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Leaders and experts come together to transform India Pharma Inc into a more value-driven industry with the help of disruptive technologies | P20

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Patient care apps serve a purpose, but need to be closely monitored

According to a recent EY report, Life Sciences 4.0: transforming health care in India, 47 per cent of top pharma companies in India now use digital means to dispense medical information for doctors while 33 per cent reach out to patients via 'virtual caregiving' initiatives spanning health tips and disease information.

US-based Abbott was the latest to launch an app in this category, a:care. India is an important market for Abbott Pharma, contributing 23 per cent of global sales, reason enough to debut the app in this lead market. Philippines, Vietnam, and Mexico are reportedly next in the pipeline, while the app also mentions Brazil and Russia. Diabetes, thyroid and osteoarthritis are the focus disease areas as of now, with more therapies to be added later this year.

India has a huge disease burden in these areas, but are these apps as benign as they seem? Besides concerns on data privacy, aren't such digital initiatives vulnerable to conflict of interests, and merely another reinforcement of the 'pharma company-doctor nexus'? Jawed Zia, Head of Abbott's pharma business in India emphasised that no Abbott brands would be promoted on the app, while the content will be neutral and non-commercial. He says 2000 doctors across the country are already on the app , and the plan is to sign up a million patients in the next five years.

Signing up doctors on the app will be the responsibility of the Abbott's sales force. These doctors receive codes from the company, which they pass on to their patients to enroll on the app. The decision to enroll is left up to patients, as is the choice to allow their doctor to review and track their health data. Anyone can download the app from the Android Play Store and access content related to the selected disease areas.

On concerns related to data privacy, the company clarified that all data is collected with consent from users and follows all applicable privacy laws. Abbott does not have access to identifiable patient data. Data entered by patients online is collected in a health record system and is used to provide services and information to users, such as pill reminders for patients or medical adherence charts for doctors.

Such apps do serve a need. Today's impatient patient is bombarded with (mis)information, from Dr Google, Professor Wikipedia and an ever increasing slew of digital health start ups, even before s/he enters a doctor's clinic for a consultation. In India, relatives and neighbours too pitch in with advice, further confusing the patient. In fact, Dr Manoj Chaddha, Consultant Endocrinologist, Hinduja Hospital, Mumbai & Immediate Past President – Endocrine Society of India, one of the doctors associated with a:care and present at the launch, has been part of putting together similar platforms for the past three years. He believes that by providing scientifically validated information and access to advice from qualified experts throughout their continuum of care, a:care will help combat misinformation and debunk myths. This would enable physicians to have high-quality engagement with patients, which can drive better outcomes.

Besides concerns on data privacy, aren't such digital initiatives vulnerable to conflict of interests, and merely another reinforcement of the 'pharma company-doctor nexus'?

Another doctor present at the launch, Dr Ram Chaddha, Consultant Spine Surgeon, Lilavati Hospital, Mumbai & Past President, Association of Spine Surgeons of India, pointed out that while an appointment or surgery is just an event, treatment is a process. Therefore such a system helps doctors remain connected to their patient beyond the clinic, helping in long-term management of chronic diseases that need continuous monitoring.

Besides increasing brand recall for Abbott Pharma to an increasing circle of patients, the app also deepens the company's connect with doctors through a:care academy, through an offline three-year continuing medical education (CME) programme. Zia reveals that they plan to expand the information service to pharmacists as well.

The app uses gamification to engage patients, with a points-based rewards programme, in which they earn points through various activities, such as taking quizzes or marking that they took their medicine. They can later use these points to get discounts when buying medicine, diagnostics or health related services from partners on the app. Abbott has already tied up with e pharmacy 1mg and plans to tie up with more e pharmacies. A company executive mentioned that the rewards system ensures that patients need to use the app for at least a couple of months, before they accumulate enough redeemable points. This is to ensure positive health outcomes of patient adherence start to kick in before the financial rewards do.

The company plans to launch a native app, interactive and regional content, a multilingual platform and personalised health coach. These services overlap with existing well established doc-patient apps like Practo, Just Doc, Lybrate, etc. Thus a:care will compete with such brands for mind share (and by extension, market share) of doctors, patients and pharmacists. We'll have to wait and watch to see how Abbott, as well as other pharma companies with similar digital outreach plans, manage to allay concerns regarding data privacy and conflict of interest.

VIVEKA ROYCHOWDHURY *Editor*
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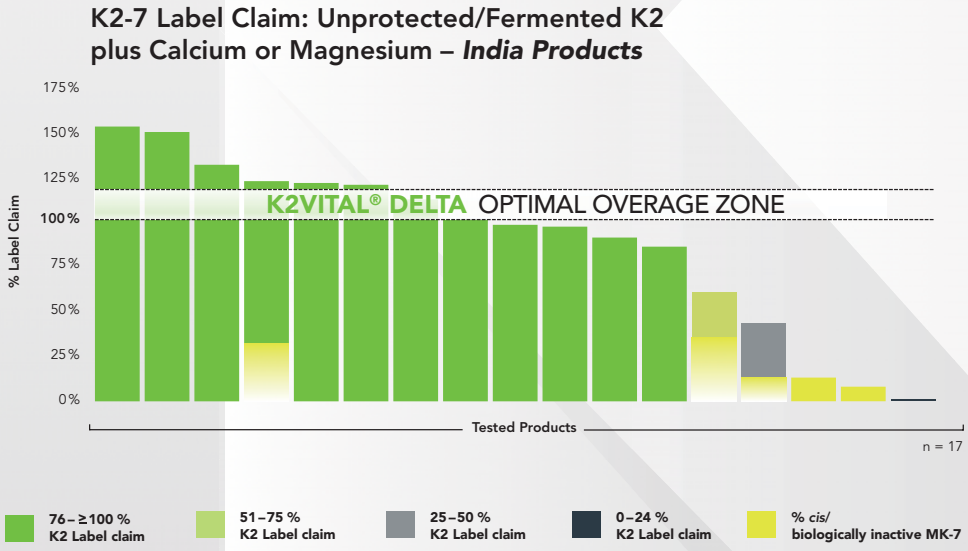

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POST EVENT

Pharma leaders discuss strategies to thrive in an era of disruption

Industry captains come together at a select meet organised by *Express Pharma* and Optel Group in Mumbai to chart the progress of the sector in a disruptive world

In the run up to *Express Pharma's* Silver Jubilee year starting this December, *Express Pharma* recently organised a round table discussion with pharma leaders, in partnership with the Optel Group in Mumbai. The round table comprised a gathering of the top notch pharma leaders who discussed and deliberated on leadership strategies needed to thrive in an era of disruption. The learnings from this initiative spanning the year will be published as a collection of thought leadership articles, designed to help pharma professionals navigate the challenging era ahead.

The discussion was moderated by Viveka Roychowdhury, Editor, *Express Pharma* and presided over by special guests Louis Roy, Founder and President, Optel Group Shaunak Dave, CEO and MD, Optel Group, India, Annie Dubé, Consule générale du Canada, Dominic Marcotte, Consulate General of Canada, Quebec Government.

Thought leadership from India's pharma sector ranged from regulators like PBN Prasad, CDSCO DDC(I) CDSCO West Zone Mumbai, pharma association representatives like Daara Patel, Secretary – General, IDMA, and corporate chieftains like Aditi Kare Panandikar, Managing Director, Indoco Remedies, Dr Ajit Dangi, President and CEO, Danssen Consulting, Dr Ashok Bhattacharya, Executive Director, Takeda Pharmaceuticals India, Vinay Pinto, Executive Director, Wallace Pharmaceuticals, BG Barve, Joint Managing Director, Blue Cross Laboratories, Kedar Upadhye, Joint President & Global CFO, Cipla, Kanish Malik, President & Global Head, Glenmark Pharma and Gagan Sharma, Vice President, Bliss GVS. Vadlamudi Rao, President, Commonwealth Pharmacists Association represented academia as well as the voice of pharmacists.

Roychowdhury welcomed the dignitaries and thanked industry for the support in reaching this memorable milestone as a successful media platform. She explained the rationale for the round table discussion and asked the leaders to share their views on the disruptive challenges shaping the pharma sector, globally and in India. The experts were also asked how can these be turned around into a competitive edge for pharma companies.

This was followed by Roy talking about Optel Group's global business strategies and highlighting the company's vision to offer a complete range of supply chain products in order to comply with the regulatory frameworks of various countries ranging from India's DGFT, US FDA, EU FMD, WHO GMP, etc. Roy further threw light on the future of the pharma industry and the way technology will empower the sector. He also mentioned that the company is leveraging artificial intelligence to further build its supply chain data which can be beneficial for pharma companies. He spoke about the demographic impact of research on drug development, and how pharma companies need to adopt patient centricity in order to disrupt the market.

Dubé from Consule générale du Canada urged pharma companies to focus on prevention of diseases. She highlighted that her country is eager to partner with India in order to strengthen healthcare systems across the globe. She also mentioned that

Leaders need to think on their feet

Dr Ajit Dangi
President and CEO,
Danssen Consulting

Pharma companies need to bring innovation in packaging

Kedar Upadhye
Joint President & Global CFO,
Cipla

Complexities and ambiguity need more time to be understood

Aditi Kare Panandikar
Managing Director,
Indoco Remedies

Canada and India are looking forward for opportunities to work and collaborate together.

Marcotte from Government of Quebec informed that presently the Quebec region had almost 630 lifesciences companies which contribute significantly to the country's economy. He also outlined some of his government's strategies planned upto year 2027 to make pharma businesses more viable and sustainable in the long run.

Dave from Optel Group talked about pricing pressures faced by the pharma sector in India. He further urged leaders to adopt value-driven leadership to achieve sustainable growth. Highlighting how technology is disrupting the world like never before, he emphasised why it is important for the pharma industry to be abreast with technological advancements to stay relevant and competitive. He spoke about the shift from Internet to intelligence and its transition to self decision making process. He also mentioned issues being faced by the industry like dependency for APIs, the fractured supply chain, pricing control in the domestic segment, operational efficiency, emerging destinations offering cheaper services and products, etc.

For gain the regulator's perspective, Roychowdhury asked Prasad from CDSCO West Zone Mumbai how pharma regulators like him are dealing with digital disruptions and what are the CDSCO's strategies to match up to technology and harmonise with global regulators, while meeting the unique needs of India's patient population and industry. Prasad agreed with Dave on the influence of digital disruption within the pharma sector. Speaking about the regulatory challenges which the pharma sector is currently facing, he said that digital technology's advancements could be harnessed for better compliance and productivity. He cited the example of the Sugam portal, an e-governance platform by CDSCO, which has been developed to ease the process of conducting pharma business in India, be it applying for various licenses, awaiting approvals etc.

Conceding that the portal is still a work in progress, he indicated that certain certification processes were being upgraded. This upgradion will also include medical devices, WHO GMP certificates, blood bank inspections, vaccine licensing etc. Additionally, in the next two to three years, the entire system will shift to online mode and applicants can track their application status on their own. According to Prasad, at present, 50 per cent of the work has been become paperless.

Patel from IDMA emphasised that members should be trained to keep updated with the requirements of global markets. He also informed that the association is working closely with the government to understand the industry's requirements and taking proactive steps in this

direction. He also pointed out that the pharma industry needs to deploy AI and Big Data in a big way to spur its progress.

Moving from regulation and policy to corporate issues, Roychowdhury quizzed the panelists on their thoughts on capital allocation – what ideas do they have for growth? Where are they putting their money? What are the future avenues of growth?

Responding to these queries, Cipla's Upadhye spoke about the company's capex strategies and investments in technologies. He talked about how pharma companies are bringing different disruptions in treatment methods by using technology. He further mentioned that disruptions and innovations driven by technology will give rise to several opportunities, drive more value and improve compliance, however, it will come with a lot of challenges. He also emphasised on the need to innovate in packaging.

The fact that strategies need to flow from senior leadership was emphasised by many speakers. Malik from Glenmark Pharma talked about inclusive leadership strategies to thrive in a price competitive market condition. He pointed out how challenges differ from generic to innovation based companies and how leaders can turn these challenges into opportunities. He also mentioned that pharma leadership needs to be more inclusive and a mindset change to thrive in an era of disruption is vital.

Dangi from Danssen Consulting focussed on a few important characteristics needed in pharma leadership for the 21st century. In a disruptive world, Dangi emphasised that leaders need to think on their feet. Pharma companies need to focus on cost of quality

Pharma companies should be focussing on patient-centric technologies

Dr Ashok Bhattacharya
Executive Director, Takeda Pharmaceuticals India

Success of digitalisation is only possible when companies discuss their issues with regulators

BG Barve
Joint Managing Director, Blue Cross Laboratories

Pharma leadership needs to be more inclusive and a mindset change to thrive in an era of disruption driven by technology is pivotal

Kanish Malik
President & Global Head, Glenmark Pharma

If supply chain visibility is adversely impacted, it can have a serious impact on businesses, especially in the pharma industry

Louis Roy
Founder and President, Optel Group

Leaders need to be groomed to empower their manpower in an era of disruption

Gagan Harsh
Vice President, Bliss GVS

Qubec government is giving considerable support to lifesceince industry and opportunities for Indian pharma companies

Dominic Marcotte
Consulate General of Canada, Quebec Government

The advice of the pharmacist is absolutely required while designing the required healthcare system

Vadlamudi Rao
President, Commonwealth Pharmacists Association

Pharma companies should be looking into data enabling not data deleting

PBN Prasad
CDSCO DDC(I) CDSCO West Zone Mumbai

When a leader does not address the problem, then the leader becomes the problem

Shaunak Dave
CEO and MD, Optel Group, India

Canada and India are always looking for opportunities to work together and collaborate together

Annie Dubé
Consule générale du Canada

Pharma industry needs to deploy AI and Big Data effectively to spur its progress

Daara Patel
Secretary – General, IDMA

Data will be a great disruptor and the pharma industry needs to learn to utilise it effectively in a disruptive era

Vinay Pinto
Executive Director, Wallace Pharmaceuticals

non-performance and how improving quality can improve the companies' bottom line. He mentioned that Indian Pharma Inc has to move up the value chain. And hence, there is the need to move from cost-arbitrage to intellectual-arbitrage with effective use of innovative technologies. He also spoke on how Quality by Design will help pharma companies to improve their top lines. He raised concerns about the low value-high volume contribution of Indian pharma companies to the global pharma sales market and advised companies stuck between reverse engineering and R&D to start focusing on research.

Bhattacharya from Takeda Pharmaceuticals, India spoke on how important it is for pharma leaders to invest in the right infrastructure and the right technology to thrive in an era of disruption. He highlighted key issues being faced by the industry due to SUGAM portal and how it has disrupted the industry.

Talking about the Indian pharma industry and its complexities, Panandikar from Indoco Remedies shared insights on how the pharma industry needs to deploy disruptive technologies to drive growth and thrive in a volatile, uncertain, complex and ambiguous (VUCA) world and derive competitive advantages. She felt that there is a transformation happening in the supply chain post GST implementation and opined that companies are handling it positively. However, she feels that complexities and ambiguity need to be better understood by the industry.

Moving from the concerns within pharma companies to concerns of stakeholders in the pharma retail and consumer-facing segments, Roychowdhury asked for Rao's views on the role of pharmacists. As president of the Commonwealth Pharmacists Association, he believed that pharmacists within the healthcare sector need to be included in the decision-making process. He emphasised on empowerment of pharmacists to thrive in an era of disruption. Unless they are more empowered the industry might face serious problems in a tech-driven future.

Harsh from Bliss GVS informed about how the audit process has changed over the years and stressed on the need for leaders to train their people in handling disruptions with confidence. While sharing his perspective about skilling, he said that pharma industry has already begun training people to tap future opportunities and tackle future challenges.

Barve from Blue Cross Laboratories talked about meaningful collaborations and knowledge sharing which will help the pharma industry to deal with the challenges and optimise the opportunities in an era of disruption. He also emphasised on a point that success of digitalisation is only possible when companies discuss their issues with regulators. Pinto from Wallace Pharmaceuticals talked about how data is going to play a huge disruptor in innovation and emphasised that there is a need to learn how to leverage the data effectively. However, the data will be a great disruptor and pharma industry needs to learn to utilise it effectively.

The select CEO Roundtable discussed several other industry issues ranging from the need for pharma companies to reduce their dependency on imports of APIs and key intermediates. Leaders also explained how disruption can be introduced at all levels. The key is to make such disruptions sustainable. For example, the focus on sustainability through traceability technology will be disruptive in nature but can be a completive edge as well. Emphasising on the need to adhere to regulations set by different regulatory authorities, they highlighted how ethics and compliance are going to be the way every leader will be evaluated.

EP News Bureau

PRE EVENTS

PharmaTech Expo 2019 & LabTech Expo 2019 to be held in Ahmedabad in August 2019

The 10th edition will focus on the pharmaceutical machinery and equipment manufacturing sector and packaging, formulations and nutraceutical

PHARMATECHNOLOGYINDEX.COM will organise PharmaTech Expo 2019 & LabTech Expo 2019, a premier event dedicated to pharmaceutical innovation, technology and knowledge. Over a period, it has emerged as a crucial platform to showcase the latest innovation and technologies throughout all phases of the product lifecycle, focussing pharma manufacturing and processing technology, pharmaceutical systems and services. This year the focus will be on the pharmaceutical machinery and equipment manufacturing sector and pharmaceuticals packaging, pharmaceutical formulations, and nutraceutical.

The event is powered by Cadmach Machinery Co, sponsored by Chamunda Pharma Machinery and Drug Marketing & Manufacturer's Association (DMMA) is the event partner.

EP News Bureau

6th edition of PharmaLytica to be held in Mumbai from June 10-12, 2019

The 6th edition will see a new pavilion for API and excipients

THE 6TH edition of PharmaLytica will be held in Mumbai from June 10-12, 2019 at the Bombay Exhibition Centre in Goregaon (E). In the 6th edition of this international trade fair and conference, the pharma community can pick up on the latest industry trends, innovations and do business with analytical, laboratory, machinery and packaging industry. For the first time ever, the 6th edition will see a new pavilion for API and excipients.

PharmaLytica conference, collocated with the exhibition is the knowledge forum and important industry gathering that will bring an entire range of topics in analytical, outsourcing, laboratory, scientific and biotechnology sector. PharmaLytica is evolving as the leading marketplace for products and services along the entire value chain in niche segments within the pharma industry.

Express Pharma is the media partner for the event. Association partners are CIPI

The Innovation Gallery will display innovative products from leading exhibitors. Visitors can attend the gallery for free and at one location to see a wide range of new products and technologies in the market. More than 300+ exhibitors will congregate at the venue which will be spread around an area of 12000+ sq mts.

EP News Bureau

Mumbai to host analytica Anacon India and India Lab Expo

More than 400 exhibitors and 10,000 visitors are likely to take part in the events, scheduled to take place from April 16-17, 2019 in BEC

ANALYTICA ANACON India and India Lab Expo, the platform for the analysis, laboratory-technology and biotechnology market, will be held in Mumbai from April 16-17, 2019. Both the events have the potential for more than 400 exhibitors and 10,000 visitors in three halls.

Both events will cover the entire value chain for industrial and research laboratories. The focussed exhibition sectors will give visitors a comprehensive overview of the market, innovations and best-practice examples: analysis, biotechnology, laboratory technology, quality control / Measuring and testing.

The conference is tailored to the Indian market. The events will give profound insights into science and research. International experts will present the latest techniques in all application sectors.

The 12th edition of analytica Anacon India and India Lab Expo welcomed 41 companies from nine countries including Japan, China, South Korea, Germany, the US, Italy, Singapore, Switzerland and the UK. The participants displayed latest international quality products from laboratory instruments, analysis, diagnostics and biotechnology from September 6-8, 2018.

EP News Bureau

FLAVOURS & FRAGRANCES EXPO 2019 to be held in Mumbai

THE THIRD edition of India's B2B International Trade Fair 'FLAVOURS & FRAGRANCES EXPO 2019' will take place between April 16 and 17, 2019 at Bombay Exhibition Centre, Goregaon (East), Mumbai.

FLAVOURS & FRAGRANCES EXPO 2019 organised by Procyon Exhibitions & Events, is a B2B exhibition primarily designed to serve as a platform for the fragrance and flavour industry in terms of business and technical content. The event will feature both– Indian as well as international exhibitors and visitors and, is planned with a view to meet the latest requirements of the global fragrance and flavour industry.

The expo is expected to witness a number of eminent and important players from fragrance and flavour, aroma chemicals, essential oils, fruit, floral, spice and herbal extracts, aerosols, as well as packaging and private label manufactures.

> The platform will allow the exhibitors to showcase their brand, collect qualified leads, and connect with potential customers and partners

FLAVOURS & FRAGRANCES EXPO 2019 this year has announced the F&F Academic Tour 2019 that will take place from April 13 to 20, 2019. Tour participants will not only get the privilege of being part of Flavours & Fragrances Expo 2019 and the power packed Interact Conference 2019 but, will also get an opportunity to visit various cultivation farms which include mango farm, cashew farm, sandalwood farm, agarwood farm and green plantation aromatic sites.

The event will provide world-class infrastructure to exhibit and also gives an opportunity to network, business relations and launch new products as they are working with various segments such as FMCG and other industries like cosmetic, personal care, hair care, household care, air care, perfumes and Doe's, bakery and confectionery, beverage industry and beyond.

The platform will allow the exhibitors to showcase their brand, collect qualified leads, and connect with potential customers and partners. It aims to be a success by the sheer collaboration of the industry segments' key representatives, through promotional activities via print, electronic and outdoor media ensuring maximum reach to the target audience, thereby further boost promoting the brands globally.

EP News Bureau

Clinical trials: Breaking the taboo

India's share of global clinical trials, minuscule to start with, has seen a steady decline from 1.5 per cent a few yearsback to the current 1.2 per cent. This is indeed inadequate for a country with the second highest population and the highest disease burden in the world. However, the recently released rules bring some much needed clarity. Adherence to regulations and ethical processes will build confidence amongst stakeholders, including patients

By Akanki Sharma

On March 19, the Ministry of Health and Family Welfare (MoH&FW) announced the new set of rules for drugs and clinical trials. These rules bring some clarity on many aspects and could change the entire scenario of clinical trials and research in India. For instance, according to new regulations, the time for approving applications has been reduced to 30 days for drugs manufactured in India and 90 days for those developed outside the country. The same was mentioned by Drug Controller General of India (DCG(I)) S Eswara Reddy at the 12th Annual ISCR Conference, Delhi held in February.

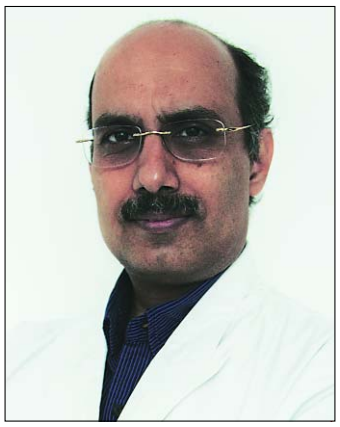
He had also said that "in case of an application for conducting clinical trial of a new drug or investigational new drug as part of discovery, research and manufacture in India, the application is to be disposed of within 30 days. And, in case there was no communication from DCG(I), the application will be deemed to have been approved."

The rules will be applied to clinical trials, bio-availability or bio-equivalence studies, new drugs and regulation of ethics committees relating to clinical trials and biomedical health research.

According to the Indian Society for Clinical Research (ISCR), the number of clinical trials being conducted in India, as a percentage of global trials, currently stands at 1.2 per cent, which was 1.5 per cent a couple of years ago. It is indeed inadequate for a country which has the second highest population and one of the highest disease burdens in the world.

As per the data available from www.clinicaltrials.gov, the US has close to 40 per cent of the clinical studies today, the European Union has close to 30 per cent, while China has almost ten times the number of studies that India has today

Dr Chirag Trivedi
President,
Indian Society for Clinical Research (ISCR)



Today, 90 per cent of diseases are still not treatable. Thus, patients need a treatment that can make them feel better, and there lies the value of research

Dr Sanjay Mittal
Senior Director – Clinical Cardiology and Head of Research, Medanta – The Medicity

Public awareness and education is an important requirement in clinical research. The public at large needs to understand the role that clinical trials play in the drug development process and the ethical and legal framework under which these are planned, conducted and reported

Suneela Thatte
Head, R&D Solutions,
IQVIA

The case of 'Ankit Sharma'

For about past one year, 59-year-old Ankit Sharma (name changed to protect the identity of the patient as per clinical trial guidelines) from Haryana has been undergoing a clinical trial in Delhi for high cholesterol. A type-2 diabetes patient, he had suffered heart attack in 2002 and had undergone a Coronary Artery Bypass Grafting (CABG).

Over the next 16 years, he made the rounds of 10 different hospitals and underwent 13 angiographies. The patient's next stop was All India Institute of Medical Sciences (AIIMS), where he underwent an electrocardiography (ECG) and then echocardiography (ECHO) came into the line. When quizzed by a doctor at AIIMS on number of angiographies, he said, "*Doctors kehte rahe, main karwata raha.* (Doctors told me to do them, I kept doing them)."

Distressed with continuous tests, he finally landed up at Medanta – The Medcity, where Dr Sanjay Mittal, Senior Director – Clinical Cardiology and Head of Research, Medanta – The Medicity advised him to join a clinical trial.

A stranger to this medical term, Sharma was a bit hesitant to pursue it. Nevertheless, once he was given a brief about the whole process, he filled the 'Informed Consent

Form' and joined the trial last year. After the required lab tests were done, he was put on a course of medication, which ultimately helped improve his condition. He remains part of the ongoing trial, and most of his reports are fine with a team of doctors monitoring his health. The trial is currently in phase three and the final result is expected to be out in about five years, inform his doctors.

Clinical trials: The key for drug development

Clinical trials is key for any drug development. It has been going on since decades and the pattern of diseases has been changing, informs Chirag Trivedi, President, ISCR. He quoted a speaker from the ISCR Conference panel discussion who had said that the burden of non-communicable diseases is such that some years down the line, the impact on the GDP of the nation, if you build roads or if you don't build roads, will be lesser, as compared to the entire negative impact on the GDP of the nation if you do not control diabetes and hypertension. "Thus, there is a need to come up with newer medication, as we are not yet able to find the cure for these diseases, we are just able to control them," Dr Trivedi had said.

Today, understanding of diseases is expanding which helps pharma companies to find out new molecules that patients need — that's where the essence of clinical trials lies.

Shedding light on the rules and regulations, Dr Trivedi informs, "Some years ago, due to certain new rules introduced then which were against the basic tenets of clinical trials, there was a significant drop in the number of global clinical trials conducted in India. Worldwide, clinical trials kept on taking place, but we were not a part of those trials, and hence those drugs would not be introduced in India because the law says that trial data is required to get a drug registered, so that it can be then available to treat patients."

What numbers speak

"We are 16 per cent of the world's population and have got 20 per cent of the global disease burden in India. It is such a large burden that we need to tackle it differently. As per the data available from *www.clinicaltrials.gov*, the US currently has close to 40 per cent of the clinical studies, the European Union has close to 30 per cent, while China has almost ten times the number of studies that India has today," informs Dr Trivedi.

In addition, he says that companies are supposed to register their studies into the public registry before they even enroll their first patient. It is a mandate since last 10 years.

Globally, it would cost $1.2 billion to $1.5 billion to get one drug from research to market, with the cost of many failures already built into this figure. The general

probability of success is that in phase one, there is just 10 per cent chance that the molecule will see the light of the day. At phase two, the odds improve to 20 per cent and at phase three, it's 60 per cent.

Dr Trivedi also informs that in 2010, we had 500 clinical trials in India, which dropped to 17 global clinical trials in 2013. Later, in 2014, these were approximately 70, which then increased to 97 in 2017, and similar numbers were witnessed in 2018 too.

The significant dip in the number of global clinical trials in 2013 caused some clinical research organisations (CROs) to shut shop post 2013. A further set back was the withdrawal of trials being run by leading academic centres like the US National Institute of Health (NIH) due to the stringent rules.

After several consultations between Central Drugs Control and Standards Organization (CDSCO) and industry representatives, the rules were amended in 2014 to make the process for clinical trials more balanced. Today, India is the only country where we have audio-visual recording of informed consents. The country also has a formula to determine compensation to be awarded for any trial-related injury, Dr Trivedi highlights.

"Earlier, the timelines were not defined for the approvals that the regulators will give for a clinical trial. Initially, it used to take approximately six to 18 months and thus many of the applications kept lying in the DGC(I)'s office. Global trials on the other hand get fast approval and this is where we fall behind while participating. In 2015, DCG(I) had said that the approvals will come in six months and the industry witnessed approvals being given around that time frame," says Dr Trivedi.

He further says, "Now, as per the current set of draft rules, they want to give incentives to the Indian companies to innovate. If an Indian company is doing the trial, they will deem the approval in 30 days if the company doesn't hear from the regulators, similar to the United States Food and Drug Administration (US FDA). For global clinical trials, where multiple countries are involved, the timeline is 90 days. Apart from it, the introduction of the pre-submission meeting or the post-submission meeting is a welcome step -- today, according to the current rules, we don't have a consultation meeting. For instance, if I have a query, there is no written recommendation for it."

ISCR had given a lot of recommendations on various aspects of these draft rules — comments on the timeline and on issues regarding discrepancies in the ethics committee, among others.

> Due to the number of global clinicial trials dipping significantly in 2013, some clinical research organisations (CROs) were shut down post 2013. And at that time, even the academic centre like National Institute of Health (NIH) of the US had said that with these rules, we cannot do trials in India

Attempts and efforts

For years, a lot of effort went in to educate people on various levels to make them understand the benefits of clinical research. The rules then got amended to become more balanced which protected the rights, safety and well-being of the patients and at the same time, facilitated the conduct of ethical clinical trials in India, emphasises Dr Trivedi.

He adds, "Currently, as per *www.clincialtrials.gov*, there are still close to 300,000 studies running worldwide, whereas India is involved in only about 1.2 per cent of those studies. With India being the second most populous country in the world and having approximately 1/5th of the global disease burden, we require more clinical research to develop drugs for our patients." Also, according to him, there are Indian as well as international guidelines that pharma companies and CROs have to follow in addition to taking approvals from the health authorities and institutional ethics committees.

The new regulation notifies that patients who are injured during a clinical trial conducted in India will be entitled to medical management for as long as required in the opinion of the trial's investigator, or until it is established that the injury is not related to the trial.

"Clinical trials in India went through a very challenging few years and we are still in the process of rebuilding the trust and confidence of sponsors in placing trials in India. It is incumbent on all those involved in clinical research to publicise the new rules so that we can have more clinical trials in India. Our patients are waiting," Dr Trivedi says.

Research means understanding your population

Patients undergoing clinical trials are an important part of the process. As Dr Mittal of Medanta – The Medicity puts it, every human being is a potential patient. He says, "90 per cent of diseases today are still not treatable. Patients need a treatment that can make them feel better, and there lies the value of research. We can just help the patient to have less symptoms and control the progress of the disease to some extent, but we don't have the best possible cure," he emphasises. He opines that research doesn't mean just clinical trials, it means understanding your population.

Sharing the example of a trial for a group of drugs targeting heart failure that took place some years ago, Dr Mittal says, "The global trial was completed and results were published in 2014. It was such a huge trial that there was remarkable difference between the old gold standard and the new drug. However, it was pre-maturely stopped in India because the interim analysis found that there was already drastic difference, but then it was approved only in 2018. It took so many years for the drug to come to the Indian market since the approval process took too long," he mentions.

He notifies that after 2012, there were certain knee-jerk reactions for which certain clauses were included into the regulations, which made it impossible to conduct most trials in India. That's the reason for the reduction in the number of trials post 2012.

In his view, as a clinical trial takes place, doctors look out for better treatments to make patients survive. "So, this population (pointing to the patient currently undergoing clinical trial for high cholesterol) has to be taken into consideration. If I don't treat with the new drug, 50 per cent of patients are still going to die when compared to the new drug where the 100 per cent survival is not possible. This thing was not taken into consideration and the report went out that there were huge number of deaths in the clinical trials," he informs.

How will the taboo break?

India saw a decline in the number of clinical trials between 2013-2015 due to an uncertain regulatory environment, says Suneela Thatte, Head, R&D Solutions, IQVIA. "However, on account of multi-stakeholder advocacy, the Indian regulators have taken several steps to restore balance and bring about transparency in regulations governing clinical research in the country," she adds.

Apart from it, she says, "Public awareness and education is an important requirement in clinical research. The public at large needs to understand the role that clinical trials play in the drug development process and the ethical and legal framework under which these are planned, conducted and reported. Also, it is equally important to spread awareness about clinical research within the medical community as many medical practitioners are not fully aware of the clinical research process and the rules and regulations governing it."

She also feels that the government should invest in good governance so that adherence to regulations and ethical processes can be monitored and non-compliance, if any, can be addressed appropriately, thereby building confidence across all stakeholders, including patients.

Thatte is appreciative of the efforts of the CDSCO and MoH&FW in bringing out the new clinical trial rules which not only promote innovation and scientific advancement, but also patient well-being. She says, "We hope that these balanced rules will bring about further clarity in regulations governing clinical research in India, promote ease of doing business and will in turn help the country to be a significant participant in global clinical research and drug development."

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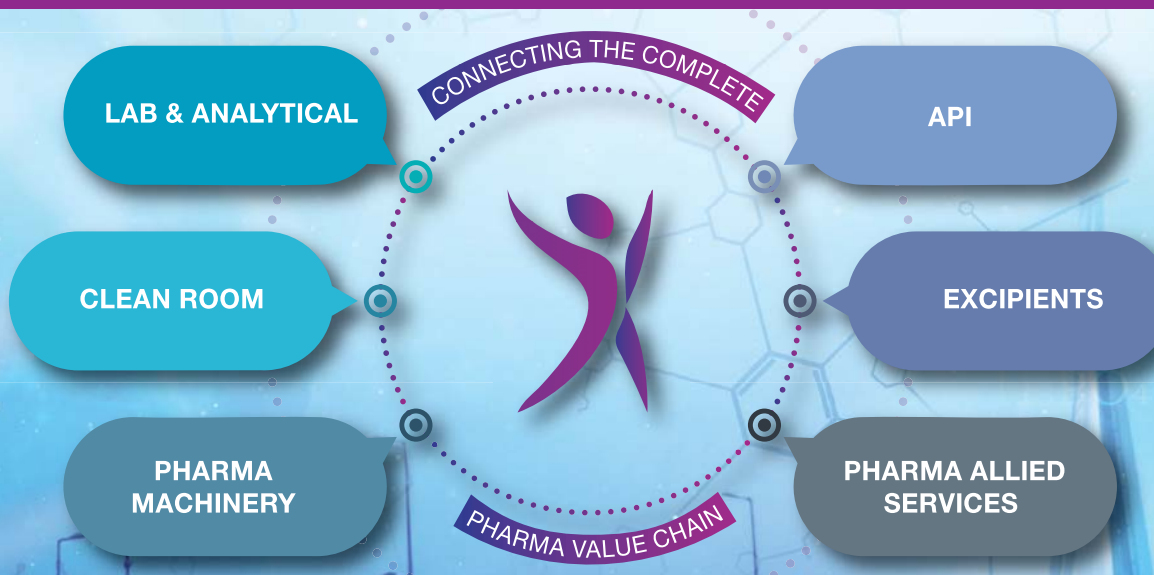

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PHARMA CXO SUMMIT 2019

DAY 1: 28-2-2019

Welcome address

Keynote Address: Transforming pharma with disruptive technologies

Special Address: Moving up the value chain

Panel discussion: Tech

Renaissance in Pharma Serialization: From Here to Eternity

Panel discussion: Role of Future Pharma CIOs

EXPRESS PHARMA EXCELLENCE AWARDS

Welcome Address

Address by Guest of Honour

Special Address

Introduction to Express Pharma Excellence Awards 2019

Presentation of Awards

Gala Dinner

DAY 2: 1-3-2019

Key Note Address

Panel discussion: Role of Intelligent Supply Chains

Industry 4.0: Driving efficient and Intelligent manufacturing

Panel discussion: Advancements in pharma packaging technology

Patient safety with technology

Enhancing patient engagement with technology

Vote of Thanks

Networking Lunch

INAUGURAL CEREMONY

(L-R) SG Belapure, Pharma Consultant; Shaunak Dave, CEO, Optel Asia; Dr Ajit Dangi, CEO, Danssen Consuting; AVPS Chakravarthi, Global Ambassador, World Packaging Organisation; Louis Roy, Founder & President, Optel Group and Viveka Roychowhury, Editor, Express Pharma

Following the successful first edition of the Pharma CXO Summit, The Indian Express (P) Ltd and *Express Pharma*, in association with the Optel Group, recently hosted its second edition with the theme 'Acing the value game: Leveraging disruptive technologies'.

Held at Novotel Airport, Hyderabad, Pharma CXO Summit 2019 witnessed leaders, experts and veterans of the Indian pharma industry come together to discuss on the trends and transformations in the industry.

It got off to an auspicious lamp lighting ceremony, followed by a Welcome Address from Viveka Roychowhury, Editor, Express Pharma.

Keynote address: Transforming pharma with disruptive technologies

Shaunak Dave, CEO, Optel Asia gave a rousing key note address on the first day of Pharma CXO Summit 2019 which centred on the potential of Indian pharma industry. Pointing out that India Pharma Inc has come a long way to become the Pharmacy of the World, he highlighted that its future progress would be dependent on the shift from volume to value.

Informing that management guru Michael Porter gave the concept of 'Value Chain' in 1985 and brought three important strategies: cost leadership, differentiation and focus, he opined that India too needs to adopt these strategies. He said, "India is great with production (volume) but this is the lowest value chain. We will have to focus on innovation, branding and unique way of new marketing to reach to consumers! "

Shaunak Dave, CEO, Optel Asia

He further said that to retain our leadership in global generics business, cost leadership strategy is applicable. And to increase product value, we must develop an innovative mind set. Disruptive technologies can help attain both!

He highlighted, "While other industries have been substantially disrupted by digital innovation, pharma industry has not been substantially affected thus far. However 'serialisation and track and trace' has opened immense possibilities to use disruptive technologies to scale up the value chain, right from raw material procurement to consumer engagement. I believe data generated from serialisation and its intelligent analysis (by AI) could be key drivers for attaining efficiency, visibility and integrity."

Concluding his address, he stated, "We have to take a call. Do we want to board the ship to explore new horizons or just stay on an isolated island and let the ship go! This is the objective of Pharma CXO Summit! These two days, let us brainstorm on this subject, exchange our views and let us plant the seed of 'disruptive technology' and grow the plant of 'value'."

> Serialisation and track and trace has opened immense possibilities to use disruptive technologies to scale up the value chain

Special Address: Moving up the value chain

Louis Roy, Founder & President, Optel Group started his address by lauding the Indian pharma industry for tracing a glorious journey and expanding its footprints to even far flung corners of the world. However, he went on to highlight that now it is time to enter the next phase of growth and this would require different sets of capabilities and new-age approaches.

He said that in order to stay competitive and profitable, and achieve their global ambitions, the companies would need to keep improving constantly. He also urged that there is a need for renewed focus on product safety and efficiency to tackle growing challenges in the life sciences industry.

He went on to highlight that an effective supply chain has a major role to play in the progress of the industry and explained how improving visibility in the supply chain can help derive significant benefits. He also pointed out that if supply chain visibility is adversely impacted, it can have very serious impact on businesses, especially in the pharma industry. He advised that technology is the tool to improve supply chain visibility and gain significant advantages, including profitability.

Louis Roy, Founder & President, Optel Group

He said that AI will bring in a lot of transparency and drive a lot of decisions with the help of data. He concluded that intelligent supply chains will be key to progress.

> We (Optel Group) are investing in the right solutions to help Indian pharma companies as they move up the value chain and continue to progress

He also assured that the Optel Group is investing in the right solutions to help Indian pharma companies move up the value chain.

Panel discussion: Tech renaissance in pharma

(L-R) Dr Firdosh S Gardin, Head – External Supply Operations India Cluster, Novartis India; SG Belapure, Pharma Consultant; Rashmi Ranjan Patra, Independent Pharma Advisor and Sanjay Jain, Executive Vice President – Operations, Amneal Pharmaceuticals

> Industry 4.0 in pharma will be characterised by factors such as smart manufacturing, intelligent supply chains, predictive maintenance, AI-based decisions etc
>
> **Rashmi Ranjan Patra,**
> Independent Pharma Advisor

> As the pharma industry continues to be transformed, the industry needs to develop the right capabilities and skills to deal with opportunities and challenges that arise in the future
>
> **Sanjay Jain,**
> Executive Vice President – Operations, Amneal Pharmaceuticals

As the pharma sector undergoes a transformation, technology has become a key factor to gain a competitive advantage. Therefore, the first panel discussion at Pharma CXO Summit 2019 was on the 'Tech renaissance in pharma.' Pharma veteran SG Belapure moderated the interesting panel discussion which comprised experts such as Dr Firdosh S Gardin, Head – External Supply Operations India Cluster, Novartis India; Rashmi Ranjan Patra, Independent Pharma Advisor and Sanjay Jain, Executive Vice President - Operations at Amneal Pharmaceuticals. They discussed on the need for rapid adoption of information and automation technology across the entire pharma chain to enhance the effectiveness and efficiency of existing operational systems.

> Automation and digitalistion is ushering a renaissance in pharma by enabling a culture of compliance, enhancing transparency, and eliminating data integrity issues
>
> **SG Belapure,**
> Pharma Consultant

The discussion touched upon various aspects such as the role of technology in ensuring regulatory compliance, meeting product specific demands, improving user experience, gaining a competitive edge and deriving a major differentiator in the value chain, be it about building a culture of compliance, enabling transparency, or eliminating data integrity issues. They said that Industry 4.0 in pharma will be characterised by factors such as smart manufacturing, intelligent supply chains, predictive maintenance, AI-based decisions etc. Therefore, digitalisation and automation will be significant in the next phase of growth.

Pointing out that the life sciences industry is becoming more proactive and progressive, panelists stated that automation is getting adopted in a big way across functions in the pharma industry. They pointed out that technology is enabling the industry in the development of next generation of capabilities, be it understanding business and regulatory environments, robust product manufacturing, improving operational processes or scaling-up/launching of products from R&D.

Measures and strategies that pharma companies need to take to become future-ready were also discussed. The leaders explored the development of more astute models for the pharma sector to deal with the requirements of the future. The experts were emphatic that success and sustainability of pharma companies would depend on the selection and implementation of the right technology in the right place. They concluded the discussion with the advice that pharma companies should invest in disruptive technologies to tap the opportunities in areas like personalised medicines, biosimilars and implantable devices.

> Pharma industry is becoming more predictive and preventive in nature. Technology will have a huge role to play in the era of personalised medicines as it would help us collect and apply data more effectively
>
> **Dr Firdosh S Gardin,**
> Head – External Supply Operations India Cluster, Novartis India

Panel discussion: The future of pharma CIOs

(L-R) Dalveer Singh, Head-IT, Kusum Healthcare; Venkata Naga Prasad Vaitla, CIO, Granules India; Gyan Pandey, Global CIO, Aurobindo Pharma and Suryamohan Surumpudi, Sr Director & Head of Quality IT, Dr Reddy's Laboratories

> CIOs have a major role to play in generating data and shaping the way information is accessed and applied in pharma companies. They have to utilise predictive analysis to drive the growth of their organisations
>
> **Venkata Naga Prasad Vaitla,** CIO, Granules India

> As we move towards automation and try to ensure compliance with global laws, the role of CIOs are becoming more complex. They have evolve from being just enablers to take on more collaborative and strategic roles
>
> **Gyan Pandey,** Global CIO, Aurobindo Pharma

The role of CIOs has transitioned from that of a being who keeps the IT infrastructure running to someone who is attuned to the company's technological needs to meet current and future challenges. The CIO has become pivotal to the growth of a company. As the life sciences industry finally implement IT best practices and become more tech-savvy, the impact of CIOs in this industry is going to be profound.

Hence, Pharma CXO Summit 2019, a thought leadership platform for the life sciences industry, witnessed a panel discussion titled, 'The Future of Pharma CIOs.' As the title suggests, the discussion saw an expert panel comprising Venkata Naga Prasad Vaitla, CIO, Granules India; Gyan Pandey, Global CIO, Aurobindo Pharma; Suryamohan Surumpudi, Sr Director & Head of Quality IT, Dr Reddy's Laboratories and Dalveer Singh, Head-IT, Kusum Healthcare, examine and explore the future of pharma CIOs.

> Rapid adoption of technologies like block chain, IoT and machine learning are transforming the pharma market. Therefore, CIOs are becoming business partners offering strategic value to strengthen businesses and achieve goals
>
> **Dalveer Singh,** Head-IT, Kusum Healthcare

The discussion covered various facets such as the CIOs' role and the opportunities they have to shape the way information is accessed and applied in their company. Pointing out that the role of CIOs are growing more complex, the experts highlighted that the CIO is not just an enabler but also a collaborator in the growth and progress of the pharma industry. They explained the strategic value of CIOs in strengthening business understanding and achieving the goals of each business unit.

The CIO leaders on the panel advised their peers that modern technologies are very nimble, very flexible, and very adaptable, they make organisations more agile and responsive. They highlighted that the CIOs need to select the right technology for his company to be a facilitator of its success. They further explained that the role of pharma CIOs will involve deploying technology to get data insights which can provide pivotal business intelligence and will help their companies to grow exponentially. They also deliberated on the deploying predictive analytics to better position their drugs, improve relationships with customers, and gain a competitive edge. The conversation also highlighted the need to develop strategies to fortify cyber security as the pharma industry deals with very sensitive and crucial data.

Experts established that the CIOs have a very crucial role to play in the future. They are walking into boardrooms and delivering their strategies to provide competitive advantages to their organisations. The discussion concluded with the observation that as they emerge as the cornerstone for a business with the skills to influence and motivate people in various ways to drive the business forward, CIOs could be the CEOs of the future.

> Today's CIOs are moving into the boardrooms of pharma companies to deliver their strategies to leverage IT and digital technologies to gain significant competitive advantages
>
> **Suryamohan Surumpudi,** Sr Director & Head of Quality IT, Dr Reddy's Laboratories

Serialisation: From here to eternity

Arjun Guha Thakurta gave an overview on the current regulatory frameworks in the world and explained the regulations and laws in the US and the EU with regards to serialisation. He highlighted that pharma companies need to look at getting their serialisation systems in place as soon as possible to stay relevant in global markets and continue their growth trajectory. He shared details of the impact and implications of Falsified Medicines Directive and discussed strategies that would help pharma companies to deal with it. For instance, he elaborated on the packaging-tamper verification features for medicinal product packaging product that would be mandatory under the FMD.

Arjun Guha Thakurta, Life Sciences Director - Operations, Life Science Consulting, a Conval Group Company

Among other things, he also emphasised on the importance of data in ensuring future progress of the pharma companies and spoke on maintaining data repositories. He also stressed on how important it is to check and recheck all the data that goes out from a company to ensure data integrity. In his opinion, ensuring that the information is uploaded to the repositories system before the medicinal product is released for sale or distribution by the manufacturer and that it is kept up to date thereafter is an important quality attribute to consider. He pointed out that technology is ushering several revolutions in the life sciences industry. For instance, he expounded on the role of these technologies in acquiring, maintaining and applying data effectively in the pharma industry. He said that block chain can transform the pharma sector. It can help make data incorruptible if effectively implemented.

> “Blockchain can revolutionise the pharma sector. It can help make data incorruptible if effectively implemented

Thus, in his address he touched upon various aspects of serialisation and other issues that have growing relevance in the life sciences industry.

1 MARCH 2019, DAY 2

Keynote address: A harmonised approach to serialisation

Sachidanantham Swaminathan, Chief General Manager, GS1 India, in his keynote address, gave a very insightful presentation on various pivotal aspects of the life sciences industry. He started his session with an over view of how technology is transforming healthcare and listed out some technologies such as remote monitoring, genomics-based medicine, big data disease tracking, etc., which would have huge impact in future.

He also gave a rundown on GS1 India, its objectives and its activities and informed that GS1 India was set up under the Ministry of Commerce in India to identify, capture and share data with industries to improve compliance and quality. He highlighted that GS1 Standards are being applied in various projects and endeavours in Indian healthcare. They are also working with the Ministry of Defence to improve quality of healthcare.

Sachidanantham Swaminathan, Chief General Manager, GS1 India

Stating that GS1 helps pharma companies to meet regulatory requirements, he informed how it is working to enable and implement serialisation. Pointing out that there is an ever growing number of coding and serialisation requirements, he asserted that serialization, electronic tagging and track & trace technologies are powerful tools in the fight against counterfeiting of drugs. He further informed that GS1 is working towards a globally harmonised approach to serialisation.

He also elaborated on GS1 India initiatives with the government such as a pilot project with NITI Aayog on drug authentication with blockchain, DAVA-Drug Authentication and Verification App, Registry of Hospitals in Network of Insurance (ROHINI), in partnership with Insurance Information Bureau of India (IRDA) etc.

> “Serialisation is a powerful tool in the fight against counterfeiting. GS1 is working towards a globally harmonised approach to serialisation

Panel discussion: Role of intelligent supply chains

(L-R) Nihar Medh, VP and Global Procurement Head, Cipla; Jinaraja Sanjeev Poojary, VP Operation, Aleors Dermaceuticals; Anil Agrawal, COO, Apnar Pharma and Lokesh Sharma, Sr Director - Supply Chain, Eisai Pharmaceuticals India

> Predictive analytics is changing the way we procure and supply products in pharma and protecting the quality of the products across the supply chain
>
> **Anil Agrawal,** COO, Apnar System

The role of an effective supply chain to become a major differentiator in the value chain, as companies seek the next phase of growth, is pivotal. And, pharma companies have awakened to the revenue building, cost-reducing potential of supply chain excellence. Hence, the panel discussion titled 'Role of intelligent supply chain', saw experts analyse the adoption and implementation of emerging new technologies in their supply chain system to create strategic opportunities for their organisations and build competitive advantages in various functional areas of management.

The panelists in this session, Nihar Medh, VP and Global Procurement Head, Cipla, Lokesh Sharma, Sr Director - Supply Chain, Eisai Pharmaceuticals India, Anil Agrawal, COO, Apnar Pharma, and Jinaraja Sanjeev Poojary, VP Operation, Aleors Dermaceuticals, had a detailed discussion on the role of a fully-integrated global supply chain to enable growth for pharma companies looking to move into new markets.

They highlighted the significance of an intelligent supply chain system for pharma companies to reduce manpower, eliminate errors, increase traceability and transparency, optimise quality and collect valuable data which will enable pharma companies to gain invaluable business intelligence. They pointed out that predictive analytics is changing the way we procure and supply products in pharma. It is also helping to protect the quality of the products across the supply chain.

> Supply chain systems have evolved tremendously and emerged as a strategic tool to drive value in pharma organisations and serve patients better
>
> **Nihar Medh,** VP and Global Procurement Head, Cipla

Pointing out that life sciences organisations should pay attention to details and ensure that each link in the supply chain is functioning properly to bring in better efficiencies in supply chain management, the panelists also deliberated on effective implementation of information technology, communication technology and automatic identification technology to build an intelligent supply chain. They elaborated on the need for adoption of data-analytics through intelligent supply chain to understand demand patterns and demand shift trends across different geographies as well as manage regulatory compliance within the supply chain and through the supply chain.

The experts also expounded how important people are in building an excellent supply chain system. While technology can bring in new efficiencies in a supply chain, we also need heads of supply chain systems to understand business objectives and have a comprehensive understanding of all the activities of the company. The experts also cautioned that supply chains are expected to be very agile and hence governance and monitoring mechanisms in supply chain management are very crucial. Just setting up processes aren't enough, it needs to be ensured that they are being implemented efficiently.

> IoT will be crucial to build an intelligent supply chain and turning it into a significant competitive advantage for any pharma company
>
> **Lokesh Sharma,** Sr Director - Supply Chain, Eisai Pharmaceuticals India

> Technologies like blockchain, IoT, AI can help in generating and protecting data through the supply chains and deploying them to bring in better efficiencies in the organisation
>
> **Jinaraja Sanjeev Poojary,** VP Operation, Aleors Dermaceuticals

Panel discussion: Advancements in pharma packaging technology

Packaging has emerged as a crucial differentiator in the pharma industry. Therefore, the discussion on 'Advancements in pharma packaging technology' at Pharma CXO Summit 2019 probed and analysed how packaging has emerged as a valuable tool to address unmet needs and gain a competitive advantage in industry. It also examined how pharma companies can utilise packaging to tackle challenges like cost reduction, regulatory compliance, altering demographics, varying treatment patterns, and counterfeiting.

It had an eminent panel comprising Chakravarthi AVPS, Global Ambassador, World Packaging Organisation; Prabir Das, Head - Pkgg Tech Services, OSD (India), Mylan Laboratories; Chandi Prasad Ravipati, General Manager, Aurobindo Pharma; Shivaji Chakraborty, Assistant General Manager, Packaging Development, Fresenius Kabi Oncology; Munindra Roy, Functional Lead - Packaging Development, Gland Pharma and Barun Dey, Director, Packaging Development, Dr Reddy's Laboratories.

(L-R) Barun Dey, Director, Packaging Development, Dr Reddy's Laboratories;Munindra Roy, Functional Lead - Packaging Development, Gland Pharma; Chandi Prasad Ravipati, General Manager, Aurobindo Pharma; Chakravarthi AVPS, Global Ambassador, World Packaging Organisation; Prabir Das, Head - Pkgg Tech Services, OSD (India), Mylan Laboratories and Shivaji Chakraborty, Assistant General Manager, Packaging Development, Fresenius Kabi Oncology

The experts conversed on different points such as evolution of packaging solutions from traditional functions of containment and protection to provide significant value-additions. They also highlighted that packaging, if deployed effectively and innovatively, can help curb non compliance greatly and provide significant benefits to pharma companies. Speaking on the importance of pharma packaging as the life sciences sector moves towards sustainability, value-based care and patient-centric medicine, they discussed the need for pharma companies to make a major shift in their strategy and structure to integrate newer packaging systems and processes.

Further, the packaging leaders showcased how technology can be great tool in building and integrating robust and intelligent packaging solutions in pharma companies. They demonstrated that technology can help improve quality of packaging material, enable packaging automation, enhance safety and efficacy of packaging solutions, increase innovation in pharma packaging and make packaging solutions more cost-effective.

The discussion concluded with the message that embracing quality by design in pharma packaging as it moves away from product-centric packaging to patient-centric packaging is the need of the times.

> Packaging, as the final point of contact with the patients, has evolved way beyond its traditional purposes in pharma. Today, it can be a crucial differentiator to achieve business excellence
>
> **Chakravarthi AVPS,**
> Global Ambassador,
> World Packaging Organisation
> (Moderator)

> Develop packaging solutions which are patient centric as the correlation between patient adherence and packaging is very significant
>
> **Prabir Das,**
> Head - Pkgg Tech Services,
> OSD (India),
> Mylan Laboratories

> Improper and in faulty packaging and labelling practices can cause severe adverse impact and result in non-compliance
>
> **Chandi Prasad Ravipati,**
> General Manager,
> Aurobindo Pharma

> Embrace quality by design in pharma packaging as it moves away from product-centric packaging to patient-centric packaging
>
> **Shivaji Chakraborty,**
> Asst. General Manager,
> Packaging Development,
> Fresenius Kabi Oncology

> Technology can be great tool in building and integrating robust and intelligent packaging solutions in pharma companies
>
> **Munindra Roy,**
> Functional Lead - Packaging
> Development,
> Gland Pharma

> Packaging can add a lot of value to a pharma product. Therefore, it is time to look at various aspects such as machinery, automation and digitalisation technology, IT etc. to drive innovation in this sector
>
> **Barun Dey,**
> Director, Packaging Development,
> Dr Reddy's Laboratories

Industry 4.0: Driving efficient and intelligent manufacturing

Rashmi Ranjan Patra, Independent Pharma Consultant gave a detailed presentation on the evolution from Industry 1.0 to Industry 4.0.

Patra informed that Industry 4.0 will be defined by the use of cyber-physical systems. He stated that in Industry 4.0, it would be essential to have fully integrated manufacturing systems which would enable sharing information across the plant floor, ensure real-time data and visibility of operations, continuous/proactive actions, technology-driven with less human intervention and use of predictive analysis.

He urged industry players to invest in systems and technologies which will help them improve productivity through optimisation and automation, enhance product quality with real time monitoring, gain business continuity with advanced maintenance; utilise predictive maintenance, leverage data and analytics to improve processes, and leverage real time data for enhanced supply chain processes and operational efficiency.

Rashmi Ranjan Patra, Independent Pharma Consultant

He also elaborated on why it is necessary for the pharma industry, one of the most regulated industries in the world, to match the technology trends and apply them effectively to deal with a lot of their challenges such as regulatory compliance, cyber security and data security concerns, raising their competency levels, connecting all resources etc. He concluded with the message that pharma leaders should invest in futuristic technologies and bring in a mindset change to thrive in Industry 4.0.

> Players must implement data effectively to improve operations, empower supply chain systems, enable business continuity in Industry 4.0

Patient safety with technology

Bejon Misra, International Consumer Policy Experts and Founder, Safe Medicines India was the last speaker of Day 2. He gave a talk on how technology can play an important role in patient safety, which is a guiding principle for the life sciences industry.

He informed about an expert group formed by former Prime Minister Manmohan Singh in 2006 to look into how technologies can play an important role in detecting spurious medicines and sub standard diagnostics centres.

Misra was also a part of this expert group. He represented the patients' perspective, and after extensive research and analysis, the group had come out with a report on the role of technology in fighting counterfeiting. Though the report was not published entirely, Misra took permission with the government and shared certain details with his industry friends.

Bejon Misra, International Consumer Policy Experts and Founder, Safe Medicines India

Revealing some findings from the report, Misra informed that the group realised many pharma companies which were using technology to trace and track their products in the market place were not sharing information in the public domain. When the Group raised queries to pharma companies about why are they not sharing it with consumers, the common replies they received that if they do so then, consumer might feel that their companies' products are most counterfeited and it might cause them a set back. Considering this fact, the expert group recommended to the government to make trace and track mandatory as traceability plays an important role and product recall will not happen without a robust traceability mechanism.

> Technology can be very important in ensuring patient safety - a guiding principle for the life sciences industry

He also mentioned that *Express Pharma* must bring out a report on the learnings gained at Pharma CXO Summit 2019, so that it can presented to policy makers to drive progress in pharma industry.

He also stressed on a point that people must not resist change. The pharma industry must embrace the change being ushered by technology and leverage it for the growth of the sector and the benefit of the patients.

Enhancing patient engagement with technology

(L-R) Bejon Mishra, International Consumer Policy Experts and Founder, Safe Medicines India; Praveen Wadalkar, Co-Founder and CEO, Techizer; Rinkesh Shah, Associate Director, Cipla and Goldee Pardesi, Associate Director, Dr Reddy's Laboratories

The dawn of the digital era has enabled pharma companies to bring a paradigm shift in its interactions with doctors and patients. The panel discussion on 'Enhancing Patient Engagement with Technology' began a dialogue within the pharma marketing community on how they can engage with patients better in order to serve their needs more effectively and achieve marketing objectives within the regulatory framework of the industry. The discussions focussed on four areas, namely: understanding the dynamics of digital marketing strategies in the life sciences industry, new age marketing strategies to engage with the patients, deploying digital technology platforms to efficiently reach healthcare professionals and consumers and ethical marketing practices for regulatory compliance.

During the discussion, panelists pointed out that pharma marketing leaders need to think beyond the pill and must reach out to patients with innovative strategies aided by digital technologies.

Discussing on the kind of marketing campaigns that exists today and the way digital technologies are changing these initiatives, they highlighted that technologies such as AI, IoT and blockchains have helped to improve efficacy and effectiveness of existing marketing campaigns and reach out to end users - patients. They also mentioned that technologies such as AI and IoT are facilitating companies to collect immense useful data as well as helping in apllying data more effectively. Whereas Blockchain is helping to provide much needed data integrity.

Moreover, experts on the panel also spoke about IoT, ChatBox, Mhealth apps etc., which can aid pharma marketing experts to reach out to patients and provide them with valuable insights on various diseases and their management.

> The moment we start looking beyond incrementals and minimal changes, that is when technology will bring in the disruptive changes in the market and can be the biggest profit making exercise for companies, government and everyone in the ecosystem
>
> **Rinkesh Shah,**
> Associate Director,
> Cipla

> While bulding strategies for marketing it is important that we all start to think beyond the pill
>
> **Goldie Pardesi,**
> Associate Director,
> Dr Reddy's Laboratories

> If you really want to optimise patient outcomes and ROI, invest in engaging patients with the help of technology
>
> **Praveen Wadalkar,**
> Co-Founder and CEO, Techizer

> Technology and packaging go hand in hand. It is important to reach out the young students and strike the right partnerships for providing and educating patients
>
> **Bejon Mishra,**
> International Consumer Policy Experts and Founder, Safe Medicines India

Express Pharma Excellence Awards honour export leaders of India Pharma Inc

This year's winners were chosen on the basis of exports turnover and exports growth rate

All the winners of Express Pharma Excellence Award 2019

Express Pharma Excellence Awards, held recently in Hyderabad was one of the highlights of the Pharma CXO Summit 2019, a thought leadership platform for the leaders, experts and veterans of the Indian pharma industry to discuss on the trends and transformations in the industry.

Express Pharma Excellence Awards is an endeavour to boost Indian pharma companies and encourage them to develop export strategies to stay at the top of the game and acknowledge the players who are already expanding India Pharma Inc's reach to all corners of the world.

The second edition of the awards continued with the initiative of acknowledging and celebrating the successes of Indian pharma companies overseas and their critical contributions in establishing India as a leading export destination. This year's winners were chosen on the basis of their exports turnover and exports growth rate.

The awards nite began with a Welcome Address by Viveka Roychowdhury. She welcomed all the delegates and explained the methodology of Express Pharma Excellence Awards. She said, "Exports are a major source of revenue for the Indian pharma industry, making up about 50 per cent of the industry's sales. Thus, exports are a good barometer of the health of the pharma sector. Which is why Express Pharma's Pharma Excellence Awards focusses on exports growth for the second edition as well."

> Express Pharma Excellence Awards is an endeavour to boost Indian pharma companies and encourage them to develop export strategies to stay at the top of the game and acknowledge the players who are already expanding India Pharma Inc's reach to the world

She explained that the vision behind the Awards is to recognise and honour pharma companies which have shown noteworthy export growth over the past two financial years. And over the past decades, these are the companies which have served to make India the Pharmacy of the World.

Shaunak Dave, CEO, Optel Asia also addressed the audience and reiterated, "We conceived this idea (the awards) to celebrate our achievements and gear up for the future challenges! Let us celebrate our achievements and brainstorm how we can create an integrated life science sector to scale up on the value chain and become a global leader, not only by value but also volume, without forgetting our sublime reason for being in this business: To ensure 7.7 billion people are healthy and happy!

Next, Annam Visala, Deputy Drugs Controller, Hyderabad gave the Chief Guest's Address at Express Pharma Excellence Awards. She lauded the initiative and spoke on the evolution of the India Pharma Inc. She also highlighted how technology is transforming the industry and urged all the stakeholders to adopt these advancements and implement them effectively to further their progress.

Louis Roy, Founder and President, Optel Group also welcomed the delegates and congratulated all the winners of Express Pharma Excellence Awards 2019.

Subsequently, Roychowdhury, Dave and Roy presented the awards to the winners. Visala, AVPS Chakravarthi, Global Ambassador, World Packaging Organisation; and Sachidanantham Swaminathan, Chief General Manager, GS1 India; also joined them in giving away the awards.

The companies were awarded on the basis of the companies' FY-17 and FY-18 exports turnovers based on exports growth, in four categories:

- Rs 5000 crores exports turnover and above
- Rs 2000 crores exports turnover to Rs 5000 crores exports turnover
- Rs 500 crores exports turnover to Rs 2000 crore exports turnover
- Rs 100 crores exports turnover to Rs 500 crores exports turnover

This year's winners are as follows: Aurobindo Pharma, Mylan Laboratories, Cadila Healthcare, Cipla, Intas Pharma, Gland Pharma, Alkem Laboratories, Amneal Pharmaceuticals, Jubilant Life Sciences, Laurus Laboratories, Shalina Laboratories, Serum Institute of India and Bharat Biotech.

EP News Bureau

WINNERS OF EXPRESS PHARMA EXCELLENCE AWARDS 2019

Category: Turnover base above Rs 5000 crores

Atul Shastri, Associate President; and Chandi Prasad Ravipati, GM, Packaging Development from Aurobindo Pharma receive the award

Category: Turnover base above Rs 5000 crores

Arvind Kanda, Head of Commercial (ARV, API, South Africa and Sub-Saharan Africa), Mylan; Prabir Das, Head - Pkgg. Tech. Services, OSD (India), Packaging Technical Services, Mylan Laboratories and Satish Mahanti, Head Commercial-API, Mylan Laboratories receiving the Express Pharma Excellence Award 2019

Category: Turnover base Rs 2000 crores - Rs 5000 crores

Anuj Singh, HR Lead, Cipla receives the award

Category: Turnover base Rs 2000 crores - Rs 5000 crores

Ganesh Nayak, COO and Executive Director, Cadila Healthcare receives the award

Category: Turnover base Rs 2000 crores - Rs 5000 crores

Giridhar Venugopal, Executive Vice President, Intas Pharma; Ravi Bhagavtulla, Sales Manager, Suprima, Intas Pharma; and Vinay Kumar, Regional Business Manager, Supriva, IntasPharma receive the award

Category: Turnover base Rs 500 crores - Rs 2000 crores

Munindra Roy, Sr Manager- Packaging and Development, Gland Pharma receives the award

WINNERS OF EXPRESS PHARMA EXCELLENCE AWARDS 2019

Category: Turnover base Rs 500 crores - Rs 2000 crores

Vijay Yelwatkar, AVP IT, Alkem Laboratories; Nitish Kumar, AGM, Alkem Laboratories; and Naresh Rao, Sales Manager, Alkem Laboratories receive the award

Category: Turnover base Rs 500 crores - Rs 2000 crores

Sanjay Jain, President, Amneal Pharma receives the award

Category: Turnover base Rs 100 crores - Rs 500 crores

Ramana Rao CHV, Vice President, IPM, Laurus Labs; V Uma Maheswer Rao, Executive Vice President, Generics(API – R&D), Laurus Labs; and Pawan Kumar, Senior Manager, Laurus Labs receive the award

Category: Turnover base Rs 100 crores - Rs 500 crores

Neelam Virji, Promoter, Shalina Laboratories receives the award

Category: Best Performing Vaccine Companies

Dr Jala Ella Chary receives the award Bharat Biotech

Category: Best Performing Vaccine Companies

Ajay Malawade, Additional Director (Q.A.), Serum Institute of India receives the award

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ACING THE VALUE CHAIN: LEVERAGING DISRUPTIVE TECHNOLOGIES

UPDATES

DuPont releases clinical study results demonstrating benefits of high-potency and multi-strain probiotic formulations

Nutrients journal publishes new study suggesting higher doses of a DuPont multispecies probiotic formulation may permit more benefits for healthy adults

Results of a clinical trial performed by Taverniti and colleagues from the University of Milan (IT) suggest that ingesting higher doses of multispecies probiotic formulations may permit higher, earlier and longer recovery of probiotics in feces of healthy adults.

The aim of the study, published in the journal *Nutrients*, was to understand the effect of bacterial count on the transient colonisation in the human intestinal tract of four different DuPont probiotic strains administered in a single, commercially available, formulation. The four DuPont strains under investigation were: Bifidobacterium lactis Bl-04, Lactobacillus acidophilus La-14, Lactobacillus plantarum SDZ-11 and Lactobacillus paracasei SDZ-22. The study compared the formulation at two different doses–seven billion and 70 billion colony forming units (CFU), with the goal of measuring cell recovery in faeces after oral administration.

In the study, 40 healthy adults of both genders aged between 18 and 60 were randomly divided into two equal groups. A single-blind, two-arm parallel microbiological pilot study was then conducted in which the volunteers, depending on which group they were assigned to, consumed either the seven billion or 70 billion CFU formulation daily for two weeks. They were then monitored for a follow-up period of an additional two weeks. For the duration of the study, the volunteers were instructed to follow their usual diet (without the intake of any other probiotic products) and to collect 19 fecal samples in total, in accordance with the study design. These samples were then tested for probiotic recovery.

The study found the first day of detection of the four probiotic strains was earlier in the high dose group when compared to that of the low dose group. Furthermore, on the last day of probiotic consumption, viable cells of all four probiotic strains were recovered from those consuming the 70 billion CFU dose, whereas recovery was not successful for five volunteers who consumed the seven billion CFU dose.

During the follow-up period of two weeks after consumption stopped, viable recovery was significantly higher and detectable longer in those who consumed the higher dose formulation than those who consumed the lower dose one. This demonstrates that higher doses of bacterial cells in probiotic formulations may allow for a higher, earlier and longer recovery time suggesting that higher doses may lead to an earlier and more stable transient colonisation. In addition, the study shows that strains belonging to diverse taxa may be combined in a single formulation and be selectively quantified upon digestion.

"Higher doses of probiotics result in higher levels of fecal recovery; this has been shown before. What is fascinating with the Taverniti study is they show a higher dose also leads to an earlier and longer detection of the consumed probiotics; suggesting a more stable 'colonisation'. This begs the question if a higher probiotic dose also leads to earlier and more reliable health benefits," stated Arthur Ouwehand, Technical Fellow, DuPont Nutrition & Health.

Valerie Delahaye, Global Leader of Dietary Supplements for DuPont Nutrition & Health, added, "Since we are experiencing a clear trend toward multi-strain and higher potency probiotic formulations in many markets around the world, it is encouraging to see study the results which may assist in better understanding the benefits of these formulations from a consumer perspective."

EP News Bureau

GSK reports positive data for experimental blood cancer drug

GLAXOSMITHKLINE received a boost for its oncology research, as it reported further positive data from a study of its experimental drug for blood cancer.

The DREAMM-1 study of patients with relapsed/refractory multiple myeloma confirmed the potential effectiveness of the medicine, GSK said. "We are aggressively advancing this potential new medicine and plan to have pivotal data to support its filing by the end of this year," Hal Barron, Chief Scientific Officer and President, R&D, GSKsaid.

The company said the data demonstrated a median progression-free survival - the length of time doctors could keep the cancer under control - of 12 months.

Multiple myeloma, which is the second most common blood cancer in the US, is generally considered treatable but not curable.

GSK received a 'breakthrough' designation from US regulators for the drug in 2017, paving the way for a speedy regulatory review of the anti-B-cell maturation antigen (BCMA) drug for multiple myeloma. This was followed by similar priority treatment granted by the European Medicines Agency.

Reuters

Biogen scraps two Alzheimer drug trials, wipes $18 billion from market value

The two halted trials were in the final stages of testing aducanumab in patients with mild cognitive impairment due to Alzheimer's and mild Alzheimer's disease dementia

BIOGEN and partner Eisai Co are ending two late-stage trials of their experimental Alzheimer's disease drug aducanumab, a major setback in the quest to find a treatment for the mind-wasting disease and a blow to Biogen.

Experts had seen aducanumab as one of the last tests of the hypothesis that removing sticky deposits of amyloid from the brain of patients in earlier stages of the lethal disease could stave off its ravages, which include loss of memory and the ability to care for oneself.

The decision was based on a so-called futility analysis of aducanumab data by an independent monitoring committee that determined the trials had little hope of succeeding.

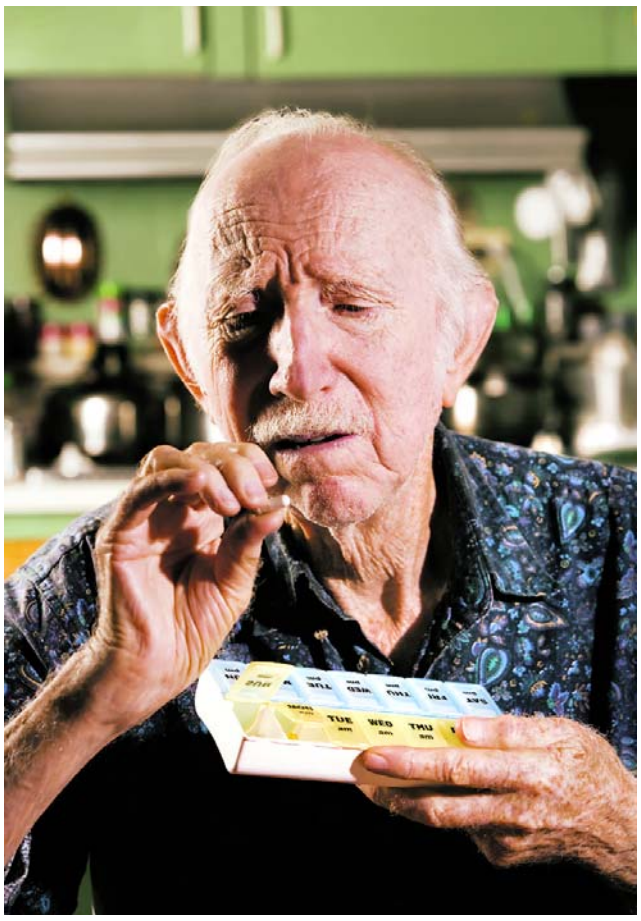
Eisai in July had touted promising but confusing 18-month results from another Alzheimer's drug, BAN2401, being co-developed with Biogen. That drug failed in a 12-month analysis.

Investors had been cautiously optimistic about aducanumab following early promising data. Without potential future revenue from Alzheimer's, Biogen has poor growth prospects as it faces patent issues over its big-selling multiple sclerosis drug Tecfidera and possible competition to spinal muscular atrophy drug Spinraza, Wall Street analysts said.

"We view this as a transformative failure for Biogen's pipeline," RBC Capital Markets analyst Brian Abrahams wrote in a research note.

Abrahams, who reduced his Biogen price target to $240 per share, said further declines were likely given that "investors owned Biogen to not miss out on what could have been one of the biggest blockbuster products in the pipeline of large biopharma."

Any successful treatment for Alzheimer's, which affects about 5.7 million Americans, is virtually guaranteed to become one of the world's top-selling drugs. But efforts so far have had a dismal track record, with more than 100 failures.



The two halted trials were in the final stages of testing aducanumab in patients with mild cognitive impairment due to Alzheimer's and mild Alzheimer's disease dementia. Detailed results will be presented at a future medical meeting.

"This disappointing news confirms the complexity of treating Alzheimer's disease and the need to further advance knowledge in neuroscience," Michel Vounatsos, CEO, Biogen said.

Eisai and Biogen said they would continue to work on other Alzheimer's treatments, including BAN2401.

Guggenheim analyst Yatin Suneja said Biogen instead should be looking to build its pipeline through acquisitions.

"They need to stop wasting or stop investing money in Alzheimer's now," Suneja said.

Suneja said Biogen has about $42 billion in financing capacity and identified potential acquisition targets such as Sage Therapeutics Inc , GW Pharmaceuticals and Zogenix Inc that are "very interesting companies that should be considered now, more seriously."

Major drugmakers, including Eli Lilly and Co, AstraZeneca, Roche Holding, Pfizer, Merck & Co and Johnson & Johnson, have abandoned Alzheimer's drugs targeting amyloid because of lack of efficacy or safety issues.

Roche is still testing an amyloid-targeting drug, gantenerumab, at a higher dose after it failed in a trial in early-stage disease.

Dr Ronald Petersen of the Mayo Clinic, who has consulted for Eisai and Biogen, said amyloid is clearly linked with Alzheimer's because it shows up in the brains of people with the disease. But removing it did not appear to help.

"Should we abandon amyloid? I'm not completely there yet, but you'd certainly like to see some kind of positive response."

Many companies including Biogen, Eisai, Lilly and AbbVie, are pursuing alternative approaches, such as focussing on tau, another Alzheimer's protein that is more closely linked with the onset of symptoms.

Others are pursuing targets aimed at reducing inflammation, which is believed to play a role in the very early formation of the disease.

Dr Howard Fillit of the Alzheimer's Drug Discovery Foundation said research must identify biomarkers and diagnostics to help "weed out ineffective drugs earlier," before they are tested in large, expensive trials.

Reuters

EISAI STARTS PHASE 3 TRIALS FOR SECOND ALZHEIMER'S DRUG

EISAI CO has begun phase 3 clinical trials of Alzheimer's treatment BAN2401, a day after the Japanese drugmaker and US partner Biogen scrapped trials for another Alzheimer's drug, aducanumab. The aducanumab announcement knocked $18 billion of Biogen's stock value.

The demise of aducanumab came after independent experts determined the trials had little hope of succeeding, marking the latest setback in the quest to treat a mind-wasting disease that affects 5.7 million people in the US States alone.

Eisai and Biogen were jointly developing three experimental drugs for Alzheimer's: aducanumab, BAN2401 and elenbecestat, all designed to target the brain-destroying protein beta amyloid. "As we have believed aducanumab was the best hope for treating Alzheimer's, ending its trials is big negative surprise," said analyst Motoya Kohtani at Nomura Securities.

BAN2401 has been met with scepticism since the partners reported promising but confusing 18-month results in July. Yet Eisai remains confident in its continued development. "We still believe that amyloid beta hypothesis is potentially the right approach for the treatment of Alzheimer's disease," an Eisai spokesman told Reuters.

Eisai will conduct phase 3 trials of BAN2401 involving 1,566 patients with mild cognitive impairment or mild Alzheimer's disease dementia with confirmed amyloid accumulation. Alzheimer's treatments are known as being particularly difficult to develop, as both diagnosis and the recruitment of appropriate trial participants are challenging. From 1998 through 2017, only four treatments have been approved with another 146 attempts resulting in failure, according to the Adis R&D Insight database. Alzheimer's is the most common form of dementia. In Japan, the government estimates there will be 7 million dementia sufferers in 2025, from 4.6 million in 2012.

Reuters

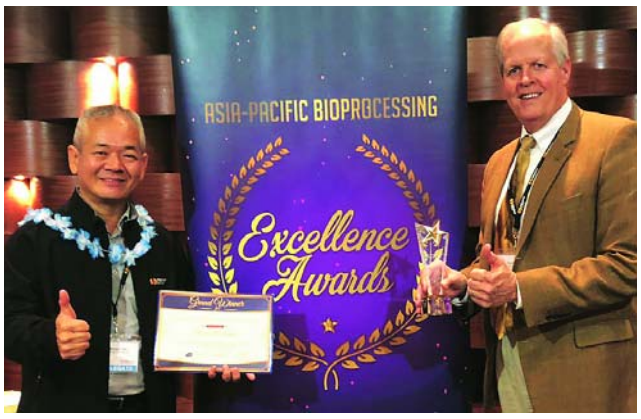
VENDOR NEWS

Pelican BioThermal bags Asia-Pacific Bioprocessing Excellence Awards

The company received the award in Passive Packaging award category

Pelican BioThermal, the global name in temperature controlled packaging, was announced as a winner at an annual awards ceremony which recognises the excellence of suppliers serving the biologics industry. Pelican BioThermal is celebrating its prestigious achievement in the Passive Packaging award category of the Asia-Pacific Bioprocessing Excellence Awards as the company continues to expand its presence in Asia.

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



Benson Teo, Pelican BioThermal's Senior Director of Sales, Asia and Kevin Lawler, Pelican BioThermal's Vice President of Sales

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

Benson Teo, Pelican BioThermal's Senior Director of Sales, Asia, said, "We are excited and humbled to receive this award from the industry in recognition of the high performing products and services we provide."

"Congratulations to the team at Pelican BioThermal on this latest award. We would especially like to thank all the customers who placed their trust in us to meet their requirements and deliver the expected results. We will continue to innovate while providing the best pioneering products possible for our customers in Asia and worldwide."

Pelican BioThermal is a global leader in providing the life sciences industry with the most comprehensive suite of patented and award-winning thermal protection packaging solutions for the safe transport of pharmaceuticals, clinical trials, diagnostics, tissue, vaccines and blood supplies.

This latest award follows Pelican BioThermal's Supply Chain Innovator accolade awarded to its team in the US in 2018. Also, in 2018 its European office, Peli BioThermal, received its second successive Queen's Award for Enterprise for International Trade, the UK's most distinguished business award.

Pelican BioThermal is a division of Pelican Products, which is a portfolio company of Behrman Capital, a private equity investment firm based in New York and San Francisco.

EP News Bureau

Aldevron releases GMP-Grade SpyFi Cas9 Nuclease

Product is the result of a partnership with Integrated DNA Technologies, and provides clinical-stage clients with a critical raw material

ALDEVRON, A leading contract development and manufacturing organisation serving the biotech industry, announced the release of GMP SpyFi Cas9 Nuclease for clinical and commercial applications. SpyFi Cas9 Nuclease, the trade name for Aldevron's research grade and GMP products, is the direct result of a partnership with Integrated DNA Technologies (IDT). The advantages of SpyFi Cas9 Nuclease include reduced off-target effects combined with clinically relevant on-target activity. Aldevron manufactures and markets IDT's HiFi S.p. Cas9 variant through a license agreement and has provided this research grade nuclease since December 2017. The release of GMP SpyFi Cas9 Nuclease provides researchers and scientists a consistent product from discovery through clinical and commercial manufacturing for gene editing programmes.

"As a strong advocate for genomics research, IDT strategically partners with companies where we identify a real benefit for investigators," said Mark Behlke, CSO, IDT. "Our Alt-R S.p. HiFi Cas9 Nuclease was developed to benefit all applications where the highest level of precision editing is required, and medical applications are an important part of this market. Our partnership with Aldevron enables immediate access to the GMP version of this important new genome editing tool for Clinical Trials. Thanks to this partnership, we are able to lower barriers and increase access to important genomics tools, helping researchers progress clinical trials faster."

This specific Cas9 protein variant resulted from a substantial amount of development of the wild-type Streptococcus pyogenes Cas9 sequence. This nuclease also functions well in ribonucleoprotein (RNP) delivery format and is compatible with ex vivo gene editing protocols. IDT's partnership with Aldevron to make a GMP version of this unique enzyme will better serve the gene and cell therapy industry. "We are excited by the release of GMP-grade, SpyFi Cas9 Nuclease," says Michael Chambers, CEO, Aldevron. "Aldevron chooses its partnerships with the client in mind – we want to provide value at every turn. Our clients no longer need to qualify and manage multiple suppliers to support the various stages of their gene editing programmes. This simplifies sourcing costs and reduces timelines with an "off-the-shelf" solution, which may help get these transformative treatments to patients even faster."

GMP-grade SpyFi Cas9 Nuclease is available in 1 mg and 10 mg vials with a documentation package to support regulatory filings. In addition, a stability study to support the use of the product for clinical applications has been initiated due to client demand.

EP News Bureau

B&R unveils futuristic corporate headquarters in Pune

The corporate headquarters of B&R Industrial Automation in Pune houses a demo room and a next generation customer experience centre, highlighting latest B&R hardware and technology

B&R INDUSTRIAL Automation has expanded its Pune office space to 16000 sq ft. This new and modern office is now fully operational with unique architecture and efficient office automation.

During the new infrastructure unveiling, Jhankar Dutta, Managing Director, B&R India, addressed employees saying, "We are proud to expand our Pune office to accommodate the rapid growth in Indian market. With our new and hi tech working infrastructure, we continue to remain extremely competitive and are confident about sustained growth. We are perfectly placed and equipped to further support our customers in increasingly important automation market." He further went on to thank customers, partners and employees for their trust and support to B&R India.

The corporate headquarters of B&R Industrial Automation in Pune also houses a demo room and a next generation customer experience centre, highlighting latest B&R hardware and technology. The futuristic design of B&R's Pune infrastructure meets the needs of modern working environment outfitting innovative technologies and providing employees with working comfort. The fully automated infrastructure has connected all the functional elements and utilities to deliver a truly connected experience for employees and customers at the same time optimising and reducing resource utilisation. The infrastructure includes thoughtful use of daylight, thus, reducing ecological footprint. In addition, the automated lights and air-conditioning ensures automatic turn off with no human presence assuring further reduction of carbon footprint and a greener tomorrow.

EP News Bureau

C2 PHARMA acquires Digoxin API Portfolio from Nobilus Ent

A fully redundant supply of Digoxin API from C2 PHARMA will be available via two CMO manufacturing sources at Nobilus in Poland and Laurus Labs in India

C2 PHARMA, a Luxembourg-based phytochemical and chemical pharmaceutical manufacturing and distribution group, has acquired the Digoxin API product portfolio of Polish company, Nobilus Ent, self-developed and inherited from Roche/Galenus Mannheim. Through the agreement, C2 PHARMA is the product owner, and Nobilus is a manufacturing partner and releasing entity for the API. Parallel manufacturing to ensure redundancy is supported by long-term partner, Laurus Labs, an India-based API manufacturer with an impeccable track record.

Since 2014, Digoxin API availability has been frequently and severely disrupted causing shortages of product due to high levels of impurities and an unreliable supply chain. To mitigate the expected future impact of those Digoxin API shortages, C2 PHARMA has taken various actions, including this recent agreement, as well as setting up a fully independent supply chain for digitalis leaves and investing in a brand new, dedicated, state-of-the-art manufacturing facility with Laurus Labs in India.

"While this type of investment is unprecedented for such a niche product, we believe that it is the most responsible path to secure a quality, continuous supply of this complex and essential API," said Andrew Badrot, CEO, C2 PHARMA. "With existing impurity and supply issues, and as regulatory authorities progressively tighten specifications, this places C2 PHARMA at the forefront of purification technology and process innovation for Digoxin API."

Tech transfer has been completed and validated, and the Digoxin API is currently in production at the Nobilus Ent and Laurus Lab sites. Purchases can be made directly from C2 PHARMA.

EP News Bureau

World's first lubricant-free prefillable glass syringe launched at DCAT 2019

The new syringe will be available in the course of 2019

LUBRICANTS HAVE long been a necessary evil for prefillable syringes. The syringes aid in reducing the injection force to make the treatment more comfortable for the patient, yet could also influence and harm the drug. Pharma packaging specialist SCHOTT has successfully tackled this challenge and presents syriQ BioPure lubricant-free – the first prefillable glass syringe (PFS) that completely eliminates the need for silicone or similar substances. The new syringe will be available in the course of 2019.

To meet the needs of the growing market for biologics that are ultra-sensitive to silicone, which applies to an estimated 10 to 15 per cent of the pipeline, syriQ BioPure lubricant-free refrains from siliconisation of the syringe barrel. To still maintain a consistent gliding force, great emphasis was laid on an accurate geometry. The new syringes are made of FIOLAX glass tubing that is 100 per cent inspected with the help of a big data process named perfeXion, ensuring tight dimensions and a high cosmetic quality of each barrel. Silicone-free plungers and stoppers from leading component suppliers round out the concept and eliminate the risk of lubricants interacting with sensitive biologics. In addition, syriQ BioPure lubricant-free also features ultra-low tungsten residuals as well as low adhesive residuals in the needle stake to limit the risk of Extractables & Leachables (E&L).

"Quite often, pharmaceutical manufacturers opt to use vials instead of prefilled syringes to avoid silicon contamination," says Nicolas Eon, Global Product Manager, SCHOTT. "With syriQ BioPure lubricant-free, we allow a new class of drugs to be manufactured and stored in PFS – a packaging class that offers a great way to save time for both patients and clinicians and reduce healthcare costs."

EP News Bureau

PRODUCTS

Gandhi Automations PCR clean room doors provide optimum solution

THE PHARMACEUTICAL and chemical industries require suppliers to meet challenging standards in areas of hygiene, sealing, operating reliability, fitting and providing efficient after sales service.

Clean room environment is required at a place where there is a high risk of air contamination through environmental pollutants like dust, airborne microbes, aerosol particles and chemical vapour. Designed for excellence, Gandhi Automations PCR clean room doors provide optimum solution for the needs in pharmaceutical, hospitals, commercial and retail environment where there is a need for clean air. The clean room doors are custom made to suit the requirements from these sectors. The clean room door helps in preventing the dust particles or pollutants enter into the room. The door is insulated with high quality PU and there is a provision for double insulated glass vision panel. Available in variants like single leaf and double leaf, Gandhi Automations PCR clean room door is made of high-quality material with absolute insulation.

Protect against drafts, humidity, dust and dirt with the Gandhi Automations PCR cleanroom doors

Cleanroom doors feature an almost airtight seal, which minimises pressure drop and protects the environment against drafts, humidity, dust and dirt. The doors comply with international cleanroom standards and are certified the Fraunhofer Institute. They are ideal for cleanroom applications in pharmaceutical, chemical, electronics and micro-mechanics industries.

Fast opening- and closing-speed helps control air exchange and reduces contaminants. A break-away system ensures maximum safety for personnel and equipment.

Gandhi Automations PCR offers perfect sealing and requires very little space. Exceptional reliability and smooth operation are insured by a motor driven by a frequency inverter. This technology ensures a soft start and stop, which increases the longevity of the motor considerably. To increase natural lighting, the door curtain can be equipped with windows or vision panels.

PCR is a compact, airtight door for medium-sized applications. With an integrated motor, it is the most space-efficient cleanroom door in the market. Fast operating-speed and perfect sealing reduce energy use and filtration costs. To increase natural lighting, the door curtain can be equipped with windows or vision panels.

PCR is designed for medium-sized openings. It provides high air-tightness and fast operating-speed. Contactless Safety Edge prevents accidents even under high speeds. Gandhi Automations PCRRR300 Clean is also available with an optional Contactless Actuator that makes it possible to open the door with a simple wave of a hand. This reduces the risk of contaminants passing between your hand and the door side frames.

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

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Waters expands accessibility to high resolution MS Data with first SmartMS-Enabled LC-MS Biopharma System

WATERS CORPORATION has introduced the BioAccord System, a purposefully designed liquid chromatography-mass spectrometry (LC-MS) solution that will expand access to high-resolution time-of-flight mass spectrometry capabilities to more scientists. The BioAccord System promises to move routine monitoring out of centralised MS labs and into the hands of more scientists by enabling more effective analysis of biotherapeutic protein attributes across development and within quality control organisations.

"The pace of innovation in the biopharmaceutical industry is accelerating, and with it, the monitoring requirements for biotherapeutics are growing exponentially," said Chris O'-Connell, Chairman and CEO, Waters Corporation. "The inherent complexity of these therapies, combined with rising regulatory standards, are driving more intensive and widespread testing requirements. Waters designed the BioAccord System as a fit-for-purpose LC-MS biopharmaceutical solution to deliver rich mass spectrometry data for improved productivity and effective decision-making."

The BioAccord System pairs ACQUITYTM UPLC I-Class Plus with the newly-developed ACQUITY RDa Detector featuring SmartMS. This system offers new levels of user experience with automated setup and self diagnosis delivered through an intuitive user interface, all within a surprisingly small footprint. Powered by UNIFI, Waters' compliance-ready LC-MS informatics platform, the BioAccord System has been optimised for intact protein, released glycan, and peptide monitoring applications, and streamlined by the use of Waters' application-specific chemistries and consumables kits.

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VALUE ADD

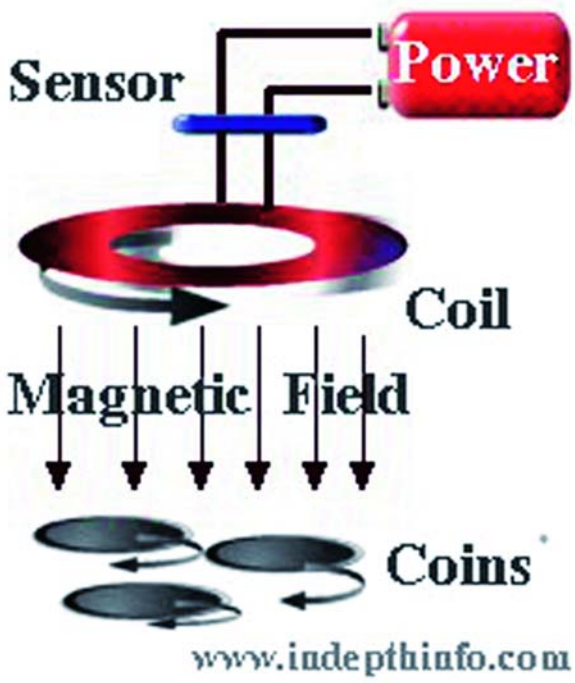
Ami Polymer: Sealing expert in silicon

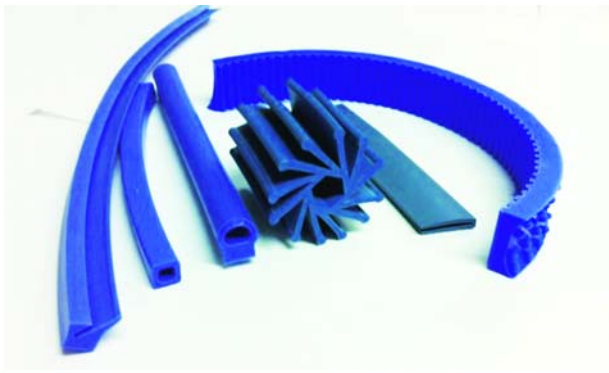
Pritam Adhikary, Executive-R&D, Ami Polymer, talks about the various uses of silicon elastometer

Metal detector silicone rubber

Silicone elastomer based on poly-dialkyl siloxane is one of most curtail material use in most critical application like medical industry, food industry, pharmaceuticals, biotechnology, microbiological research and as well as in prosthetic application owing to its biocompatibility. Silicone elastomers are used as hose, tube, diaphragm, gasket of different machineries in those field. So concerns within the food and beverage industry of eroded silicone elastomeric by-products originating from processing equipment entering the process lines is widespread and that cannot be detectable. In response to the commercial problems of downtime and large quantities of waste being produced from such contamination.

To reduce that problem metal detectable silicone composite have been established. If any contaminated particle is fragile to the online stream product it would be detachable by metal detector. A metal detectable silicone elastomer composite that can be detected by integrated metal detectors fitted along the processing lines. In the event of eroding particles from a silicone seal entering the process line, such particles will be identified. The production process can then be quickly stopped, contaminated products segregated and the process modified to overcome the problem. The commercial benefit for the manufacturer is that the risk of production downtime and probability of waste being produced will be greatly reduced due to the properties of metal detector silicone composite enabling early detection of contamination.



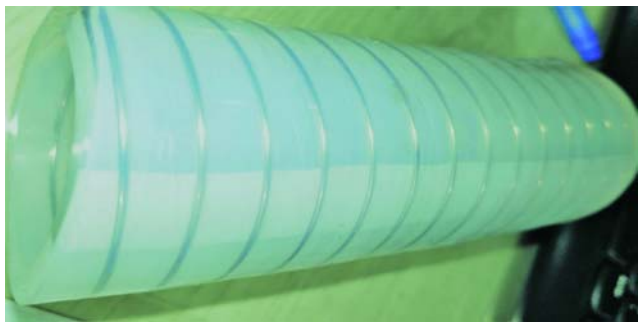


Metal detector is principally based on electromagnetism phenomenon. Different metal detectors work in various different ways, but here is the science behind one of the simpler kinds.

So, to make a material metal detectable it should be a metal or a composite by contain metal. Metal detectable silicone elastomer have been prepared by incorporating metal powder into it at the stage of mixing. This metal particles response to metal detector.

Antistatic Transparent hose

Now-a-days silicone elastomer- based hoses are widely used mostly in the area of medical, pharmaceutical, biological, biotechnical, artificial cell culture industries due to its cent percent biocompatibility, high and low temperature resistance, solvent resistance properties, high pressure flow of aggressive liquids and low leachability. The problem with conventional silicone hoses is the development of static electricity due to friction. A static electric charge is developed whenever two adjacent surfaces are in frictional contact. Here charges are developed when fluids are passing through silicone hoses or due to electrical induction when tubes are close vicinity of some electrical instruments in medical, pharmaceutical, hospital sectors. As silicones elastomers are insulator so that accumulated charges are stagnant followed by catastrophic static discharge leads to a fatal accident. This fatal accident comes with outputs like static shock or fire hazards. So removal of static charges are very important in those critical areas.



Antistatic transparent tube is most challenging area of development. Industries are developed antistatic transparent hoses. This hose are transparent as well as it can dissipate static charges if charges are developed due to friction or induction.

This transparent antistatic hose use both in high pressure application and as well as to reduce static discharge failure. Also, transparency gives aesthetics look.

VALUE ADD

HMX helps Al Waha tower reduce chiller load

The Al Batha Group, one of the largest private business groups in the UAE, consists of more than 20 autonomous companies that operate in the diversified sectors of pharmaceuticals, automobiles, contracting, manufacturing, electronics, FMCG, real estate, education, and more

AL WAHA Towers, a premium residential complex owned by the Al Batha Group in the UAE reduced the load on its chiller by using HMX pre-cooling units to cool the make-up fresh air, resulting in reduced capex and opex.

Background

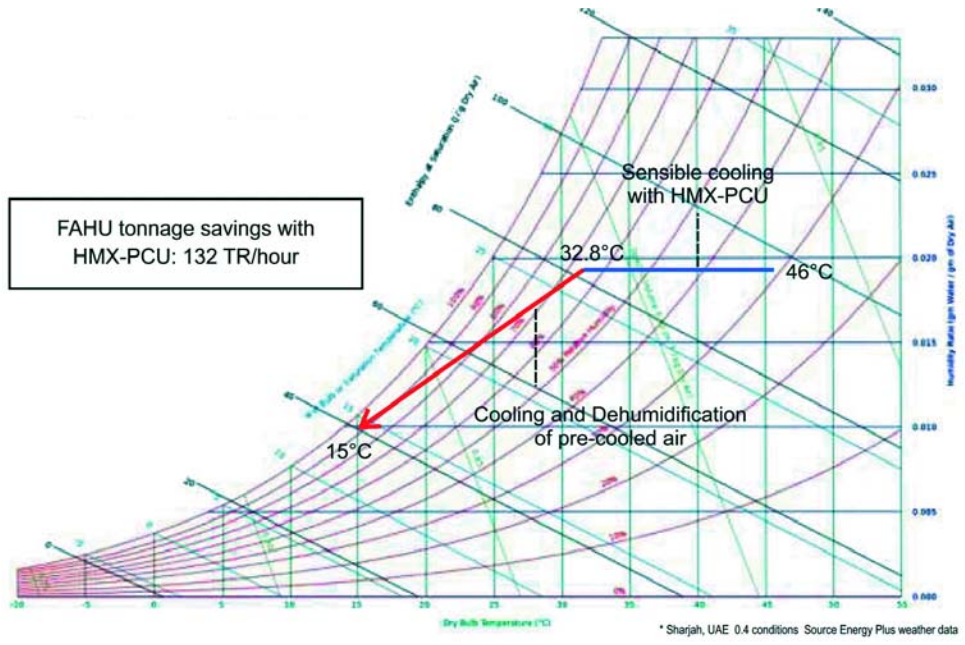
The Al Batha Group is one of the largest private business groups in the UAE. The Group consists of more than 20 autonomous companies that operate in the diversified sectors of automobiles, pharmaceuticals, contracting, manufacturing, electronics, FMCG, real estate, education, and more.

The real estate arm of the Al Batha Group was established in 1986 and is directed towards meeting the multifaceted property needs of the UAE – from building warehouses and showrooms to managing commercial, residential, and retail space. Over the years, Al Batha's real estate business has enjoyed considerable success as the UAE real estate industry flourishes.

Challenges

Al Waha Towers is one of the Al Batha Group's premium residential properties. Located in the severely hot and humid climate of Sharjah, UAE, The Al Waha-Towers arecentrally air-conditioned. The central air-conditioning system covers all common areas, such as lobbies, corridors, and lift areas of the 44 floor building while the residential areas have packaged airconditioners of their own. The Al Batha Group found it difficult to maintain a constant comfortable temperature in the common areas of the building; temperatures in these areas were always 2-3°C higher than the required temperature. To overcome this challenge, the Group looked at several solutions:

Installation of HMX-PCU at Al Waha towers.



Psychrometric representation of cooling with HMX-PCU

1. Addition of a chiller: Adding a chiller to the existing system would make it possible to maintain the required temperatures inside the common areas. However, this would also mean significant capex and a higher opex.

2. Recovery of air through ERW: Energy recovery wheels (ERWs) would take in the air from the conditioned space and circulate it back to the same space by recovering the heat energy. This would require additional ducting from the ground floor to the top floor where the ERW would be installed. Moreover, installing an ERW would also require significant capex and high opex.

3. Closing/reducing the make-up fresh air: Every building requires some amount of fresh air to be inducted occasionally to maintain good indoor air quality (IAQ) while the remaining air (which work has been done to cool it) is re-circulated. This is generally done through FAHUs (Fresh Air handling Units) also known as TFAs (Treated Fresh Air units). Even though the quantity of fresh air inducted is only 15 per cent of the entire air quantity, the load on the air conditioning system to cool this air can go upto 30 per cent, especially during summers. Closing the fresh air dampers would mean that more tonnage can be allotted to the chiller and less to the FAHUs but this would come at the cost of reduced IAQ and increased health hazards.

Al Waha tower had two FAHUs installed (capacity: 30,000 CFM each) to treat their 15 per cent make-up fresh air. The FAHU cooled anddehumidified the make-up fresh air from the ambient 50°C to 15°C. The FAHU tonnage consumption for this was 510 TR/Hr. In spite of the fresh air quantity being only 15 per cent, the tonnage consumed was almost 30 per cent of the entire chiller load. This meant less available tonnage for cooling the recirculated air and therefore, inadequate cooling for the fresh air being supplied.

Solution

The Al Batha Group searched for a solution that would help maintain their desired requirements in terms of temperature and an appropriate fresh air quantity without significant capex or opex and with minimal alteration to their existing systems. This was when they approached HMX for a solution.

HMX retrofitted the two FAHUs with two HMX-PCUs of 30,000 CFM capacity each. The HMX-PCU is essentially an IECbased (Indirect Evaporative Cooling) pre-cooling unit that cools the ambient air without the addition of any moisture. This is done with the help of water as the cooling media and without any dependency on the chiller system or on return air ducts.

The HMX-PCU has a clear advantage over other technologies; it provides a host of benefits such as:

- Low capital investment
- Smaller footprint
- Reduced energy consumption
- Elimination of return air ducting
- Zero cross contamination
- Minimal maintenance and
- Better life cycle

Result

The HMX-PCU helped reduce the enormous load on the chillers that was used to treat the make-up fresh air. With considerable tonnage now freed up, the air conditioning system at Al Waha towers is efficiently cooling the common areas as desired.

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VALUE ADD

Biorelevant dissolution testing: Media effects

Aditya Marfatia, Director, Electrolab and **Dr Namita Varde**, Application Scientist, Electrolab, highlight the significance of biorelevant media in dissolution testing to better mimic in vivo product behaviour

DISSOLUTION TESTING plays a critical role throughout the product development cycle. In formulation development, it is used to rank order formulations based on their release behaviour. It is also used to conduct comparative studies on generic and innovator products. It remains a key quality control tool to monitor batch-to-batch consistency and thereby to facilitate batch release. A robust, discriminatory and reproducible dissolution test may be used as a surrogate for clinical studies once an IVIVC is established. Thus, dissolution testing can be used to obtain biowaivers from bioequivalence (BE) studies. Use of dissolution test as a surrogate for clinical studies shortens the product development timelines and lowers the costs of development significantly. Use of biorelevant media and other tools such as DissoFlux and GastroPlus increases the chances of developing a better IVIVC.

The main factors affecting dissolution can be divided into: i) API related- Physicochemical properties of the API such as solubility, permeability, etc., ii) Dosage form related- Excipient characteristics, manufacturing process, etc and; iii) Apparatus, method and dissolution medium related. In addition to the above mentioned factors, in order to accurately predict *in vivo* drug performance, it is essential to conduct *in vitro* dissolution tests considering key parameters of the human gastrointestinal (GI) physiology. Such dissolution testing is also known as biorelevant dissolution testing. *Table 1* summarises the critical parameters for biorelevant dissolution testing and the observed *in vitro* and *in vivo* variability in these parameters.

Aditya Marfatia, Director, Electrolab

Media selection is one of the most critical elements of developing a biorelevant method. There exists two main types of media – compendial media and biorelevant media.

Compendial Media

These are USP approved media, which mimic the *in vivo* gastric and intestinal fluids under fasted state. All compendial media lack in simulating the *in vivo* environment post food intake and therefore, are not suitable in predicting food effects on drug dissolution.

Simulated Gastric Fluid (SGF)

This is a USP compendial media used to simulate gastrointestinal fluids in the fasted state. This medium (pH 1.2) contains hydrochloric acid, sodium chloride, pepsin and water. This medium takes into consideration several qualities of the gastric fluids such as pH, surface tension, enzymes, etc. SGF media can be prepared with or without pepsin (SGFsp). There still exist a few major deviations from *in vivo* gastric fluids in terms of high pepsin concentration in fasted state and high surface tension of approximately 70 mN/m compared to much lower average surface tension of 35 – 50 mN/m observed *in vivo*. In addition, the average gastric pH lies in the range of 1.5 – 1.9. For weak acids and neutral drug molecules, this minor change does not affect dissolution, however, for weak bases; the results with SGF might overestimate the dissolution rate.

Dr Namita Varde, Application Scientist, Electrolab

Water

Water has been widely used in quality control dissolution testing due to its simplicity. Water as a dissolution medium has been argued to being more physiologically relevant as most formulations are administered with water. In certain diseased conditions such as hypochlorhydria (elevated gastric pH), water acts as suitable medium as it reflects the increased gastric pH and the low buffer capacity. However, the pH of water may vary with its source and water has no buffer capacity. Alternatively, a diluted HCl or NaCl solution has more biorelevance.

Simulated Intestinal Fluid (SIF)

This is a USP compendial media to simulate small intestinal fluids in the fasted state. The only parameter changed from SGF is the pH of the medium (6.8). SIF media can be prepared with or without pancreatin (SIFsp).

Biorelevant Media

Biorelevant media are better at mimicking in vivo fluids compared to compendial media. They contain key ingredients such as bile salts, phospholipids, etc. which are not a part of compendial media. In addition, biorelevant media can simulate both fasted and fed state conditions *in vivo*. They can therefore be used to predict *in vivo* food effects. Biorelevant media can increase chances of developing a successful IVIVC. However,

TABLE 1

Parameters	in vitro	in vivo
Media	Compendial media (SGF, SIF) Biorelevant media (FaSSGF, FaSSIF, FeSSIF)	Gastrointestinal fluids
Volume	Variable ◗ Apparatus type ◗ Fasted or Fed state	Variable ◗ Fasted or Fed state
Duration	Variable ◗ Dosage form ◗ Apparatus type ◗ Fasted or Fed state	Variable ◗ Dosage form ◗ Fasted or Fed state
Hydrodynamics	USP Apparatus 1-7	Gastrointestinal motility
Location	Constant (unless media changeovers)	Variable with time
Amount of drug	Constant in closed loop system Decreases in open loop system	Decreases as drug is absorbed

while formulating biorelevant media *in vitro*, raw materials purity requires consideration. Media prepared with substandard raw materials may lead to stability issues such as increased viscosity, appearance of a yellowish tinge to the final solution, etc. In addition, the hygroscopic nature of the powder concentrate has to be considered.

Fasted State Simulated Gastric Fluid (FaSSGF)

This medium simulates gastric fluids in the fasted state. This medium (pH 1.6) contains sodium taurocholate, lecithin, pepsin, sodium chloride, hydrochloric acid and water. Sodium taurocholate and lecithin are biological surfactants whereas pepsin is the digestive enzyme. These three are the main components present in the human gastric fluids.

Fasted State Simulated Intestinal Fluid (FaSSIF)

This medium simulates intestinal fluids in the fasted state. This medium (pH 6.5) contains sodium taurocholate, lecithin, sodium dihydrogen phosphate, sodium chloride, sodium hydroxide and water. In addition to the biological surfactants, this medium contains phosphate or maleate buffer system to maintain alkaline conditions.

Fed State Simulated Intestinal Fluid (FeSSIF)

FeSSIF simulates intestinal fluids in the fed state. This medium (pH 5) contains sodium taurocholate, lecithin, acetic acid, sodium chloride, sodium hydroxide pellets and water. The FeSSIF medium has high osmolality (~670 mOsmol/kg) and high buffer capacity (~72 mEq/pH/L) compared to FaSSIF (~270 mOsmol/kg and ~12 mEq/pH/L) medium to better mimic in vivo conditions. This increase in osmolality and buffer capacity was achieved by the presence of acetate or maleate buffer. High concentrations of sodium taurocholate and lecithin are present in FeSSIF compared to FaSSIF to reflect biliary response to meal intake.

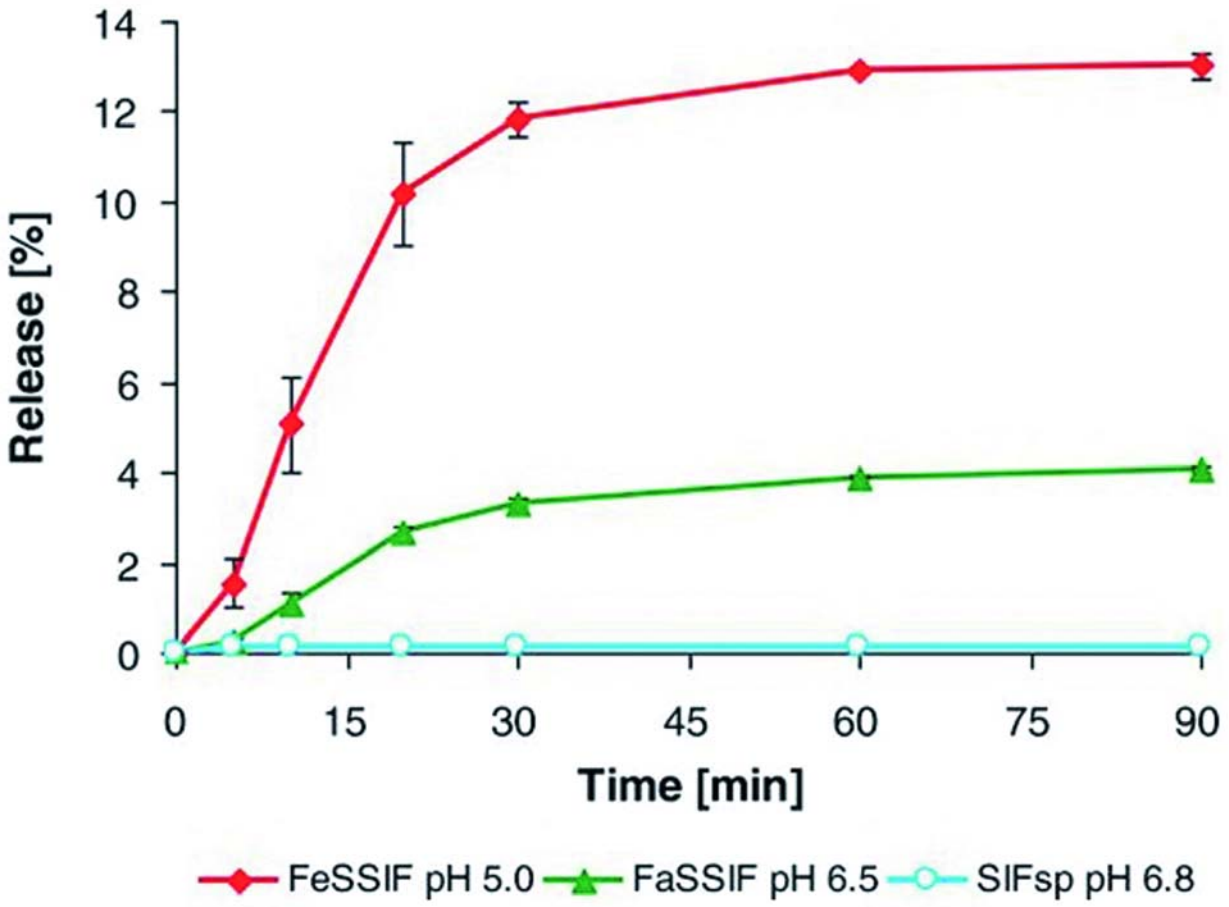

Figure 1: Dissolution profiles of danazol tablets in different media *(adapted from Galia et al)*

Significance of Biorelevant Dissolution for Class II and/or IV drugs

In case of drug products containing BCS class II or IV drugs, it is mandatory for Indian drug manufacturers to submit result of BE study for obtaining the license from CDSCO. Biorelevant *in vitro* dissolution may lead to better understanding of in vivo performance, especially for low solubility drugs (BCS Class II and IV drugs). For BCS Class II drugs, the rate-limiting step for drug absorption is dissolution, whereas for Class IV drugs, both dissolution and permeation are rate-limiting. Development of in vitro methods capable of predicting in vivo performance remains a major challenge for such drug candidates. In these cases, use of biorelevant media for dissolution increases the chances of more accurate *in vivo* performance predictability.

Galia et al. studied the *in vitro* dissolution of tablets containing danazol (a BCS Class II drug) using the USP apparatus 2 (100 rpm and 500 mL media). Three different media were evaluated: Simulated Intestinal Fluid sine pancreatin (SIFsp), FaSSIF and FeSSIF. Danazol demonstrated negligible release in SIFsp media, which reflects its low aqueous solubility (Figure 1). An increase in dissolution was observed as the bile salt components increased. The drug release in FeSSIF was three to four times higher compared to FaSSIF. These results conclude that the bioavailability of danazol would be better when the drug is administered in the fed state.

Biowise Science has developed BioWise, a ready to use blend of biorelevant media powder concentrate. The powder concentrate has been manufactured with high quality raw materials in a cGMP facility. The preparation is simple, quick and user friendly. The pack size of one bottle is good for one dissolution test, which completely avoids problems surrounding the storage of leftover powder concentrate.

The powder in this container will make 3.5 L

The powder in this container will make 7 L

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VALUE ADD

Integrated automation solutions smart manufacturing

B&R presents complete portfolio for batch-size-one manufacturing

AT THE Hannover Messe trade fair, B&R will show how a conventional plant can become a smart factory in Hall 9, Booth D26. B&R enables the automation of all production areas and allows them to interact seamlessly. B&R's portfolio makes it easy to implement efficient, high-quality production down to batch size one, ensure safe human-machine collaboration, and obtain a clear overview of machine performance data in the cloud.

B&R's first cloud application allows OEMs to collect data from their global fleet around the clock and view it in a convenient dashboard. They can use it to make well-targeted machine upgrades, offer next-level service and unlock new revenue streams. The cloud application indicates where maintenance is necessary and provides the basis for tailor-made maintenance service.

Integrated machine vision

In addition, B&R will be exhibiting the world's first machine vision solution to be fully integrated into the automation landscape. B&R's machine vision solution includes intelligent cameras, image processing algorithms, and an innovative selection of lighting technology. With these products, B&R serves a broad spectrum of applications: from simple machine vision sensors to high-end smart cameras. Ready-made software components are available for creating applications with minimal new programming.

Human-track collaboration

B&R is the first manufacturer of intelligent track systems to introduce human-track-collaboration. Visitors to the B&R booth will see how five integrated safety functions allow humans to work directly alongside the track with no safety barriers – without impairing productivity.

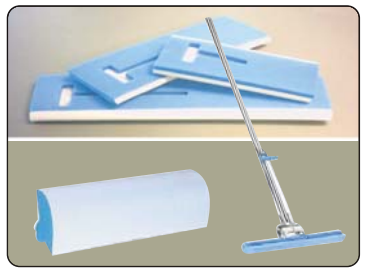
SUNNY ENTERPRISES

Leaders In Clean Room Contamination Control & Preventive Products

Clean Room Garments

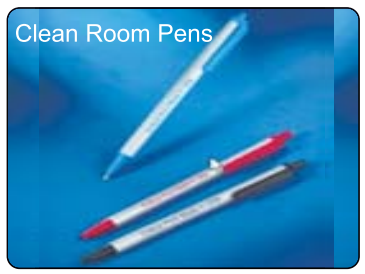
Disposable Garments

Sticky Mats

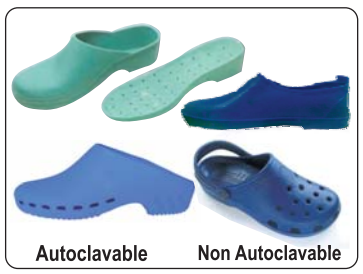


Clean Room Mopping Systems

Rust Removal System

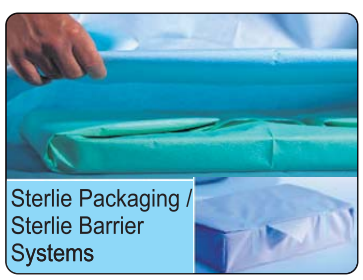


Clean Room Stationery



Clean Room Shoes

Autoclavable Goggles

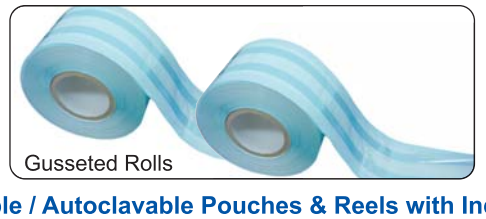


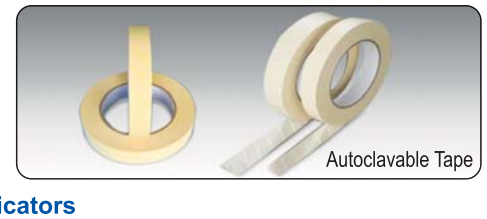
Sterlie Packaging

Clean Room Wipes

Fogger for Fumigation

Autoclavable Clean Room Trolley Systems: Plastic & Stainless Steel





Sterlizable / Autoclavable Pouches & Reels with Indicators

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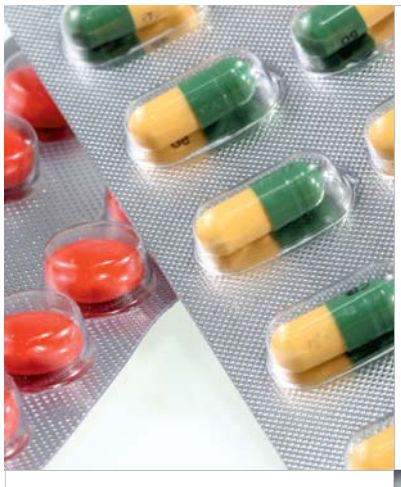
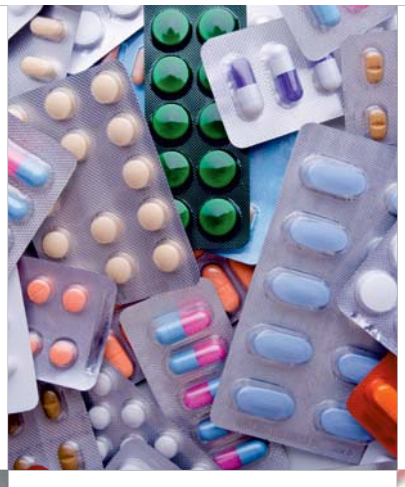


PVC RIGID FILM FOR BLISTER FORMING

US FDA Type III
DMF: 032495



TRIPLEX LAMINATE

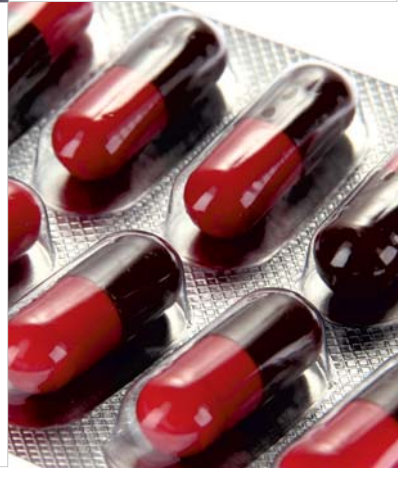
US FDA Type III
DMF: 032497

ALU ALU LAMINATE

US FDA Type III
DMF: 032494

PVdC COATED PVC FILM

US FDA Type III
DMF: 032496



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RECOGNITION

Kiran Mazumdar-Shaw conferred with honorary doctorate from Deakin University, Australia

She was recognised for her pioneering entrepreneurial role in the field of biotechnology and sustained significant contribution to industry-academia collaboration between Australia and India

Kiran Mazumdar-Shaw, CMD, Biocon, has been conferred with the 'Honorary Doctorate' by Deakin University, a leading global university based in Victoria, Australia. Mazumdar-Shaw has been recognised for her pioneering entrepreneurial role in the field of biotechnology and for her sustained significant contribution to industry-academia collaboration between Australia and India.

Speaking on the occasion, Mazumdar-Shaw said, "I am immensely proud to receive this coveted recognition from the prestigious Deakin University of Australia and feel even more inspired to be presented with this honour in the year when Deakin University is celebrating 25 years of association with India, the longest sustained period of engagement by any Australian University with India."

Deakin Honorary Doctorates programme recognises eminent individuals who have made an inspiring or significant and sustained contribution to the community aligned to the University's objectives. Past recipients of Deakin University Honorary Doctorates include eminent leaders like Julia Gillard, Australia's first female Prime Minister.

Mazumdar-Shaw has also been appointed as Australian Global Alumni Ambassador by the Department of Foreign Affairs and Trade, Australia in 2016 and she is also the Victorian Business Ambassador for the State Govt of Victoria, Australia.

EP News Bureau

APPOINTMENT

LTE appoints India and South-East Asia exports manager

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

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

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

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

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

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

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