.

Further, a large number of organisations including PHARMEXCIL, Engineering Export Promotion Council (EEPC India) Indian Pharmaceutical Association (IPA), Delhi Branch, Himachal Drug Manufacturers Association (HDMA), Ambala Scientific Instruments Manufacturers' Association (ASIMA), Drug Marketing & Manufacturers Association (DMMA) and other industry associations and industrial houses had given consent as supporting organisations / sponsors to the event.

A seminar on 'Recent Developments in Indian Regulations and Needs of Pharma Industry' was also organised by Indian Pharmaceutical Association, Delhi Branch and PharmaTechnologyIndex.com.

During the seminar, Dr Naresh Sharma, shared his thoughts on regulatory systems in India with reference to global prospects and revised Clinical Trial and Medical Device Rules at par with global standards and its implementation. Siddharth Sahai Malhotra, Assistant Drugs Controller , CDSCO spoke about requirement of BA/BE Study in line.

Sushant Sharma, Assistant Drugs Controller (I) spoke about regulatory requirement for approval of dual use NOC of drugs.

Ankit Sharma, Assistant Drugs Controller (I) spoke about FDC and other eminent speakers from industries covered Revised Schedule M draft and data integrity. The overall programme was well appreciated by 120 participants from industries.

Dr DN Dixit, Ex-Regional QA-Head, Sun Pharma gave an overview of new draft Schedule M in comparison to the Existing Schedule M with focus to data.

Dr GS Pandey, Director, Kopran Technologies spoke about data integrity and data reliability.

EP News Bureau

PRODUCT

How to control the cleanroom environment?

CLEANROOMS ARE widely used in scientific research and manufacturing, which act as a place to minimise airborne contamination, while strictly controlling factors like temperature and humidity.

This makes them a crucial space for a number of industries such as pharmaceuticals, bioengineering, electronics, and micro-mechanics — where cleanliness and precision are vital.

A level of cleanliness and sterility that is not comparable to any other place is essential in the sterile room, or better, the clean room.

An environment with a zero level of pollution, an area of experimentation that requires extreme cleanliness, where the air inside the rooms is - 20,000 times cleaner than outside air.

In the rooms that require a special clean air, access is allowed only to trained personnel.

Cleanroom classification

With this in mind, there are increasing regulations for cleanrooms to ensure production remains safe and free from contamination.

Basically, cleanrooms are classified by how clean the air is. Air is constantly filtered and recirculated through filters to maintain its quality.

As the sole entry and exit point for most contaminants (i.e. people), doors are crucial to meeting international classification standards. The right door goes a long way to minimising potential variables.

Airtightness

The first question to ask is: are the doors well sealed? Effective doors should be as secure as possible, with near impermeable seals. Many laboratories even use airlock systems for entry and exit.

However, the process of air filtration moves air around within the room — we need to breathe after all. Cleanrooms tend to maintain high air pressure, which occurs when slightly more air is being put in than taken out.

This means the excess air looks to escape, so any airflow around the door when it's opened and closed will be moving outwards, restricting the access of external contaminants.

Door speed

Another key component of keeping a cleanroom...well, clean, is the speed of the door. Generally speaking, the faster the better.

Doors with fast opening and closing speeds regulate air exchange and reduces the risk of contaminants such as draughts, moisture, dust and dirt. The less time a door is open, the easier it is to maintain stable air pressure.

Specialised doors can't be treated as an afterthought. They must fit their purpose – in this case, maintaining a clean, controlled environment to ensure testing and manufacturing processes are as precise and efficient as possible.

High-speed cleanroom doors protect against drafts, humidity, dust and dirt

Gandhi Automations, one of the leading cleanroom door manufacturers, delivers high-speed cleanroom doors perfected for controlled environments. The cleanroom doors feature an almost airtight seal, which minimises pressure drop and protects your environment against drafts, humidity, dust and dirt. These advanced high-speed doors are ideal for cleanroom and associated controlled environment applications in pharmaceutical, chemical, electronics and micro-mechanics industries.

Prime Clean Reset high-speed cleanroom doors

Prime Clean Reset high-speed cleanroom doors help to minimise contamination risks and meet hygienic standards for controlled environments without compromising product quality or worker safety. Exceptionally fast speeds, near airtight seals and durable performance provide greater control over particle concentration and air changes while maintaining stringent cleanroom requirements.

Clean room doors (Prime Clean Reset) are designed for inside applications requiring limitation of leak flow. The perfect sealing properties of Prime Clean Reset provide environmental control and protect the inside environment against draughts, dust and dirt. Clean room doors provided by us also has self- repairing system.

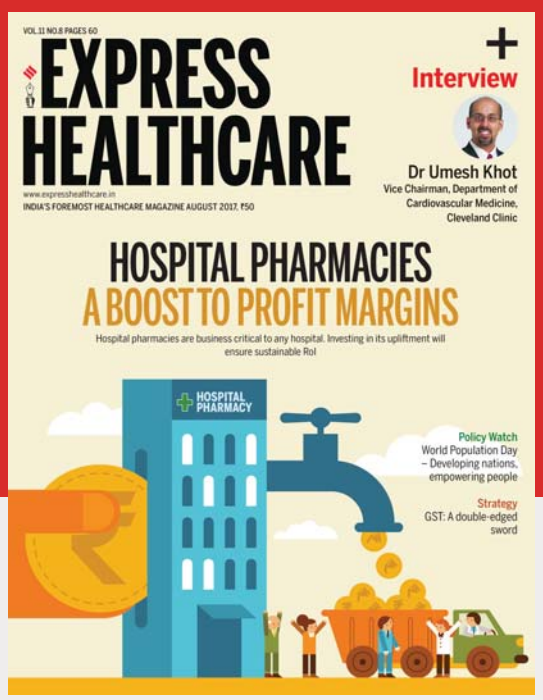
One of the most imperative aspects of clean rooms is the door you choose for clean room facility. Time for which door is open will play a critical factor in avoiding dirt, temperature, humidity etc. Opening and closure of door has to quick enough to isolate the two areas.

Gandhi Automations provide clean room high speed doors specifically designed for above purpose. The high speed doors are best suited for pharma industry where there is the need for a controlled environment. The opening and closing of door is fast enough to separate two areas.

Contact details

Gandhi Automations
Chawda Commercial Centre,
Link Road, Malad (West),
Mumbai - 400064,
Tel: +91-22-66720200 /
66720300 (200 lines)
+91-22-66720201
e-mail: sales@geapl.co.in
customercare@geapl.co.in

THE BOOSTER FOR THOSE WHO BOOST THE HEALTHCARE SECTOR



When it comes to nourishing this sector, experts prescribe a regular diet of Express Healthcare. The magazine has been the source of a healthy dose of expert information, incisive category analysis and remedies for industry ailments since 20 years, thereby earning the trust of industry professionals. It's no wonder then that the finest in the field trust the foremost in the field.

For any queries, call 022-67440002
or email at healthcare@expressindia.com.

EXPRESS HEALTHCARE

www.expresshealthcare.com

VALUE ADD

Controller and multi-touch HMI in one device

B&R's new Power Panel offers a dedicated processor for HMI

THE POWER Panel C50 provides the combined advantages of a powerful controller and a modern projected capacitive touch screen in a single HMI device. The Power Panel is equipped with a dedicated processor for the HMI application, and is therefore an optimal solution for mapp View HMI applications. It can be used at temperatures ranging from -20°C to +60°C and does not require a fan.

The modern multi-touch HMI is available with clear or anti-reflective glass, and is ideally suited for premium machine designs. The touch screen reacts precisely and reliably even when operated with thick leather gloves. Gestures such as zoom or swipe provide an intuitive user experience. The Power Panel C50 is available in widescreen format in four different sizes from 7.0" to 15.6".

Compact and maintenance-free

This Power Panel has an extremely compact design, minimal installation depth and an intelligent cable outlet arrangement, making it an easy-to-mount space saver. With no hard disks, fans or batteries, it is also maintenance free. The front of the panel provides IP65 protection, making it extremely well-suited for harsh industrial environments.

Numerous interfaces

To allow optimal use of this performance, the Power Panel C50 has a wide range of integrated interfaces, including POWERLINK, Ethernet and USB. I/O modules, axes and safety components can also be connected directly to the panel. There's no need for additional controllers.

Using the advantages of mapp View

The high-performance Power Panel C50 is ideal for running mapp View HMI applications. With the mapp View software package, B&R offers direct access to the wide world of web technology right from the engineering environment. Automation engineers have all the tools they need to create powerful and intuitive HMI solutions. There is no need to deal directly with HTML5, CSS and JavaScript technology. mapp View is based entirely on web standards, ensuring optimal viewing on any device. Content of multiple screens can be customised for specific users or user groups.

In-sync with robots

B&R software better utilises the potential of robots

B&R HAS added new functions to its mapp Motion software package. It is now possible to represent the actual structure of a complex machine intuitively in the configuration. The various subsystems of a machine can simply be linked together. The movements of robots can be easily synchronised with gantry systems or workpiece tables with no additional programming. The 'Frame hierarchy' function can be used to represent the actual structure of a machine. Coordinate systems can be positioned at key points, such as the tool mounting flange. Each coordinate system can be assigned a name that identifies it within the application. This ensures clearly organised, easily readable code – even in complex applications.

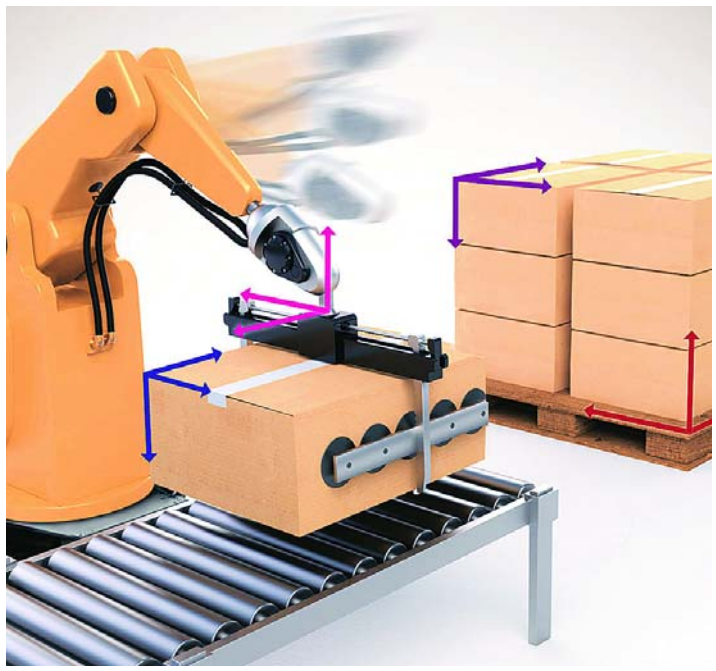
Optimised robot movements

The 'Programmed moving frame' function couples a coordinate system to an axis and defines an additional degree of freedom. This allows optimised movements and better utilisation of robot dynamics. The function incorporates the movement of the gantry system into the path calculations of the robot. The programmer doesn't need to coordinate the movements of the gantry system and robot manually. The same applies in cases where robots or CNC machines are combined with moving workpiece tables.

General path planning

Only one controller is necessary for the machine, robot and other moving components. The robot and additional components act as one unit. Coordinated path planning allows optimal utilisation of the dynamic limits of the individual components. It also guarantees that all specified process parameters are adhered to, such as the relative speed between tool and workpiece.

Contact
B&R Industrial Automation
8, Tara Heights, Mumbai-Pune Road
Wakdewadi, Pune 411 003
T +91 20 414 78 - 999 | F +91 20 414 78 - 998
E | www.br-automation.com



VALUE ADD

HPTLC-latest technique in USP/EP

HP-TLC has been making waves in the chromatography world, since it is the latest chromatography method to be added to USP from a couple of years. We interviewed **Akshay Charegaonkar**, Director, Anchrom Enterprises. The company's India-Specific HPTLC Applications Research Lab is churning out new methods of analysis, for all kinds of organic materials, particularly pharmaceuticals, foods, etc. On the occasion of their expansion of office space, **Express Pharma** interviewed him

You have recently expanded your office premises. Were there any specific needs behind the decision?
One real need was to expand our analytical research activities and training facilities. Our new office adds about a 1500 sq ft space to existing 3000 sq. ft.

For a single product selling company, this is quite impressive.
Yes. Thank you. But our real assets are people. All our core team members are with the company for more than 20 years. Our analytical R&D team has 14 members. We have all the latest CAMAG equipment to support this intelligent team.

What is your estimate of the market size of LC and HPTLC?

I think in India, it is 100:1 presently. However, LC is occupying a lot of space that HPTLC should occupy. Many labs are using expensive and cumbersome missiles for many jobs that drones can do easily, cost effectively and equally reliably.

But numerous labs have multiple LC systems.
Two myths are prevalent about LC. It is called High Performance Liquid Chromatography instead of High-Pressure Liquid Chromatography. Secondly and more importantly, LCs have to be repeatedly purchased because it is the slowest technique in any lab and not because there are that many samples!

Is LC the slowest technique in modern laboratories?
Yes. Firstly, it requires hours to set up and during when changing over samples. Then the run time per sample is usually between 5 to 60 min, with an average of about 25 min. That is why LCs have to be purchased repeatedly in direct proportion to even small increase in number of samples.

Why should analysts consider HPTLC as the alternative liquid chromatography now?
HPTLC has only recently (in Dec 2016) become an official technique, although the standardized methodology was proposed by CAMAG in 2004. Any company that uses 4-5 LCs should consider HPTLC otherwise they would just keep eternally investing in more LCs. And LC is very expensive to run and maintain. In labs where LC and HPTLC are available, HPTLC is far more popular because it is

easy, simple, visible and step-wise procedure.

How popular is HPTLC in the west?
This is to be noted. HP-TLC is only a 2-year-old technique. Imagine LC when it was 2-years old. HPTLC is now official and its effects, in the West as well, will be felt in the next few years. But how long should we look to the West? Developing new methods and validating them as per ICH guidelines does not require a high-level expert. A lot of analysis can be shifted to HPTLC because it is 10 times faster and cheaper to maintain than LC. Analytical R&D heads would be able to save crores and crores for their companies if they used HP-TLC successfully.

Are people reluctant to use HP-TLC?
Yes. Mostly because they confuse it with their knowledge of traditional TLC. HPTLC is now a technology based official method and practiced in a very ultra-modern way. The old argument about "HPTLC" being not official does not hold any more.

Can HPTLC methods comply with ICH guidelines?
Definitely. There are numerous publications. In reality, ICH guidelines do not cover the visible aspect of HPTLC and therefore need to be updated. The Indian Pharmacopoeia Commission Laboratory has published quantitative HPTLC papers. This should end all doubts about the quality of results and its acceptance by Indian authorities.

What are the unique features of HPTLC?
Firstly, the samples are literally "visible" to the human eye, throughout the analysis! Secondly the analysis is a batch process. A series of five to six physically independent instruments, but controlled by a system manager software, comprises a "HPTLC Chromatograph". So up to six different samples and up to 20 of each can be analyzed in parallel! There is no pressure or temperature used in chromatography. Hence no wear and tear. Breakdowns are rare. The separation medium, i.e. the plate, is disposable. So, any sample with matrix can also be taken up for analysis. HPTLC analysis is risk free because the samples remain on the plate and cannot contaminate the chromatograph. Being a batch process, any sample can be taken up on demand. Samples received by 3 pm, can be analysed by 5 pm. There are numerous other unique features.

What are the limitations of HPTLC?
Technology overcomes most limitations in all fields in the world. That is true for HPTLC. The biggest weakness i.e. chromatography development system is "open" to atmosphere has been completely overcome by an automatic development chamber. The second weakness of inter lab reproducibility of separations has been overcome by equilibrating silica gel layers with 33% RH, as prescribed in USP/ EP. The third is that the separation bed to be used is only 100 mm long. But HPTLC can accommodate 12-15 fractions. HPTLC is not an alternative to LC but must be checked for suitability before using LC. Today, the only solution is LC. While on the topic of limitations, I would like to add that using LC is a herculean job for MSMEs. The push for LC has hurt all our small, medium and large chemical industries badly. It's a kind of technical barrier.

What about training facilities for this "new" technique?
Being a step-wise process, without the use of pressure or temperature, and the fact that samples are visible makes learning HPTLC quite easy. Only one needs to learn it as a new technique and not improved TLC or substitute for LC. Our company has been offering free training on HPTLC to Government lab employees, Research guides and PG/ PhD students, since 1994. But much more needs to be done.

Why is Anchrom dedicated to HPTLC since so long?
Anchrom intends to make India, the global leader in the use of HPTLC. It is the liquid chromatography technique of first choice for the developing countries, going by the level of automation today. If fully automated, yet retaining all the advantages of a batch process, it will be very attractive even to the west.

Who uses HPTLC in India?
More than 450 labs used instrumental TLC in India. Now if they adopt the USP/ EP methodology, they can claim to be doing HPTLC, the results of which can hardly be challenged.

What is your message to the Indian authorities and chromatographers?
Adoption of HPTLC in a big way is absolutely essential to tremendously increase sample analysis capacity, with comparative little investment. Only with HPTLC, the Government can monitor food, pharma and other markets by screening hundreds of samples at a very low cost and high speed. The instrumentation base substantially exists in India. Only the USP/ EP methodology needs to be used in conjunction.

VALUE ADD

Tribasic calcium phosphate – one compound, so many possibilities

Daniel Zakowiecki, **Marek Lachmann**, **Tobias Hess**, in this article have introduced the possible ways of using various types of tribasic calcium phosphate excipient manufactured by German company Chemische Fabrik Budenheim KG and advantages that they can offer **(Part 1)**

TRIBASIC CALCIUM phosphate is well established compound which has been used for many years in a pharmaceutical technology as an excipient. The compound is known under a few different names such as hydroxyapatite or tricalcium phosphate and has monographs in major pharmacopoeias: for tribasic calcium phosphate in USP/NF or for calcium phosphate (tricalcii phosphas) in Ph.Eur. The compound can be chemically described as pentacalcium hydroxide triphosphate having a molecular formula of $Ca_5(PO4)_3(OH)$ or $Ca_{10}(PO4)_6(OH)_2$.[1,2,3]

The substance itself has very interesting physical and chemical properties. It is white, odourless and tasteless. It gives a neutral pH and has very high true density of 3.14 g/cm^3.[1] Owing to its very high melting point of around 1670 °C there is no danger of neither melting nor chemical decomposition under elevated temperature used during some technological processes such as drying, fluid bed granulation or even hot melt extrusion. Tribasic calcium phosphate is chemically and physically stable and has no tendency for caking during storage. The substance is practically insoluble in water however it is soluble in diluted mineral acids such as hydrochloric acid.[1,4] It means that in acidic conditions prevailing in a stomach the substance dissolves without threat of retaining a drug substance, negatively impacting dissolution and consequently bioavailability.

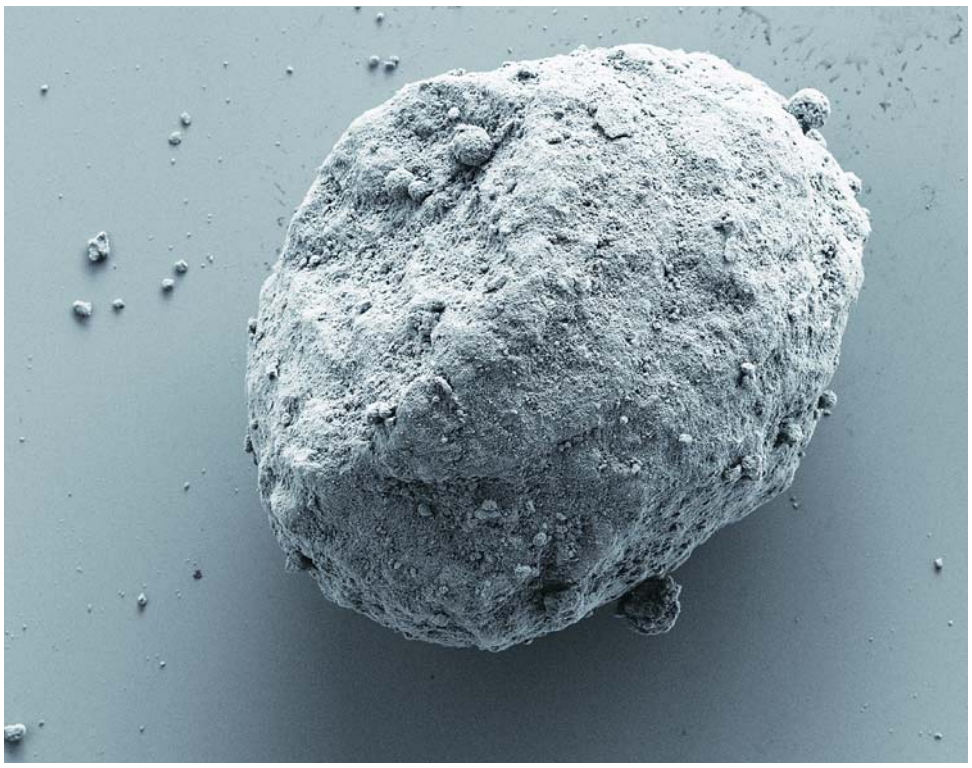


Fig.1. SEM picture of TRI-CAFOS 500 (magnification of 1.2 kX)

Tribasic calcium phosphate is commonly used as a tablet and capsule diluent however the same chemical compound can be produced in different ways resulting in different properties and application possibilities.

For example, spray dried product (TRI-CAFOS 500) with the median particle size of around 80 - 90 µm has particles with almost spherical shape enabling good powder flow. They consist of aggregated primary particles which gives the material a huge surface area and very special properties for the enhancement of tablet porosity or to provide additional binding capacity to poorly compactible mixtures. *(Fig. 1)* For comparison, precipitated, fine material (TRI-CAFOS 200-7) thanks to its unique structure and properties can be used as a flow regulating agent. In comparison with other popular glidants it has much higher bulk density (around 200 g/l) and thus reduces dust formation and exposition of operator to dust. *(Fig. 2)*

Another fine material (TRI-CAFOS 250) with median particle size of around 5 µm and low bulk density of around 250 g/l is a standard material, frequently used in granulation processes. The product has neutral a pH and a high specific surface area of around 60 m^2/g. *(Fig.3)*

In the article the authors introduced the possible ways of using various types of tribasic calcium phosphate excipient manufactured by German company Chemische Fabrik Budenheim KG and advantages that they can offer. Detailed description of functionality of these products can be also found elsewhere.[5,6,7]

The first part of the article focusses on directly compressible, coarse tribasic calcium phosphate: TRI-CAFOS 500. This excipient with a specific surface area of around 80 m^2/g is often used in tablet formulations to increase their porosity and hence reduce disintegration times. Furthermore, application as co-diluent, increases the bonding capacity of powder mixtures and helps to obtain a higher tablet hardness.

Improvement of tablet properties

Mechanical strength of tablets (breaking force) depends to a large extent on the properties of tableting mixture itself. Considering the fact that a large number of drug substances exhibit poor compactibility, improvement of the properties of the powder mixtures becomes crucial, especially for the production of tablets with a high content of active substance. Modern excipients come here to help, and in many cases they even allow direct tableting of drug substances with poor tableting properties.

Due to the big specific surface area (about 80 m^2/g) and high porosity (about 80 per cent), TRI-CAFOS 500 is particularly noteworthy in this application area. As a tribasic calcium phosphate, during compression it mainly undergoes plastic deformation[1] and its high binding capacity results from the extensive

specific surface area.

The specific surface area is one of the most important characteristics of a substance that affects the tableting process and the properties of the tablets themselves. On the one hand, it increases the bonding capacity of a tableting mixture due to the presence of a large number of potential binding sites.[8,9] Consequently, it improves the mechanical strength of the tablets. On the other hand, it increases the porosity of the tablets, which facilitates the penetration of water into their body and accelerates disintegration. Shortening the disintegration time in many cases may improve the dissolution and consequently also bioavailability of the drug.[10,11]

The results presented in *Fig. 4 and 5* show impact of 30 per cent (w/w) admixture of TRI-CAFOS 500 on tablet hardness (expressed as tensile strength) as well as on disintegration time. The tableting mixture consisted of 68.5 per cent by weight of the selected tablet filler: anhydrous dibasic calcium phosphate (DI-CAFOS A60, DI-CAFOS A150) or spray-dried lactose monohydrate, 1.0 per cent of croscarmellose sodium as a disintegrant and 0.5 per cent of magnesium stearate as a lubricant. The results obtained were compared to tablets containing 98,5 per cent (w/w) of above mentioned fillers (without admixture of TRI-CAFOS 500). Prior tableting all ingredients were blended at a rotational speed of 32 rpm using a Turbula mixer (Willy A Bachofen, Muttenz, Switzerland). Powder mixtures were compressed into tablets using the Fette 102i rotary tablet press (Fette Compacting GmbH, Schwarzenbek, Germany) at 62.5 rpm using flat faced punches of 8 mm in diameter under three compaction forces: 10 kN, 20 kN and 30 kN (equivalent to 200 MPa, 400 MPa and 600 MPa respectively).

The results show clearly that a 30 per cent (w/w) admixture of highly porous tribasic calcium phosphate resulted in significant improvement of tablet hardness. *(Fig.4)* This improvement was especially visible in case of tablets containing DI-CAFOS A60 – the material having not so enhanced tableting properties as other tested materials – where tablet tensile strength was doubled when the material was combined with TRI-CAFOS 500. Apart from improvement of tablets hardness also a significant impact on the disintegration time was observed. This was an effect of increment of tablet porosity which facilitated penetration of water into a tablet body. The most prominent effect was achieved in the case of tablets containing lactose monohydrate where the disintegration time was shortened two to three times depending on tablets hardness. *(Fig. 5)*

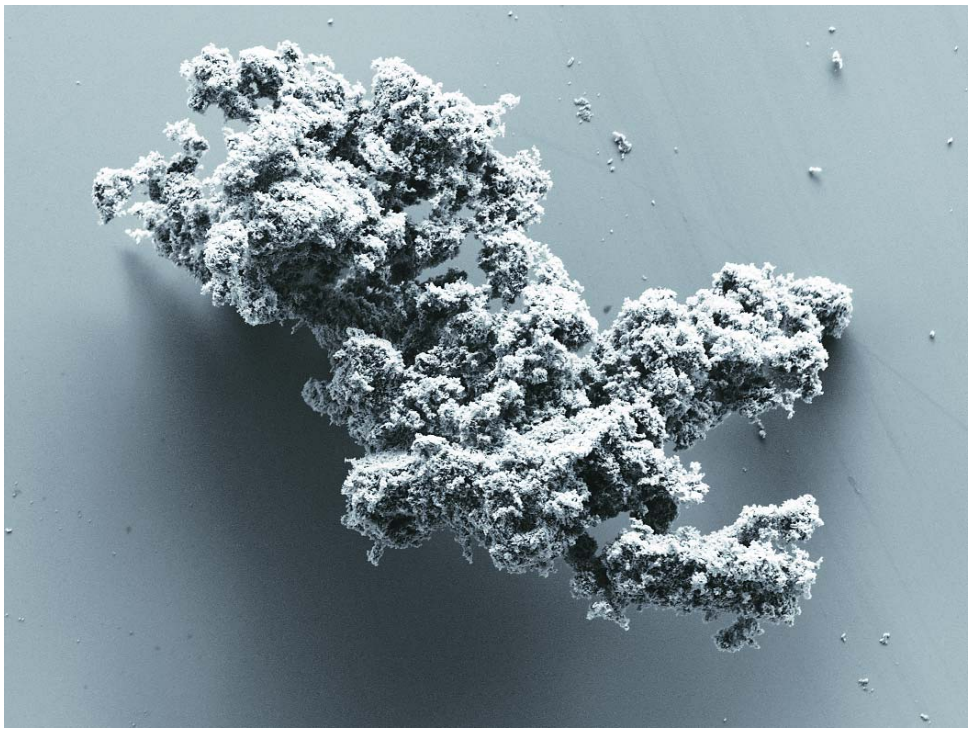


Fig.2. SEM picture of TRI-CAFOS 200-7 (magnification of 7 kX)

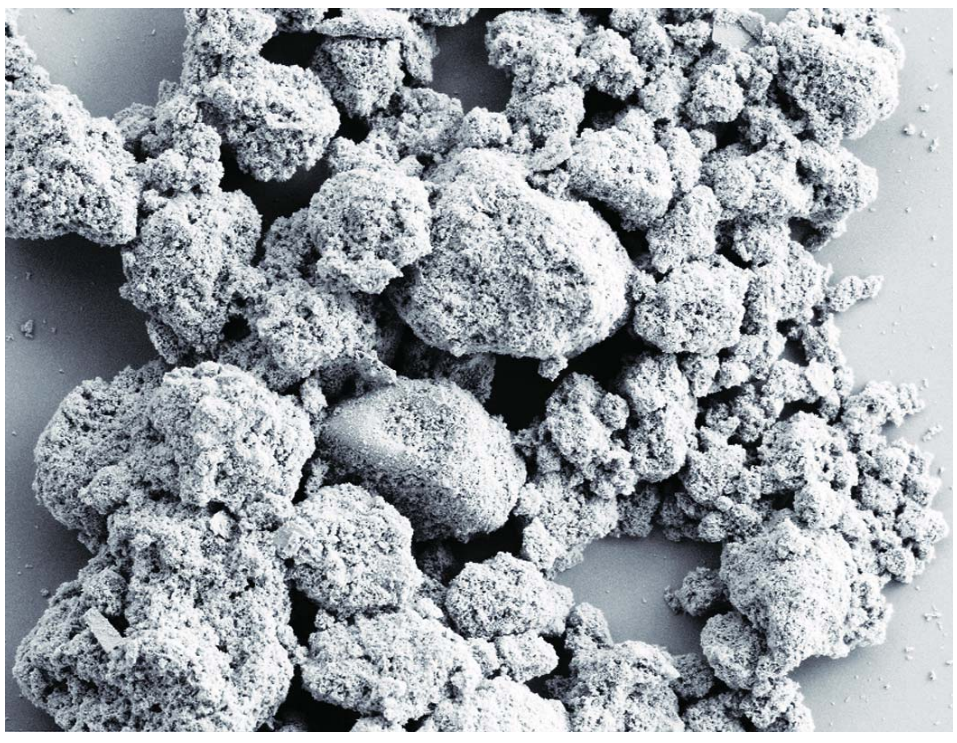


Fig.3. SEM picture of TRI-CAFOS 250 (magnification of 5 kX)

Summary

Tribasic calcium phosphate is commonly used as a tablets and capsules filler. The presented examples show that the spray-dried, highly porous TRI-CAFOS 500 has the ability to improve tableting properties of powder mixtures, and thereby also to increase the mechanical strength of the tablets. At the same time, it increases tablet porosity and thus facilitates the penetration of water into the interior of the tablet and improves the effectiveness of disintegrating agents. This reduces the disintegration time and in many cases can also positively impact the dissolution.

References

1. Rowe RC, Sheskey PJ, Quinn ME. Handbook of Pharmaceutical Excipients. 6th ed. Pharmaceutical Press, London, UK, 2009

2. Monograph: Tribasic Calcium Phosphate. United States Pharmacopeia 38 National Formulary 33; The United States Pharmacopeial Convention; 2016

3. Monograph: Calcium Phosphate (Tricalcii Phosphas) Pharm.Eur.; European Pharmacopoeia 8.0; European Directorate for the Quality of Medicines & Healthcare; 2016

4. Schmidt PC, Herzog R. Calcium phosphates in pharmaceutical tableting. 1. Physico-pharmaceutical properties. Pharm World Sci. 1993; 15(3): 105-15.

5. Zakowiecki D, Lachmann M, Hess T. Beyond just a filler – application of calcium phosphates in direct compression formulations. Express Pharma 2017, 13 (3): 90-92

6. Zakowiecki D, Lachmann M, Hess T. A new perspective on flow enhancement in solid oral dosage formulation – advantages of an unique glidant material TRI-CAFOS®200-7 (Part 1). Express Pharma, Goa Pharma Summit Special, November2018:17-19

7. Zakowiecki D, Lachmann M, Hess T. A new perspective on flow enhancement in solid oral dosage formulation – advantages of an unique glidant material TRI-CAFOS®200-7 (Part 2). Express Pharma, CPhI&P-MEC India Special 2018,14(4):142-44

8. Bolhuis GK, Chowhan ZT. Materials for direct compaction. Pharmaceutical Powder Compaction Technology (ed. Alderborn G, Nyström C). Marcel

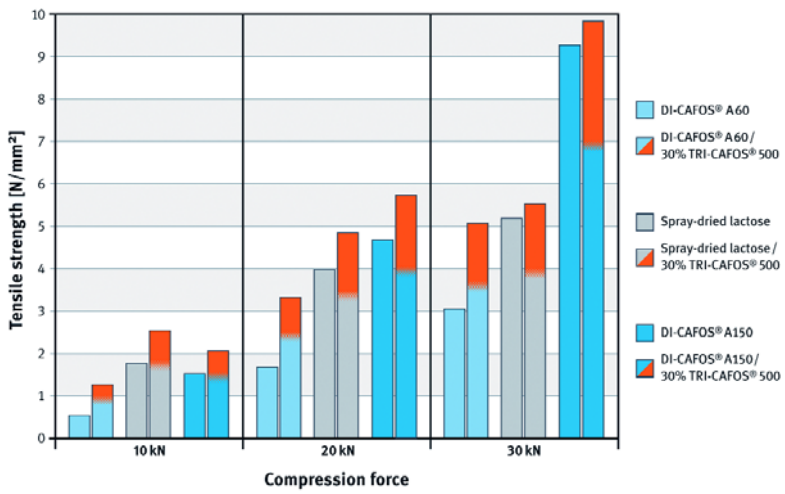


Fig.4. Impact of TRI-CAFOS 500 on tablet hardness (tensile strength)

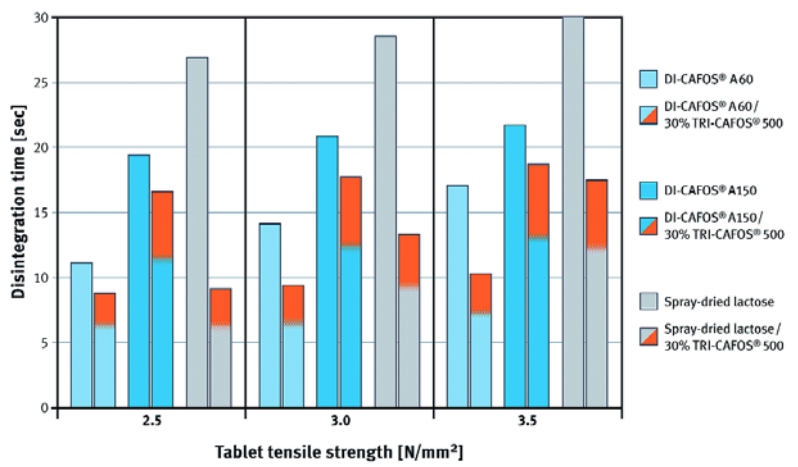


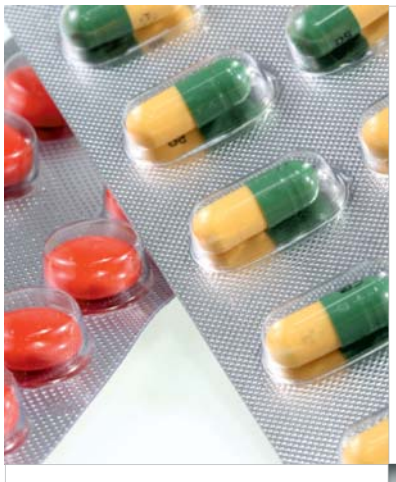
Fig.5. Impact of TRI-CAFOS 500 on tablet disintegration time

Dekker Inc., New York 1996, pp. 419–478

9. Patel NK, Patel BR, Plakogiannis FM, Reier GE. An evaluation of tricalcium phosphate excipients particularly using instrumented rotary and single station tablet presses. Drug Dev. Ind. Pharm. 1987; 13: 2693-2718

10. Shenoy V, Agrawal S, Pandey S. Optimizing fast dissolving dosage form of Diclofenac Sodium by rapidly disintegrating agents. Ind J Pharm Sci 2003; 65 (2): 197 – 201

11. Zakowiecki D. Lachmann M, Hess T. The use of highly porous calcium phosphates in the development of a quickly disintegrating formulation: ibuprofen 250 mg / caffeine 50 mg tablets. Poster presented at AAPS Annual Meeting and Exposition, 2017 November 12-15; San Diego, CA, USA



PVC RIGID FILM FOR BLISTER FORMING

US FDA Type III
DMF: 032495

TRIPLEX LAMINATE

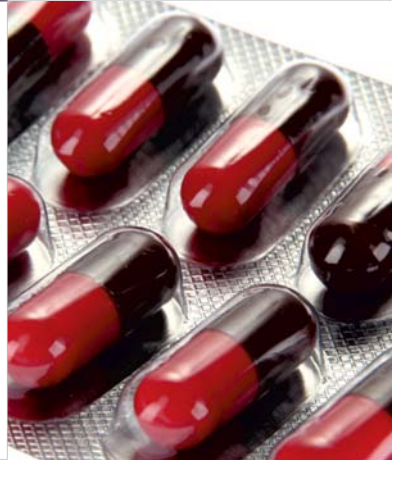
US FDA Type III
DMF: 032497

ALU ALU LAMINATE

US FDA Type III
DMF: 032494

PVdC COATED PVC FILM

US FDA Type III
DMF: 032496



EMERGING AS THE MOST PREFERRED PRIMARY PACKAGING SOLUTIONS PROVIDER FOR THE PHARMA INDUSTRY.

Uniworth Enterprises LLP with it's location at Ahmedabad, INDIA, is ideally suited to cater efficiently to the Indian market and with ICD facility and excellent connectivity by road to Nhava Sheva port, Mumbai, can also service the export market with minimum time lag between production and export.

- CALENDER
- SLITTER
- COATING LINE
- LAMINATOR

- Dust Free & Fully Air Conditioned Factory
- Fully Equipped Analytical Lab
- Producing 60 Micron PVC Film by Direct Calendering without Stretching.
- **ISO 9001:2015 & ISO 15378:2017** Manufacturing site
- 29000 Sq. Mtr. of Manufacturing Area
- 6000 Sq. Mtr. Built-up Area

WE PACKAGE GOOD HEALTH.

UNIWORTH
ENTERPRISES LLP

Corp. Off: 804, Siddhi Vinayak Tower B
off. S.G. Highway, Makarba, Ahmedabad -380051
Factory: Chharodi - Sanand (Gujarat)
+91 -9726430369 / 7433966038

info@uniworthllp.com • www.uniworthllp.com

Mark Vi Trac Systems

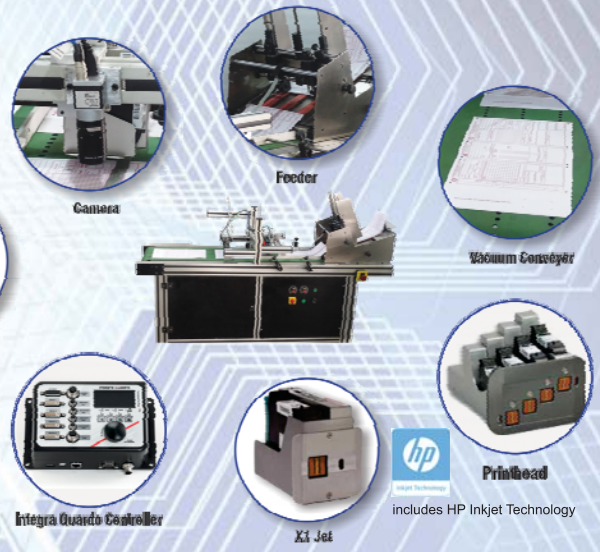
Brings you HP Smart Card technology
Enhance Intelligence in your Coding & Marking Systems

VISIT US AT
PharmaLytica Evolution Accelerated
Hall No. 1, Stall- E-06
10-12 June.2019
BEC, GOREGAON, MUM.

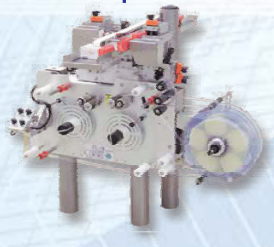
Benefit from built-in security solution

Intelligence built into the print cartridge offers an improved end-user experience.
Delivering authentication, ink data & cartridge data, the smart card technology enables consistent quality supplies and more predictable uptime.

MVT Series 1 Media Transport System



Weber Tamper Evident Label Dispenser



Special Features:
- Sealing labelling for protection against counterfeits
- Two-sided corner labelling of folding boxes
- Output clocking up to 300 items per minute
- Short set-up times when switching to other product formats
- Processing of transparent, perforated labels
- Speed-independent labelling via Tamp-Wipe-On method
- Dual label roll unwinding

MVT Series 1 Carton Rotating System

Advantages:
- Space saver design
- Feeding, rotating and realignment process on a single conveyor
- High speed of operation
- Foam encapsulated rotator prevents damage to carton
- Space allowance for printer mounting after rotation
- Economy of operation and running costs

Bluhm Weber Group
Weber Marking Systems GmbH
Head Office: Maarweg 33.
D- 53619 Rheinbreitbach,
Germany - Phone: + 49(0)2224 7708-0.

Mark Vi Trac Systems

Unit No. 111 & 112, Diamond Indl Estate No. 2, Ketkipada,
Near Dahisar Toll Naka, Dahisar (East), Mumbai 400 068
Tel.:+91 22 28977078 : +91 9820509630
Email: sales1@markvitrac.com / hm@markvitrac.com
www.markvitrac.com

---

advanced enzymes
Where ENZYME is Life

DIGESTIVE AIDS
- ✓ Alpha amylase / fungal diastase / fungal amylase
- ✓ Alpha galactosidase
- ✓ Bacterial alpha amylase
- ✓ Hemicellulase
- ✓ Lactase
- ✓ Lipase
- ✓ Bile extract
- ✓ Papain
- ✓ Pepsin
- ✓ Pancreatin
- ✓ Protease (acid / alkali)

ANTI-INFLAMMATORY ENZYMES
- ✓ Serratiopeptidase
- ✓ Peptizyme (enteric coated serratiopeptidase granules)
- ✓ Trypsin Chymotrypsin mix (6:1)

PROBIOTICS
- ✓ Saccharomyces boulardii
- ✓ Lactic acid bacillus
- ✓ Bacillus Subtilis
- ✓ Bacillus Clausii

CIRCULATORY HEALTH
- ✓ Nattokinase

BIOCATALYSTS
- ✓ Addzyme Liquid
- ✓ Addzyme Powder
- ✓ Addzyme Immobilized

Clinical Studies available for Lactic Acid Bacillus

Non-GMO Products | WHO CGMP | FDA

ADVANCED ENZYME TECHNOLOGIES LTD.
Sun-Magnetica, 'A' Wing, 5th Floor, LIC Service Road, Louiswadi, Thane (W) 400 604
Tel: +91-22-4170 3200 | Fax: +91-22-2583 5159
Email: info@advancedenzymes.com | www.advancedenzymes.com

Trust · Quality · Commitment

Arihant Innochem Pvt. Ltd. is one of the largest and highly respected distributors of Specialty Ingredients in India. We have extensive and well integrated Technical and Sales network throughout India, with long-standing customer relationships.

We are Channel Partners for a wide variety of Principals for Specialty Ingredients in multiple segments including Pharmaceutical, Personal care, Food and Home care.

The cornerstone of our business is our unparalleled commitment to Quality. Arihant Innochem's enthusiastic and knowledgeable Core and Support Teams understand the current trends and market dynamics and work in close association with the Development Scientists for a win-win partnership.

OUR PRINCIPALS

for Pharmaceutical Excipients and Food Ingredients

Shin-Etsu · Lubrizol LifeSciences (Polymers | Formulation | Manufacturing) · AsahiKASEI · Stearinerie Dubois (Our esters in mode expert) · Pharmatrans Sanaq AG (Pharmaceuticals - Switzerland) · Jungbunzlauer · Venator · VitaSweet · whc · Lecico (Lecithin + Phospholipids) · ICV · Tereos · Domino Specialty Ingredients · Nisso · AIGLON Groupe · Freund · Chemic

For more information please contact :

Arihant Innochem Pvt. Ltd.

Tel No.: +91-22-67674895 | Email : enquiry.pharma@arihantinnochem.com | Website: www.arihantinnochem.com

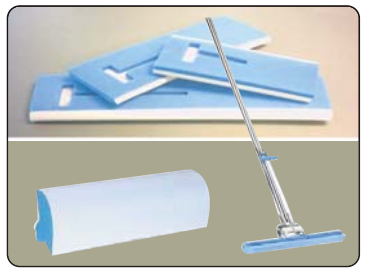
SUNNY ENTERPRISES

Leaders In Clean Room Contamination Control & Preventive Products

Clean Room Garments

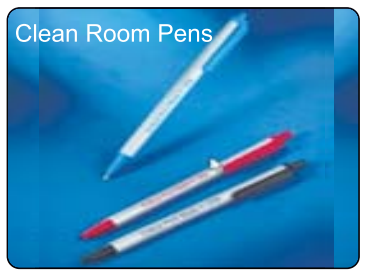
Disposable Garments

Sticky Mats

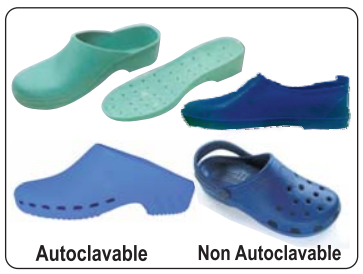


Clean Room Mopping Systems

Rust Removal System

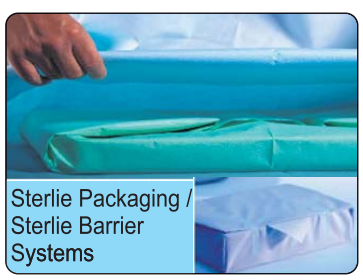


Clean Room Stationery



Clean Room Shoes

Autoclavable Goggles

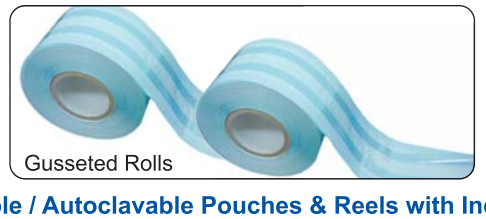


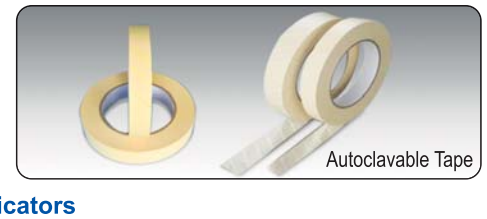
Sterlie Packaging

Clean Room Wipes

Fogger for Fumigation

Autoclavable Clean Room Trolley Systems: Plastic & Stainless Steel





Sterlizable / Autoclavable Pouches & Reels with Indicators

Other Products: • Sterilization Rolls • Autoclavable Mop Heads for Floor Cleaning, Autoclavable Wall and Panel Cleaning System •Autoclavable Mop Heads for Wall & Panel Cleaning • Disposable Garments • Autoclavable Lint Free Hand Gloves • Disposable Wipes etc...

"Meeting the Standards, Beating the Prices."

SUNNY ENTERPRISES
Plot No. 82, Raja Industrial Estate, P. K. Rd., Sarvodaya Nagar, Mulund (West), Mumbai 400 080, Maharashtra, India.
TEL # +91-22-2592 22 45, 25617205 • **FAX #** +91-22-2591 22 75
CELL # +91 99 87 17 77 32 (Viren) +91- 93 23 58 35 95 (Shirish) +91- 98 92 96 23 25 (Sunny)
Email: sales@sunnyenterprises.in • **Website:** www.sunnyenterprises.in • www.cleanroomgarments.in

PharmaLytica

Connecting the complete Pharma Value Chain

INTRODUCING API's + Excipients

UBM

Bringing your pharma business **to the hub of pharma success.**

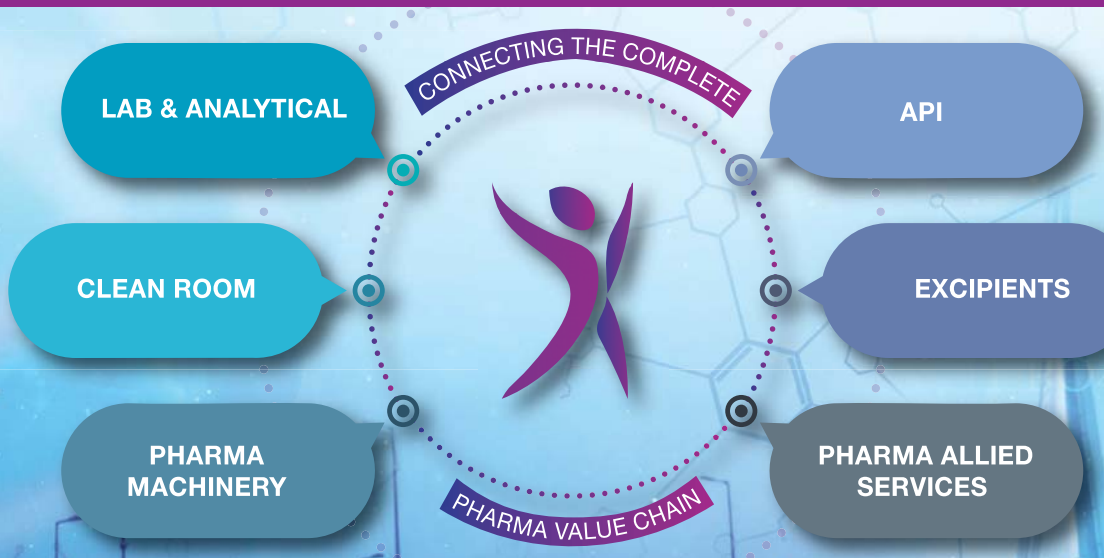
10-12 June, 2019

Bombay Exhibition Centre (Hall 1), Goregaon (E), Mumbai

PHARMALYTICA 2019 FEATURES

- 12000 sqm of business space
- 300+ Exhibitors
- Exhibitor Showcase
- NEW ARRIVAL — API and Excipients pavilion
- Pre-fixed B2B meetings

and many more...



See You There

FOR SALES AND PARTNERSHIP ENQUIRIES
Niket N. Donde: E: niket.donde@ubm.com
T: +91 22 6172 7140 | M: +91 98208 59902

FOR MARKETING & ALLIANCES
Grenville Collaco: E: grenville.collaco@ubm.com
T: +91 22 6172 7116 I M: +91 90806 74389

To register, scan the QR code

www.pharmalytica.in

Our Excellence is now EXCiPACT Certified

Certification Standard for Pharmaceutical Excipient Manufacturers or Suppliers for Good Manufacturing Practices (GMP)

ACRYCOAT® Methacrylic Acid Copolymer

Enteric coating | Film coating | Sustained release
Taste masking | Moisture barrier coating

COLORCOAT™ Ready-to-use Coating System

Film coating | Enteric coating | Moisture barrier coating
Transparent coating | Flavour coating

ACRYPOL® Carbomer

Thickening agent | Suspending agent | Emulsifying agent
Topical application | Oral care application

KYRON™ Taste Masking & Super Disintegrant

Taste masking of drug | Suspension | Dry syrup
Chewable tablets | Mouth dissolving tablets

ACRYSOL™ Castor Oil Derivative

Vitamin solubilizer | API solubilizer | Cream emulsifier
Oil & Perfume solubilizer | Dissolution improver

ACRYFLOW™ Stearate Derivatives

Tablet lubricant | Sustained release

NUTRACOAT™ Natural Coating System

Sustained release | Moisture barrier coating | Taste masking

www.brandaid.in

COREL PHARMA CHEM

COREL House, Opp. Bhagwat Petrol Pump, Gota, S.G. Highway, Ahmedabad - 382 481, Gujarat, INDIA
Tele: +91-8000880011 / 22 / 33 | **E-mail:** corel@corelpharmachem.com,
marketing@corelpharmachem.com | **Website:** www.corelpharmachem.com

REGD.WITH RNI NO. MAHENG/2005/21398, POSTAL REGD. NO. MCS/164/2019 – 21, PUBLISHED ON 5TH / 20TH EVERY FORTNIGHT,
POSTED ON 5TH, 6TH, 7TH & 20TH, 21ST, 22ND OF EVERY FORTNIGHT POSTED AT MUMBAI PATRIKA CHANNEL SORTING OFFICE, MUMBAI – 400001