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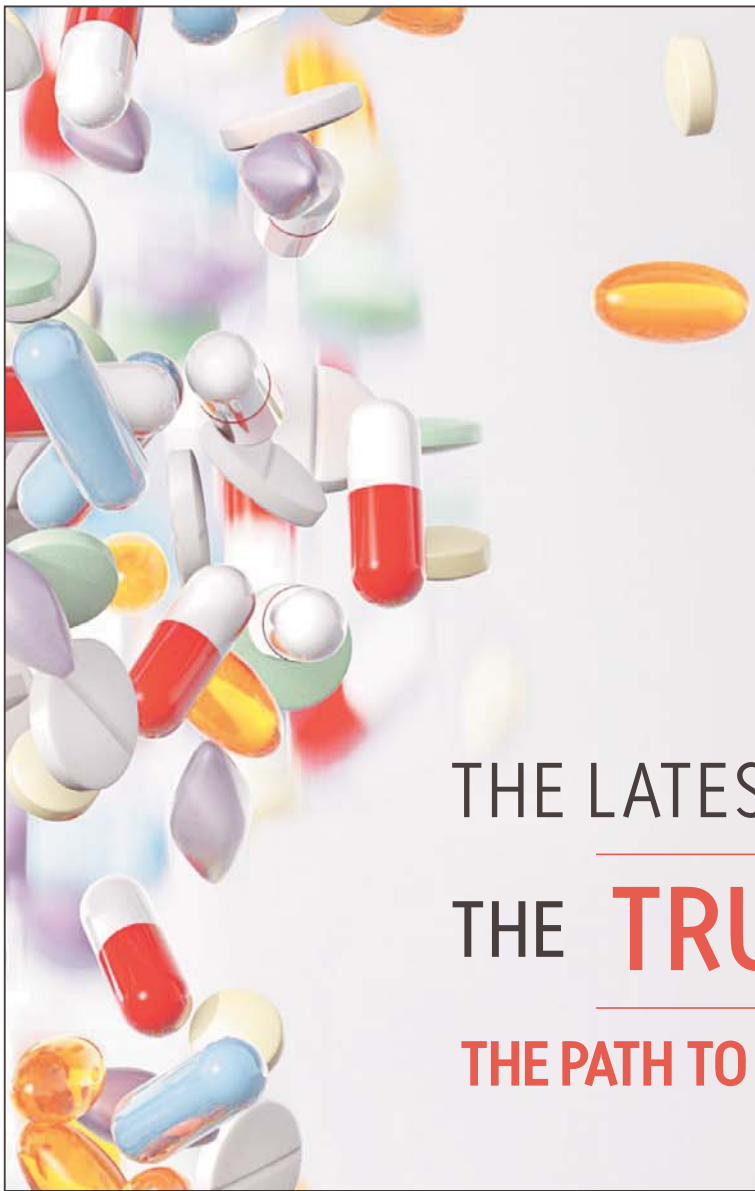

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CONTENTS

API BARCODING: BENEFITS AND BOTTELENECKS

The Union Health Ministry announced that the government will make it mandatory for all API packages to be barcoded. The industry is anticipating that it will minimise the misuse of counterfeit drugs, brand names and their sale. With the implementation of QR coding on labels of API packages, tracing the origin and movement of API manufacturers to drug manufacturers can be traced through a system of networking. Experts reveal more about this control measure adopted by the government | P21

POST EVENT

12 | **OPPI ORGANISES CONFERENCE ON FUTURE OF SUPPLY CHAIN MANAGEMENT IN MUMBAI**

15 | **IPE 2019 HELD IN NEW DELHI**

INFRASTRUCTURE

P24:**INTERVIEW**
Kalidas Bhangare
MD,
Testo India

HR

P46:**INTERVIEW**
A Vaidheesh
Vice President,
South Asia and
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Protect IP to grow GDP

August will be a crucial month for negotiations concerning the Regional Comprehensive Economic Partnership (RCEP) free-trade agreement. The RCEP is often seen as the Asian counterpoint to the US-led Trans-Pacific Partnership (TPP).

The RCEP bloc involves 16 countries, comprising 10 ASEAN countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam) and trading partners Australia, China, India, Japan, South Korea and New Zealand. These nations are home to nearly half of the planet's population, hence the RCEP negotiations are being closely tracked. While the negotiations started in November 2012, this year-end could see a final deal. The 26th round of the RCEP negotiations was held in Melbourne, Australia in early July and will be followed by the 27th round in China and a later round in Vietnam.

Intellectual property (IP) related provisions in the RCEP have been a major point of debate. Groups like Médecins Sans Frontières (MSF) have campaigned that provisions proposed in the negotiations would threaten the availability of generic medicines, which play a huge role in making healthcare more affordable. According to MSF, two of these provisions relating to medicines – patent term extensions and data exclusivity – have been removed from the RCEP.

But MSF also pointed out that a range of damaging IP enforcement provisions proposed by Japan still remain on the negotiating table. These provisions reportedly go beyond the requirements of the WTO Trade-Related Aspects of Intellectual Property (TRIPS) Agreement and are similar to those included in the Anti-Counterfeiting Trade Agreement (ACTA), a treaty abandoned by the European Union after intense public and political scrutiny.

The RCEP negotiation is one of the BJP-led NDA-2 government's first challenges. It links directly to the stated goal to make India a $5 trillion economy by 2024. The government is seeing these negotiations as a way to balance the trade deficit with 11 RCEP member countries, including China, South Korea and Australia. Commerce and Industry Minister Piyush Goyal has reportedly held meetings with experts from various sectors to prepare for the next round of meetings in China. Until now, India has stood firm on IP related to medicines and the agri sector. One hopes that IP will not be sacrificed for trade gains and a bump up in GDP.

The RCEP negotiation is one of the BJP-led NDA-2 government's first challenges as it links directly to the stated goal to make India a $5 trillion economy by 2024

That this government places special emphasis on nurturing I is well documented. This was the first year that the Government of India hosted and partnered the release of the Global Innovation Index for 2019 (GII 2019), where India climbed five ranks to the 52nd place among 129 countries. The jump from the 81st to 52nd rank, a move of 29 places in the last five years, the biggest by any major economy in this year's index and is being cited as a major achievement of Prime Minister Modi. As the BJP twitter feeds puts it, 'Under the leadership of PM Shri @narendramodi, India continues on improving innovation including ICT services, exports, patents and R&D.'

Beyond the politics, with the theme of Creating Healthy Lives—The Future of Medical Innovation, this year's index is a good barometer of the areas with the most action in health research. For instance, medical technology is now the most frequent patenting field, present in 19 clusters while pharma dropped to second place.

A reflection of the dropping productivity of pharma research, GII 2019 predicts that medical innovations such as artificial intelligence (AI), genomics, and mobile health applications will transform the delivery of healthcare in both developed and emerging nations.

It is heartening that among lower-middle-income economies, India, along with Vietnam, is among a small group of countries that achieve high impact for their innovation efforts. But, we have a long way to go. Three cities — Bengaluru, Mumbai and New Delhi — feature in the global top 100 science and technology clusters. For perspective, China has 18 of the top 100 science and technology clusters, second only to the US on this metric. China is at the 14th rank, climbing up from 17.

As he released the report, Goyal mentioned that the GII is a useful tool for governments to map out their strategies to foster innovation. If this is true of NDA-2's intentions, will we see more funding for R&D? The recent budget was a disappointment on this front so we hope things improve from here on.

VIVEKA ROYCHOWDHURY *Editor*
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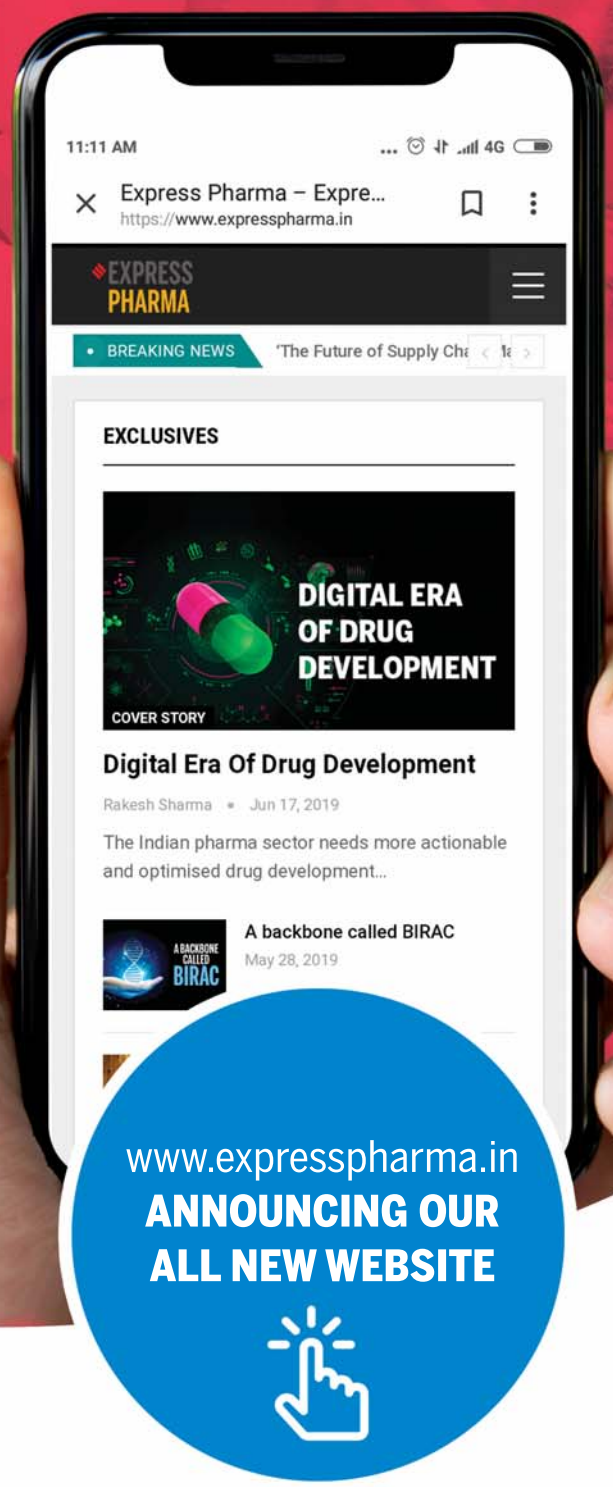

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INTERVIEW

India is a key focus country under renewed global strategy

Sandra de Wild Charonnens, Strategic Advisor, Life-Science & Health, NFIA, informs why the Netherlands is an attractive destination for India's life sciences companies with its attractive business climate and wide-ranging scope for innovation, in an exclusive interaction with **Sanjiv Das**

> Currently, there are over 18 leading Indian pharma giants that have their presence in the Netherlands. The Dutch life-science healthcare sector has identified India as of the few countries of key focus under its renewed global strategy

What type of opportunities is Netherlands offering to pharma companies, making it an attractive market?
The Netherlands is Europe's densest and most innovative life sciences and health community. The country's central geographic position, combined with its accessibility and excellent infrastructure, makes it the location of choice to 2,900 life science and medical technology companies and research organisations, employing over 34,000 people, University Medical Centre's and research organisations.

Together with leading multinationals such as Janssen, MSD, Boston Scientific, Abbott, Amgen, GlaxoSmithKline, Medtronic, Pfizer, Novartis — the Netherlands boasts one of the most concentrated life sciences regions in the world within a 200 km radius. Their operations include R&D, production to logistics and marketing. Some have established their European Headquarters in the Netherlands or have invested in Dutch SMEs.

Dutch companies hold strong positions in the fields of molecular imaging, medical informatics, biopharma, human and veterinary vaccines, regenerative medicine and biomaterials, medical technology, and health infrastructure.

The Netherlands provides an attractive business climate with wide-ranging scope for innovation. It is known for its competitive and stable tax regime, attractive R&D incentives, excellent research facilities and top-rated educational institutions that result in a well-educated and multilingual workforce with a high level of productivity.

How many of these pharma and healthcare companies are based out of India?
Currently, there are over 18 leading Indian pharma giants that have their presence in the Netherlands to name a few Aurobindo Pharma, Serum Institute, Dishman Pharmaceuticals, Sun Pharma, GVK Biosciences, Lupin Pharmaceuticals, Dr Reddy's Laboratories, Intas Pharmaceuticals etc.

Recently, European Medicines Agency (EMA) moved their base from the UK to Amsterdam. Will this help the Netherlands to strongly position itself as a pharma hub in the EU region? How will the market benefit from this move?
The EMA, a decentralised agency of the European Union (EU), ensures the safety, effectiveness and quality standards of all medicines available on the EU market.

The EMA assesses, supervises and monitors the scientific development of medicines in the EU and protects human and animal health in 28 EU Member States and the countries of the European Economic Area. In other words, it monitors a market that serves more than 500 million EU residents.

The EMA's relocation from London to Amsterdam is a direct consequence of Brexit.

The move will enhance the already dynamic Dutch pharma sector. Not only does it put the Netherlands in the spotlight, but it also offers huge opportunities to attract new biopharma companies and service providers to the Netherlands. The Dutch government expects that the arrival of the EMA in Amsterdam will create thousands of new jobs in the pharma industry and the service sector. Moreover, specialised lawyers, patent experts and consultants will also relocate to Amsterdam in order to be close to the EMA.

These are interesting times in the Indo-Dutch bi-lateral trade relations, the relocation of European Medical Agency from UK to Amsterdam post Brexit enhances NL's prospect as an export gateway to Europe for Indian LSH companies.

In the coming years, what business activities are you expecting from the Indian market?
Currently, the Dutch life-science healthcare sector has

identified India as of the few countries of key focus under its renewed global strategy. Life Science and Health (LSH) is one of the top nine priority sectors designated by the Dutch Ministry of Economic Affairs for its ability to address global social problems.

In 2018, NFIA saw an investment of approximately 250 million euros from Indian companies in the LSH sector, in NL, thereby offering 700 job opportunities.

The emerging synergies in digital, e-health and research collaboration will enhance the knowledge ecosystem in NL and create new jobs in both countries. The Netherlands is a global leader in patents in LSH and ranks 2nd in patent application for biotech in the world.

sanjiv.das@expressindia.com

KEY REASONS TO INVEST IN THE LIFE SCIENCES AND HEALTH SECTOR IN THE NETHERLANDS

Strategic location: The strategic location of the Netherlands, bordering the three largest economies in Europe (Germany, the UK and France), makes it the perfect gateway into Europe

Overview of some Dutch USPs

- Eight University Medical Centres (UMCs) with the unique combination of higher education and scientific research, training, clinical research and the associated care.
- Over 200 biobanks and cohorts that store the data of thousands of people.
- Scannexus, an Ultra-High-Field MRI centre
- Pivot Park Screening facility, includes state-of-the-art robotic systems, instrumentation for biological profiling and a collection of 300,000 high quality drug-like compounds.
- More than one third of the total global production of isotopes is fabricated in The Netherlands
- The HUB (Hubrecht Organoid Technology) was founded on the pioneering work of Prof Dr Hans Clevers who discovered methods to grow organoids from tissues of patients. Applications are in drug discovery and drug screening
- Biotech training facility provides hands-on pharma training in a GMP environment

Few important facts and figures

Dutch Life Sciences & Health industry:
Companies: 2,900, employees 34,000 ~
Employees: 34,000

[Source: Ministry of EZ -2017]

- Health budget 2015: 71.3 billion EUR (11,8 per cent of GDP)
- Average health exp. over a lifetime: 280,000 EUR
- 1.1 million workers in healthcare (excl. volunteers)
- 8,865 General Practitioners
- 92 Hospitals (incl. eight university medical centres)
- Hospital beds: 4.7 per 1,000
- Average stay in hospital: 5.8 days

Source: Dutch Ministry of Health (2014)

OPPI organises conference on future of supply chain management in Mumbai

Key stakeholders of the pharma industry congregated at the event to confer and converse on the blueprint to build an effective and efficient supply chain ecosystem for the life sciences industry and drive continuous improvements in its management

OPPI recently organised a day-long conference in Mumbai for the stakeholders of the life sciences industry on the theme, 'Future of Supply Chain Management.' It aimed to showcase the importance of effective supply chain management in an age of biologics, gene therapies and personalised medicine which mandates products to be shipped in temperature-controlled conditions within tight timelines.

A Vaidheesh, President, OPPI and VP, South Asia & MD India, GlaxoSmithKline Pharmaceuticals

Sanjit Singh Lamba, MD, Eisai Pharmaceuticals India

Dhaval Buch, Former CPO, Unilever

Pallavi Darade, Commissioner Food & Drugs Administration, Maharashtra State

Rubina Bose, Deputy Drugs Controller (I), CDSCO

Dr YK Gupta, Principal Advisor (Projects), THSTI

Viveka Roychowdhury, Editor, Express Pharma & Express Healthcare

A Vaidheesh, President, OPPI and VP, South Asia & MD India, GlaxoSmithKline Pharmaceuticals commenced the event with his welcome address. He highlighted that healthcare needs are changing with time and as a result, the challenges too are unprecedented. He said, "Global best practices ensure that the quality of medicine is not compromised for the Indian patient. Today, healthcare is about longevity of life along with good quality of life. And, one important aspect to enable this would be a responsive and efficient supply chain system. We need a supply chain which ensures that patients receive the right medicines of optimum quality at the right time. Quality of medicines should not be compromised because of challenges in last-mile delivery."

Next, Dr Sanjit Singh Lamba, MD, Eisai Pharmaceuticals India, drew attention to the fact that India Pharma Inc has lofty ambitions and intends to touch $50 billion by next year. But, it is also at crossroads and needs to rethink its strategies and revamp its systems for continued progress. Emphasising that revamping our supply chain and reducing its complexities is imperative to improve our pharma ecosystem, he opined that there is an urgent need to harmonise standards and services within the supply chain system to facilitate better efficiency and efficacy. Decongesting road pathways and leveraging the potential of rail and water pathways was also one of his recommendations.

The subsequent speaker, Dr YK Gupta, Principal Advisor (Projects), THSTI, took the stage to inform about the significance of drafting policies which will improve our supply chain management. He also said, "We need to make them ready from the academic level itself. Education in good supply chain practices should be given to all stakeholders at all levels in the pharma industry."

Representatives from the regulatory authorities, Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone, Ministry of Health and Family Welfare and Pallavi Dharade, Commissioner Food & Drugs Administration, Commissioner of Food Safety, Maharashtra State also addressed the audience at the conference.

Dr Bose spoke on the pivotal role played by supply chains in ensuring regulatory compliance, dealing with spurious suppliers and ensuring optimum quality. She also rooted for increased collaboration between regulators and industry to optimise the potential of supply chains. Dharade, on the other hand, underscored the importance of good distribution practices and product security while elaborating on the role played by technology in achieving these objectives. She said that tech-driven innovations are revolutionising supply chain systems with better adeptness and far-reaching impact. She also spoke on the measures taken by food regulators to improve quality and urged each stakeholder to do their best towards driving continuous improvements in supply chain management.

Dhaval Buch, Former Chief Procurement Officer, Unilever took the audience through the evolution of supply chain

system 1.0 to supply chain system 4.0. He spoke on how priorities have changed and highlighted that the pace of transformation has become very rapid. He informed, while 1.0 to 2.0 took 50 years, the change from 3.0 to 4.0 will leapfrog. He stressed that now transformation will also be driven by predictive demand and therefore all the providers in the supply chain need to be more proactive and get future-ready.

Representing the fourth estate, Viveka Roychowdhury, Editor, Express Healthcare & Express Pharma, accentuated that a patient-centric supply chain is the need of the hour. Elaborating on the urgent measures needed to make it a reality, she stated that pharma companies should break down silos between functions to build an integrated and collaborative supply chain system. She also cautioned pharma companies to strengthen their links and iron out all chinks in their supply chain systems carefully since their products will only be as secure as their weakest link.

Experts also commented on the importance of preserving integrity in supply chains and how technology is facilitating this

Sudarshan Jain, Director General, Indian Pharmaceutical Alliance (IPA) also spoke on patient-centricity in supply chains and said, "The future of pharma supply chain will need to ensure that medicines delivered to patient retain effectiveness. Tech-enabled supply chain will not only increase the efficiency and quality of medicines dispensed but will also encourage patient-centred care."

Experts also commented on the importance of preserving integrity in supply chains and how technology is facilitating this.

Kanchana TK, Director General, OPPI said, "Making medicines is a series of complex processes involving manufacturing, supply chain, intermediaries and markets. Ensuring the integrity of the supply chain till it reaches the patient is critical. The future of the pharma supply chain will only get more advanced with the advent of technology and its interface."

Daara Patel, Secretary General, Indian Drug Manufacturers Association (IDMA) was just as emphatic on the importance of supply chain integrity. He said, "We have several thousand manufacturers involved in making medicines. Making sure that they all adhere to global manufacturing practices is important to patient safety." The event also witnessed interesting panel discussions revolving around pertinent issues about supply chains. In the first two panel

discussions, experts and veterans from the industry discussed and deliberated on topics such as good distribution practices (GDP) and product security and the readiness of logistics and warehousing in India to support their implementation.

Nitin Soundale, Partner, PwC; Mohan Bhandari, MD, Bilcare; Dr Rustom Mody, Sr Vice President and Head R&D, Lupin (Biotechnology Division); Manoj Lekhrajani, CMD, Pharmapoint Group of Companies; Aninda Shome, Director, India Cluster & Indo China, Global Supply Chain Lead, Pfizer India; Javin Bhinde, Director and Co-Founder, SynCore Consulting, Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone, MoH&FW; Manjunath MS, Cold Chain Innovation Specialist, Global Cold Chain Alliance & Advisor, Cold Box; Rahul Agarwal, MD, Kool-ex Cold Chain; Krishnakant Parab, Senior Director - Supply Chain, Sanofi India; Mehul Shah, CEO, Logos India were the participants in these two discussions.

These discussion focussed on several aspects of good distributions practices and on the various measures to enable their implementation. The panellists spoke on the impact of technology and its immense potential to improve GDP from warehousing to distribution. They recommended the industry to adopt more eco-friendly and pay utmost importance to the safety of the products and the people involved. They also said that training is key to improving warehousing and supply chain strategies. Skill building, creating an attitude which is pro-safety are very important. The experts also expressed hope that in the next five years, pharma supply chains will transform significantly in terms of better compliance, better standardisation, improved operations, better patient convenience, systems optimisation etc.

The third discussion was on 'Business Practices for enduring and sustainable performance' and comprised eminent panellists such as Ameesh Masurekar, Director, AIOCD Pharmasofttech AWACS; Sudarshan Jain, Secretary General, IPA; Daara B Patel, Secretary General, IDMA; Jagannath S Shinde, President, AIOCD and Darshan Patel, Partner, PwC. They underscored the importance of putting the patient at the centre of healthcare delivery and medicine. They also discussed strategies to meet global standards in supply chain management to ensure safe, efficacious and quality medicines to people who need them, when they need them. The panellists also shared learnings and from their experiences and stressed that more government support, improved technology adoption, infrastructure building, significant investment etc. would be essential to build a really good supply chain.

The fourth panel, under the topic, 'Decoding applications of AI ML and Blockchain in Pharmaceuticals' reflected and pondered on Ayushman Bharat and its impact, building a digitally-led pharma ecosystem, data security, role of robotics in tackling counterfeiting, and a lot more. The experts also explained, with the help of case studies and examples from international examples, how artificial intelligence and blockchain technology ensure that supply chains operate with 100 per cent precision. They also urged the pharma industry to become more digitally savvy and leverage their huge potential to leapfrog towards further progress. Amit Mookim, MD, IQVIA; Ravi Chandrasekaran, Practice Partner - Blockchain at Wipro Technologies; S Sridhar, Managing Director, Pfizer India; and Sanjay Mehta, Principal, Mehta Ventures were the panellists for this discussion.

Thus, the day-long event saw a lot of knowledge sharing and was very well received by the audience. *Express Pharma* was the media partner for this event.

(Collated by Lakshmipriya Nair)

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(L-R) Mohan Bhandari, Managing Director, Bilcare; Dr Rustom Mody, Sr Vice President and Head Research and Development at Lupin, (Biotechnology Division); Manoj Lekhrajani, CMD, Pharmapoint Group of Companies and Aninda Shome, Director, India Cluster & Indo China, Global Supply Chain Lead, Pfizer India

(L-R) Javin Bhinde, Director and Co-Founder, SynCore Consulting; Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO West Zone, Ministry of Health and Family Welfare; Rahul Agarwal, Managing Director, Kool-ex Cold Chain; Manjunath M S, Cold Chain Innovation Specialist, Global Cold Chain Alliance & Advisor to Cold Box; Krishnakant Parab, Senior Director - Supply Chain, Sanofi India and Mehul Shah, CEO, Logos India

(L-R) Darshan Patel, Partner, PwC; Jagannath S Shinde, President, AIOCD; Daara B Patel, Secretary General, IDMA; Sudarshan Jain, Secretary General, IPA and Ameesh Masurekar, Director, AIOCD Pharmasofttech AWACS

(L-R) Amit Khanna, Partner, PricewaterhouseCoopers, S Sridhar, Managing Director, Pfizer India, Sanjay Mehta, Principal, Mehta Ventures, Ravi Chandrasekaran, Practice Partner - Blockchain, Wipro Technologies and Amit Mookim, MD, IQVIA

IPE 2019 held in New Delhi

The expo provided eminent stakeholders in pharma industry a chance to generate new business leads and to maximise revenue potential

THE INDIAN Pharma Expo 2019 was inaugurated by DC Sahu, Dy Director MSME DI Okhala, New Delhi M/O Micro, small & Medium Enterprise, Government of India with Dr Monica Sood Bhatia MD CIMS Medica India & Middle East, which was held in New Delhi recently. IPE was an ideal platform for companies to witness latest advancements in manufacturing, research and development, packaging solutions, supply chain management, franchising, distribution and many more domains. In addition, the expo provided eminent stakeholders in pharma industry a chance to generate new business leads and to maximise revenue potential.

The Business Excellence Awards' in the presence of Chief Guest P Raghvendra Rao, Secretary Ministry of Chemicals and Fertilizers; Government of India along with the Guest of Honour Vijay Kumar Addl Director, MSME – Development Institute, New Delhi, felicitated the achievers in the pharma industry in the fields of R&D, active pharmaceutical ingredients, formulations, manufacturing, packaging, distribution, marketing, franchising, outsourcing, supply chain and logistic management, and other support services.

8500+ visitors participated in the event from China, Southeast Asia, Latin America, Middle East and Africa.

EP News Bureau


MAX
MIN

SWADESHI VISIONARY

The 'Made in India' success story of HiMedia Labs, one of the top three global media manufacturers and its contributions to scientific progress, under the aegis of its able leader, Dr Gangaram Warke

By Lakshmipriya Nair

"Bombs and pistols do not make a revolution. The sword of revolution is sharpened on the whetting-stone of ideas."

- Bhagat Singh

Since Independence, ideas conceived and executed by countless Indians, sung and unsung heroes of this country, have proven these words true. Their invaluable contributions have led to India's emergence as one of the fastest growing economies in the world today.

And, in our Independence Day Special issue, *Express Pharma* brings you one such story. The journey traced by Dr Gangaram Warke, an Indian microbiologist turned entrepreneur, to ensure that his country's scientific progress is not hampered.

Today, HiMedia Laboratories, the company that he began over four decades ago, is one of the leading biosciences companies in the world with a presence in more than 140 countries.

Thus, it is a riveting tale of struggle, strife, toil and subsequent triumph.

At HiMedia, we have always tried and developed cost-effective best quality media and raw materials using our state-of-the-art R&D and manufacturing facilities so that the final cost of pharma and healthcare products would be reduced to the great extent

Dr Gangaram Warke
Founder, CMD, HiMedia Laboratories

Nurturing a vision

HiMedia Laboratories was born in 1976 with a vision to alleviate the huge struggle faced by Indian researchers to obtain cost-effective microbiology media and allied products on time.

The years spent on his doctoral research as well as working in the R&D and quality control departments of pharma companies had led Dr Warke to realise that India was largely dependent on the US and Europe for these products and had to procure them at exorbitant prices. This, in turn, was a drain on the funds for research and an impediment to progress.

Dr Warke's solution to this conundrum was to establish his own company and manufacture culture media in India itself to make it self-reliant. But, it was an audacious dream at a time when the market was dominated by a 400-year-old German corporation, a 120-year-old US giant and a 90-year-old British conglomerate.

Yet, buoyed by the unstinting support of his brother Vishnu Warke and wife Saroj Warke, Dr Warke started HiMedia and commenced with the production of a portfolio of some key ready-to-use culture media for scientists, researchers and small companies.

Dr Warke reminisces, "HiMedia started manufacturing culture media over 40 years ago expressly to serve the Indian users with home grown substitutes without compromising on quality."

Braving the challenges

But, the trajectory of the company's founders to build an empire out of a business that began from a kitchen has definitely not been easy. Trials were many and the triumphs hard-won. Dr Warke even recalls going door-to-door of companies who needed HiMedia's products and trying to convince them to change their foreign vendor and start buying from a domestic provider. But, they braved the challenges and set about changing the minds of the disbelievers and naysayers, though its took a lot of time, effort and ingenuity. For instance, Dr Warke used to supply free samples of his products, so that the customers can make their own mind about the quality.

Gradually, HiMedia's ability to walk the talk by providing what was needed, both qualitatively and quantitatively, at a price which was much lower than its global competitors, won over even the toughest sceptics. The winning combination of quality with afford-

HiMedia team members

ability gained a lot of popularity the company's products. HiMedia was soon able to not only carve its niche in the domestic market but also fledge its wings in the global arena. Within a few years of its inception, it found an export market in Japan and started shipping its products overseas.

Soaring high

There has been no looking back since then. The company grew from strength on the back of its own technology and its founder members knowledge in this field. Today, it has flourished into a global firm with an eclectic and huge portfolio of over 7000 biosciences products. It exports to all the leading and emerging markets including the US, China, Japan, European Countries, Middle East Countries, Asian Countries, African Countries, Russia and CIS Countries, North- Central-South American Countries including Caribbean Countries and Australia and New Zealand etc. HiMedia also has direct presence in the US and Europe (Germany) to ensure rapid delivery of products and services.

Globally it ranks among the top three suppliers of dehydrated microbiology media and in India, the company owns around 85-90 per cent of the market share in this segment. Dr Warke states, "The global response to quality culture media over the years has enabled us to win the support of distinguished users around the globe. HiMedia's unique biosciences products are appreciated globally across 140 countries for excellent quality, accuracy, and reasonable prices."

Accolades galore

Thus, the company has been instrumental in furthering progress in the biosciences sector and this has gained it worldwide recognition. It has been the recipient of several prestigious awards and accolades. To cite an example, the American Society of Microbiology mentions HiMedia as one of the top three global microbiology media manufacturers in their 'Handbook of Microbiological Media'. Likewise, HiMedia was honored with the prestigious 'Pride of Maharashtra Award' under the category of 'Bést Company of the Year for 2018' and has been named as 'Brand Ambassador of Maharashtra' for 2018 (Category: Research & Innovation) by Maharashtra Industrial and Economic Development Association (MIEDA).

DR. G. M. WARKE RECEIVES SELF MADE INDUSTRIALIST AWARD (UDYOG PATRA AWARD) FROM VICE-PRESIDENT OF INDIA, HON'BLE SHRI M. HIDAYATULLAH

MR. V. M. WARKE RECEIVES IMM-BATA MARKETING AWARD 1984 FOR THE SMALL ENTREPRENEURS FROM HON'BLE PRESIDENT OF INDIA SHRI R. VENKATARAMAN

HIMEDIA AWARDS & RECOGNITIONS

- Pride of Maharashtra Award' for Bést Company of the Year in 2018
- Rajiv Gandhi National Quality Award 2011
- Rajiv Gandhi National Quality Award 2007
- IES Udyog Shree Award – 1993
- IMM – LIC Award for Successful Small Scale Company of Year – 1993
- CHEMEXCIL First Export Award – 1993-94
- CHEMEXCIL Certificate of Merit – 1989-90
- Certificate of Outstanding Performance in the Export of DCM – 1984-85
- IMM-Bata Marketing Award for Small Entrepreneurs – 1984
- Certificate of EXPORT MERIT – 1982-83
- UDYOG PATRA Self Made Industrialist Award – 1982
- UDYOG PATRA Certificate for Self Made Industrialist - 1982

So, what's next for this rapidly growing company?

Revolutionising life sciences: With over 70 per cent of the company's revenues comes from the life sciences sector, it has always been of a major growth area for HiMedia and continues to be one.

Informs Dr Warke, "The global medical microbiology testing market is predicted to record a CAGR of around 9.4 per cent during 2019-2024. therefore, right from studying disease-causing agents to clinical testing/trials of drugs, different varieties of high-quality media and other raw materials are demanded in a huge amount by the pharma and healthcare industries. Thus, we understand the enormous opportunities for development in these areas. As the pharma industry is expanding at almost 18-20 per cent CAGR, we are also keen to expand our portfolio in this segment, especially in the supply of varieties of ready-to-use media. We are also upgrading our existing manufacturing units and setting up a new unit for ready prepared media to meet the increasing demands of international markets."

He further updates, "Regenerative medicine is a booming area which involves a transitional research in tissue engineering and molecular biology using stem cells and primary cells. Biosimilar and other monoclonal antibodies (mAbs) production are also burgeoning segments. Therefore, supplying explicit media

for regenerative medicine research, chemically designed serum-free media (CDSFM) for biosimilar production and PCR diagnostic kits for molecular biology research at affordable prices is a major area of focus for us."

Thus, HiMedia is on an accelerated growth trajectory but for Dr Warke, it is not about just profits. He is in the pursuit of a larger vision – making healthcare more affordable to the masses. He believes that the impact he can create with his business is huge and explains, "The quality and cost of media and raw materials can eventually decide the total cost and quality of the final products of pharma and healthcare services. If pharma and healthcare industry get the best quality of raw materials and media at reasonable costs, ultimately all the healthcare services and drugs would be cheaper and affordable for the common man."

"At HiMedia, we have always tried and developed cost-effective best quality media and raw materials using our state-of-the-art R&D and manufacturing facilities so that the final cost of pharma and healthcare products would be reduced to the great extent. And we promise to do it persistently through our research and innovation," he assures.

MRS. SAROJ G. WARKE RECEIVES THE PRESTIGIOUS RAJIV GANDHI NATIONAL QUALITY AWARD, 2006 FROM HON'BLE MINISTER OF STATE FOR CONSUMER AFFAIRS SHREE MOHAMMED TASLIMUDDIN

Dr GM Warke honoured by Dr Raghunath Mashelkar

Venturing into new areas: HiMedia is also dedicatedly working on innovative, new products to serve the bioscience community. This is evident from its ever expanding portfolio of new-age products across arenas such as animal cell culture, plant tissue culture, molecular biology, agroindustry, hydroponics, and others. For instance, the company is a pioneer in the manufacture of veg-peptones and provides an entire gamut of 100 per cent animal-free culture media under the HiVeg range.

As a result, HiMedia's products are also finding increasing application across diverse areas such as agriculture, food fermentation and processing, environmental care, cosmetics, dairy, water sanitation, educational and research institutes, etc.

Expanding global footprints: The company also has ambitions of stregthening its existing footholds and fledging its wings in newer markets. Therefore, it is finding new avenues to reach out to a larger global customer base. To begin with, it has launched upgraded versions of several kinds of microbiological media such as dehydrated culture media (DCM) and ready prepared media (RPM), HiEncap (encapsulated media), HiCrome (chromogenic media), granulated media, HiCynth (chemically defined media- TSE/BSE/GMO risk-free), harmonised culture media, HiVeg Peptones (Vegetable-based peptones), chemically defined serum-free media (CDSFM), newer sophisticated versions of PCR machines such as Palm PCR, InstaDNA Card and many more.

The company is also expanding its distribution and technical services worldwide. "Alongwith producing unique, innovative, excellent quality, customised products, our after sales services, niche marketing abilities and huge distribution network are some of our strengths. These ensure that our products are delivered to clients in minimum time with zero delivery issues which are possible due to our extensive distribution network. Currently, we have already collaborated and started manufacturing of ready prepared media in Siberia. We also have our wholly owned subsidiaries HiMedia LLC in Philadelphia, the US and HiMedia GMBH in Einhausen Germany. In addition to this, we are in the process of setting up the offices in countries like Dubai, China, Thailand and Philippines to cater to the nearby countries," updates Dr Warke.

Thus, it has several plans in the offing and while Dr Warke didn't divulge a fixed sum, he informs that significant investments would be made to fortify the company's growth prospects in the times to come.

HiMedia is dedicatedly working on innovative, new products to serve the bioscience community. This is evident from its ever expanding portfolio

In times to come

Thus, the company is now poised to grow exponentially in the coming years. And, with the next generation, Dr Vishal G Warke, Dr Rahul G Warke and Dr Rajas V Warke, infusing new energy into the company, it is gung-ho on growth and raring to achieve new heights of glory.

Whether it will be able to sustain the same pace of growth in the years to come, is a question which only time can tell. But, what's undeniable is the fact that that the company has been a trailblazer and written its own formulas for success.

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API BARCODING

Benefits and bottelenecks

Recently, the Union Health Ministry announced that the government will make it mandatory for all API packages to be barcoded and this initiative was welcomed by the industry. The objective was to detect spurious drugs and monitor imported and indigenously produced raw materials. The industry is also anticipating that it will minimise the misuse of counterfeit drugs, brand names and their sale. Nearly a week after the announcement, the intelligence Cell of the CDSCO gathered information about certain bulk drugs being imported illegally without registration certificate and import license. With the implementation of QR coding on labels of API packages, tracing the origin and movement of API manufacturers to drug manufacturers can be traced through a system of networking. Experts reveal more about this control measure adopted by the government

By **USHA SHARMA**

Awez Pathan, QA Head, Shilpa Medicare

The main purpose of barcoding is to eliminate possible human error, improve reliability and less time to scan than manual system. However, this will not completely eliminate the misuse. Possibly better traceability and control over the misuse can be achieved by implementing track and trace global database system. This track and trace system is already implemented and mandatory for all finished dosage forms being exported to US and Europe.

The only stopper will be readiness of API manufacturers for adopting this system due to the initial cost involved in installation and the recurring cost in system maintenance.

Aditi Kare Panandikar, Managing Director, Indoco Remedies

APIs are critical components that make drug formulations potent against diseases. Good quality of APIs is critical to the manufacturing of safe and effective drugs. The supply chain with respect to its security and integrity in proper storage condition plays a very important role to enhance quality supply of APIs. It has been a challenge to ensure the integrity of the API throughout the supply chain from the point of origin to destination. There are serious concerns over malicious activities in API, as well as the excipient business like refilling, relabeling, converting food grade or other similar grade materials to pharma grade by changing labels.

Raw materials are usually supplied in bulk and its authenticity definitely affects the quality of the final product. Once the barcoding regulation is implemented, the misuse of brand names and sale of counterfeit medicines will be eradicated.

Barcoding of the API packages is a welcome move by DCG(I)to have stringent control over the traceability of material across the supply chain. They may include barcodes, QR code or RFID. Barcoding is having several benefits considering its industrial use. However, this discussion is all about the recommendation of the DCG(I) having barcoding control of API packs. Like any other control, this too has its own pros and cons as mentioned below.

Merits

- Barcoding ensures complete traceability of the product by giving idea about the content, type, manufacturer, manufacturing date, shelf life, pricing, etc. It will help to determine whether the supplies are coming from the registered company, especially while dealing with companies in other countries from where raw materials are sourced.
- Any mishap done with labeling of the material can be easily identified to protect the interest of the producer and end user. Any kind of tinkering done with the label of the material can be traced and investigated at a faster pace.
- Being a machine readable mechanism, it is difficult to tamper and duplicate and this eliminates the possibility of human error. The occurrence of errors from manually entered data is significantly higher than

that of barcodes.
- This will improve customer satisfaction by giving confidence about the integrity of the API. A mutual understanding between the supplier and customer will provide higher level of assurance for its usage for pharmaceutical drugs.
- It will improve the communication between supplier and customer by sharing information about the material being supplied.
- A barcode scan is fast and reliable, and takes less time than entering data manually. A barcoding integrated with GPS enabled device can also track the movement of the product pack from point to point.

Demerits

- Barcoding is limited to tracing and tracking of the material. Illegal activities like repacking, refilling, etc, cannot be ruled out by this, which is prime focus of DCG(I). Still there will be possibility of finding the content of the pack different from the content mentioned on the label. So, the risk of spurious drugs will be always there.
- Barcoding system cannot prevent unethical manufacturers who illegally repack and resell expired material with authentic barcoded labels. These APIs will be again be put into the market. APIs are generally packed in polyethylene bags as primary package, followed by fiber or high density polyethylene drums as secondary package. This type of packaging makes it easy for miscreant to get involved in such unethical practices for commercial gains. This way, the risk of spurious drugs looms big on API industry.
- It is susceptible to environmental damage. Dirty and damaged barcode cannot be read by scanner, leading deficient tracking of the packs. In this case there is no way to scan the product. So, manual entries will need to be made on labels.
- Barcodes became commercially successful when they were used to automate at point of sale checkout systems. They are directly applied on the packaging of ready-to-use products. On the contrary, APIs are meant for further manufacturing of finished dosage forms. They are packed in bulk packaging like drums, depending upon their volume and demand. The volume makes this system a challenging task.
- Pricing of the APIs varies depending upon different types of customers and the target market. So, having barcode with uniform pricing is not possible. However, it can be handled through customisation while designing a barcode.

Though it may not eliminate the risk of spurious drugs, it will definitely minimise the risk. It will give improved degree of assurance for the API supply chain. In a nutshell, barcoding is a step towards strengthening the supply chain of API industry and industry shall welcome this move by DCG(I) wholeheartedly.

Kushal Suri, Head- International Business Development, Morepen Laboratories

At the very outset we warmly welcome this decision by the government alongside inputs and crackdown by the CDSCO to track all spurious API (active pharmaceutical ingredient) being imported into the country. Morepen in the past has taken a very strong stand to not take part in such activities which are ethically wrong and promote unhealthy competition at the cost of patients. The unethical practices of importing spurious APIs forces a lot of Indian companies to also manufacture spurious APIs in order to compete with those coming from other countries. Tracking these APIs end to end will hopefully put an end to such unethical practices.

Though these spurious APIs are being imported by a lot of small companies, they end up being lined for sale to big brand Pharma Companies, which are forced to cut corners due to prevailing competition and, in some cases, due to NPPA.

We don't have any doubts that if implemented correctly this will be successful. Under the prevailing structure, the purchase of raw materials and export of finished goods is

tracked for companies who take export benefits under various government schemes and taking GST input credit completes the domestic cycle financially. The E-Way Bills further help to close the physical loop. This new initiative will further connect all the dots and fill the pot holes.

The April 25th Crackdown in Chennai was a major eye opener for the government. However, in terms of the size and seizure of the quantities caught, it was a drop in the ocean of these spurious APIs. The new system should prevent such anomalies.

It is pertinent to note that China uses very high quality APIs for consumption within China, these quality standards are sometimes as high as Japanese benchmarks, which are higher than US FDA and EDQM Standards. Due to the high consumption of regulated high quality API's used in China, they import a lot of it from India and western countries. The Chinese are very strict about the quality of APIs being imported into China against the quality being exported out of China.

Sandhya Shenoy, Associate Vice President, FDC

API (active pharmaceutical ingredient) constitutes the most critical component of the finished dosage form. Successful treatment and desired clinical outcomes are governed by the right amount and quality of the API's in the finished dosage form.

Healthcare is riddled with a plethora of issues including those related to adherence to treatment, patient compliance, which in turn is increasing the disease burden. Spurious drugs pose the biggest danger to health and could be indirectly contributing to the increasing menace of antibiotic resistance. Preventing counterfeit drugs and misuse is thus of prime concern.

The Drugs Technical Advisory Board (DTAB) has put forth a recommendation to the Health Ministry to make it mandatory to have barcodes on labels of API packages. The Health Ministry is contemplating to implement this recommendation. This is being sought as a measure to trace the movement and authenticity of API's starting from the manufacturer throughout its journey in the supply chain. Implementation would provide a better solution to trace, prevent misuse and reduce counterfeit drugs. There have been several instances in the past where misbranded API's have been passed off as made in India. Recently, the intelligence cell of CDSCO (Central Drugs Standard Control Organization) also came across manufacturers importing bulk drugs without valid registration and import license. Barcoding may serve as a deterrent to unscrupulous elements responsible for endangering human lives. The biggest advantage lies in the ability to capture timely and accurate information across the supply chain, helping to map the physical flow of material. In addition, barcodes are traceable and fully auditable, promoting theft deterrence.

Organisations are aware that implementing best practices will additionally save time and money in the long run. Industry is receptive and willing to implement systems and procedures to strengthen the supply chain. In order to make this happen, the DTAB and the Health Ministry together needs to evolve a process to seek inputs from all stake holders. There is also a need to have a continuous dialogue between industry and regulators to address any hurdles and clear the grey areas. A mechanism to ensure that feedback is well received and utilised to fine tune the implementation process would be most welcome.

This would mean investing in technology for the smaller API manufacturers, the returns on which may not be immediate. In order to have unanimous acceptance and success, the Ministry could consider providing incentives to smaller manufacturers. Most medium and large companies already have an information system such as ERP (enterprise resource planning) or warehouse management system. The new barcoding solution will need to be integrated with the existing system. This requires an understanding of how the data will arrive at the system's database from the barcode label. Global manufacturers selling API's in India need to be given sufficient notice to prevent supply disruptions to avoid shortages.

It would be advisable and in the larger interest to address all the pros and cons affecting the API business. This will help to avoid ambiguity as it happened in the earlier recommendations of barcoding on antibiotic packs and also provide much needed relief to industry on the uncertainty shrouding the implementation. Success can be assured only when we are well prepared and ready for advancements and make best use of technology. A half-baked idea would do the system no good and lead to poor acceptance and definitely a stomach ache!

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INTERVIEW

‘We wish to equip the pharma sector with technology that seamlessly functions with highest accuracy’

Kalidas Bhangare, MD, Testo India, speaks on his company’s offerings for the pharma sector and their ability to drive both, quality and compliance, in an exclusive interview with **Lakshmipriya Nair**

How is the Indian pharma market evolving? What are the growth opportunities opening up in the pharma sector, globally and in India?
Pharma is probably the most important and critical industry sector among others. Upcoming biopharma companies, new medicines/drugs and latest technologies are creating an infrastructural renaissance. Government of India’s Pharma Vision 2020 aims to make India a global leader in end-to-end drug manufacturing. On a global level as well, there are so many advancements that are phenomenal. As per studies, nearly 200 new drugs are forecast to be launched in the next five years, with a high number of new molecular entities (NMEs) expected to be launched annually. Artificial intelligence is becoming very prominent to achieve greater efficiency with inclusion of analytical tools and cloud technology. Innovation will also be driven by an increase in collaboration across the pharma sector where companies with different facilities come together to create more value products. R&D, testing and experiments have increased for good. So much of development in the sector ensures greater growth opportunities.

> With our products for environmental monitoring and data logging, we wish to equip the pharma sector with technology that seamlessly functions with highest accuracy and fortifies the process

What are the trends which would shape the industry in the recent future? How poised are you to leverage these opportunities?
System automation and digitalisation has almost taken over the industry where processes and work practices are becoming more self-driven with less human interventions. The existing trend included building management systems where the entire building used to be monitored and kept under control so that there are no deviations from the standards. But, now the entire sector is taking a leap with more inclusive technology which is environment management system (EMS) where the building climate along with the equipment and instruments are controlled through a common management system. Testo strives to answer the emerging needs of the pharma division with our products that help in climate monitoring, air quality measurement, maintaining necessary ambient temperature, humidity and differential pressure etc.

What is your vision for the India pharma industry? What kind of new paradigms do you want to usher into the industry today?
Testo India, as market leaders for measuring instruments and data monitoring systems, understands that no other sector is as strictly regulated and monitored as the healthcare and pharma sector. With our products for environmental monitoring and data logging, we wish to equip the pharma sector with technology that seamlessly functions with highest accuracy and fortifies the process. With such seamless solutions, you have the certainty of always being on the safe side be it in the manufacture, storage or transport of pharma products. Testo data loggers and Testo Saveris data monitoring system play a very crucial role in shaping up this segment. Our data loggers are EN 12830 and 21 CFR Part 11 compliant, which ensure complete documentation of

Continued on Page 26

INTERVIEW

‘We strive to provide our expertise in developing complete solutions for our customers’

Amar Kaul, Chairman and Managing Director, Ingersoll Rand India, reveals more about the future of compressed air business for the pharma sector and his company’s strategies to leverage the potential in this sphere, in an interaction with **Tarannum Rana**

We understand that Ingersoll Rand is a manufacturer for various industries. How much of your business is dedicated to the pharmaceutical industry?
In the pharma manufacturing industry, a number of applications are required for compressed air and each application may require air of differing pressures and purities. The pharma industry also requires oil free compressors which meets the stringent air quality requirements. As the industry is growing, so has the use of compressed air for equipment, and instrument air operation.

The pharma industry is an important market for us and we have a significant focus. Ingersoll Rand is a world leader in creating comfortable, sustainable and efficient environments. With a legacy of 100 years, we have been a trusted global provider of compressed air systems and solutions. Our objective is not just to provide air but a peace of mind which comes from having a compressed air supply that seamlessly meets customer’s needs.

Can you shed some light on the eco- friendly products that the company manufactures?
Ingersoll Rand is a global leader in producing world-class compressed air technologies. We offer a unique and reliable oil free compressor — Nirvana. It comes with an energy efficient Hybrid Permanent Motor (HPM) with built in variable frequency drive (VSD). This innovative compressor is loaded with a unique feature which saves huge energy during low and fluctuating demands at the plant. Apart from being a 100 per cent oil free compressor, it also delivers Class 0 quality pharma air for the customer.

> India is termed as an emerging market and the numbers are only growing. In a very short span of time from its inception, Testo India has grown exponentially, thanks to our advanced products and German technology

We have also recently launched TA2000 Centrifugal compressors. It offers efficient, economical and reliable solutions for delivering compressed air. It starts from 500 cfm up to 1650 cfm delivering 100 per cent oil free Class 0 pharmaceutical air to the customer. The power consumed by this machine is the lowest in the industry with complete consistency in efficiency throughout the process.

Often sustainability results in higher investment costs. How do you deal with this cost sensitivity?
At Ingersoll Rand, we strive to provide our expertise in developing complete solutions for our customers. Basis our customer’s feedback, we have designed our solutions around three key aspects which is critical to a ‘worry-free’ compressed air system: -

- Efficiency: Our technological advanced products has been designed to give maximum energy efficiency and minimal impact on the environment
- Reliability: Today, customers are looking at products which offer value for money along with all the advanced features, highest return on investment over an extended

Continued on Page 26

‘We wish to equip the pharma...

Continued from Page 24

parameters, be it humidity, temperature or absolute pressure. These data logging systems are totally audit proof as the reports cannot be altered or lost and is safe with the software. Another advantage that it brings is the surety of highest data compliance for audits and inspections because even 99 per cent certainly is not enough in pharma industry.

How is automation and digitalisation changing the way the sector operates? How will they shape the sector’s machines, methodologies, processes, and most importantly, its workforce?

A sector like pharma which is governed by strict norms and regulations must operate with full efficiency. Automated processes and increasing digitisation of the existing systems can surely provide the desired results. Testo Saveris system for instance, is an automated system suited for temperature and humidity monitoring in the pharma industry. This system is 21 CFR Part 11 compliant and constitutes of wireless or ethernet probes that are connected to one base station which documents and monitors all measurement data of its own uninterrupted making the process full proof. It even provides a number of alarm options for non-favourable situations to reduce human efforts and mistakes.

What is the competitive edge you offer to your customers through your solutions? How cost-effective are they?

As mentioned, our data loggers and monitoring systems for pharma are 21 CFR Part 11 compliant. Testo Saveris system is one-of-its-kind which is a mixed system that provides option of both wireless and wired probes connected to the base station. Another unique advantage of this system is that data from multiple locations or areas can be monitored centrally at one location via VPN network i.e. probes at multiple locations such as in QC labs, store room, process control lab, clean rooms etc communicate to the centrally located base station. This is a major step ahead in the T&M industry. Apart from what the product delivers, Testo also has a NABL-accredited service and calibration LAB that takes care of the after sales support locally from Testo India head office. This facility is highly cost effective as it delivers international standards very conveniently.

What are your growth plans and strategies for the next three years? How would you raise funds for expansion, especially in a scenario where businesses are finding it difficult to find investors?

India is termed as an emerging market and the numbers are only growing. In a very short span of time from its inception, Testo India has grown exponentially, thanks to our advanced products and German technology. Our manufacturing unit is in Germany where nearly 10 per cent of the total company turnover is utilised for R&D purpose in innovation, analysing new application areas and requirement of customers and accordingly coming up with the solutions. Ensuring our legacy, we have come up with our latest offering for the pharma sector, testo 190 data logger system for validation of sterilisation and freeze-drying processes with unbeatable efficiency. The system comprises five data loggers for temperature and pressure, 21 CFR Part 11-compliant software with audit-relevant reporting and two multifunction cases. All models are produced in stainless steel and robust polyether ether ketone (PEEK). Designed especially for the pharma industry, this testo 190 product family is ideally suited for tightness or overpressure testing in autoclaves and freeze-drying systems also efficient temperature monitoring of sterilisation and freeze-drying processes. Simultaneous configuration and readout of several data loggers via the multifunction case is possible to ease out the measurement process.

A data–led revolution is opening up new avenues for decision making across all functions of the pharma industry. Tell us how Testo India is providing added value and innovation in this landscape with its products?

Yes, it is true that the segment is data driven and the emphasis is on data which can include measurement values as well. Also, due to stringent norms in the pharma industry, it becomes obligatory to adhere to correct data and reports. Data security is one of the major concerns. Testo offers exactly that along with comprehensive analysis and evaluation of all the recorded measurement data. Our data loggers come with professional software where the data recorded cannot be tampered. Testo Saveris data monitoring system comes with three levels of access set up where we can restrict the authority to access the recorded data to three individuals. Also, there is a facility to provide only viewing access if need be. With this system, the data is stored in the probes, so even if software connectivity is lost the data is safe and can be downloaded once the software is logged in. Our system supports the user as they can monitor, record, analyse their data at any time and eventually carry out actions and decisions based on the reports.

lakshmipriya.nair@expressindia.com

'We strive to provide...

Continued from Page 25

period of time. We have built our products to deliver high output, for a worry-free experience for our customers.

◗ Productivity: We design our products that are easy to install, operate and maintain. It helps in managing the time of the customers and enhance their productivity.

How important is India in Ingersoll Rand’s global business strategy, especially when it comes to the Indian pharma industry?

India is a key market for Ingersoll Rand globally with the pharma industry being an important vertical. Indian pharma accounts for 20 per cent of global exports in generics. In 2019, these exports are expected to cross $19 billion. The domestic market is also expected to reach $27.9 billion by 2020. The Indian biotech industry is also estimated to grow to $100 billion by 2024-25.

(Source: https://www.ibef.org/ download/ Pharmaceuticals-Report-June-2018.pdf)

With the growing pharma market and potential in the sector, combined with the fact that compressed air is a major utility required at any plant, Ingersoll Rand has a huge focus to drive business in this sector.

What sets Ingersoll Rand apart from its competitors? Why should any company prefer it?

Ingersoll Rand comes with a legacy of more than 100 years in manufacturing and packaging of air compressors. Product improvement and development is a continuous process at Ingersoll rand. Over the years, the company has developed and introduced market leading products which are designed to reduce the operating costs, minimising our customer’s risk which are designed to improve customer’s ROIC. Ingersoll Rand designs its compressors for reliability first!

We have also launched the world’s smallest centrifugal compressor with range starting from 160kw. This unique solution offers the best-in-class efficiency, high reliability, energy efficiency and lowest life cycle cost.

Ingersoll Rand’s life cycle management and predictable spent on compressed air systems with reduction year over year is a need to stay competitive in market for pharma industry. This is where Ingersoll Rand’s revolutionary equipment insurance policy – Lowest Total Cost of Ownership (CARE offerings) gives the customer predictable spent, uptime and peace of mind.

What are the company’s expansion plan in India?

Our largest manufacturing facility is present in Ahmedabad, Naroda since 1965. Recently, the facility was upgraded with a fresh investment of more than Rs 100 crores to make it a state-of-the-art lean manufacturing plant. Air compressors are being manufactured here with a range starting from 0.5 kW till 3MW. Some of the salient features of the manufacturing plant are: -

◗ Designed and constructed as per Seismic Codes
◗ ‘IGBC’ Green Build compliant
◗ FM Global compliant
◗ Lean process (3P) designed product lines
◗ State-of-the-art test infrastructure fully complying with safety norms

Ingersoll Rand also have two engineering R&D centres based in Bengaluru and Chennai which contributes to the company’s global growth by providing high-tech, niche engineering solutions and technologies, as well as support regional product development.

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VENDOR NEWS

Gandhi Automations bags Innovation Award at All India Cold Chain Seminar 2019

The company has a vision to help cold storage owners achieve maximum efficiency, energy savings, cost savings, faster loading and unloading time to increase their productivity

GANDHI AUTOMATIONS has bagged Innovation Award at the All India Cold Chain Seminar and Exhibition, Agra, organised by the Federation of Cold Storage Association. The award was jointly recognised by the federation members. The product offerings were well received by the cold storage facility heads and owners. The displayed products were highly acclaimed by Mayor Naveen Jain, Member of Parliament Rajkumar Chaharji and Minister of Forest and Environment Dara Singh Chauhan.

A statement of Gandhi Automations mentioned, "We're honoured to receive this award in recognition of the positive impact that these cold storage doors and loading bay technology has on improving the energy efficiency, maximising system up-time, and enhancing productivity."

With this recognition, Gandhi Automations has established its firm foothold in cold chain and refrigeration industry as well as being able to introduce new and innovative technology to the same. Gandhi Automations sees a huge scope in the cold chain industry across various sectors be it pharmaceuticals, food processing, dairy, meat and poultry, agriculture, horticulture, grains and seeds to name a few.

With the advent of the high-speed technology as well as the new range of cold room sliding doors, Gandhi Automations has a vision to help cold storage owners achieve maximum efficiency, energy savings, cost savings and faster loading and unloading time to increase their productivity.

Gandhi Automations with its strong pan India service network and a dedicated R&D team as well as engineers is able to deliver the most reliable cold chain automation solutions in the industry with a keen eye to bring new innovations and technology across the sector.

EP News Bureau

CVC Capital Partners in agreement with Bosch

All 6,100 associates in 15 countries will remain with the business

BOSCH PLANS to sell its packaging machinery business, based in Waiblingen, to a newly incorporated entity managed by CVC Capital Partners (CVC). The company and its pharma and food units will remain intact. Based in Luxemburg, CVC is a leading private equity and investment advisory firm with 24 offices in Europe, Asia, and the US. It currently manages more than $75 billion of assets.

The parties signed an agreement on July 11, 2019 effecting the transfer of the entire packaging technology business and its 6,100 associates in 15 countries. It has been agreed that the purchase price and other details of the purchase agreement will not be disclosed. Completion of the sale is subject to the approval of various bodies, including antitrust authorities, and is expected to close at the turn of the year.

Dr Alexander Dibelius, Managing Partner, CVC, said, "Bosch Packaging Technology is a strong company in an attractive market with long-term growth prospects. Packaging Technology has an excellent reputation for quality and innovation, a broad product range, a global footprint, and experienced associates. Together with the management team, we will work to take the business forward in the years ahead, and to make it even more competitive."

Dr Stefan König, President, Robert Bosch Packaging Technology, said, "My colleagues and I in executive management regard this new partnership with CVC as a huge opportunity for our future success. Just under two years ago, we completely modified our strategy. It now includes working on a completely new range of smart and sustainable process and packaging technologies. This will allow us to offer our customers even more attractive product solutions and services in the future. Our customers and our associates will benefit from the progress we have made."

Dr Stefan Hartung, Member of the Board of Management, Robert Bosch and Chairman of the supervisory board Robert Bosch Packaging Technology said, "With its experience in growing companies over the long term, its broad industrial expertise, and its viable strategy for taking the division forward, CVC was the right choice for us. The growth concept it has presented, as well as the investments it plans to make, are very promising. For packaging technology and all its associates, our aim was to find a reliable new owner with a long-term approach, under whose leadership the business can develop successfully. We have achieved just that."

EP News Bureau

B&R to display new range of products at PackPlus 2019 in New Delhi

The company is opening up entirely new levels of machine and line performance in terms of increased flexibility and availability at all stages from primary, secondary packaging to end-of-line solutions

B&R WILL present its comprehensive range of products and solutions for automating and digitising machines and factories for the packaging industry at PackPlus from August 28-31, 2019 in New Delhi.

B&R is opening up entirely new levels of machine and line performance in terms of increased flexibility and availability at all stages from primary, secondary packaging to end-of-line solutions. B&R products make it easy to seamlessly integrate advanced automation into packaging machines, including web services, advanced motion control and robotics, safety, vision systems and IT connectivity.

To be globally competitive, manufacturers must eliminate all sources of inefficiency. Continuous line monitoring enables early identification and elimination of problems, thus, increasing efficiency and boosting production output. "With just a few mouse clicks, a convenient line monitoring system can be implemented using APROL process and factory automation system from B&R. The solution is based on OMAC's PackML standard, which can be applied to virtually any machine," says Dinesh Mungi, Packaging Industry expert, B&R India.

Packaging lines place a stringent demand on productivity and flexibility across the board. "B&R's adaptive machine, ACOPOStrak represents the fourth generation of packaging machinery technology, which allows cost-effective mass customisation. Across the globe, a number of packaging machines ranging from fillers, cappers and labelers to cartoners, assembly systems, rainbow packers and indexing systems are benefitting from ACOPOStrak," explains Mungi.

"ACOPOStrak boosts overall equipment effectiveness (OEE), multiplies return on investment (ROI) and accelerates time to market (TTM)," he further asserts.

"B&R's new machine vision solution can be directly integrated in a machine controller on a network, rather than using a separate vision system. It also features a powerful lighting capability. This simple implementation allows any automation engineer to develop a large portion of machine vision applications on their own," adds Mungi. This flexible and versatile machine vision solution can be used for product inspection and position detection; raw material, quality, process and label inspection; presence check; position detection; and registration mark inspection to achieve highest quality.

Packaging lines place a stringent demand on productivity and flexibility across the board

EP News Bureau

PRODUCTS

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 the 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.

PCR clean high-speed cleanroom doors

Gandhi Automations PCR clean 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, including ISO Class 5 and GMP Class C.

Flexible rapid self-repairing roll-up door typology Prime Clean Room HSD is entirely made in stainless steel and is the result of research studies. This flexible rapid door ensures excellent quality that responds to science prerogatives, according to the regulations of companies operating at the highest level of hygiene. Through the rapid door for these special areas.

The areas that require prime clean reset HSD are companies that require easy maintenance of high standards of cleanliness and hygiene. The mechanics of these flexible rapid door is performed only inside the carter of the uprights and the transom of the structure; engine, rotor and all other components are preserved inside the door, so that one can get the highest possible sterility. Most suitable areas are business environments with experimentation rooms, where the presence of dirt will be crucial for the work performed into the room.

Prime clean reset doors is equipped with powerful engines capable of opening and closing the door very quickly and especially with great safety. Gandhi Automations provide a great product in great security.

The industrial doors made by Gandhi Automations are unique and not repeatable, always be wary for copies.

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

Prime clean reset doors is equipped with powerful engines capable of opening and closing the door very quickly and especially with great safety

room doors provided by Gandhi Automations also has self- repairing system. An imperative aspect of clean room is the door one chooses 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 be quick enough to isolate the two areas. Gandhi Automations provide clean room high speed doors specifically designed for above purpose. The doors are best suited for pharma industry where there is a need to have a controlled environment. The opening and closing of door is fast enough to separate two areas.

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MeasureTest Instruments' SteraMist provides complete room decontamination

SteraMist cleanroom fogging decontamination System

- Effective whole room treatment in just under 45 minutes including application time and contact time and aeration time
- Fully transportable
- Application is not a vapour

Advantages SteraMist has over its competitors

- Classified only as an Irritant!
- No mixing required, no special clean up, no rinse, no wipe, no residue!
- No hazardous Dept. of Transport restriction for world-wide transportation, no special requirements for transportation!
- No special storage requirements!

The SteraMist Environment System is transportable, automated, remote controlled and provides complete room decontamination using three applicators per system.

Additional Features

- Six-Log Kill (99.9999%) on Clostridium difficile spores.
- Automated/remote controlled system with downloadable data sets.
- Less down time than competing technologies.
- Precise measurement of H2O2 disbursement.
- Fully validated to comply with GMP Standards.
- iHP (Ionises Hydrogen Peroxide) fog kills and inactivates bacteria and viruses in even the most hard-to-reach areas.
- Kills pathogenic bacteria and deodorises by killing odour causing bacteria.

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Imaprene: New age tubing solution from Ami Polymer

IMAPRENE IS opaque tubing especially known for its excellent flexibility and flex crack resistance. Imaprene is manufactured by using advance grade thermoplastic elastomer. It is manufactured and packaged in dust free environment of ISO 9001 QMS, ISO 14001 and OHSAS 18001 certified facility. It has excellent chemical and solvent resistance (Ex. IPA). It is superior flex crack resistance and durable for any application. It has smooth bore to ensure least contamination. It is non-toxic and non-haemolytic. Highly recommended for medical, food and pharma applications. Sterlisable by using different techniques like autoclaving, ethylene oxide and gamma radition.

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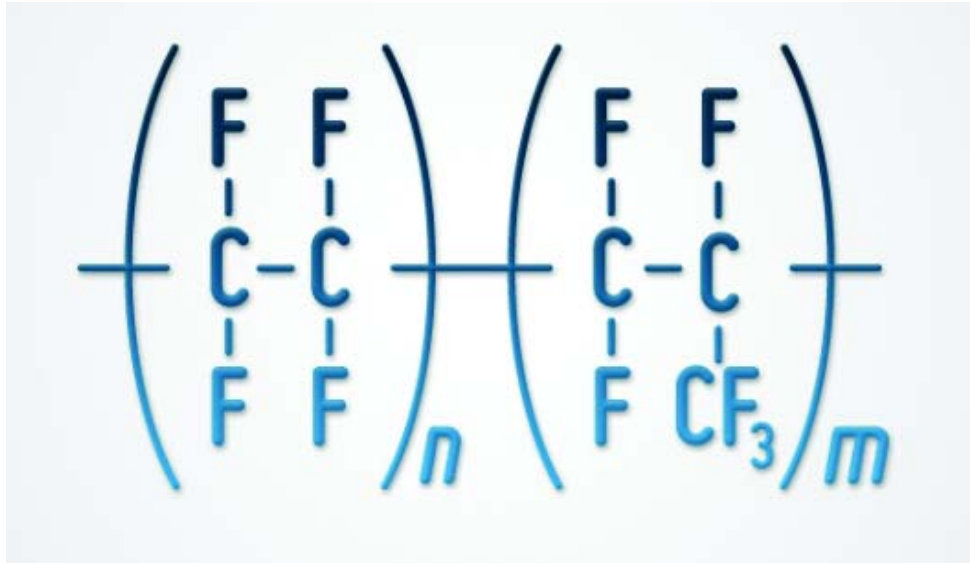
VALUE ADD

FEP tubing and its rising demand

Shrikant Dethe, Business Development, Ami Polymer, gives an insight about FEP and how it has become an ideal choice for sterile filling, diagnostic equipment, cell transfer and laboratory use

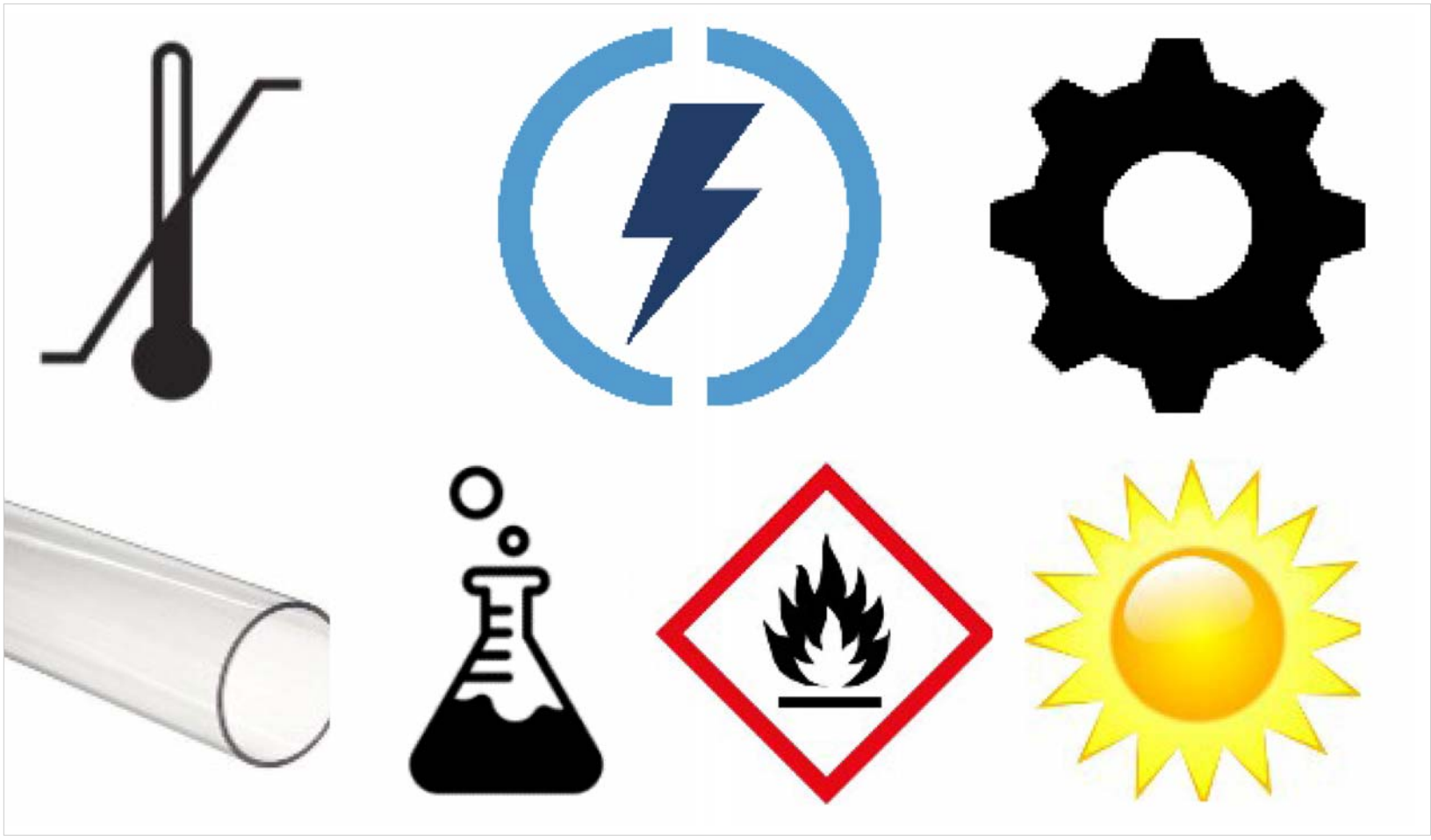
Understanding FEP

The accidental discovery of PTFE in 1938 by Dr Roy J Plunkett has turned out to have the lowest coefficient of friction of any known solid material. But as PTFE lacks the melt-processability, a need of other fluoropolymers was generated. FEP shares the same basic monomer and is commercially obtained by free-radical polymerisation in an aqueous media via addition of tetrafluoroethylene (TFE, CF2=CF2) and hexafluoropropylene (HFP, CF3-CF=CF2).



Properties of FEP

Structure of FEP is semi-



crystalline, giving it not only a distinct and sharp melting point, but also generally better mechanical properties than those of the amorphous type of polymers. Sterilisation of the tubing can be done by gas (EtO), steam (autoclave) and gamma radiation.

Applications

Engineered fluoropolymer lining, tubing and fabricated products for aerospace industry relies on its ability to resist damage from aggressive chemical fuels and withstand wide variation in temperature.

Further, its non-stickiness nature makes a top choice in food and beverage processing industry. FEP tube is also used for hot sterilizing water transfer in purification system and UV water treatment.

FEP tubing's inability to absorb materials, high chemical inertness and full sterilisation capacity makes it ideal choice for sterile filling, diagnostic equipment, cell transfer and laboratory use.

In electrical industry, FEP has well established itself due its low dielectric constant value and high electrical breakdown voltage property.

Retractable coiled FEP tube

In the recent years, the gradual downfall of PFA retractable coil has been observed due to its incompatibility with solvents. This has increased the consumption of FEP tube which serves greatly because of its high chemical inertness, heat resistance and flexibility. Additionally, it is used in chemical dispensers, deionised water recirculators and even in heat exchangers.

How different is it from PTFE and PFA?

Most of the properties vary slightly among these 3 fluoropolymers.

- FEP and PFA can be extruded and thermoformed unlike PTFE.
- FEP has a lower working temperature than PTFE and PFA.
- PFA deforms more under load compared to FEP. This indicates better retractability for FEP.
- Better abrasion resistance of FEP than PFA.

This has resulted in the fact that in the whole family of recently developed fluoropolymers, FEP stands out in its range of applications. Current research is trying on a fluoropolymer which would resist harsh chemicals and is flexible too. This would serve for a large number of the applications and would serve universally.

VALUE ADD

Tribasic calcium phosphate – one compound, so many possibilities

Daniel Zakowiecki, **Marek Lachmann**, **Tobias Hess,** Innovation and Application Development, Pharmaceutical and Medical Products, Budenheim, 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. The **Part 2** of the series

Daniel Zakowiecki

Marek Lachmann

Tobias Hess

TRIBASIC CALCIUM PHOSPHATE (Ca5(PO4)3(OH) or Ca10(PO4)6(OH)2) is well established excipient which owing to its good tabletting properties and anhydrous nature has been used in a pharmaceutical technology for many years. A few synonymic names for this compound are used –hydroxyapatite, tribasic calcium phosphate (USP/NF), calcium phosphate - tricalcii phosphas (Ph.Eur.) or frequently used, yet not correct: tricalcium phosphate.[1,2,3]

Thanks to favorable functional properties, such as flowability and compactibility, tribasic calcium phosphate is widely used in tablet and capsule formulations as a diluent/filler which can facilitate technological processes.[4] It should be kept in mind, however, that there is many different tribasic calcium phosphate excipients available on the market. The same chemical compound can be produced in various ways resulting in different functional properties and consequently application possibilities.

In the present article the authors would like to introduce the possible ways of using various types of tribasic calcium phosphate excipients manufactured by German company Chemische Fabrik Budenheim KG and advantages that they can offer. The first part of the article focused on directly compressible grade, TRI-CAFOS 500 *(Fig 1)*, and the role it plays when used as a co-diluent in direct compression formulations.[5]

This second part of the article presents the possibility of processing some liquid, oily substances into a solid oral dosage form through utilisation of a highly porous structure of TRI-CAFOS 500 *(Fig 2)*. Moreover, it shows how fine grade of tribasic calcium phosphate (TRI-CAFOS 200-7) can be employed to enhance flowability of poorly flowable powders *(Fig 3)*. The big advantage of this excipient in comparison with other glidant materials is higher bulk density (around 200 g/l) which facilitates its handling as well as reduces dust formation and exposition of operator to dust. Detailed description of advantages given by TRI-CAFOS 200-7 are described elsewhere.[6,7]

Turning liquid into solid

The highly elevated specific surface area of tribasic calcium phosphate can be successfully employed as a carrier for oily substances such as simethicone. Simethicone is an anti-foaming agent which is used in pharmaceutical formulations for treatment of certain disorders within the lower gastro intestinal tract, e.g. extensive gas formation (bloating). Formulating simethicone in a solid dosage form brings along many technological challenges. First of all, the loading capacity of commonly used carries is limited and in consequence may impact tablets or capsules size. Secondly, during the tableting process the liquid can be squeezed-out from the tablets. In addition it can be problematic to prepare tablets of appropriate mechanical strength. Porous tribasic calcium phosphate, TRI-CAFOS 500, allows preparing simethicone tablets in few, easy steps and avoid abovementioned problems at the same time.

Fig 4 shows the relationship between breaking force of simethicone tablets and the applied compression force. Tablets consisted of 17 per cent (w/w) of simethicone Q7-2243LVA from Biesterfeld (Hamburg, Germany), 51 per cent (w/w) of TRI-CAFOS 500, 30 per cent (w/w) of DI-CAFOS A150, 1 per cent (w/w) of croscarmellose sodium and 1 per cent (w/w) of magnesium stearate. At the beginning simethicone Q7-2243LVA was loaded onto TRI-CAFOS 500 with the help of a Diosna P1-6 high shear mixer (Diosna Dierks & Söhne, Osnabrück, Germany). This method allowed loading sustainably up to 25 per cent by weight of the fluid onto porous tribasic calcium phosphate. The obtained powder showed very good flow properties and during processing no simethicone leaking away from the granules was detected. This mixture was blended with other excipient and compressed into tablets on a the Fette 102i rotary tablet press at 80 rpm using 12 mm in diameter round punches with a score-line under three compaction forces: 5 kN, 15 kN and 25 kN (equivalent to 44 MPa, 133 MPa and 221 MPa respectively).

No squeeze out of the simethicone was observed during compression and after tableting the tablets showed a dry surface with homogeneously white colour. Furthermore, during storage simethicone was kept within the tablets and no changes in the appearance of the tablets were observed. The tablets showed good mechanical strength especially when compressed with higher compaction forces. The addition of only 1 per cent of a disintegrant resulted in fast disintegration of the tablets which was completed within around three minutes.

The defoaming activity is the most important parameter to test the efficacy of the final dosage form. This parameter can be measured by observing the collapse of a well-defined foam. To obtain such foam the detergent octoxynol-9 is mixed with water at a concentration 1 per cent (w/v) and shaken vigorously. Rapid collapse of the created foam was observed. Within 45 seconds the foam was destroyed completely. *(Fig. 5)*

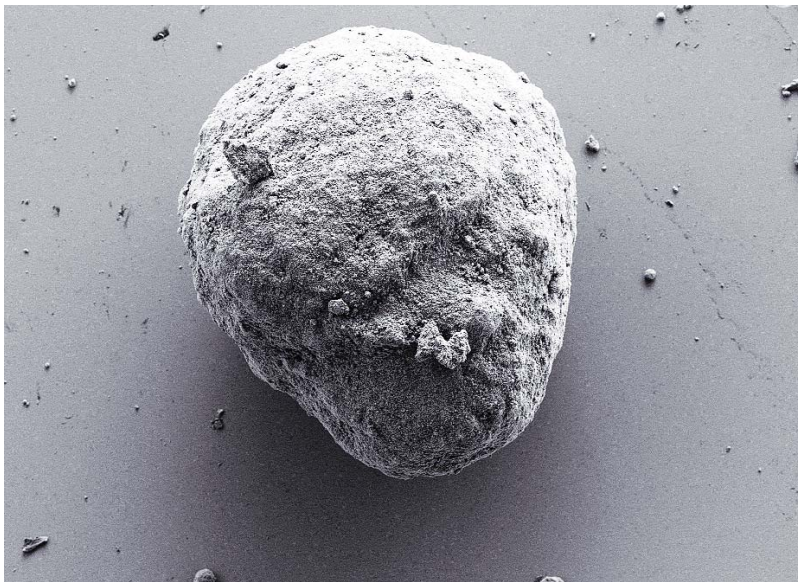


Fig. 1 SEM picture of TRI-CAFOS 500 (magnification of 1 kX)

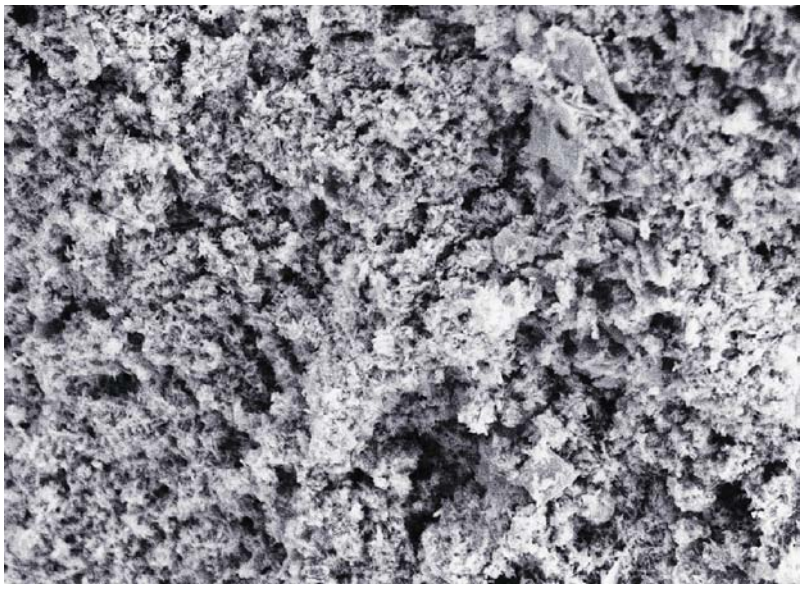


Fig. 2 Close-up on TRI-CAFOS 500 highly porous surface (SEM picture, magnification of 8 kX)

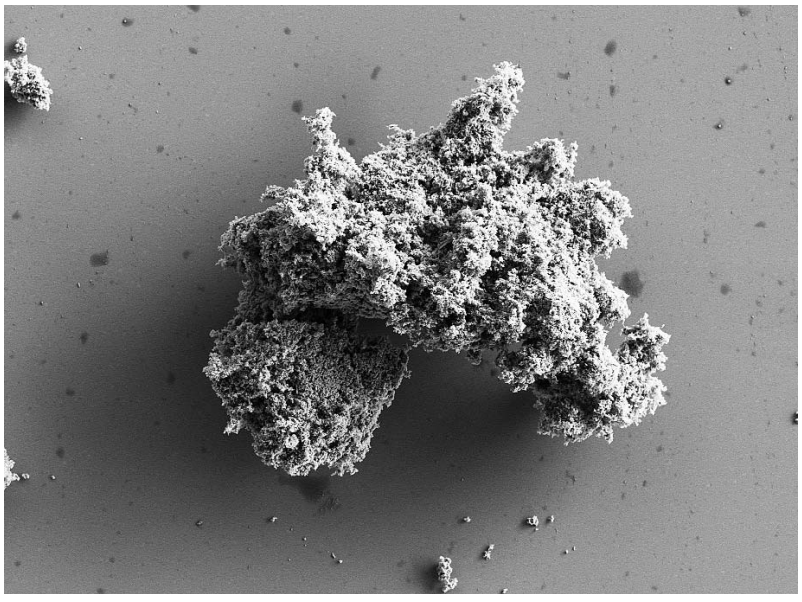


Fig. 3 SEM picture of TRI-CAFOS 200-7 (magnification of 7 kX)

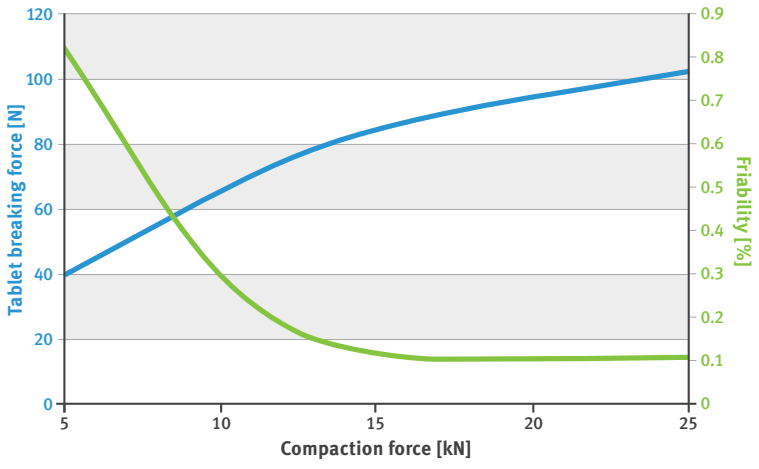


Fig. 4. Breaking force (blue line) and friability (green line) of simethicone tablets compressed under different compaction force

Regulation of flow

Fumed silica and talc are probably the best known and commonly used glidants. Tribasic calcium phosphate is still in this application area a novel material, not known to many formulation scientists. However it can be successfully used as an alternative for other popular glidants offering some additional advantages such as higher bulk density and lower dust formation. [6,7]

TRI-CAFOS 200-7 particles are agglomerates of very small primary particles which, when mixed with other substances, have the ability to cover the surface of the host particles, separate them physically and reduce cohesive forces. This phenomenon can positively affect the flow properties of powders.

Fig 6 shows SEM picture along with EDX analysis of ibuprofen 50 (BASF, Ludwigshafen, Germany) mixed with 1 per cent (w/w) of TRI-CAFOS 200-7. Fields marked in green are places of occurrence of calcium and marked in red - phosphorus. The analysis shows how homogenously surface of ibuprofen crystals is covered by tribasic calcium phosphate fine primary particles during mixing process.

Fig 7 shows the effect of 0.5 per cent and 1.0 per cent (w/w) admixture of TRI-CAFOS 200-7 on flowability of ibuprofen 38 (BASF, Ludwigshafen, Germany) and caffeine (Sigma-Aldrich, Steinheim, Germany). Both drug substances (mixed in a weight ratio of 5 : 1) were blended together with tribasic calcium phosphate in a Turbula mixer for 10 minutes at a rotational speed of 32 rpm. The powder flow characteristic was assessed using a compendial method – evaluation of angle of repose.

The angle of repose of the mixture of ibuprofen 38 and caffeine corresponded to a poor/very poor flowability. The addition of 0.5 per cent (w/w) of TRI-CAFOS 200-7 improved the flow characteristics to passable, and 1 per cent (w/w) to fair/good (according to Ph.Eur.). The improvement of the flowability of the powder mixture was good enough to use it for the preparation of tablets containing 250 mg of ibuprofen and 50 mg of caffeine by direct compression. The obtained tablets showed proper mechanical strength, short disintegration time and fast dissolution rate of both drug substances. [9]

Apart from glidant activity TRI-CAFOS 200-7 can be used as an anticaking agent having even ability to dea-

Fig. 5 Defoaming activity of the simethicone tablets

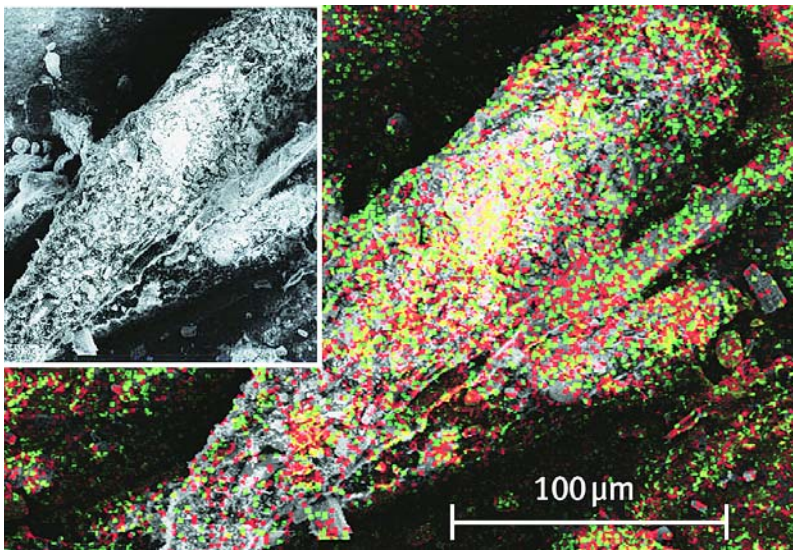


Fig. 6 SEM picture of ibuprofen 50 mixed with TRI-CAFOS 200-7 (magnification 900x) together with identification performed with EDX technology [8]

glommerate lumps of certain drug substances formed during transport or storage. This ability is shown in the *Fig. 8*. Ibuprofen 50 used in this experiment showed a strong tendency to form lumps during storage. As a result of mixing with 1 per cent by weight of TRI-CAFOS 200-7 (without subsequent screening), the lumps were deagglomerated, and the resulting mixture could be later used in further unit processes without any problems.

Summary

In two parts of this article some possibilities of the use of tribasic calcium phosphate (hydroxyapatite) in pharmaceutical technology were presented. The examples showed that the same chemical compound depending on the method of preparation may have different functional properties, giving many interesting possibilities of application during development of drug products.

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 tablets. At the same time, it increases their porosity and thus facilitates the penetration of water into the interior of the tablets and improves the effectiveness of disintegrating agents. This reduces the disintegration time and in many cases can also positively impact the dissolution.

The high porosity and the elevated specific surface area of TRI-CAFOS 500 can be successfully used as a carrier for liquid, oily substances such as simethicone. Thanks to high sorption capacity it allows turning the liquids into solid dosage forms including tablets without squeezing out the liquid during compressing.

Fine tribasic calcium phosphate, TRI-CAFOS 200-7, possess properties allowing the use as an alternative glidant material for effective regulation of powder flow. Higher bulk density facilitates its handling and reduces dust formation during processing.

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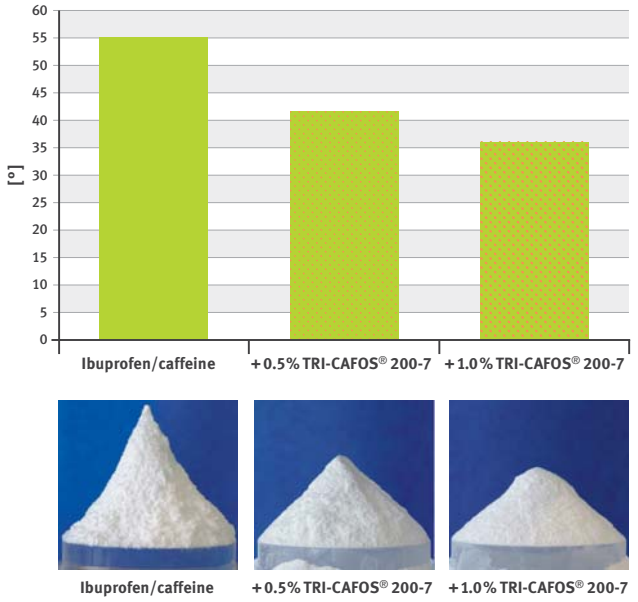

Fig. 7 Impact of 0.5 per cent and 1 per cent of TRI-CAFOS 200-7 on the flow characteristic of ibuprofen 38 and caffeine mixture (angle of repose evaluation)

Fig 8. Deaglomeration of ibuprofen (left hand side) by mixing it with 1 per cent w/w of TRI-CAFOS 200-7 (right hand side)

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INTERVIEW

GSK will invest up to £600k to support 'Trust in Science' initiative

Pharma major GlaxoSmithKline Pharmaceuticals (GSK) has launched 'Trust in Science' initiative in partnership with the Regional Centre for Biotechnology (RCB), to develop PhD courses in biostatistics and bioinformatics. **A Vaidheesh**, Vice President, South Asia and Managing Director, GSK tells more to **Akanki Sharma**

> For India to take a consistent and successful path into original pharmaceutical research, there is an urgent need for trained biostatisticians and bioinformaticians in the country

Kindly share a brief about the 'Trust in Science' programme. What does it offer and who are its beneficiaries?
Globally, GSK Pharmaceutical's 'Trust in Science' initiative is a novel public-private partnership model to build R&D capacity for development and discovery in science. The pillars of this initiative are scientific excellence, trust and talent development in line with GSK's science, technology and cultural values.

In India, we have launched the 'Trust in Science' initiative in partnership with the Regional Centre for Biotechnology (RCB), one of India's academic research institutions to develop PhD courses in biostatistics and bioinformatics. The initiative covers scholarship costs and provides expert guidance to 12 students, so that they can complete their doctoral degrees. Any student with a master's degree in biostatistics and bioinformatics is eligible to apply for this programme.

What prompted you to initiate a doctoral programme for bioinformatics and biostatistics only? How do you think it is going to benefit the pharma sector in India?
Our industry is generating huge amounts of biological and genomic data. This means we are dealing with massive data sets which were unimaginable some 20 years ago. Now comes the challenge of mining this data for insights and trends which can be extrapolated in a way that leads us to think and plan our future more strategically. Both bioinformatics and biostatistics offer immense promise here. Both the fields can drive the investigation and processing of large sets of biological information in a short period of time. This is of great value to a country like ours, with large sample sizes and varying factors that influence disease and healthcare delivery.

For India to take a consistent and successful path into original pharmaceutical research, there is an urgent need for trained biostatisticians and bioinformaticians in the country. We have in-house experts who can mentor and guide these PhD scholars. Initiatives like this can help India emerge as a centre for biopharma research and fuel breakthrough medical, clinical and public health research in the country. We strongly believe that through this collaboration, young researchers will develop high-end expertise in drug discovery, and we hope it will become a springboard for them to transition into a full-fledged pharma career in the future.

What role does RCB play in this programme and how much has GSK invested in it? Also, do students need to pay any fees to enrol in this programme?
Under this initiative, the RCB is responsible for creating programme content, managing logistics and overseeing the running of the full-time programmes. GSK will provide funding and ensure that all course content is shaped to address current industry needs and opportunities.

GSK will invest up to £600k (approximately Rs 5 crores) to support this programme, which will be matched by the Department of Biotechnology (DBT). The company will also offer students a monthly stipend of Rs 45,000. Beyond funding, we will give the PhD scholars access to the latest research that is relevant to their theses. Further, we will give them opportunities to attend seminars, lectures and training sessions to help stimulate their thinking and network with others in the field. Students do not need to pay any fee to enrol themselves in this programme.

What's the process of enrollment and how many

students will be enrolled in the first year? Will it begin in this academic year? Also, how do you plan to scale it up?
The RCB is in charge of student selection on the basis of merit. All students with a master's degree in biostatistics and bioinformatics are eligible for the PhD programmes. So far, five students have already been shortlisted. Over the course of three years, we will support a total of 12 students. The programme began in the month of July.

What are the current industry needs and opportunities for pharmacy students in India? How will this programme be a catalyst for the same?
Recently, India's vice president called on the pharmaceutical industry to help make India an International Capital of Generic Medicines. I believe that along with this, it is important for India to also become known as a hub for original drug research. For this to happen, we need to start young.

As young scientists begin to contemplate pursuing research as a career, we need to give them the tools and skills they need to do breakthrough drug research. One way to do this is by developing a new crop of trained biostatisticians and bioinformaticians in the country. Young scientists who have the ability to mine data and gather insights will one day set new standards for drug discovery. Through this programme, it is our goal to provide students with a specialised course that addresses current industry needs and opportunities. This, we believe, will help them better contribute to India's biopharma and medical research needs.

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Is there a lack of opportunities for pharmacy students in India? Can you share some statistics on the same? What better opportunities will 'Trust in Science' programme bring for pharmacy students?
The 'Trust in Science' programme in India will allow the formation of a new group of skilled people trained in the areas of bioinformatics and biostatistics applied to the pharmaceutical industry.

This programme was initially launched in 2011 to engage with leading researchers and institutions in Latin America. What is its current status?
'Trust in Science' is currently working strongly in Latin America, mainly in Brazil and Argentina, with additional efforts in Uruguay and Mexico. Currently, nine research projects are being supported in the areas of immuno-oncology and immuno-inflammation.

Will you be tying up with any other individual pharmacy colleges in India or elsewhere for this programme?
We are working with the Ministry of Science in Argentina on a fellowships programme for Argentinian scientists to work at the Crick Institute in the UK, in research programmes of interest to GSK.

akanki.sharma@expressindia.com

NEWS

Novartis continues to build healthcare talent ecosystem, announces BioCamp 2019

BioCamp engages students around scientific advances to address unmet medical needs and entrepreneurial opportunities and offers 50 post-graduate students insights into the pharmaceutical industry through direct interaction with experts

THE NEXT edition of Novartis Biotechnology Leadership Camp (BioCamp) will be taking place in Hyderabad from October 13 to 16, 2019. Now in its 11th year, BioCamp has attracted top talent from across faculties to the healthcare industry thus contributing to the ecosystem.

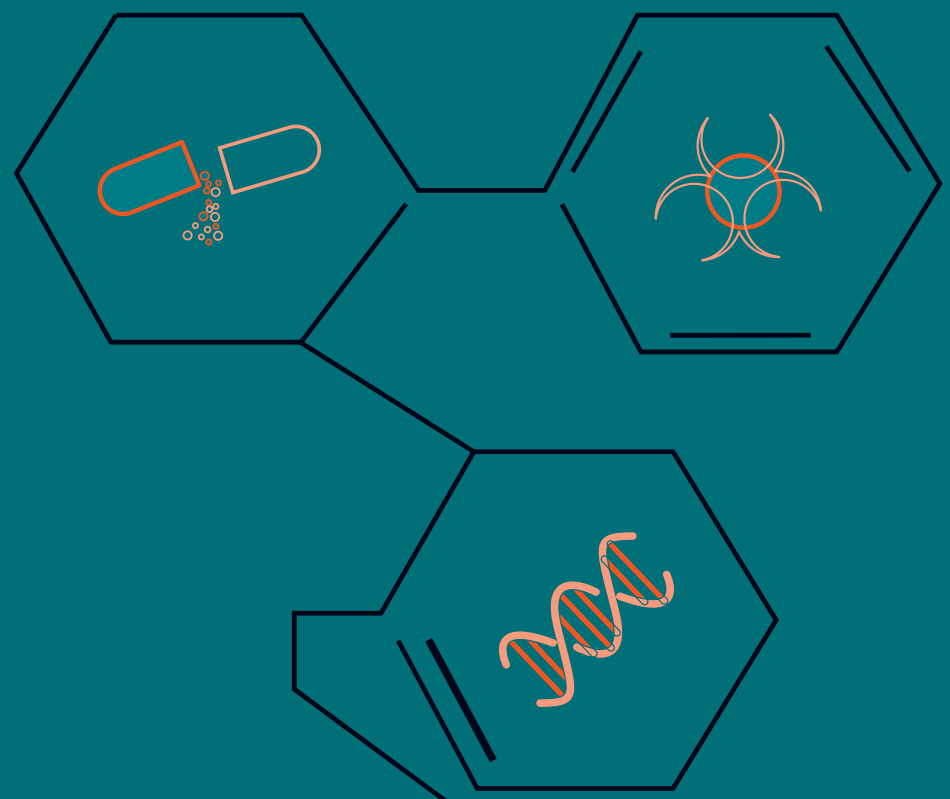
"BioCamp provides top talent in the country – the opportunity to understand trends, challenges and opportunities in the pharmaceutical industry. We believe these insights help them envision the role they can play in influencing the course of healthcare in the country through their career choices, while providing a talent pipeline to the industry," says Sanjay Murdeshwar, Country President, Novartis in India.

BioCamp is part of the Novartis commitment to supporting the exchange of ideas and thoughts between young talent in science and business. It is designed to provide students with a platform to collaborate across faculties and interact with thought leaders who lead the company's unique approach to address patients' unmet medical needs. The programme is open to postgraduate students and young researchers in natural sciences, medicine, biotechnology, bio-informatics, pharmacy, business administration, chartered accountancy or law (specialisation in Intellectual Property Rights) interested in pursuing a career in the pharmaceutical industry.

Previous speakers include Alok Srivastava, Professor Hematology – CMC, Vellore; Arijit Sarker, Director, Google India; Prof K Srinath Reddy, President, Public Health Foundation of India (PHFI); Dr A S Soin, Chief Hepatobiliary and Liver Transplant Surgeon; Kiran Mazumdar-Shaw, Chairperson and Managing Director, Biocon and G V Prasad, Co-Chairman and CEO, Dr Reddy's Laboratories, among others.

The jury will select three individual winners and one winning team based on their contribution, performance, leadership and teamwork. Novartis India has introduced around 500 top students to the pharmaceutical industry and entrepreneurship since launching BioCamp in 2009.

EP News Bureau



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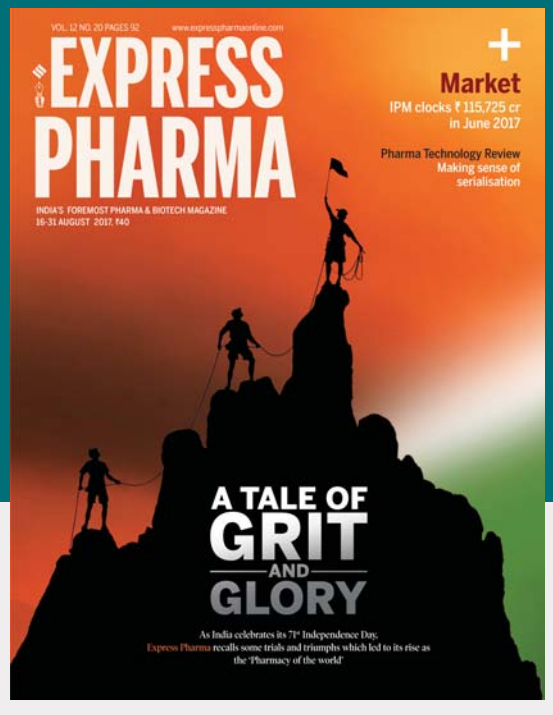

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Biocon Academy: Shaping the new pharma talent

Building a best-in-class academic programme is crucial to the pharma industry and Biocon Academy is committed to this cause. Since its inception, the academy is working towards transforming the academic knowledge into industrial skills which are required for the development of the application of in-depth understanding of technology and regulations. In addition, an eight-week full-time certificate programme in Quality Control Analytical (QCA) course will commence its first batch in Mid August

BY **USHA SHARMA**

AS PER All India Council for Technical Education (AICTE), there are more than 500 pharmacy institutes across India and this number is increasing every year. For the current academic year (2018-19), AICTE has approved and certified 290 pharmacy colleges to give diplomas to applicants along with 102 technical institutes aiding under-graduate and post-graduate degrees in medicine. However, these institutes are still failing to fulfil the demands of the global pharma industry, despite the large numbers. As a result, the Indian pharma industry is facing a talent crunch. Herein the question lies- where do these institutes fall short?

The answer is simple: the Indian pharma industry is growing at a significant rate and is witnessing rapid regulatory changes. That makes it difficult for academic institutions to keep up. Furthermore, there is a difference between the knowledge being extended through books and practical world knowledge. So, how can this gap be bridged?

This issue is being consistently contemplated by industry stalwarts and to make a difference, Biocon, an innovation-led fully integrated biopharmaceutical company, decided to start an academy which will train professionals and enhance their skills with advanced learning. This happened in the same year when the Indian government enacted Section 135 of the Indian Companies Act prescribing a mandatory "Corporate Social Responsibility (CSR) spend of two per cent of average net profits under the Companies

SS Easwaran, Academic Dean, Biocon Academy

Act, 2013 and when India became the first country in the world to mandate and quantify CSR expenditure.

SS Easwaran, Academic Dean, Biocon Academy shares the inception details of the academy. He informs, "Biocon Academy was set up as a CSR initiative of Biocon, to address the wide gap that exists between the quality of human capital available in India and the growing needs of the biotech industry. The academy is committed to developing a high-quality talent pool that is industry-ready to enable the biotechnology sector in India to remain globally competitive."

Biocon Academy offers high-quality innovative programmes focussed on biosciences business to empower experienced professionals and to develop fresh biotech graduates. The advanced learning and industrial proficiency offered through customised curriculum modules focus on integrating the subject knowledge with industry experience. It imparts job-skills essential to build a promising career and emerge as future leaders in the biotech industry.

In January 2014, the company launched its first programme and successfully executed its first batch with 100 per cent placement. They have not looked back since as every year they add new courses and churning out more talented and skilled professionals ready to conquer their career graph

Quality Control Analytical (QCA) Course is a highly instrument intensive segment of the industry where the ability to work with complex and high-end equipment is a job mandate. Having hands-on experience in these instruments in addition to providing the knowledge of operations and also providing them ways to address deviations in results. Recently, the academy announced its collaboration with M S Ramaiah College of Arts, Science, and Commerce, Bangalore for introducing eight-week full-time certificate program in Quality Control Analytical (QCA) course. The course is designed to provide specific job skills, which will emphasise on the instrumentation and regulatory background to help the participants to find meaningful employment in the quality function and start delivering with limited training requirements.

Explaining the needs of such courses in the present scenario, Bindu Ajit, Programme Dean, Biocon Academy mentions, "In the current scenario, the fresh talent pool that is passing out from college possesses theoretical knowledge but they lack hands-on experience, exposure

Bindu Ajit, Programme Dean, Biocon Academy

to the industrial processes and work demands. We launched the Biocon Ramaiah Certificate Programme in Quality Control Analytical (QCA) which will aim at providing an exposure to the students so that they understand both the strong regulatory framework as well as learn the skills required to work on high-end laboratory instrumentation."

She also informs other salient features of this programme. She says that it will also offer experiential learning at Biocon in the areas of Quality Control Analytical at the state-of-the-art Biocon labs using sophisticated analytical instrumentation. And the programme will impart training on the working of analytical instruments combined with operational, application and regulatory know-how related to QC and QA. It will also provide practical experience into the basic principles of troubleshooting. Besides this, the course is designed with a special module, under which a week-long residential hands-on training will be given at the Thermo Fisher, IIT Mumbai Campus to the students.

The training at the Thermo Fisher's Centre of Excellence (CoE) will help the students to gain visibility to the wide variety of analytical instruments manufactured by Thermo Fisher. To have a fast-paced growth in this area of quality control, exposure to instruments used in both assay and impurity profiling of products and supplies will be of great help.

Course enrollment requirements

Biocon Academy is an advanced learning-educational initiative which takes forward Biocon's commitment to affordability and greater access. Like its other programmes, Biocon Ramaiah Certificate Program in QCA is being made available to students with Biocon Scholarship of 60 per cent. Revealing more information about the course, Bindu says, "The first batch of QCA programme will begin by August mid-week and since it is a pilot batch it will comprise of maximum 15 -20 students. The eligibility of the programme is MSc., Chemistry, (Analytical/ Organic/Inorganic/ Pharmaceutical/ Industrial), MSc, Biochemistry, Cumulative Grade Point Average (CGPA) should be 6.8 and above on a scale of 10 and applicants should have 65 per cent and above." So if the applicants meet the requirements can enrol themselves for this exclusive programme which is designed to enhance the knowledge and skills of aspiring chemistry and

biochemistry postgraduates. This unique collaboration between Biocon and MS Ramaiah, is a envision to accelerate learning in the fast-growing field of Quality Control Analytical & Regulatory Sciences in pharma and biopharma sector as this is a highly instrument and regulations intensive area."

There are about 12 well-trained faculties from M S – Ramaiah, who will be teaching the students and the faculty who have been identified for teaching this course have industry experience/ exposure and were also trained in Biocon. To this, the academy will also invite guest lecturers from the industry on every Monday during the course period.

Why MS Ramaiah faculties were trained by Biocon? Commenting on the need of giving training assistance to MS Ramaiah faculties, Easwaran says, "For the student participants in the programme, to speak the industry-specific language, it is very important to orient the faculty to the industrial applications of the scientific principles. As a part of the orientation programme, the faculty of MS Ramaiah was addressed by the managers and leaders of Biocon and also taken to the Quality Control Analytical departments for them to see the applications."

The academy seems positive and enthusiastic with the introduction of the new course of QCA, as its all other courses have worked well and set the benchmark with 100 per cent placement in the industry.

Building a collaborative culture Biocon Academy has taken the collaborative route to design unique industry-oriented programmes. It has tied up with academic institutions such as the Keck Graduate Institute (KGI), California, BITS, Pilani, and M S Ramaiah College, as well as, life sciences companies like Thermo Fisher Scientific, BiOZEEN and Narayana Hrudayalaya Hospital to impart best in class industry-ready programmes. Its flagship programme is the Biocon KGI Certificate Programme in Biosciences. Bindu highlights, "With a broad-based international curriculum encompassing R&D, Production as per GMP, Quality, Regulatory, Product Development and Professional skills, the Biocon-KGI Certificate Programme in Biosciences equips Biotech students with the necessary knowledge, skills and industrial training to make them employable in the industry. And we have completed 13 batches with 100 per cent placement record for all students in leading pharma and biopharma companies."

Besides this, it has also designed other programs which have tremendous industry requirements of trained professionals are: 1. BITS Biocon Certificate Programme in Applied Industrial Microbiology (AIM)2. Biocon KGI Certificate Programme in Clinical Development (CDP)3. Faculty Development Programme

Highlighting the requirement of designing these courses Bindu points out, "Industry is always in the pressure of producing high-quality medicines in the shortest possible time incurring least expenses to be competitive in the market and to make the medicines accessible to the common person. In this context, the industry would find it difficult to train a fresh talent from the college and start seeing the deliverable coming after a year or so. On the other hand, the industry is certainly in its inflexion point to get into the rapid growth pace. To encash the opportunities and to keep up with the pace of growth, it is important to have the right and relevant talent pool in place. Creating the right talent pool for the industry is one of the key intervention industry could do and Biocon Academy has taken the fits step of this unique model keeping in mind the overall benefit to the industry ecosystem."There is a huge need for the right talent and alone it will be difficult to accomplish the entire task. Therefore, industry stakeholders need to come together and work closely in bridging the gap. Easwaran significantly points out, "More companies/ industries participating will certainly take this initiative to the next level of creating the right talent pool for the Indian as well as for the global market. And the need of the hour is collaboration. As the model is created by Biocon Academy and found to be working extremely successful in the benefit of the industry, more and more industries should start similar initiatives. Segment-wise approach including bioscience, clinical research, quality etc. is one way of going about and region-based expansions like having similar models working in each pharma-biopharma hubs of India like Hyderabad, Ahmedabad, Baddi, Goa, Mumbai etc. can bring about a focused development of highly efficient talent pool in the country and is relevant to take the sector to next level of growth."

Shared responsibility model may work effectively and the academy believes in following before they preach!

Mentoring mentors , one of its unique course is the Faculty Development Programme which is designed for working faculties. Why there is a need for mentoring the mentors?

So, the objective of education or knowledge is not only teaching or learning but also updating themselves with changes. So, the regulatory requirements of the global pharma world are changing considerably and therefore gurus too need to be updated and kept informed. Their knowledge enhancement will certainly add values in designing the right talent for society.

Easwaran highlights, "It is a unique programme which is aimed at the faculty who are teaching biotechnology or any bioscience subject in institutes. It is a two weeks full-time program, delivered at the Biocon Academy which comprises of 20 interactive lectures delivered by subject matter experts/managers from Biocon and 24 hours of experiential learning at Biocon's high-end and world-class manufacturing facilities, quality and research labs."

A way forward

Biotechnology research is revolutionising the way the diseases are being diagnosed by using genetic and molecular biological methods. The overall research in the biotech sector including the healthcare, agriculture, alternative fuels and bioinformatics has made such a significant impact that the company can move from therapeutic to predictive healthcare which benefits the patients in a big way. However, companies focus on biotech research is still at its primitive stage and it has a long way to go. Commenting on the potential of research work in the biotech arena, Bindu says, "Biotechnology research is shaping the overall healthcare in a very different way. Now we have developed capabilities to replace the painful radiotherapy and chemotherapy for the life-threatening diseases like cancer with biological drugs and ensure a better quality of the extended life span. India is one among the leaders in the global biosimilar market and the bio-similar research has made so many drugs accessible to the common people."

"And with glocal approach of the biotech markets, Biocon has identified the importance of exposing its managers to the way the markets behave and how to connect their work to the over-all business outcome," adds Bindu. Over 500 students have graduated from the academy spanning across 25 batches – all programmes put together and have been placed across 50 leading biotech, pharma and service companies. With the success of the pilot batch of Biosciences Management batch, the company's next in pipeline programme is the MBA in Biotechnology in association with Keck Graduate Institute. The other programmes which are at the concept level include Applied Bioinformatics and International Regulatory Affairs. "We are also working towards holding a conference on the Applications of Artificial Intelligence in Drug Discovery," informs Bindu.

A quote of Nelson Mandela's goes so apt with the Biocon Academy's objective, which says, "Education is the most powerful weapon which you can use to change the world." And the initiatives which have been taken by Biocon Academy are heading in the right direction.

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