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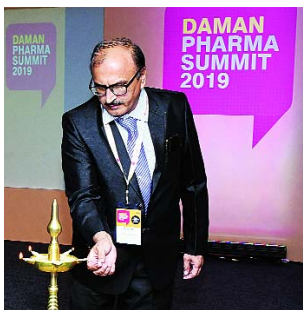

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INFRASTRUCTURE

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Will regulators catch up in 2020?

As we mark 25 years of *Express Pharma*, we invited experts to review past milestones as well as predict those around the corner. We thank the pharma fraternity for their unfailing support over the years. Do write in your suggestions so that the years ahead exceed all expectations.

The last month of 2019 was marked by debate on three important issues and all are awaiting long pending regulation: online pharmacies, pharma marketing practices and defining supplements versus medicines. Regulation in all the three areas could herald major changes to India Pharma Inc.

On November 28, an order from DCG(I) VG Somani, directing all states and Union Territories to prohibit the sale of medicines through unlicensed online platforms till draft rules to regulate e-pharmacies are finalised and put in place, stirred up the debate once more.

The past year has seen an evolution of the e-pharmacy business model, with the two sides in tacit cooperation. For the offline part of the business, e-pharmacies have empanelled traditional pharmacies, with registered pharmacists verifying e-prescriptions before fulfilling orders. Many offline pharmacies are experiencing the benefits of becoming empanelled with - or going the franchisee route - with e-pharmacy chains as they get better inventory control as well as extended customer reach.

Quite predictably, the lack of policy has not dulled the sheen of the e-pharmacy sector. According to industry estimates, the sector has received funding of over $700 million from private equity and venture capital. A sector update from Motilal Oswal Institutional Equities estimates that the size of the e-pharmacy sector is expected to increase to Rs 250 billion by 2022 compared to just Rs 3.5 billion in 2018.

Though e-pharmacies currently account for just three per cent of the overall pharma market in India, their share is expected to increase. Increased Internet usage, an aging demographic (the 50+ age group is expected to increase 26 per cent by 2035 versus 18 per cent in 2015) leading to a shift from acute to chronic ailments is expected to drive more patients to shop online for medication.

This is precisely why regulators are being so careful. While the benefits of online pharmacies for pharma companies are a given, in terms of better inventory control and market insights, it is the patient/consumer who needs to be protected from counterfeit medicines entering the supply chain as well as harmful overuse of certain categories like antibiotics.

The industry will always find ways to slip through legal loopholes. Will regulators catch up in 2020?

The debate on pharma marketing practices was revived by a report by Dr Arun Gadre and Dr Archana Diwate of Support for Advocacy and Training to Health Initiatives (SATHI). Published in August, the authors reviewed the 'Practices of the Pharmaceutical Industry and Implementation Status of Related Regulatory Codes in India' and give ample evidence that regulation has failed to curb unethical promotional practices. Though the study is qualitative in nature, based primarily on 50 in-depth interviews with mainly medical representatives, in six selected cities across the country, the authors present enough examples to justify their conclusion that when even mandatory Medical Council of India regulatory codes are not being enforced, voluntary codes like the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) remain only on paper.

For instance, the authors detail the role of Propaganda Cum Distribution Companies (PCDs), which are franchisees of pharma manufacturing companies, which buy drugs in bulk from the manufacturers, give their own brand name and directly sell them to retailers and doctors, at huge discounts and incentives (gifts/cash/hospitality/travel facilities etc.).

The regulators are showing some signs of cracking down on the third issue: pharma companies tweaking their formulations to get them licensed as foods under the Food Safety and Standards Act, 2006 by the Food Safety and Standards Authority of India (FSSAI). This is to escape price control and higher scrutiny under the Central Drugs Standard Control Organisation(CDSCO).

For instance, the FSSAI was alerted by the CDSCO that various brands of methylcobalamin were being manufactured and sold under the FSSAI. The CDSCO pointed out that only two variants of vitamin B12, cyanocobalamin and hydroxycobalamin were covered under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary use, Food for Special Medical Purpose, Functional Food and Novel Food) regulation 2016 which did not cover methylcobalamin. On October 31, the FSSAI ordered a surveillance drive against such manufacturers based on the CDSCO's alert.

Let's hope 2020 and the decade ahead see the harmonious resolution of debates like the three issues outlined above.

VIVEKA ROYCHOWDHURY *Editor*
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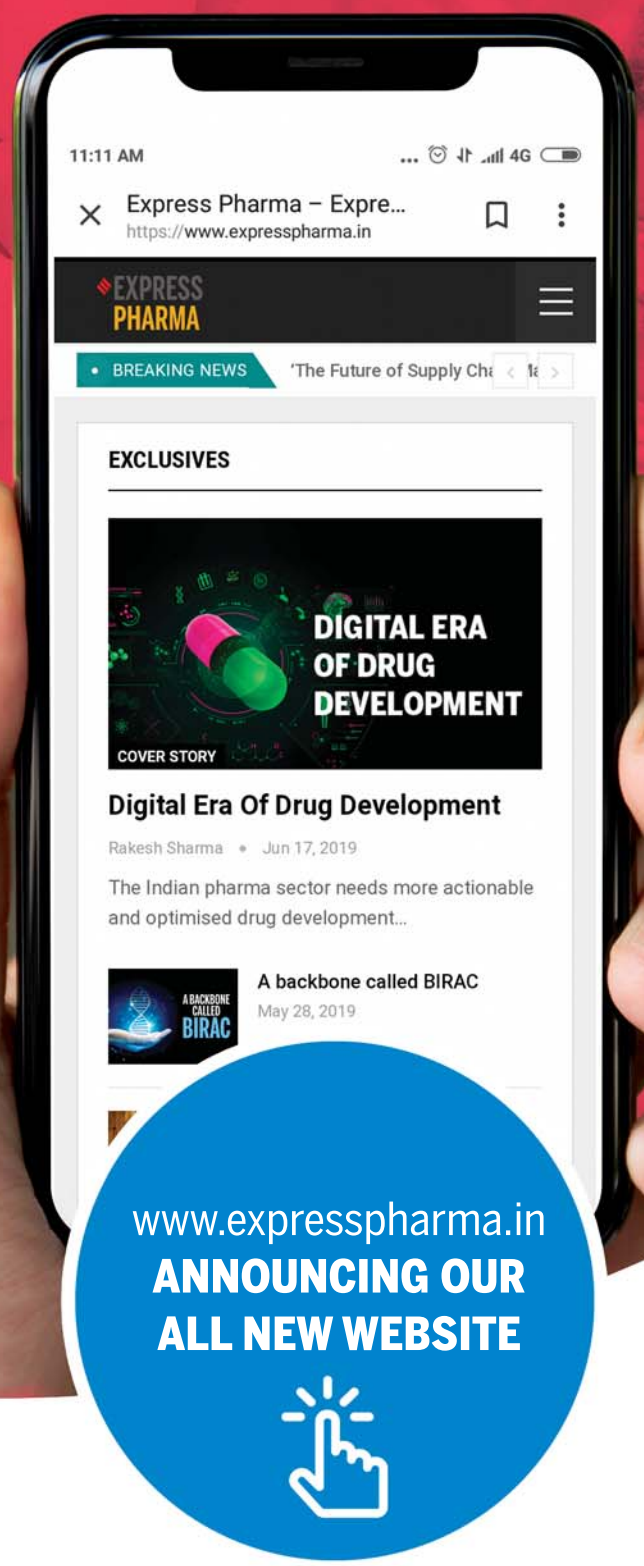

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Chennai to host 71st edition of Indian Pharmaceutical Congress

The theme for this year is 'Pharma Vision 2030: Health care system- Role of Regulators'

Coming December 20-22, 2019, the 71st Indian Pharmaceutical Congress - one of India's largest pharmaceutical congress will be held at Sri Ramachandra Institute of Higher Education and Research (DU), Chennai and organised by the Indian Pharmaceutical Congress Association.

Five national associations under one umbrella constitute the Indian Pharmaceutical Congress Association (IPCA). The constituent federations are sizeable and active in themselves. The associations comprise Indian Pharmaceutical Association (IPA), Indian Hospital Pharmacists Association (IHPA), Association of Pharmaceutical Teachers of India (APTI),

Indian Pharmacy Graduates Association (IPGA), and All India Drugs Control Officers Confederation (AIDCOC).

The objective of the IPC is to disseminate industry specific information to students, academia and constantly update the industry with latest advancements in pharma. This year's IPC will be hosted by AIDCOC. The All India Drugs Control Officers' Confederation was framed on December 28, 1995 at Visakhapatnam as a result of untiring efforts of many officers across the country and the initiative taken by the Andhra Pradesh Drugs Inspectors' Association, the Kerala Drugs Control Enforcement Officers' Association and Tamil Nadu Drugs Inspectors' Association.

The theme for this year is '**Pharma Vision 2030: Health care system- Role of Regulators**'. The scientific programme has been designed to address challenges associated with offering quality medicines at affordable prices and fostering good manufacturing practices amongst pharma manufacturers. The conference will also cover advancements in new drug discoveries and delivery.

Besides this, the conference programme will also offer sessions that will widen career opportunities and update students on scientific and academic advancements in pharma. Apart from the conference, AIDCOC will host a training programme on animal experimentation and regulatory toxicology and a skill development programme.

There will be poster presentations as well. Thus the congress promises to provide immense food for thought and will act as a feast for the intellectual mind.

EP News Bureau

PHARMACONNECT 2020 to be held in Mumbai

The event's purpose is to demonstrate the importance of an optimised pharma supply chain and devise innovative practices to overcome current operational inconsistencies

PHARMACONNECT 2020 edition will be held on January 16, 2020 at The Lalit, Mumbai. The event will feature interactive sessions, specialised tracks related to the pharma supply chain. Reportedly, PHARMACONNECT's last edition was attended by more than 300 delegates in Mumbai and earned accolades from top industry leaders.

The event aims to demonstrate the importance of an optimised pharma supply chain and devise innovative practices to overcome the current operational inconsistencies. It is supported and attended by several pharma supply chain professionals and experts. Leading logistics associations of India like Air Cargo Agents Association of India, Association of Multimodal Transporters Association of India, National Association of Container Freight Stations of India, Federation of Indian Export Organizations, Federation of Freight Forwarders Association of India, Air Cargo Club of India, Custom House Association Delhi also support the event.

> The event will coincide with CARGOCONNECT Excellence Awards, which are based on Performance Excellence Survey of more than 2,500 market participants from different supply chain verticals

The event will coincide with the CARGOCONNECT Excellence Awards, which are based on the Performance Excellence Survey, a survey of more than 2,500 market participants from different supply chain verticals to determine the top players. The awards, commenced by CARGOCONNECT, are presented annually to players in the logistics domain who achieve the highest points in the survey. It is based on several performance factors, keeping in view the holistic and integrated approach taken by the Government in structuring the National Logistics Policy and the new steps and initiatives taken to strengthen quality in the existing ecosystem.

Important information

- The selection procedure for Awards nomination is sequential.
- The project will be first nominated through a Form
- The project will be evaluated according to the laid down criteria by the expert team.
- The project will also be evaluated by an independent set of jury members
- Winners will be announced at the Conference venue.
- The Winner in each category will be presented with a CARGOCONNECT trophy
- A booklet of the awardees in each category with the citation will be published in upcoming edition of CARGOCONNECT magazine.

The above mentioned Awards would be decided by the eminent Jury governing rules & procedural system for the evaluation of the entries. The Award selection process will go through a dual process of Jury. The selected winners will be felicitated with Awards at the PHARMACONNECT 2020 Conference held on 16th January 2020.

Nomination forms can be downloaded from www.surecommedia.com.

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Express Pharma hosts maiden edition of Daman Pharma Summit

Under the theme 'Reinvigorating Daman Pharma Inc,' *Express Pharma* organised a thought leadership summit in Daman in November. The summit witnessed experts from the industry discuss the advantages that the pharma industry enjoys in the region, the operational and regulatory challenges it faces and the need for infrastructure up-gradation in the region

The competition in the generic medicines market is touted to become fiercer. According to ICRA, the generics medicine sector is set to grow at 11-13 per cent in FY2020. However, in the face of ever-evolving factors challenges like regulatory reforms, pricing pressures, etc, the industry will have to gear up for a tough road ahead. Under such circumstances, it becomes imperative for the Indian Pharma Inc to examine its existing avenues to remain relevant in the competition. Daman, with nascent infrastructure, is one such avenue with potential that remains untapped. Many major domestic pharma companies have already stationed their export-oriented manufacturing units which are meeting global regulatory requirements. Though the leisure period of tax incentives is over, companies have still opted to continue their operations in the region. Yet, the fact remains that the tiny Union Territory situated on the western coast of India still has a lot of transformation to go under before it can significantly boost

Prakash Pursnani, Assistant Commissioner-Valsad, Chief Guest of the evening, during the lamp lighting the ceremony and addressing the audience

Nitish Singh, Manager- Sales and Marketing, Ami Polymer

Parmeshwar Bang, VicePresident, JB Chemicals

Piyush Jani, Deputy Manager, Application Specialist, Shreedhar Insruments

Dr N Ramamurthy, Head Quality - Pharmaceuticals and Intermediates Business, Atul Pharma

Ramanuj Samal, Application Specialist, Beckman Coulter Life Sciences, India

Sunil Kumar Sharma, Deputy General Manager- Quality, USV

the Indian Pharma Inc's growth.

On this line of thought, *Express Pharma* organised its maiden knowledge summit in Daman on November 15, 2019, at The Deltin, Daman. Under the theme 'Reinvigorating Daman Pharma Inc', Daman Pharma Summit witnessed experts from the industry discuss the advantages that the pharma industry enjoys in the region, the operational or regulatory challenges it faces and the need for infrastructure upgradation in the area.

After a welcome note by *Express Pharma*, the event was started on an auspicious note by a lamp lighting ceremony performed by the Chief Guest of the evening, Prakash Pursnani, Assistant Commissioner – Valsad. While addressing the audience later, he spoke about the government's commitment to help the industry keep up with the stringent global regulatory procedures. "Our department is continuously improving our strength, and the strength of our officers, by conducting various training sessions to sharpen

A delegate being awarded by the Chief Guest

Delegates participating in an ice-breaking session

their knowledge and make them more efficient."

The Chief Guest's address was followed by a talk on 'Leveraging India advantage-Advantage Daman' by Parmeshwar Bang, Vice President, JB Chemicals. Acknowledging that since the past 25 years, the domestic pharma regulation and CGMP regulation have evolved exponentially, Bang noted that Indian regulatory system is now almost at par with the global pharma standards. "Our regulations and regulatory framework have evolved significantly in the last few years. We now have a better understanding of the regulatory procedures in other countries as well, boosting compliance," he stated.

Talking about the evolution of the Indian Pharma Inc over the past few decades, he said, "India has an established domestic pharma industry with a network of 3000 drug companies and over 3500 manufacturing units. Clearly, we have a very large manufacturing base and it is only going to increase in the future. Out of the 3500 manufacturing units, 1400 are World Health Organisation (WHO) GMP certified or approved, 1,105 units have an European Certificate of Suitability CEP approved, more than 950 units comply with TGA guidelines and about 584 manufacturing units are approved by the US Food and Drug Administration (US FDA), making India the country with the largest number of units approved by the US FDA outside the US. We also have world-class machinery and equipment suppliers which are significantly more cost-effective than those in other countries."

He noted that in 2018, Indian pharma companies received 290 ANDA approvals from US FDA which contributes to 35 per cent of the total ANDA approvals by the US FDA. "These achievements are no mean feat. This qualifies India as a global supplier," he believes. He talked further about various other factors that give India an operational advantage and said, "We have R&D centres set up by various companies and those funded by the government specialising in process development and development of cost-effective technology." Maintaining that India's diverse topographical and climatic variations have proved it to be an excellent clinical trial centre, he informed that various global companies are now outsourcing clinical trial research work to Indian companies.

"Multiple factors contribute to Daman's potential as an upcoming pharma hub," Bang said as he talked about the advantage that Daman possesses for the industry at large. However, he pointed out that indeed, the region may not have grown as desired and expected over the past 25 years, "In the 1988 budget, when VP Singh was the Finance Minister, Daman was qualified as a backward area and a lot of benefits in terms of taxes were given to industries to set base here. But this region came in limelight only after 1995 and saw a surge in industrial setup which peaked in mid-2000s. However, expansion has slowed down since then," he said.

Maintaining that Daman still has a lot to offer to the industry at large, Bang pointed out the unique advantages that the Union Territory has to offer, "All regulatory agencies including the FDA are based in near vicinity. Also, being surrounded by a pharma hub like Gujarat gives Daman a definitive edge. Availability of technically sound and skilled manpower is a plus for a knowledge-based industry like pharma." He further added, "Another important advantage that Daman has is that power and energy costs here are lower compared to the neighbouring states. Since pharma manufacturing and operations consume a lot of energy, this is indeed a huge advantage. Transportation is another plus — the region is very well connected by road, railway, air and sea. The nearest airport is Surat, 120 kms away and Mumbai is at a distance of 180 kms. This is a huge advantage as both Mumbai and Ahmedabad are OEMs hubs. Also, one of the largest ports in India, Jawaharlal Nehru Port Trust,

Q&A session in full swing


Attendees participating in a competition organised at the event


An engrossed audience

(JNPT) is loacted nearby."

The pharma industry in Daman, as previously mentioned, has hit certain roadblocks over the last few years. Lack of water supply is one important issue that the industry demands the government to address. Bang said, "The government needs to establish a permanent and well functioning setup for the supply of clean, potable water to the industries. The companies have to manage their water requirements on their own."

Bang also spoke about how better coordination between the industry and government agencies can check any environmental damage that drug manufacturing may cause in Daman. He said, "The government can establish a common effluent treatment plant to curb pollution. This will help the industry comply with the regulations better. Moreover, the Daman administration can also consider setting-up a separate Pharma Industrial Zone with all the basic industrial requirements like continuous power supply, water supply, effluent treatment, competitive land rates, etc."

He ended his talk by asking the authorities to reconsider providing tax incentives to boost the pharma industry in Daman. It will benefit the existing industries and attract new investments.

Next to take the stage was Piyush Jani, Deputy Manager, Application Specialist – Shreedhar Instruments, who gave a presentation on 'Environmental Monitoring and Particle Characterisation of Pharmaceutical Formulations.' His presentation was followed by Nitish Singh, Manager- Sales and Marketing – Ami Polymer who spoke on 'Polymer Solution for Pharma Industry.'

Later, Dr N Ramamurthy, Head Quality - Pharmaceuticals and Intermediates Business, Atul Pharma, spoke about the need for infrastructure up-gradation to boost productivity. He informed the audience about the need for infrastructure development which basically lies in three spheres, namely, human resource, machinery used and the materials that are used in the processes. He added, "Our people are well educated, have ample experience, but lack in training and advanced skill development. This affects our overall effectiveness. Reskilling is a must if we want to have any sort of infrastructure up-gradation."

Continuing, he said, "Secondly, we devote a lot of time in collecting all sorts of data. But who do we collect this data for? What use is it for us if we do not analyse it? Pharma companies collect a giant pool of data and we need to start analysing it efficiently."

Ramamurthy proudly stated that Indian Pharma Inc is definitely well equipped with the latest technologies. "In fact, we are world leaders in exporting pharma equipment. Although we do lag in terms of automation compared to other countries," he argued.

Further, expressing his concern about the quality of materials that are used by the industry, he said, "We need to be careful about quality standards at every stage of production and not just during the final stage. We should remember at every stage of the drug-making process, that we are creating a product that will save millions of lives. These

thoughts need to be in our minds at all times."

He advised that companies should be proactive with their quality compliance so that audit visits do not cause any unnecessary disruption or stress. "We should set our own quality standards in a way that audits become a hassle-free process," he said.

Ramamurthy also talked about the initiatives the government has undertaken to boost infrastructure. He informed that the government will provide a one-time grant to the established common facilities in any bulk drug park promoted by the state governments or state corporations to provide financial assistance. The maximum limit to the grant aid would be $14.64 million per bulk drug park and $2.93 million per cluster for Common Facility Centres.

Talking about the Cluster Development Program for the pharma xector, he says, "The total size of the scheme is proposed to be at $2.93 million for 2018-20. It will be implemented in a public-private partnership format." He also talked about the Pharmaceutical Promotion and Development Scheme started by the government to promote exports in the pharma industry.

Next up, Ramanuj Samal, Application Specialist – Beckman Coulter Life Sciences, India, gave a presentation on 'Improve compliance, reduce workload and costs with Anatel online TOC analysis of pharmaceutical waters'. Afterwards, talking about the regulatory challenges that the pharma industry faces in general, Sunil Kumar Sharma, Deputy General Manager-Quality, USV said, "Daman has almost 500 small and big pharma industries operating currently. Majorly, the challenges that these industries face are regulatory compliance, especially when it comes to the US FDA. While we try to keep up with the regulations, warning letters are quite common during inspections. Not just in Daman, but all over India, receiving 483s and warning letters has become very commonplace."

He further added, "It becomes very important to be careful with investigation processes, development processes and data integrity. We may also need to check our attitudes and become more proactive about regulatory requirements. The *sab kuchh chalta hai* attitude will have to go."

Towards the end of the event, a Q&A session was held with Pursnani, Bang, Ramamurthy and Sharma on the expert panel. One of the major take-aways from the session was that the Indian pharma industry should step up and take the onus of quality compliance on itself, rendering the need for any regulatory authority to criticise its operations. "Our regulations and our industry need to become that proactive that our quality standards set global precedents. One India, One CDSCO, One Certificate. India is on the path to become the world leader in pharmaceutics. The industry and the regulators need to work together seamlessly to achieve this feat as soon as possible," said Ramamurthy as the event concluded.

Our regulations and our industry need to become that proactive that our quality standards set global precedents. One India, One CDSCO, One Certificate

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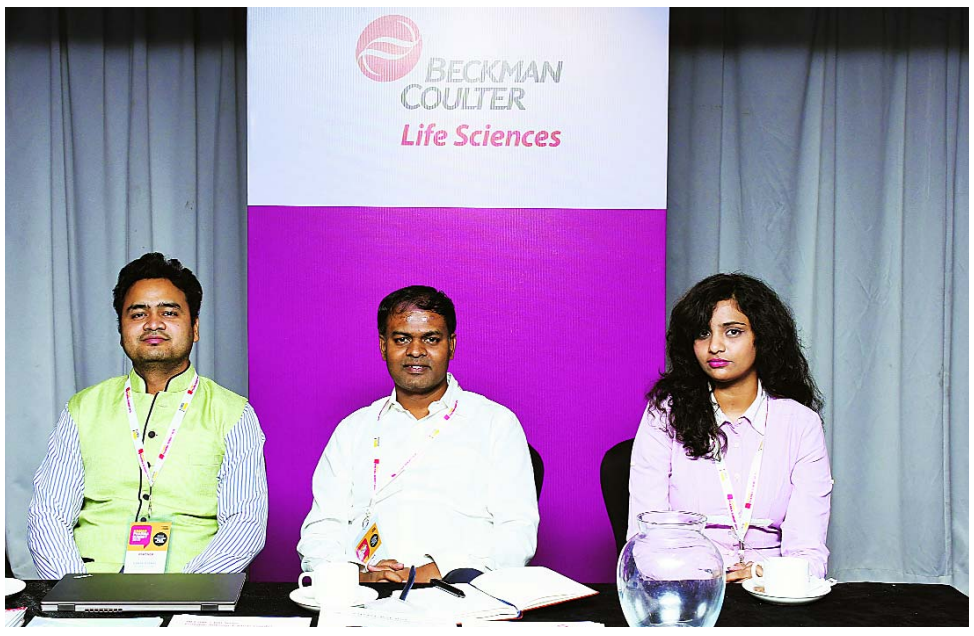

Fourth Digital Marketing Conference for Pharma and Healthcare held in Mumbai

Organised by MediaMedic Communications, the 2019 conference theme was 'Integrated Marketing Communications in the Digital World'

DigiSights 2019, the fourth edition of the Digital Marketing Conference for Pharma and Healthcare, was recently held in Mumbai. Organised by MediaMedic Communications, the 2019 conference theme was 'Integrated Marketing Communications in the Digital World'.

The conference kick started with the keynote address by Sanjiv Navangul, CEO-Global Specialty, Alembic Pharmaceuticals. As a seasoned executive with decades of experience in the pharmaceutical industry, he gave an overarching view of how digitalisation has started to revolutionise pharma marketing. His most important message for the young guns of Pharma was – "Take risks, solve the larger problem, do not be overwhelmed by the digital transformation."

The second keynote speaker was Joy Chakraborty, COO, Hinduja Hospital, a healthcare marketeer with over 21 years of experience. He said, "The onset of digitalisation has had a significant impact on patient monitoring. Today, the healthcare and the pharmaceutical industry are more intricately entwined than ever before. It's impor-

tant to monitor patients at every stage of the disease and the pharma sector can play a very significant role in this."

The world today is fast becoming aware of the power of artificial intelligence. The healthcare sector in India is only beginning to become aware of how AI fits into their industry. Vikram Kumar, Founder, Multiplier Solutions gave a live demo of how healthcare can benefit from AI. He stated, "Growing restriction on medical representatives to visit the doctors is one of the major challenges in the pharma industry. AI can help create tools and bridge this gap."

What added to the real-world relevance of this conference were the two power-packed panel sessions. The first panel session that provided insights on integrating digital and PR into brand plans, had panelists from a wide array of backgrounds.

Vivek Khanvilkar, Vice President-MR, SFE, Digital and Direct Marketing, Sun Pharma, believes that over the course of the year, for most brand managers, digital becomes just a tick and not an initiative that is well-thought of. It is high time that the brand team seriously introspects and identifies those pain points which can today be resolved only by digital initiatives," he adds.

Priti Mohile, MD, MediaMedic Communications, said, "Some companies are conducting only tactical activities that aren't completely built into their brand plans to deliver real business value." But this trend is changing, she adds, "We do see a lot of interest from more companies now, in understanding how to integrate communications."

The other panelists include Anumita Tripathi, Manager-External Communications, for Medtronic; Adarsh Rodrigues, GSK; and Dr Yashpal Chugh, GSK. They gave examples of some digital initiatives that produced good results for the company.

While India is still getting accustomed to the Digital Transformation, the next panel session took an international deep-dive and offered global perspectives on integrated communications. The panelists included some of the GLOBALHealthPR APAC & USA partners of MediaMedic Communications.

Tim Goddard, the President of GLOBALHealthPR, USA kicked off the international panel discussion talking about the transformation of the communications industry in the last few years – "As agencies, we are structuring our businesses to reflect the convergence of channels. No longer is PR or communications about media objectives, it's about looking at a client's business objectives, coming up with smart, multi-channel strategies and having the capabilities to deploy across all those channels."

His thoughts were further added on to by the rest of the panelists that included — Jonathan Wilson, CEO, Spectrum Science, USA; Kirsten Bruce, VIVA! Communications, Australia; John Wong, Madison Communications, HongKong; and Dr Peter Velev, Founder, CredoWeb.

The digital transformation marks challenging times for what up until now was an essentially traditional pharmaceutical industry. However, Manoj Saxena, MD, Bayer Zydus, wants pharma marketeers to look the challenge dead in the eye. He challenged CEOs to adopt technology and new-age media for pharma marketing.

In the age of technology, whatever isn't possible? Dr Peter Velev spoke of his product CredoWeb, a digital platform whose sole intention is to connect all healthcare stakeholders and facilitate

Sanjiv Navangul, CEO-Global Specialty, Alembic Pharmaceuticals

Joy Chakraborty, COO, Hinduja Hospital

Dr Peter Velev, Founder, CredoWeb

Dr Manjeeta Gupta, Medical Lead, Serdia Pharma

Jonathan Wilson, CEO, Spectrum Science, USA

Manoj Saxena, MD, Bayer Zydus

Dinesh Chindarkar, Co-founder and Director, MediaMedic

Salil Kallianpur, Founder, Arks Knowledge Consulting

communication between them. The platform claims to provide accurate targeting, a broader reach, precise statistics, and deep insights.

Dr Manjeeta Gupta, Medical Lead, Serdia Pharma presented an interesting case study on how Serdia garnered huge visibility through an integrated campaign on Angina awareness.

Transformation is here to stay. Every second, of every day, technology is enabling us to become faster, better, more accurate, more relevant. Relevance plays a massive role in creating top level industry intelligence reports. Spectrum Science, USA gave a demo of Galileo6, a marketing intelligence platform, capable of scanning through hordes of information and providing with the most relevant analytics & information. Wilson stressed on the importance of the changing transformative insights and analytics when developing strategic marketing campaigns, while speaking about the capabilities of the Galileo6. Chris Bath, Digital Insights Lead, Aurora Healthcare Communications, UK presented Data driven insights & its measurements in Pharma.

The conference ended with an engaging talk by Salil Kallianpur, Founder, Arks Knowledge Consulting who said that disruption is here to stay and "the interruptive marketing strategy of Pharma is complete no-no." He urged pharma marketeers to "think disruption and package your offerings into the daily life of a doctor."

Dinesh Chindarkar, Co-founder and Director, MediaMedic gave the closing remarks mentioning about the right adoption in this changing world solving real-world problems.

The event of DigiSights was a day-long immersion which concluded on the note that the changing marketing environment requires integrated, multi-channel marketing with a need to adapt to the digital transformation, rather than stay put in the traditional ways of pharma and healthcare.

EP News Bureau


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Over the past 25 years, Express Pharma has been faithfully tracking and capturing the pulse of the life sciences industry. Be it policy and regulatory reforms or technological disruptions, therapeutic innovations or ground-breaking research, business strategies or blockbuster deals, it has been at the forefront in keeping readers abreast of the latest and future trends in this sector. At the same time, it has also served as a vehicle for key opinion leaders to convey their views and insights on the most pressing and topical issues faced by India's pharma industry.So, in continuance with that tradition, our anniversary special issues will comprise a diverse mix of articles, interviews and opinion pieces which will reflect on the many milestones achieved by India Pharma Inc and outline strategies to enable its next phase of growth.Express Pharma is exceedingly grateful to all its readers, champions and well-wishers for your continuous support and trust. We hope and believe that you will continue to partner us in our mission to spur progress in this sector.

The Indian Pharmaceutical Industry: Pride and Growth Lever of India

Sudarshan Jain, Secretary General, IPA and **Archana Jatkar**, Associate Secretary General, IPA reminisce on five significant steps which changed the course of India's pharma industry and outline five steps that the industry needs to take for sustained growth over the next 25 years

The Indian pharmaceutical industry has achieved tremendous growth over the years and has made massive impact on the global market. Today, India is the pharmacy of the world and supplies over 60 per cent of global demand for various vaccines and ARV drug supplies, 30 per cent of UNICEF's annual supply globally and about 60 per cent-80 per cent UN purchases of drugs come from India. India also contributes approximately 57 per cent of APIs and 69 per cent Finished Pharma Products (FPP) to the Pre-Qualified list of WHO. The Indian pharma industry contributes nearly 40 per cent of generic drugs requirement in the US and 25 per cent in the UK.

From being almost non-existent in the 1970s, the Indian pharma industry has come a long way to being one of the largest and most advanced pharma industries in the world. This significant contribution of Indian pharma industry became possible due to several initiatives both at policy and business level. The five watershed moments in the growth of industry are as follows:

Sudarshan Jain, Secretary General, IPA

The Indian Patents Act, 1970

The Patent Act, 1970 was the first Patent Act in independent India. The Act had provision for only process patent and did not allow for patenting of the end product which enabled manufacturers to develop alternative processes for proprietary products that were already in the market. Another important feature of the Act was that it provided for a shorter term for patent protection. Both these features helped Indian pharma industries to flourish.

The Drug Policy, 1978

The Drug Policy of 1978, along with the Price Control Order of 1979, were landmark events for Indian pharma industry. The policy not only set up a National Drug Authority but was also drafted to give a 'Directional Thrust' to the Indian pharma sector. It aimed at maximising production of bulk drugs locally, providing leadership to the public sector undertakings (PSUs), reduction of imports of bulk drugs, encouragement for growth of local industry, reduction in selling prices of essential drugs and their formulations. The Policy had a stimulating feature which emphasised on 'production of bulk drugs by high technology'. This compelled multinational companies and large Indian companies to produce newer bulk drugs with the objective of marketing formulations thereof from the 'basic' starting materials. The basic starting materials were either available locally or could be produced utilising local materials. The Policy fuelled the growth of pharma Industry in India.

Hatch-Waxman Act, 1984

The enactment of Drug Price Competition and Patent Term Restoration Act - better known as the Hatch-Waxman Act, by the US Congress in 1984 was also very significant. Even though it was enacted in the US, it paved the way for spread of generic medicines over last two decades and is crucial for Indian generic industry. The Act seeks to streamline the process for generic pharma approvals and preserve incentives for innovation, including the creation of a procedure for patient litigation involving generic pharma. The Hatch-Waxman Act established the legal and economic foundation for today's generic pharma industry.

Economic Reform in India, 1991

In 1991, India launched giant economic reforms and stepped into globalisation. These economic reforms propelled market liberalisation, synergising Indian industry with the world economy. This also marked the end of the 'License-Raj', thereby allowing industry more freedom in the Indian market, creating leverage for domestic players and allowing market competition to drive product excellence. The Indian pharma industry benefitted from these reforms as this period of liberalisation allowed Indian industries to launch operations in foreign countries. Ever since these reforms took place, the Indian pharma industry has grown exponentially and today exports medicines worth $19 billion across the world.

Archana Jatkar, Associate Secretary General, IPA

The economic reforms in India also coincided with establishment of World Trade Organisation and its Agreement on Trade Related Aspects of Intellectual Property (TRIPS). India's accession to the TRIPS Agreement led to fundamental changes in the country's patent regime. However, the Government of India was able to utilise the flexibilities of the TRIPS Agreement to its advantage in public interest. India introduced two provisions in the amended Patents Act – i) Section 3(d) that does not allow patents on minor modifications of existing products and ii) possibility for the granting of compulsory license in certain circumstances. Both these provisions have stood scrutiny, including by the highest court of the land. The amended Patent Act, which is TRIPS compliant, has sought to balance between pharmaceutical innovation and affordability of access to medicines in public interest.

Furthermore, the pharma industries in its entirety and some of the leading companies have demonstrated significant improvement in R&D intensity since previous decade. An indicator of better performance of the industry has been the increase in its patenting activity. Also, the leading companies continue to expand their presence both in domestic and international markets, notwithstanding the uncertainties they faced following the introduction of TRIPS compliant patent regime.

Entrepreneurship which helped leverage local manufacturing

In 1991, the government of India liberalised the economy and this changed the competitive landscape. The business opportunities in India increased manifold. While the existing entrepreneurs/business families adapted to new economic policy to not only survive but compete against the MNCs, a good number of new entrepreneurs seized the opportunities and grew from small-scale to a big company. The businesses, today, have increased access to venture and growth capital and hence are able to create wealth for the company. The pharma sector also thrived in this entrepreneurial era to produce many well-known companies

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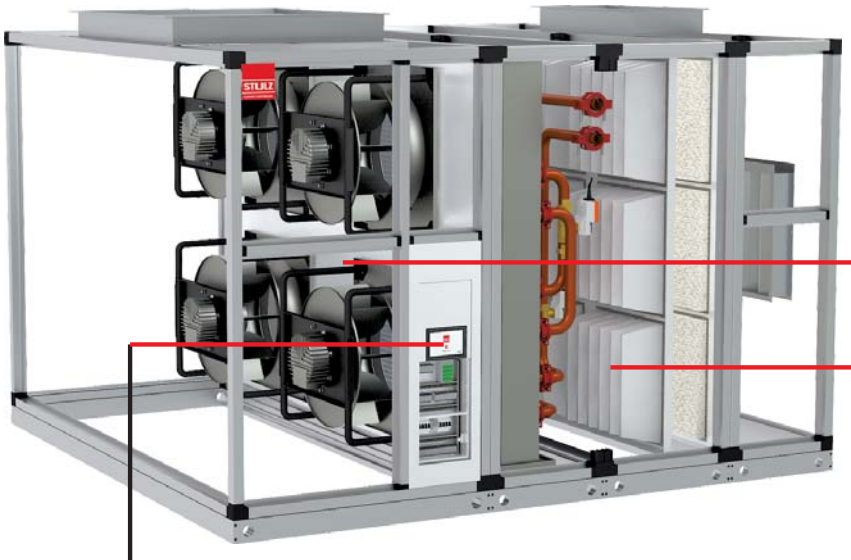

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that continue to grow.

The Indian pharma industry's success has been built on the foundations of its unique capabilities in vital areas of the value chain, such as manufacturing, product development and process innovation. Having achieved this unique distinction, the Industry now needs to ensure that enabling environment is created to fuel its growth over the next two decades. At current rates of 7-8 per cent CAGR, the industry can grow to about $80 to 90 billion by 2030. If India sets an ambitious target of 11-12 per cent CAGR, it is possible to grow to annual revenues to about $120 to 130 billion by 2030. However, what got us here will not get us there and growth will require multiple growth cylinders to fire simultaneously. Going forward, India will not only need to grow but will also need to move up the value-chain. This comes with its own set of challenges, however, concerted efforts and stronger collaborations between all stakeholders can accelerate growth.

Therefore, the industry needs to take the follwoing five steps for sustained growth over the next 25 years:

Exploring newer markets: While the industry has made a mark in export markets such as the US and EU, the next wave of growth is likely to come from increasing exports to large and traditionally under-penetrated markets such as Japan, China, Africa, Indonesia and Latin America. For example, the Japanese pharma market was worth over $85 billion in 2018, in which the Indian pharma companies having a share of less than one per cent.

Expand collaboration with international agencies: As Indian pharma industry aspires to grow further and explores new markets; a deeper relationship with respective governments to create enabling regulatory environment is important. The regulatory authorities in India will have to foster deeper relationships with their international peers. One way of doing this is to strengthen the exchange of best practices with global peers by at participating Pharmaceutical Inspection Convention (PIC) and ICH so also collaborating with regulatory bodies of other countries. This will improve quality perception of Indian drugs and help expedite approvals for industry.

If India sets an ambitious target of 11-12 per cent CAGR, it is possible to grow to annual revenues to about $120 to 130 billion by 2030. But it will require multiple growth cylinders to fire simultaneously. India will not only need to grow but will also need to move up the value-chain

Improved access to medicines: Improving access to medicines will broaden possibilities for all healthcare ecosystem players. In this context, efforts should be in the direction of accelerating universal healthcare access by strengthening the healthcare infrastructure using digital technologies. Further, the government could increase expenditure on healthcare to 2.5 per cent by 2025 from one per cent of GDP now and to five per cent by 2030, in line with the other developed economies in Europe and North America. This will help in improving the accessibility of medicines and healthcare facilities at affordable price to public.

Up-skilling: The industry has now moved beyond simple generics. Innovating and pursuing opportunities in newer classes of products such as biosimilars, gene therapy and specialty drugs would fuel the growth of the industry. There is limited supply of talent pool with advanced skills and there also exists a gap between the college curriculum and industry's requirement. In this context, intervention to build 'at-scale' capability building programs to create an industry-academic collaboration will prepare a talent pool.

Promote innovation: Create a research ecosystem that is supported through competitive tax breaks on R&D investments, technology transfers, besides targeted regulatory simplifications, will propel sustained growth. Such an ecosystem will incentivise the industry to build a strong innovation pipeline (with two to five new molecular entities launched or in late clinical trial phases and 10–12 incremental innovation launches per year by 2030). This will make Indian pharma industry move up the value chain and increase its significance beyond generics, to biologics, new drug development and incremental innovations.

The way forward

Indian pharma industry has earned the reputation of being a reliable and high quality supplier of drugs across the globe. The industry has played a key role in improving access to affordable medicines in India and across the globe, while also making significant contributions to Indian economy. A clear aspiration for growth and concerted efforts among Indian pharma companies, government and regulatory agencies, can unleash the huge potential of this knowledge-driven industry.

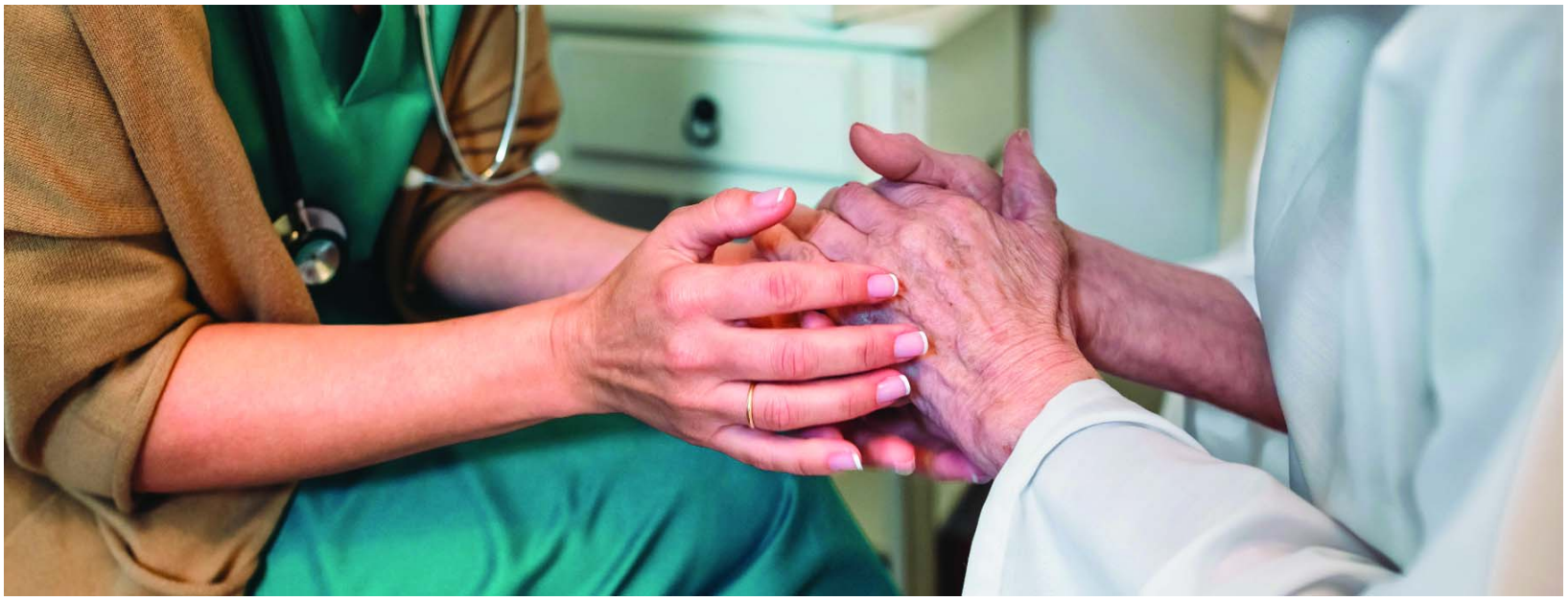
Patient-centric innovation – catering to future needs

Manoj Saxena, Managing Director, Bayer Zydus Pharma, talks about how technology has become an essential tool that complements the personal and physical interaction with a healthcare professional to help patients lead a healthier life

William Osler, the Father of Modern Medicine said – *'A good physician treats the disease; a great physician treats the patient.'* To me, this succinctly explains the benefits of putting patients at the centre of treatment and for this, patient-centric innovation, that prioritises the safety and well-being of patients is fundamental.

Over the past years, the healthcare industry has been witnessing a seismic shift in the way it has approached treatment and diagnosis. Today, the patient is the pivot around which innovations occur, be it in R&D or using technology to ensure healthcare is simplified and accessible. The new approach is also more focussed on 'prevention' wherein the industry is now looking at delivering holistic end-to-end healthcare solutions.

Shift in healthcare demo-



graphics is fundamentally defining how the healthcare industry needs to engage with the consumer/patient. India has more than 600 million young people and how they look at healthcare is going to define the very future of this industry. India also has a huge aging population and this will lead to industry focus on specific solutions catering to the segment of 'healthy ageing'.

In our patient-centric approach, Bayer has kept the millennials as well as the aging population in mind as it moves towards developing novel solutions based on the principles of technology, artificial intelligence (AI), biomarkers and/or robotics among others. Technology is now an essential tool that complements the personal and physical interaction with a healthcare professional (HCP) to help patients lead a healthier life and it will continue to play an increasingly important role in the future.

With patients today reading about their ailment on the internet, we have the phenomenon of the 'google doctor' that paradoxically juxtaposes with a population who now questions every prescription, every diagnosis of the HCP. They prefer HCPs who are tech savvy, and use emails and WhatsApp for communication. New research and innovation will therefore need to be driven by factors such as convenience and ease of accessibility of information and treatment more than anything else.

Use of AI in finding novel solutions

Artificial intelligence (AI) is everywhere. In the medical field, AI when combined with big data, can enable a more precise identification of suitable drug targets. It can also help predict the outcome of laboratory experiments and provide us with a better understanding of the day-to-day patterns and needs of the people on which to base our innovation. At Bayer, we are using AI to leapfrog our R&D through a series of collaborations. For example, Bayer and Merck are collaborating to use artificial intelligence software for Chronic thromboembolic pulmonary hypertension (CTEPH) pattern recognition. CTEPH is a long-term disease caused by a blockage in the blood vessels that deliver blood from the heart to the lungs. Development of the CTEPH Pattern Recognition AI Software will use deep learning methodology to support radiologists by identifying signs of CTEPH in imaging scans and ultimately help drive an earlier diagnosis to improve patient outcomes. The software analyses image findings from cardiac, lung perfusion and pulmonary vessels in combination with the patient's clinical history.

The era of personalised medicine

Today's generation want customised and tailor-made solutions. Drug discovery has to focus on developing precision medicine that can provide these personalised solutions. The search of such solutions begins with studying and understanding unique individual genetic makeups and disposition. At Bayer, we have invested in BlueRock Therapeutics that is using its unique platform to direct cellular differentiation and genetically engineer cells to create an entirely new generation of cellular medicines in the areas of neurology, cardiology, and immunology.

New models of collaboration

We need quick and new scientific breakthroughs if the industry is to match the pace of change and speed with which the healthcare landscape is changing. The millennial generation is in a tearing hurry for answers. For them, healthy is not equivalent to 'not being sick.' They seek holistic solutions and the term 'wellness' for them encompasses both mental and physical health. 'Leaps by Bayer' is an initiative wherein Bayer is collaborating with external partners and is focussed on curing and preventing disease. We have a two-pronged approach: not only do we invest heavily in a few key areas (DNA editing, microbiome, RNA inhibition, RNA activation, stem cell therapy), but we also actively help build up young biotech companies.

We understand the future lies in new technologies like gene editing and that is what our investment with Casebia Therapeutics is focussed on. Casebia is working to optimise gene editing across multiple disciplines and create therapies that will unlock the full potential of gene editing for patients.

Our synergies amongst stakeholders is also aimed at improving quality of life. We collaborated with FOGSI (Federation of Obstetrics and Gynaecological Societies of India) to launch the key practice points for endometriosis – VISION (Valuable Insights in Indian Endometriosis - Redefining Outcomes). Endometriosis is a chronic disease that affects five to 10 per cent of women of childbearing age. About 176 million women suffer from it globally, and of these 26 million women belong to India alone. Over 200 thought leaders were involved in formulating the protocols of practice on endometriosis. The objective of VISION is to understand the current usage pattern of various therapeutic options in endometriosis and develop an algorithm to guide doctors at the point of care in the management of endometriosis based on different patient profiles. The protocol will focus on providing management recommendations for endometriosis to physicians and patients from an Indian perspective.

Patient safety at the heart of patient-centric innovation

We cannot have patient-centric innovation if we do not put patient needs and safety first. Today's generation is actively engaged in the management of its own healthcare and they are also more likely to stay healthy. Keeping this central to our innovative approach in healthcare, we recently launched 'SafeTrack', a quick, simple and convenient adverse event reporting tool for the public. Available in eight different languages, SafeTrack makes reporting adverse events quick and easy. The web-based tool is simple to use, balancing the need to capture comprehensive data against ease and speed of use.

The future of healthcare rests in the hands of millennials that seek quick answers, prefers technology, is 'App-driven', more informed and therefore more demanding when it comes to safety, thereby making healthcare better for everyone.

INTERVIEW

"Patient-centric marketing will become a fundamental pillar in the future of pharma marketing"

Sumita Mohapatro Pani, Senior General Manager, Lupin speaks to **Viveka Roychowdhury** on the rewriting of the pharma sales and marketing playbook in the past two decades and highlights what makes pharma brand positioning so unique

Sumita, you have spent more than 24 years in pharmaceutical sales and marketing, across verticals spanning cardiology, neurology, psychiatry, nephrology, urology and oncology. Can you highlight a couple of major changes in pharmaceutical sales & marketing strategies in the past two decades? How do you see the integration of marketing strategies playing out?

There have been several major changes in the pharma industry over the last two decades, leading to a rewriting of the pharma sales and marketing playbook. Pharma firms have strategically intensified their focus on cardiological and respiratory disorders, diabetes, and neuropsychiatry due to a rise in their prevalence. They have also started paying more attention to oncology, nephrology and urology.

The concept of 'Category Captainship' has evolved from broad categorisation of 'Chronic – Acute' to Segment Captainship – Cardiology /Diabetology / Anti-infectives/ Neuropsychiatry etc. This is now further narrowing down to Therapy Captainship including 'Anti hypertensives / Heart failure / Antiplatelets within Cardiology, Anti Epileptics /Antidepressants /Dementia etc. within neuropsychiatry and so on. Strategically, firms are working towards attaining Therapy Captainship which also ensures a level and fair playing field for the smaller players and new entrants.

The conventional levers of market creation including expanding therapy to new doctors, indication expansion, geography, deepening penetration in established

markets, and building underrepresented markets have always been and continue to be important. However, going forward, market creation would entail changing the patient funnel by increasing awareness and treatment and in turn increasing the patient pool. Thus, the term patient-centric marketing /healthcare is moving beyond just being a 'buzzword' to becoming a fundamental pillar in the future of pharma marketing.

Leather bags containing 40 pages of visual aid with feature-benefit selling points, tons of samples, scientific literature, gimmicks, and other promotional materials have given way to sleek sling bags. These contain tablets for scientific communication, engaging brand ads, animations, studies, references, and latest updates pertaining to the brands. In-clinic brand promotion has also become totally paperless and dissemination of scientific information is faster than ever. We will also see virtual reality being used more.

Apart from this, integration of marketing strategies would play out in a big way. Firms will deploy brand promotion communications on various platforms, besides visual aids like social media, other digital platforms, app-based information etc. Though different communication would need varied degrees of scientific content, the consistency and integration in the essence of communication would need to be maintained.

Operationally, the conventional sales planning by representatives is evolving into a dynamic, analytically enabled model. This can provide the right insights to deliver the right interactions, to the right customer, at the right time. Going forward, we must prepare for the convergence of big data, automated analytics and real-time sales planning processes to stay ahead in the game.

What will be the most salient changes that you anticipate in the near future?

Though there are several changes on the cards, I would like to highlight the three most important ones that I anticipate in the near future.

> Marketing was once largely an art form in which creativity was paramount. Now, data will be integrated with this approach for more impact

1. Patient centricity

Some firms have made great strides towards patient centricity, while others have taken tentative steps. In the times ahead, firms would work on expediting their transformation to patient-centricity. This would mean empathising with the patients' experience, what they value and need, and then placing them at the centre of business activity. For this, firms will need to build new capabilities, possibly set up a dedicated patient care department that hears them out and understand what will make them seek a doctor. They will also need to build patient advocacy through disease awareness and increase patient's acceptability to the disease condition. Focus will also need to be given to patient experience by truly understanding and empathising with their condition and leading them to right diagnosis and treatment. This will further enhance patient engagement and firms will be able to work around what behaviour will impact patient's adherence to medication.

Based on patient segmentation insights, strategies would need to be tailored for each segment, with different channel mix and messaging. Firms will also need to collaborate with other industries such as IT, telecom, food, and fitness to deliver 360-degree treatment and experience to patients. Going forward, patients will be at the heart of all marketing and business efforts in the pharma industry.

2. Artificial intelligence

Artificial Intelligence (AI) is no longer a futuristic topic but something that has penetrated almost all aspects of our lives. This is also true for the pharma industry and marketers are already ramping up application of AI including in administration. This includes its use for handling paperwork, chatbots for patient interaction, CRM activities, patient databases, etc.

Going ahead, AI can immensely facilitate assistance throughout the patient journey from pre-diagnosis to adherence. For instance, a patient who has not been feeling well lately and is trying to search for the symptoms and related causes on an AI-enabled search engine. Based on her search behaviour, AI predicts that she might be prediabetic and pushes awareness information on type 2 diabetes targeted for her on the site she normally visits. Concerned about her health, the patient calls a doctor for an appointment. She undergoes all relevant tests, and an AI-enabled lab helps the doctor during diagnosis. The doctor designs a treatment for the patient and suggests certain lifestyle improvements. The patient then asks the bot to book an appointment with the pharmacist and an AI-enabled adherence app continues to remind her to take medication at regular intervals. She misses a dose and asks the chatbot about what should she do in this case; the bot sends a reminder to renew the medicine in a timely manner, and she is also able to connect with the AI- assisted patient support group on social media to stay on track. This is but one example of how AI can facilitate assistance to the patients throughout their treatment and management journey, thus making their life better. In the next five years, more AI-powered predictive models will help to better understand adherence, drop-off risks, coverage, reimbursement, treatment and clinical decisions, sales planning, ROI monitoring, etc. Marketing was once largely an art form in which creativity was paramount. Now, data will be integrated with this approach for more impact.

3. **Compliance**

In response to the changing business environment, shifting industry dynamics and regulations, the Indian pharma industry has made efforts towards ensuring compliant and ethical business practices in its marketing promotions. Going forward, there would be increased emphasis on better ethical standards of promotions and stringent adherence to compliance. Firms would need to set up robust processes to ensure compliance in their interaction with all stakeholders.

With so many generic brands, how do pharma companies create a unique brand positioning?

Pharma brand positioning is unique due to many reasons. First, the decision maker of choosing a brand is the HCP and the end user is the patient. Second, the pharma market is a cluttered branded generic market where given a molecule there are no less than 80 to 100 brands with minimal brand or benefit differentiation. Third, in other segments, the customers engage mindfully to buy a product. However, in the case of pharma products, it is the diagnosis that makes them opt for a certain category. For instance, a person buys luxury travel gear out of choice. However, they are likely to buy products for diabetes because they have been diagnosed with the condition.

Conventionally, brand positioning was designed around features and benefits of the brand, efficacy, safety, and dosing which would appeal to the HCP or the decision maker. For instance, 24-hour blood pressure control, OD dosing convenience, synergistic action etc. However, the trend has now become more patient centric. They are the ones diagnosed with health conditions and also the ones who will benefit from medication etc. Thus, the positioning should be around the impact that the brand promises to make in the patient's life and how this will translate into

benefits. A unique brand positioning is one that integrates the core unmet need and product benefits.

The process of brand positioning is also interesting and one of the models I follow and have found success with revolves around answering five questions.

For: The product is for treatment of patients with....

Is: Is the molecule .... with the proven efficacy in therapeutic areas of ....

That: enables the HCP to treat ...

Because: .... Core differential action ... core differential benefit

So: Helps patients live ...(how it impacts the patient's life for better ..)

What are the basic building blocks deployed by pharma companies to create profitable and sustainable business models, given the intrinsic challenges unique to this sector?

A company's business model is the means by which it makes a profit, addresses its marketplace, develops offerings, and maintains business relationships. To build a sustainable business model, it is important to answer some pertinent questions

- What is our current business model? Does it play sufficiently to our strengths?
- What kind of company are we and what do we want it to be going forward?
- Will our current business model enable us to expand into new markets and satisfy the expectations of our evolving customers?
- If not, how big is the gap and what model do we need to reduce the gap?
- Have we calibrated opportunities and risks of the new model? And how can we maximise the opportunities and minimise the risks?
- Do we have a tactical plan ready?

Many new pharma companies have been launched and existing ones have also expanded in the last two decades. To build a sustainable business model, in the sales and marketing perspective, the right portfolio with high growth – high margin must be selected in line with the business goals. Manpower deployment (the major cost head) must be meticulously planned considering customer dispersion, segmentation based on thorough research, customer value proposition, deployment of key resources, formulating key operational processes, and mechanisms to capture and maximise ROI. A business that considers the above aspects goes ahead to become profitable and sustainable.

The pharma industry has many challenges around regulation, how do you see the sector's growth in the coming decade, 2030?

According to a recent IPA report, the Indian pharma industry is expected to grow to about $80 to 90 billion by 2030. To achieve this growth, there is a need for regulatory support from the government including budgetary allocations for healthcare and promotion of innovation, a coherent pricing policy framework, simplification of regulatory approval processes, etc. The key challenges are around aggressive action on pricing, among other things. There is also a need for regulations on quality and creating an enabling environment for strengthening the domestic pharma industry. A strong, independent, and empowered regulatory system is the need of the hour in this sector. This can be made possible with concerted efforts by all stakeholders including the Indian pharma companies, the government and regulatory agencies and IPA, and drive the industry to achieve the 11 per cent to 12 per cent CAGR it aspires for.

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Routine pneumococcal vaccination rates remain high in children, but subpar in elderly: GlobalData Report

The company's latest report, 'Pneumococcal Vaccines: Epidemiology Forecast to 2028', reveals that the average pediatric pneumococcal vaccination rates in the combined 7MM are expected to marginally change from 85.98 per cent in 2018 to 85.12 per cent in 2028

Pneumococcal vaccination rates in children are expected to remain steady at approximately 85 per cent in the combined seven major markets (7MM*) by 2028, while vaccination rates in the elderly are expected to slightly increase to only 62 per cent in the combined six major markets (6MM**) by 2028, according to GlobalData, a leading data and analytics company.

The company's latest report, 'Pneumococcal Vaccines: Epidemiology Forecast to 2028', reveals that the average pediatric pneumococcal vaccination rates in the combined 7MM are expected to marginally change from 85.98 per cent in 2018 to 85.12 per cent in 2028. In contrast, the average elderly pneumococcal vaccination rates in the combined 6MM are expected to slightly increase from 58.32 per cent 2018 to 62.03 per cent in 2028.

Natasha Karim, MPH, Managing Epidemiologist at GlobalData comments: "With pediatric pneumococcal vaccination, the primary reason for non-vaccination is vaccine hesitancy. In contrast, with elderly vaccination, the primary reason for non-vaccination is a lack of awareness about the pneumococcal vaccine from both the patient and healthcare professional."

"While pediatric rates are promising, there is still room for improvement. Addressing vaccine hesitancy requires further investigation and analysis into specific social, behavioral and economic factors that play a role in whether or not an individual gets vaccinated. Furthermore, to help overcome insufficient doctor-patient communication and knowledge about vaccines, incentives or certifications should be offered to doctors who remain up-to-date on national vaccine guidelines and who are properly trained in vaccine counseling."

"In the future, continued efforts should focus on carrying out a targeted, actionable, and effective country-specific approach to overcome vaccine hesitancy, increase vaccine awareness, and ultimately reduce invasive pneumococcal disease incidence worldwide."

SCHOTT Glass strenghtens India facility as Asian hub

With investments of close to €47 million in India over two years, global pharmaceutical glass manufacturer SCHOTT AG clearly sees the country as a vital cog in its global strategy. **Georg Sparschuh**, MD, SCHOTT Glass India and **Dr Patrick Markschläger**, Executive VP, SCHOTT AG, Business Unit Tubing reveal the company's strategy to build India into an Asian hub for SCHOTT pharma tubing, their endeavours to be as sustainable as posssible and how investing in the futures of the communities in which their manufacturing plants are based is simply good business practice

By **Viveka Roychowdhury**

Twenty one years after it bought over a company producing pharmaceutical tubing in Jambusar district in Gujarat state, SCHOTT AG has earmarked the plant as a production hub not just for the country, but for SCHOTT pharma tubing in Asia.

The plant is an ideal example of Prime Minister Modi's campaign to "Make in India, for the world." According to Georg Sparschuh, MD, SCHOTT Glass India, the Jambusar plant had reached up to 40 per cent export rate, in addition to the rapidly growing domestic demand. While domestic demands have been their main focus, the increased capacity with two new tanks, is expected to cater to the exports, which may even cross 40 per cent.

Solely owned by the Carl Zeiss Foundation, the parent company SCHOTT AG is present across many sectors besides pharma and life sciences, including home appliances, electronics, optics, automotive and aviation industries. The company has production sites and sales offices in 34 countries.

In fiscal year 2017/2018 (October 1, 2017 to September 30, 2018), the Mainz, Germany headquartered company clocked global sales of Euro 2.08 billion in 34 countries, with Europe's share the highest (46 per cent, Euro 963 million; 9,450 employees).

> We are the first ones to follow the market trend
>
> **Georg Sparschuh**
> MD, SCHOTT Glass India

The Asia and South Pacific region made up 25 per cent of sales (Euro 517 million; 2,800 employees) with North America in the third place, with 23 per cent sales (Euro 475 million; 2,050 employees). The annual report does not provide a break out of sales per segment, but Dr Patrick Markschläger, Executive VP, SCHOTT AG, Business Unit Tubing indicated that pharmaceuticals - Pharmaceutical Tubing and Packaging - is the biggest business for SCHOTT Glass.

As both domestic and global demand for pharmaceuticals rises, so will the demand for high quality packaging material. This explains why the company pumped in €21 million last year in the first phase of its expansion of the pharma tubing plant in Jambusar, which culminated in the inauguration of a new tank facility this November. *(See report: https://www.expresspharma.in/latest-updates/schott-inaugurates-new-production-facility-at-gujarat-plant/)*

> Asia has driven the market growth over the last few years, not so much Europe or the Americas
>
> **Dr Patrick Markschläger**
> Executive VP, SCHOTT AG, Business Unit Tubing

A further €26 million investment is planned for the second tank facility in 2020. The second investment is larger than the first as it includes expansion of support facilities as well as building a new chimney for the new plant.

Pivot to exports

Sparschuh says that over the decades, he has seen a shift in focus of Indian pharma companies from the domestic market to exports. All of SCHOTT Glass India's products and the factory itself are fully globally certified, making them the ideal choice for companies making this transition.

"We are the first ones to follow the market trend," said Sparschuh, explaining the year-on-year expansion plans. "While this first phase expands capacity by 50 per cent, the second step will add another 50 per cent. So we will double our capacity."

Building on their experience of the first phase, construction work on the second phase has already started. The first phase was completed in a year's time, even though this year's unusually prolonged monsoon delayed construction. Learning from this experience, Sparschuh is targeting to have

the second tank ready before the 2020 monsoons. The tentative date for the completion of this expansion is August 2020.

The cumulative investment of €47 million in India over two years is logical as growth shifts from the more mature markets to emerging ones.

"Asia has driven the market growth over the last few years, not so much Europe or the Americas," said Markschläger. Besides India, the company's global production footprint includes facilities in Germany and South America. The company will soon be starting a greenfield manufacturing facility in China as well.

Adding to Sparschuh's point that the (pharma manufacturing) market is shifting volume-wise to India, he points out that many global companies are also moving to India, looking to make India their production hub.

The expansion of the Jambusar facility is part of a $1 billion investment over the next six years in the global expansion of the pharma business as the world prepares for more biological medicines requiring glass ampoules, vials, etc.

Green initiatives

The Jambusar facility has an almost 100 per cent recycling policy, with no wastage of glass. According to Sparschuh, low cost transport and labour charges in India allow their pharma clients to also send their glass wastage back to the Jambusar facility for re-use, which is then added to the glass melt after appropriate quality checks.

Other green initiatives include a zero-discharge policy when it comes to water used. The plant also has a rain harvesting system.

Since glass making is an energy intensive process, requiring continuous power supply, Sparschuh said the plant has installed more than 7000 solar panels to meet the energy requirements and improve the green footprint of the facility. He claims that these measures make it one of the leading factories in Gujarat in terms of sustainability initiatives.

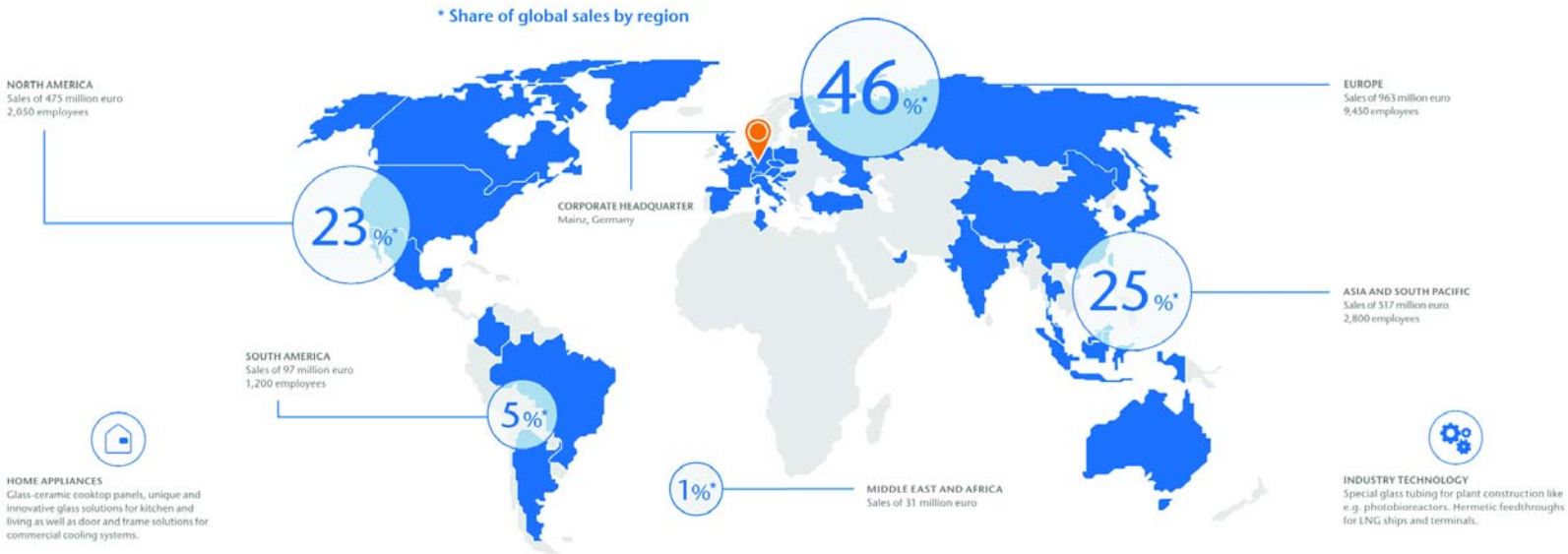
Skilling India

SCHOTT Glass' Jambusar facility is a major employment provider in the area. Before the first phase of expansion, the staff strength was 300 employees on payroll and 150 on contract. Approximately, another 100 payroll and 150 contract employees will be added for the facility after the November expansion. Sparschuh estimated that the second phase might add another 70 payroll and 50-80 contract staff. The current site has enough free land here for future projects, he said.

There is another reason for not looking to expand to a new location: the availability of skilled manpower in Gujarat. Sparschuh pointed out that the current plant is fully automated, built on the latest Industry 4.0 principles. This requires workers with high technical skills, who are available in the state.

The branded FIOLAX® pharma tubing produced in Jambusar, and indeed at all SCHOTT Glass sites across the

SCHOTT is a leading international technology group in the areas of specialty glass and glass-ceramics. With more than 130 years of outstanding development, materials and technology expertise we offer a broad portfolio of high-quality products and intelligent solutions that contribute to our customers' success.
SCHOTT is an innovative enabler for many industries, including the home appliance, pharma, electronics, optics, life sciences, automotive and aviation industries. We strive to play an important part of everyone's life. The parent company, SCHOTT AG, is solely owned by the Carl Zeiss Foundation.



Source: Company Facts & Figures, Fiscal Year, 2017/2018

world, follows SCHOTT's perfeXion® process since 2017, where the system has transitioned from statistical quality control to 100 per cent automated inspection of each individual FIOLAX® tube – based on big data. Hence, it is introducing Germany's Industry 4.0 to its Indian factory in the most effective manner.

The use of such systems requires skilled rather than unskilled labour, which might be difficult to find, especially in rural areas like Jambusar and the like.

Which is why over the past many years, SCHOTT Glass has supported their current employees to educate their children as well as given inputs to local schools and initiatives, where trainers go to rural schools to prepare students to take on such roles.

Markschläger also informed that SCHOTT had been collaborating with Indian universities and training institutes to focus on skilling, preparing trainees to match the demands of future

SCHOTT Glass India manufacturing plant at Jambusar, India

Industry 4.0 requirements.

As a result, "all SCHOTT products have the same quality, irrespective of which geography they have been produced," he said.

In addition to investing in the futures of the communities in which their manufacturing plants are based, SCHOTT AG also encourages their suppliers to upgrade their systems to meet the global standards. Sparschuh mentioned a recent supplier meet where rather than discussing rates and prices, the discussion was about aspiring towards international quality standards right from the raw materials like sand, sodium nitrate, packing material etc as well as equipment required for their machinery.

SCHOTT Glass' expansion at Jambusar is thus a logical reflection of their pharma clients' strategy to move to more cost effective manufacturing locations. The company will no doubt be a vital part of pharma supply chains as they evolve to cope with new business realities.

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Bluebird bio, Bristol-Myers' multiple myeloma therapy shows promise in early study

Bb21217 belongs to a class of drugs called CAR-T therapies that involve drawing white blood cells from a patient, processing them to target cancer cells, and infusing them back into the patient

Bluebird bio Inc and Bristol-Myers Squibb Co reported encouraging initial data from an ongoing early-stage study testing their experimental therapy for multiple myeloma in patients who did not respond to prior treatments.

The lowest dose of the therapy, bb21217, had a median duration of response of 11.1 months and an overall response rate of 83 per cent in heavily pre-treated patients with at least three prior lines of therapy, according to data presented at American Society of Hematology Conference.

Bb21217 belongs to a class of drugs called CAR-T therapies that involve drawing white blood cells from a patient, processing them to target cancer cells, and infusing them back into the patient.

Typically with CAR-T cell therapy, after around six months of receiving the treatment, the presence of CAR-T cells available to fight the tumour cells diminishes to levels that are no longer measurable, said Dave Davidson, Chief Medical Officer, Bluebird bio.

With bb21217, the companies are looking to prolong the persistence of CAR-T cells in the body, which could translate into more durable clinical responses following treatment, he added.

Bluebird and Bristol-Myers reported positive results from a mid-stage trial for another CAR-T therapy, Ide-cel, for multiple myeloma. [nL4N28G3QL]

The safety profile of bb21217, which targets a protein linked to multiple myeloma known as BCMA, was consistent with the known toxicities of CAR-T therapies, regardless of dosage, the companies said.

Reuters

Augmenting India's medical arsenal: Genomics will facilitate developing new-age medicines

Pranav Anam, Founder, The Gene Box explains how pharmacogenomics can create far reaching impact in the pharma industry such as addressing medicine wastage and establishing health equity

The global pharma market, of which India is an important part, expected to reach $1.5 trillion by the end of 2023. It is going through a rapid transition, hinging on technological advancements and innovation that adds value to the existing products. One of the best ways to add value to a product is to tailor it and suit individual needs. Pharma players have seized the opportunity as they added personalised medicine as a key focus area for growth – personalised medicine may transform the entire value chain, from early product development to go-to-market models.

The term pharmacogenomics was first used in the 1950s, and has become one of the mainstays of this breakneck growth – it is a scientific discipline that looks at how a person's genetic makeup influences his or her response to drugs. According to estimates, as much as 40 per cent of the medicines people take every day are not effective; for some medicines this may go up to 50 per cent. The value of wasted medicines, by the time we cross a quarter of the century, can well be the GDP of a cluster of small countries. Applying pharmacogenomics in pharma industry can help address the wastage and establish health equity.

Pharmacogenomics helps to choose the right drug and dose

Taking medicine may not be enough to eradicate the disease. The way our genes react with the drug, its specific ingredients, or the form in which it is taken can play an important role in determining its usefulness and varies from one person to the other. In healthcare, one size does not fit all, that can impact the course of treatment depending upon the genotype. Pharmacogenomics helps to understand how a certain body type breaks the drug and supplies to the intended area. Absorption, distribution, metabolism, and excretion (ADME) – the factors that decide a drug's pharmacokinetics – depend a lot on pharmacogenomics. There are crucial enzymes that are coded by a set of genes which play a vital role in this function. There are three key areas of pharmacogenomics:

- **Drug reception**: Some drugs need to attach to receptors, i.e. proteins on the surface of cells, to work properly. The type and number of receptors one has are determined by the DNA; one might need a higher or lower amount of the drug than others or a different drug for the same problem. Pharmacogenomics can help in adjusting the dose or drug type for better efficacy.
- **Drug uptake/absorption:** Some drugs can act only when taken into the target tissues and cells. However, the genes can affect this uptake. Decreased uptake can prevent the drug from being effective and can cause build-up in other parts of the body, causing further problems. The genes can also affect how quickly some drugs are removed from the cells in which they act. If the drugs are removed from the body too quickly, it may not have enough time to act upon, reducing the efficacy of the drug for the particular individual. The time taken by an individual's bodyto flush put drugs is governed by genes, and any variation may impact the drug efficacy.
- **Drug breakdown:** A drug can work in the body only when it breaks down, a process that is again affected by the genes. The faster- or slower-than-normal breakdown will reduce efficacy for drug that generally works and the doctor will require increasing dosage or changing the drug.

Addressing critical needs in the Indian context

Many countries who chose pharmacogenomics to address their typical challenges have come out satisfied. Thailand, for example, was battling the onset of Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), two severe mucocutaneous (skin) reactionscommonly triggered by carbamazepine and risperidone medicines, prescribed for autism spectrum disorder (ASD)– genetically-mediated SJS/TEN are rare and only induced by certain drugs, and only in people with specific kind of immune genes. The condition of affected patientscan be serious and require admission in burn care facilities, suffering excruciating pain, inability to eat, urinate or open their eyes. Thailand decided to screen patients for this variant of gene so that they are not administered with the medicine. Dr C Sukasem invented a low-tech approach in 2011 and introduced a wallet-sized pharmacogenetic plastic card, something that was identified as an 'opportunity' by the delegates at Global Leaders in Genomic Medicine Summit, a multinational coalition of genomic and policy experts from over 20 countries working to implement genomics in clinical care.

India has its share of challenges – diabetes is one of the raging non-communicable diseases (NCDs) in India and more than 30 per cent diabetics in India do not respond to metformin, an FDA-approved drug that works perfectly fine in the US population. In fact, adverse drug reactions are the fourth leading cause of death in the US, while in India, drug side effects are the reason for 3.4 per cent of hospital admissions, 3.7 per cent readmissions, and 1.8 per cent death. A card like this can usher in a real change in how doctors prescribe and people consume medicine. Pharmacogenomics can set the ball rolling for precision medicine in India. India is on the path of creating a genetic database and pharma companies should leverage the opportunity to develop life-saving medicines using pharmacogenomic to cater to population-specific diseases with less side effects. Adopting pharmacogenomic is also likely to reduce the drug development timeby up to two years and push down costs by up to 20 per cent, not to mention the benefits of selecting patients during the clinical trial phase.

The average lifespan of Indians has increased across the board but it has also increased the incidence of age-related degenerative diseases, e.g. neurological and orthopaedic diseases, which were more 'western' until a few decades ago, making people more dependent on drugs to maintain the quality of life. With disease patterns becoming more like the developed countries, India needs to augment its medical arsenal, which in turn, will also improve its status as a hub for contract manufacturing for foreign pharma companies. Besides, pharmacogenomics will provide better options to doctors and reduce the 'trial and error' method they are compelled to adopt now, and thus, improve patient safetyand compliance to the therapy – they will see the results in form of improvements in quality of life.

Bengal Chemicals - Biggest turnaround story in the corporate world

Bengal Chemicals, the first pharmaceutical company of India founded by Acharya Prafulla Chandra Ray 1901, has made the biggest turnaround in the corporate world after reporting losses for five decades. This turnaround was possible due to the dynamic leadership of PM Chandraiah, Managing Director and Director Finance.

Before Chandraiah joined Bengal Chemicals in November, 2014, as Director (Finance), the company reported a net loss of Rs 36.55 crores in 2013-14. The company and its all directors were listed in the defaulters list of ROC, Kolkata, due to non-filing of annual reports for a number of years. Chandraiah realised that without updating company's records nothing is possible to change within the company. Hence on a war footing basis, he completed three years pending annual accounts and six years pending cost audit reports in a very short period of eight months. Now the company stands at No.1 position out of all PSUs to conduct annual general meeting every year since 2016-17.

Loss-making Bengal Chemicals became a profit-making company and reported a net profit of Rs 4.51 crores in 2016-17, Rs 10.06 crores in 2017-18. The company touched the landmark performance of Rs 120 crores income and an all time high net profit of Rs 25.26 crores in 2018-19. The turnaround

was possible due to synchronised effort of the employees under the able guidance of Chandraiah. This complete transformation of BCPL was possible due to the steps / actions by the present management like introduction of centralised procurement system, centralized accounting system, centralised collection system, centralised payment system, centralised bill processing system, centralised payroll system, centralised stores system, centralised billing system, centralised fund management system, centralised HRM Record Maintenance System, etc. in addition to installations of CCTVs to closely monitor the work culture of the company and installation of bio-metric attendance system.

Further, the systems in the company are closely monitored Chandraiah who has inculcated the feeling of ownership and togetherness amongst all the employees. Recognition of this transformation came in the way of Government of India's approval for implementation of long-awaited 2007 pay scales for the employees as well as extension of the term of Chandraiah in Bengal Chemicals as Director (Finance) and Managing Director (I/C). Perfect planning of the management and hard work of employees led Acharya Prafulla Chandra Ray's Bengal Chemicals & Pharmaceuticals towards a profit-making turnaround company and created history not only in India but also in the entire corporate world.

INTERVIEW

‘We consider the ever-evolving needs of the industry as an opportunity to do more and serve better’

Ashok Kumar Prusty, Executive Vice President, Bry-Air reveals more about hi company’s offerings for the pharma sector, in an interaction with **Sanjiv Das**

How big is the market for dehumidification? What is the pharma sector’s share in this market? What percentage of it is catered to by Bry Air?
Dehumidification or moisture/ humidity control solutions is almost essential across all the various stages and processes of the pharma industry. Be it processing, manufacturing, storage, research and testing, or packaging, all require ideal RH conditions to be maintained and hence dehumidifiers become all the more important.

Like other industries, the pharma industry too is witnessing a major shift led by changing consumer lifestyle. With people opting for a healthy lifestyle and the economy moving towards preventive healthcare, the pharma market too is undergoing a major change.

And, with current Good Manufacturing Practices (cGMPs) regulations picking pace and being enforced by FDA, the pharma industry is all the more cautious and the focus once again has shifted to manufacturing, processing and storage of the drugs. The use of technology, systems and equipment to prevent contamination, ensure safety and hygiene during the various stages of pharma manufacturing is all the more paramount.

Therefore, humidity control or dehumidification systems, thus, becomes an integral part of the entire process till the product reaches the consumer.

Pharma and food processing business accounts for 75 per cent of the dehumidification market in India. Bry-Air is a leader in this category with as much as eight out of every 10 pharma companies using our dehumidifiers for their humidity control needs.The growth is led by increase in adoption of energy-efficient dehumidification products and solutions by the pharma companies.

What are the trends in this area? How has Bry Air leveraged this?
With India holding leadership position in some of the key drugs and vaccines in the global pharma market, it is now time for us to focus on the upcoming trends.

The industry needs to put more emphasis on research, innovation and enhancing the technology to serve the pharma industry better for a brighter and stronger standing of the country in the global market. Iinvestment in latest dehumidification technologies is a necessity for the pharma companies in the country.

Since the majority of the pharma products are highly hygroscopic and tend to suffer physical, enzymatic, microbiological and biochemical deterioration after coming in contact with moisture- the loss of potency during storage influences the efficacy and safety of pharma products are some of the biggest problems faced by the sector. The task is to enhance productivity through environment control, efficiency in terms of time, cost, maintaining product quality and increase in throughput levels, followed by reduced downtime.

With the nutraceuticals and other health supplement product market picking up pace in India, the requirements of customised dehumidifiers is also shaping well.

At Bry-Air, we have designed a forward-looking solution that enables the manufacturers to increase productivity at a low cost, gain higher throughput with limited resources, and reach economies of scale. Our range of best-in-class Bry-Air’s BrySmart series (BBS) Desiccant Dehumidifier are capable of delivering energy savings of upto 48 per cent, plus an additional 20 per cent through a customised rotor which reduces initial react energy input for equivalent performance of standard dehumidifiers.

What are your competitive advantages when compared to your peers?
At Bry-Air, we consider the ever-evolving needs of the industry as an opportunity to do more and serve better. Our solution-oriented approach towards humidity and moisture-control problems faced by the customer has helped us stay ahead of the curve. Over and above that, our knowledge and experience gained in over 55 years has helped us serve our customers in achieving their business goals — profitability, productivity and sustainability.

Who are your pharma clients in India and abroad?
Almost all the pharma companies (domestic, exporters, international — MNCs, Fortune 500) have Bry-Air dehumidifiers installed at their plants in India. More than 80 per cent of the dehumidifiers installed at pharma companies in India are of Bry-Air. We are proud to partner the pharma industry for over five decades and provide innovative and customised solutions to cater to their quality air requirements.

What are your plans for the Indian pharma market? How did CPhI India 2019 helped you achieve your objectives?
Today, we are talking about Machine 4.0, what it means less of human interface and more machine to machine interface. We are committed to continue to serve our customers with customised need based solutions. Our new super BrySmart (BBS) Series is built with that in mind.

With 70-75 per cent of the business in the dehumidification market pouring in from the food and pharma industry and Bry-Air being the leader it is next to impossible to miss the significance of the industry platforms like CPhI. It is great platform to meet the demand and supply for the equipment manufacturing in pharma and to learn of various new advancements taking place to better align the future needs of various stakeholders.

We are happy to showcase our cutting-edge products and solutions at CPhI and be able to reach prospective customers, fellow manufacturers to collaborate and discuss the roadmap for next decade.

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The United Engineering Company: Serving the pharma industry for the last five and half decades

THE UNITED ENGINEERING COMPANY (UEC) with the brand name 'UNITED' is known for being the pioneer and commander in packaging machinery manufacturing in India. UEC, which was started in the year 1963 by GD Roy, has attained high reputation in providing machines and services of highest standards since the beginning. With the founder's innovative ideas and unmatched leadership qualities, UEC crossed various boundaries in different fields of work.

Initiating the business with solutions for parenterals (ampoules and vials), UEC has diversified its business into the bottle packaging sector and has also mastered in providing machines for automatic tablet coating

Initiating the business with solutions for parenterals (ampoules and vials), UEC has diversified its business into the bottle packaging sector and has also mastered in providing machines for automatic tablet coating. UEC also provides customised solutions for its customers.

With a vision to provide the best pharmaceutical manufacturing technology, UEC has also ventured into different industries such as distilleries, cosmetics, foods and beverage, paints, chemicals, home care, office and student stationery and others.

The company has also expanded its footprints abroad in a large way. Today, 'UNITED' machines are exported to more than 21 countries across the globe namely the US, Canada, Bolivia, Nigeria, Kenya, the UAE, Iran, Sri Lanka, Bangladesh, Malaysia, Indonesia, Vietnam, Korea, Russia, Ukraine and others.

UEC puts in a lot of effort for

their R&D and strives to provide the best and optimized solution to its customers. By virtue of dedication and continuous hard work of their R&D team, 'UNITED' machines provide technically advanced solution for its customers. Presently, UEC is having its head office in Kolkata. It has three manufacturing units in West Bengal, covering an area of over 10000 sq ft. UEC is having its marketing and sales office in Mumbai to cater to the eastern part of the nation and overseas. The company has also set up well equipped service shop in Mumbai to service its clients. The United Engineering Company has been honoured by the prestigious 'Innovator's Award' from the Indian Pharmaceutical Congress for their innovation and development and continuous value additions to the pharma packaging industry.

For its customers, UNITED machines are cost effective but are guaranteed with the highest quality, optimum production and ensured unconditional service

Today, at UEC, machines are equipped with the latest technology. For its customers, UNITED machines are cost effective but are guaranteed with the highest quality, optimum production and ensured unconditional service.

UEC is equally focussed on being a corporate citizen. It has never shirked the responsibility of the society and has always been an active participant in numerous social events which help in uplifting the quality of living of the deprived. With almost every pharma formulation manufacturer being an 'UNITED' machine user coupled with more than 50 years experience, UEC commits in becoming better than the best in the near future.

VENDOR NEWS

IMCD opens three new centres in India, China, Southeast Asia

The move adds to the company's further expansion of global network in the Asia Pacific region

IMCD, distributor of speciality chemicals and food ingredients, has announced the expansion of its global network of Pharmaceutical Technical Centres with the opening of three new locations in India, Southeast Asia and China.

These three new centres are part of IMCD's continued global expansion of its pharma network and are the company's most substantial investment to date in bolstering its technical pharma infrastructure.

The new technical centres will each be able to provide formulation support to the pharma industry in their respective geographies, offering a complete range of formulatory capabilities in oral solid, semi solid and topical pharma formulations. These capabilities will not only support customers in formulation development but will also provide training and development opportunities for IMCD's sales team in Asia Pacific. This network of technical centres will be invaluable in growing both IMCD and its supplier partners' business pipeline in the years ahead.

Paul Mimnagh, Asia Pacific Pharmaceuticals Business Group Director, IMCD, comments, "The Asia Pacific region is the engine of global pharma growth with rising GDP, increasing access to medicine, improving regulatory landscape, increasing drive for production efficiency and an increasing focus on innovation; all important factors for driving market growth rates far in excess of what we see in the more mature markets of Europe and the North America. Alongside our recently announced acquisitions, this investment in the supporting infrastructure for our pharma business strengthens our global footprint and our capabilities to offer a world-class, value-based offering, locally delivered to our clients in Asia."

While each centre will offer a regional support and training function in their respective markets, each will additionally focus on specific areas of formulation technology as part of IMCD's efforts to cross-fertilise expertise in its growing global network. The Mumbai location will have a focus on topical pharma applications; SEA will specialise in nutraceuticals, controlled release and coatings expertise; while China will focus on being a Centre of Excellence for reverse engineering and for supporting our generic customers.

EP News Bureau

SP acquires Spain-based i-Dositecno

i-Dositecno is a global provider of complete sterile filling lines for pharmaceutical, cosmetic and ophthalmic applications

SP Industries, a designer and manufacturer of state-of-the-art laboratory equipment, pharmaceutical fill-finish manufacturing solutions, laboratory supplies and glassware, announced recently that it has acquired the assets of privately held i-Dositecno. Located in Mataro, Spain, i-Dositecno is a global provider of complete sterile filling lines for pharma, cosmetic and ophthalmic applications.

"i-Dositecno has a well-earned reputation for producing high quality, fill-finish equipment complemented by strong software engineering capabilities and innovative servicing and support," stated Brian Larkin, CEO, SP.

Larkin continued by saying, "As biological drug development and treatment protocols have become more specialised, we expect short-run aseptic liquid filling to continue to drive pharmaceutical growth. With the addition of i-Dositecno to our SP brand, we now join a very select group of manufacturers with the capability to provide full lines. And, while SP has traditionally had a stronger equipment footprint in the US, i-Dositecno's efforts and success have primarily been within Europe and Asia. These relationships, as well as the addition of a Spain location to our current UK manufacturing within Europe provide significant opportunity to better serve the world-wide market."

Key manufacturing, engineering, sales and service personnel from i-Dositecno have joined the SP team to insure continuity in operations and service. Oriol Casoliva, founder and past CEO of i-Dositecno, will join SP's Executive Leadership Team and is expected to be instrumental in maximizing i-Dositecno and SP's performance within the aseptic pharmaceutical manufacturing space.

EP News Bureau

Ideal Cures wins CPhI India Pharma Awards

The honoured product was INSTACOAT Sugar Fast Coating (SFC) which is an aqueous ready-to-use sugar coating formulation with HPMC and sucrose

(Third from right) Saryu Pareek, VP Corporate Marketing; Sanjay Negi, GM R&D and Techincal Services; Pulkit Gupta, VP Corporate Office

Ideal Cures has been named as the winner of the CPhI India Pharma Awards in the category of Excellence in R&D, cost/functional improvement of existing product. CPhI awards recognise winners for their innovation and dedication to driving the pharmaceutical industry forward and the announcement of the title holders was done during the awards ceremony on the opening night of CPhI India, held on November 26-28 2019 in New Delhi, India.

The honoured product was INSTACOAT Sugar Fast Coating (SFC) which is an aqueous ready-to-use sugar coating formulation with HPMC and sucrose that can be sprayed and is well suited for all type of coating equipment. Some of the key benefits of Instacoat SFC are one-step suspension preparation, zero dependency on highly skilled labour and uniformity in finish and appearance. All the raw materials in Instacoat SFC are GRAS approved.

The age-old technique of sugar coating is a laborious and time consuming process. Instacoat SFC simplifies the process of sugar coating and provides both cost and time savings to the pharma industry. SFC saves up to 50 per cent of the coating time which result in significant cost savings for the customer. The reduction in energy consumption helps in reducing the carbon footprint by 53 per cent. In spite of tremendous reduction time, tablets coated with Instacoat SFC have smooth and glossy finish.

Suresh Pareek, Managing Director, Ideal Cures commented on the achievement saying, "Our team is dedicated to innovate in a way that brings value to our customers and makes a positive impact on the environment. Instacoat SFC simplifies the process of sugar coating and takes it from an art to science"

The CPhI Pharma Awards celebrate the thinkers and creators driving the industry forward through their innovations, technologies and strategies. The awards invite all pharma and biopharma companies engaged in the design, development, manufacture, production and distribution of large and small molecule drug products.

EP News Bureau

AAF opens regional office in Electronic City, Bengaluru

The office will serve support for EEMEA, CIS and SAARC countries

AAF (American Air Filter), a Daikin group company, has opened a new regional office in the IT hub, Electronic City. This regional office is the centre of excellence for EEMEA (Easter Europe, Middle East and Africa), CIS and SAARC countries.

The existing office-cum manufacturing plant in Jigani, Bengaluru will function for India. The new branch will incorporate our firm's ever-expanding business support departments - marketing, IT, finance and customer support team. These teams will serve EEMEA, CIS and SAARC countries from India.

(L-R) Ramanathan Sankaran, Regional Chief Finance Officer, EEMEA, CIS and SAARC countries, Rahul Uppal, Chief Operating Officer, EEMEA, CIS and SAARC countries and Arun Verma, Regional Director High Purity Business and R&D, EEMEA, CIS and SAARC countries

Rahul Uppal, COO – AAF-Daikin, EEMEA, CIS & SAARC said, "AAF has served clean air for nearly 100 years now. We are expanding our business to provide clean air globally."

He further said, "We are delighted to announce the expansion of our business with the launch of our regional office at Electronic city. Our new space will be exclusively for regional team which will be focused on global marketing, IT, finance and customer service support for AAF EEMEA, CIS & SAARC countries. We are hiring people in a large scale to make Bengaluru as a centre of excellence for global business. Our expansion in India will help us better serve our global customers."

EP News Bureau

Signet cohosts Inhalation Insights in Mumbai

Signet along with Meggle, the global leader in Lactose, co-hosted the seminar in collaboration with Constantia Flexibles, Copley Scientific, Harro Hofliger and Merxin

Signet, a leading distributor of pharma excipients in India has collaborated with 25 leading excipient manufacturers from the US, Europe and Japan offering over 450 various excipients for almost every application and dosage form.

Signet along with its Principal partner Meggle, the global leader in Lactose, co-hosted a seminar on Inhalation Insights in collaboration with Constantia Flexibles, Copley Scientific, Harro Hofliger and Merxin. The seminar was held in Mumbai. Around 90 participants from different pharma companies who are actively working on inhalation products participated in this event. The seminar focused on DPI and nasal formulation technologies along with the complete development cycle from powder characterization, formulation, filling techniques, analysis, device design and packaging.

Five eminent speakers representing the above companies shared their expertise in various fields of inhaler formulations.

Dr Mirjam Kobler, Head of R&D Excipients and Technology, Meggle, presented on Lactose in DPI Formulations and its impact on performance of final drug product. Different aspects of formulation strategies were also discussed.

Anna Sipitanou, Business Development Manager, Copley Scientific, a leading manufacturer and supplier of inhaler testing equipment spoke on latest developments in *In-vitro* testing methods for Orally Inhaled and Nasal Drug Products (OINDPS). The presentation focussed on methods to improve the clinical relevance of testing for bioequivalence as well as specific USP monograph updates and FDA requirements.

The third session was covered by Dr Philippe Rogueda of Merxin. They are designers and suppliers of medical device platforms. Their devices include multidose blister DPI, capsule DPI and fine mist inhaler. Philippe shared his expertise on selecting appropriate device for customer specific requirement. His talk focussed on how one can accelerate the development of inhaled dosage forms by optimising device development, by reducing risk, cost and thus increasing the chances of success.

Thomas Schwarz, Technical Key Account Manager at Constantia Flexibles International GmbH who are the 4th largest producer of flexible barrier packaging, spoke about the technical aspects of aluminium-based inhalation packaging and materials that can be used as primary and secondary packaging for inhalation products.

Lastly, Marco Laackmann, Director Inhalation Products at Harro Hofliger shared his knowledge on Powder Dosing and DPI manufacturing technologies. The complexity with respect to fill weight, container closure system and manufacturing technique requirements from lab to commercial scale were discussed. Harro offers various platform technologies for customer specific projects and turnkey systems.

All the sessions were very informative and addressed various DPI formulation challenges of the industry.

EP News Bureau

Signet, Roquette conducts technical seminar across four Indian cities

The objective of the seminars was aimed at imparting knowledge about Roquette's excipients for use in solid dosage forms, solubilisation and varied novel drug delivery systems for pharma and nutraceutical industry

Roquette, a global leader in plant-based ingredients for food, nutrition and health markets, in collaboration with its channel partner, Signet Chemical Corporation, recently conducted technical seminars concerning pharma excipients in four different cities (Mumbai, Ahmedabad, Hyderabad and Bengaluru).

The objective of the seminars was aimed at imparting knowledge about Roquette's excipients for use in solid dosage forms, solubilisation and varied novel drug delivery systems for

pharma and nutraceutical industry. Additionally, it focussed on an in-depth understanding of Roquette excipients meeting all the regulatory standards for various markets including China.

The concept of improving palatability of formulation and patient was elaborated. The role of KLEPTOSE, KLEPTOSE HPB/HP and KLEPTOSE Linecaps were explained in taste masking, enhancing solubility and stability of APIs. Various grades of polyols (PEARLITOL, NEOSORB, SWEETPEARL, LYCASIN, XYLISORB and DEXTROSE) for improving mouthfeel and texture of solid/liquid oral dosage forms were discussed. The advantages of high functionality DC grades of polyols such as PEARLITOL Flash, NEOSORB XTAB, XYLISORB XTAB and SWEETPEARL DC especially in ODTs and chewable tablets were also presented.

Newly launched products like MAGNESIUM STEARATE, LYCATAB CT from India and Kleptose HPB-LB from France were showcased during this event. The challenges of registration in China as well as other support provided by Roquette were explained. Over 300 customers attended these seminars from pharmaceutical and nutraceutical organisations. Five eminent speakers shared expertise and experience in their respective fields.

EP News Bureau

Plastivision 2020 to be held in Mumbai from January 16-20

B&R will also exhibit its machine vision solution, which is fully integrated into the automation landscape

Plastivision 2020 will be held from January 16-20 at the Bombay Exhibition Centre in Mumbai. At this leading exhibition for plastic, B&R's entire product range will be on display in Hall 1 Booth C4-2. The highlights will be B&R's state-of-the-art solutions for machine builders, end users and system integrators in the plastics industry. These innovations from B&R are opening new opportunities for them to build and strengthen their competitive edge.

"In our opinion, India's plastics industry is always keen to try new technologies and appreciates the benefits of our completely integrated automation solution. With the extraordinary scalability of our products, machine builders can easily and cost-effectively tailor their solutions to meet their customers' demands," says Dharmendra Patel, Plastics industry expert at B&R India. "From control and HMI to drives, motors and safety technology, B&R offers the entire spectrum of machine and factory automation solutions and is always leading the industry with innovation."

Faced with enormous cost and quality pressure, users are seeking solutions to reduce maintenance costs and downtime while optimising availability and utilisation. Production processes generate huge amounts of data, which helps generate valuable reports about equipment utilisation, asset availability, productivity and energy efficiency. Real time data acquisition with APROL enables complete online performance monitoring and visual overviews that make it possible to track quality for

the entire manufacturing process and plant. The ready-to-use solutions available with B&R's APROL process control system for energy monitoring, condition monitoring, advanced process control and process data acquisition provide higher benefits and strengthened core competencies.

B&R will also exhibit its machine vision solution, which is fully integrated into the automation landscape. "In the plastics industry, our vision solution is best for quick qualitative analysis where processes are complex. In the production process, our integrated machine vision system can be deployed for applications such as calibration, measurement, orientation, inspection, barcode reading, locating, positioning, preprocessing and comparison. "Defective products can be immediately rejected, which saves raw materials and makes it possible to rectify problems at the same level – resulting in increased quality and productivity," says Patel.

All visitors to the B&R booth will also be able to experience ABB products and services for the plastics industry, which helps manufacturers achieve higher quality, comply with standards and become responsive to the challenges of global markets.

The highlights at the B&R booth will be state-of-the-art solutions for machine builders, end users and system integrators in the field of plastics.

EP News Bureau

PRODUCTS

How can a business comply with the temperature control requirements?

The simplest way to meet the requirements is to ensure that potentially hazardous food is received, stored, displayed or transported either very cold (5°C or colder) or very hot (60°C or hotter). Potentially hazardous food should also be cooled and reheated quickly and prepared in as short a time as possible.

If for some reason you do not wish to, or are unable to store, display or transport food at 5°C or colder, or at 60°C or hotter, or meet the cooling and reheating time and temperature requirements, you must be able to show that you have a safe alternative system in place.

The standard specifies the ways in which a food business can demonstrate to an enforcement officer that it is using a safe alternative system. You can use a food safety programme, or follow recognised food industry guidelines, or use a system based on sound scientific evidence. More information on requirements here.

Therefore, it is crucial for these businesses to go beyond operating an effective cold storage facility, and further into maintaining the temperature for their facility.

The design and construction of food premises must

(a) Be appropriate for the activities for which the premises are used;

(b) Provide adequate space for the activities to be conducted on the food premises and for the fixtures, fittings and equipment used for those activities;

(c) Permit the food premises to be effectively cleaned and, if necessary, sanitised; and

(d) To the extent that is practicable

- exclude dirt, dust, fumes, smoke and other contaminants;
- Not permit the entry of pests; and
- Not provide harborage for pests.

The FDA guidelines outlines several measures to take in order to control cold store temperatures effectively:

- Minimise air temperature variation by reducing the number of door openings and traffic movement in and out of the cold storage facility
- Install necessary mechanisms to lower temperature as soon as they are increased
- Ensure defrost cycle systems are adequately designed to prevent any product heating up
- Install appropriate trigger alarms to ensure prompt corrective action
- Ensure damaged walls and door seals that could leak cold air out and allow hot ambient air in are promptly repaired
- Ensure optimum stacking patterns and floor layout to facilitate airflow

Most importantly, conduct regular checks of the facility including compressor, defrost cycle, thermostat, cooling tower equipment, walls and doors to ensure everything is in good working order.

The simplest way to maintain cold store temperature

One of the key aspects of a cold storage facility is the main entry door, as it is the means by which the cool temperature is locked within the room. In addition, the door is potentially the simplest way to maintain cold store temperature, as compared to complex cooling systems or monitoring tools.

Aside from taking the appropriate measures such as minimising door openings or the traffic in and out of the facility, one can control the temperature of the cold storage facility more effectively with the right door.

The ideal door for temperature and air transfer control? — The rapid roller door

An ideal cold storage facility door should have the capability to seal a room properly to maintain the internal cool temperature. When it comes to freezer doorways, where multiple openings per hour reduce effectiveness of insulated doors, yet necessitate exceptional air-tightness; it is necessary to have a door with insulated and heated guides and frames to ensure the room is sealed properly when the door is closed.

It is also crucial for this door to have high-speed operation to close as soon as traffic has entered or left the room. Slow-closing doors allow warm air 'spikes' to enter the cold storage facility and will adversely impact temperature stability, energy costs, and quality of the food stored.

Combining these two features is achieved in what is commonly known as a rapid roller door. It comes with a tight seal and high-speed mechanism to ensure quality is maintained without further maintenance costs. Suitably specified high speed doors will prevent air infiltration to your cold store, freezer or temperature zoned facility to maintain and improve the shelf-life of stored products, ultimately protecting your business from costly temperature loss or gain.

Prime Freeze High Speed Doors by Gandhi Automations are a perfect solution where cold storage with negative temperatures to as low as – 20°C is required. The curtain is made of reinforced PVC vinyl with heated side guides. Optionally a

special and innovative insulated flexible curtain is also available. High speed freezer doors are the solution when temperature control is critical and where forklift traffic is high.

The basics of cold storage warehouse dock equipment

The needs for safety, efficiency and detailed data collection are transforming modern docks from mere openings to critical components of an enterprise's success.

Because the standards for performance and safety have changed dramatically in the last decade, 'basics' is a relative term. In fact, it might take even less time than that for the descriptions of a modern dock in this article to seem downright old-fashioned. However, for every up-to-date dock there are many, many more that fall short of these basics. Rather than negligence, this is due to the sheer number of docks in use and the rate at which dock technologies have progressed.

From the traditional basic docks; Now you see push-button dock levelers, typically bigger and with heavier capacities,

which have increased by 15,000 to 22,000 tonnes weighing capacity. So, anyone who used to buy a lower capacity is now in the higher capacity range.

The overhead door—also push-button operated—is now usually bigger than the trailer, which is locked to the dock by a vehicle restraint as opposed to mere chocks or emergency brakes.

In the 1980s, the industry was in the infancy of getting the message of dock safety off the ground. Now, there's no question whether there will be a restraint; the question is which kind. Over the years, there has been a big evolution in size, shape and capacity, but also in terms of the equipment's operation and level of complexity."

The modern dock includes interlocks, a series of mechanical and electronic safety measures that prevent anything but the optimal sequence of events. For example, to open the door, the vehicle restraint must first be positively engaged. To operate the leveler, the door must be open. A food, beverage or pharmaceutical company might design its sequence to minimise infiltration of air, dust or critters.

A facility in hot climates might choose this setup simply to conserve air conditioning. On the other hand, managers might like to leave doors open on occasion to get some fresh air, but interlocks will only allow this once after a physical barrier is engaged to prevent people or equipment from falling off the dock.

For those customers concerned with securing access to the back of the trailer, energy efficiency and/or sanitation, dock enclosures may be designed to prevent even a sliver of outdoor light from creeping in. Taking it one step further, the interlock sequence might also include a step where photos or videos are captured to verify security and product condition after transit.

Gandhi Automations manufactures loading bay solutions like dock levellers, dock shelters, sectional overhead doors. Dock equipment are designed and factory-made in state-of-the-art manufacturing facility. This dock equipment meet international safety standards like EN1398 for dock levellers and product is CE marked.

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Top Syringe develops Inox TRÜTH Glass Syringe

Top Syringe Mfg Co (P), Mumbai has developed a special Inox TRÜTH Glass Syringe used during Intracerebral inoculation especially during the testing of the protective potency of serum against live virus introduced in subject.

The Inox TRÜTH Glass Syringes are offered in 0.5ml and 1ml size. The components used for these syringe include a glass barrel, silicone O ring and a metal plunger rod. All these components are inert and there is no plastic reaction which could take place thus maintaining the potency of the serum at all times during the testing phase.

The Inox TRÜTH syringe have a special clear Black colour Graduation to ensure clear visibility while inoculation since the live virus liquid is generally yellow in colour. They come in various graductions and sizes such as :

1) 1ml in four major graduations at 0.25ml, 0.50ml, 0.75ml and 1ml with minor markings at 0.01ml intervals (Catalog no - TX-100-250R)

2) 1ml with continuous graduations markings of 0.025ml 40 times (Catalog no - TX-50-300)

3) 0.5ml with markings at 0.03ml,0.06,0.09 upto 0.50ml (Catalog no - TX-100-2500)

The graduation allows the closing of the requisite amount required for Intracerebral inoculation that can be administered in a mouse. Customers have been successfully using the Inox TRÜTH syringes during testing of various vaccines including DTP Vaccine, antirabies vaccine, pneumococcal conjugate vaccine, measles-rubella vaccine etc. Generally the syringe can be reused as per protocol. As per customers' feedback, it can be reused up to five times.

Contact details
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B&R expands mobile automation portfolio

B&R is expanding its mobile automation portfolio to include the Power Panel T50 mobile. The operator panel offers highly reliable operation for agricultural, construction and municipal vehicles. It is available with display diagonals of 5", 7" or 10.1".

The Power Panel T50 mobile's die-cast aluminum housing provides the necessary mechanical rigidity. With IP67 protection, it easily handles heat, cold, dirt, moisture, shock and vibration. The projected capacitive touch screen can even be operated in the rain. With no fans or batteries, it's also maintenance free.

Compact and space-saving

A compact design, shallow installation depth and optimised arrangement of cable outlets make the Power Panel an easy-to-mount space saver. Available mounting types include standard brackets, panel mounting or front plate mounting.

Web-based HMI

The versatile Power Panel has an embedded browser for viewing HMI applications created with B&R's mapp View software. Built on the web standards HTML5, CSS3 and JavaScript, mapp View ensures optimal viewing on any device. B&R offers a multitude of widgets that can be dragged and dropped into place to create attractive user interfaces with gesture operation.

Numerous interfaces

The Power Panel T50 mobile is easy to configure. Its Ethernet interface on an M12 connector allows for communication with the X90 controller, which acts as an HMI server. The supply voltage, a USB port and digital I/Os can be found on the Superseal multi-connector.

B&R's industrial controllers take performance to a whole new level

The new B&R X20CP3687X controller combines the performance of an industrial PC with the compact design of the X20 controller series. With powerful processing, additional RAM and integrated onboard flash memory, the high-performance controller can handle complex control algorithms or even robotics applications that previously would have called for an industrial PC.

With a TSN-enabled Ethernet interface, the X20CP3687X is well-equipped for the future. It is fully prepared for communication using the manufacturer-independent communication standard OPC UA over TSN. The controller comes standard with connections for USB and POWERLINK.

Additional interfaces can be added via interface modules. Despite its powerful capabilities, the new module has exactly the same design and dimensions as all the other controllers in B&R's X20 series.

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VALUE ADD

HPTLC: For high throughput, at low cost

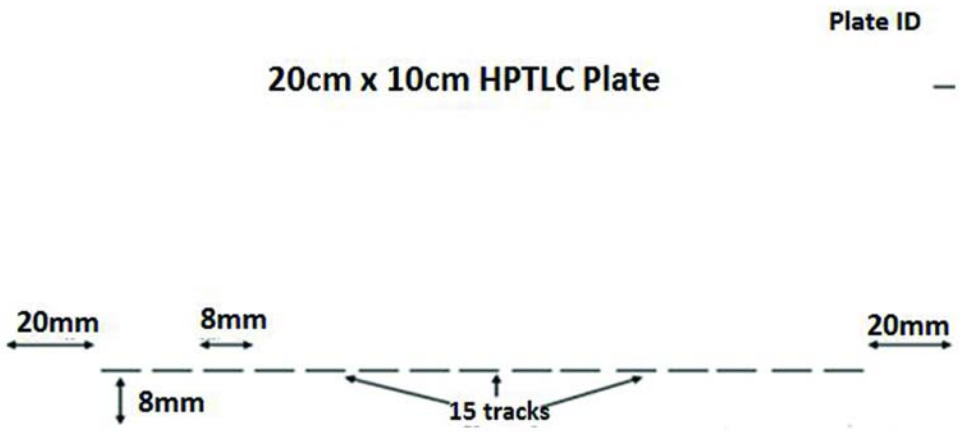
HP-TLC specific software is of utmost importance not only for calculations, but to stepwise integrate the separate instruments into one chromatograph. An insight

MODERN chromatography analysis techniques have a very high standard and replaced the manual techniques they originated from e.g. paper chromatography (PC), thin layer chromatography (TLC), column chromatography (CC) etc. Today HPLC users do not even remember CC. Same should happen with HPTLC, which now meets all the regulatory requirements and expectations, of analysts.

High Performance Thin Layer Chromatography (HP-TLC) today is performed by semi-auto or fully automatic s/w-controlled instruments, methods (validated as per ICH guidelines) and suitably trained analysts.

HP-TLC specific software is of utmost importance because not only for calculations, but to integrate stepwise the separate instruments into one chromatograph. Of all chromatography methods, HP-TLC generates the highest data about samples. e.g The image document system can produce upto six different images of the same plate at 254 nm, 366nm and white light, before and after derivatisation, Instrumental TLC was the first to adopt computers in early eighties to process so much data, while GC/LC still used integrators.

The scanner quantifies the samples at any UV or visible wavelength and in fluorescence. Absorbance spectra in UV and Vis can be recorded. Next, fractions of interest can be fed into a single or triple quad mass spectrometer to obtain m/z values of selected fractions. Fractions of interest can be eluted into vials for NMR/ IR data. Lastly, the chromatograms can be used for bio-autography to test for anti-oxidant or anti-biotic or anti-fungal activities or toxicity etc. So much data can be generated because the 'chromatogram' i.e. the fractions of the sample are stored on the plate and do not into waste.



HPTLC is complimentary to HPLC because it uses normal phase silica gel (adsorption) for separation verses reverse phase silica gel (partition) in LC. Adsorption is more selective than partition and isomers can be separated rather easily. HPTLC can be used for pilot work for LC method development.

HP-TLC boasts of numerous sub-techniques e.g. sample application can be done for four purposes. viz. quantification, in-situ clean-up, super imposition and micro-preparative chromatography. In LC, one can only inject a fixed volume of sample. In HP-TLC samples are sprayed on as uniform bands, 6-8 mm long. Spraying with simultaneous drying ensures that the bands are about 1 mm wide, irrespective of the volume!

For chromatographic separation too, several options are available, like vertical or horizontal development, flat bottom or twin trough chambers, manual or automatic development chamber, gradient chamber. Another chamber assists in quick and systematic method development.

Once the chromatogram is developed i.e. fractions are separated, the plate can be image documented at 254 nm. 366nm and white light. Then measured by the scanning densitometer at specified wavelength for quantification and then for absorbance spectra. Both these are non-destructive measurements. Then destructive measurements can be done on the same plate, in three different ways.

i) Elute specified fraction from one part of the plate into a MS. The elution cycle of one fraction is completed in three minutes.

ii) Derivatise second part of the plate with one of the hundreds of known reagents for specific and ultra-sensitive detection. Only in HPTLC, it is possible to derivatise each and every sample for extra information or confirmation. That too, very simply.

iii) The third part of the plate can be used for bio-autographic methods. This is of great importance in new drug research and foods analysis.

Like all chromatography methods, HPTLC is used in QC as well as R&D analysis. HP-TLC is the only analytical technique in the world that can analyse in parallel, upto 20 samples and standards of six different samples i.e. about 120 samples. Each step of the HP-TLC procedure is carried out by independent hardware but connected by a System Manager Software, to get one result. It is therefore possible that the same HP-TLC system is being used at the same time, without interfering in each other's work, by upto six analysts. Some of these could be from QC and remaining from R&D. An education institute can support a radius of 15-20 kms with one HPTLC. Compare that with buying dozens or even hundreds of LCs, Just because it is the slowest and most tedious technique.

QC methods require extreme control of the experimental parameters. Up until 2017, there was no consensus in the whole world about standardisation of HPTLC parameters. In early 2017 USP announced the parameters for HP-TLC vide their chapters 203 and 1064 followed by EP (chapter 2.8.25) and WHO. This introduced the concept of "HP-TLC fingerprint" which is the only way to identify very complex samples by photographic images that represent its phytochemical composition. This unique technique of 'HPTLC fingerprint' is extremely simple yet very powerful to confirm identities of extracts or detect adulteration.

HP-TLC methods have to validated as per ICH guidelines including System Suitability Test. Development of an entirely new method from scratch and its complete validation takes about a week and costs a few thousand rupees. At a time, it is possible that just one HP-TLC is doing in parallel two new methods development, two validation of methods and many routine samples. Converting TLC methods into HP-TLC is equally easy. Now compare them with LC.

HPTLC is a 'green' technique as it produces very little waste. A batch of 15-20 samples would need about 50 ml of solvents and produce one plate as waste. Latest instruments require only 3 ml of reagent for derivatising a 20x10 cm plate.

In terms of output of one HP-TLC system in one shift, analysis of about 100 samples is easily possible and would cost between Rs 1000 to 10,000 depending on materials consumed. Samples submitted by 3 pm can be reported on same day. Any urgent sample can be taken up for analysis upon receipt, without affecting other analysis going on.

Mixtures containing 8-10

components can be easily tackled by HPTLC in most cases. Pharma samples have only 1-3 components for quantification. There is no need to use LC for such analysis like in content uniformity or multi-drug formulations, dissolution rate studies etc. This will save large amount of investment, expenses and time.

Comparison of composition of unknown samples has to start with HP-TLC because it is a risk-free analysis method. The samples are embedded on the plate and never physically come into contact with the chromatograph. Cross contamination is impossible. No overload. No deposition. HPTLC is the only technique that can take up samples for chromatography even without knowing the name of the sample!! Microprep isolation (2-3 mg) is easy.

It is very easy for manufacturers to HPTL chromatogram their samples along with competitor or foreign buyer's samples reverse engineering.

The most popular sample preparation method in HPTLC is weigh some mgs in 1 ml methanol, sonicate, centrifuge, use supernatant. Very inexpensive and simple.

USP 203 specifies that sample application format is as follows.

For chromatogram development, USP specifies the following: -

i) Twin trough chamber with, paper lining

ii) Saturate chamber for 20 mins

iii) Layer humidity conditioning to 33 per cent RH. (Mg Cl2 sat. soln)

iv) 70 mm development (effective 62 mm)

v) Vertical drying, cold air

HPLC's weakest point is (was!) that it is an open technique. Different atmospheric humidity can cause different amount of water in the hygroscopic silica gel. More the water, lesser the adsorption and more the partition. Hence, the same plate can behave differently in different labs. USP therefore, dictates that all samples be chromatographed at 33 per cent RH, which is best done in an automated chamber at least in pharma companies.

Only room temperature and pressure are used in HPTLC. There is no time wasted in setting up or standing down. Maintenance is negligible. HPTLC becomes obsolete by technology or age and not due to heavy wear and tear caused by high pressure or temperature.

The ICH guidelines, as yet, do not recognise the visual aspect of HPTLC. Moreover, only in HP-TLC, samples and standards are chromatographed in exactly identical conditions. Any deviation affects both equally which makes the analysis extremely robust and reliable.

HPTLC's numerous advantages can only be accepted when analysts unlearn TLC and stop comparing it with HPLC, which is currently the most dominating technique inspite of its major weaknesses, especially in the Indian context.

Any lab that studies HP-TLC and uses it correctly, can cut the waiting time for samples drastically. It would also reduce the huge repetitive investment in LCs and even higher running and maintenance costs. HP-TLC is the latest chromatography method to become official. It is the right time to evaluate the same, without prejudice, particularly by the regulators, commercial labs and pharma industry. India is on the way to lead the world in HP-TLC applications.

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WHITE PAPER

Labelling best practice in a challenging manufacturing landscape – A survival guide for pharma companies

NiceLabel sets out seven current challenges for the pharma industry, together with proposed solutions that will help companies to understand labelling in the context of these challenges. Excerpts from the white paper

THE NUMBER of challenges for the global pharmaceutical industry is perhaps higher than ever before. Competitive pressures, new stipulations from governments and regulators, products coming off patent and market pricing pressures have combined. Pharma companies are increasingly obliged to seek competitive advantage through efficiency and cost reduction measures.

Among the available options, labelling technology offers many opportunities for pharma companies to successfully tackle rising challenges, as this white paper demonstrates.

A typical wish list for a major pharma company would be to:

- Align and harmonise label requirements
- Establish ownership and governance for label content, including creation and maintenance of layouts, outside the company's IT department
- Reduce the number of label layouts, particularly redundant layouts due to different systems
- Transition from paper-based labelling catalogs to digital document management systems
- Reduce the amount of development required to a minimum
- Split data and design modeling
- Enable compliance with increasing regulatory requirements
- Minimise the need for re-labelling

Digital transformation of labeling

The potential impact from straightforward changes in labelling processes may be surprising to many in the industry.

> Drug recalls have increased more than 65 per cent over the past ten years. Source: GS1
> 50 per cent of pharma recalls are due to errors in product labeling or packaging artwork. Source: Xtalks
> The average cost to distribute a recall notice is $8 million. Source: GS1

Data integration

Rising demand for fast response times in manufacturing has prompted the pharma sector to implement new data integration processes. Chief among them is integrating Manufacturing Execution Software (MES) and Enterprise Resource Planning (ERP) systems with a modern label management system.

Pharma companies have long seen the need to integrate labelling with their MES and ERP systems; however, most have hard coded labels inside these systems, a practice that requires extensive IT development and maintenance resources. Modern label management enables a pharma company to integrate labels with the master data, digitise the entire label creation process and empower business users to handle change requests.

This type of data integration enables pharma companies to address a number of label management issues, including:

- Reducing labelling complexity
- Avoiding costly set-up and downtime
- Consolidating the number of templates
- Reducing risks from label data and mislabelling errors
- Streamlining label design, approval, maintenance and support processes
- Maintaining regulatory approvals (such as from the FDA and EU regulators)
- Ensuring label and brand consistency

A modern label management system also prevents the creation of data silos — or reduces them if they already exist — so that pharma companies can rely on a 'single source of truth' for their labeling needs.

By digitising label information and eliminating paper-based catalogs, business users can access a company's entire label library from one interface. They can quickly locate and compare labels across all of their operational locations, searching not only based on label names but also content, and get instant query results. Users can search all text fields, variables, fonts and barcodes across all of their label storage. Business users can also more easily compare and identify differences between label variations and revisions, thus improving accuracy and template consolidation.

Summary

Modern label management systems enable organisations to consolidate and avoid redundant label development and maintenance tasks, moving the responsibility for these areas from specialist developers to the general business user. This organisational transformation prevents inconsistency, eliminates latency and achieves new levels of quality control, label data accuracy and template consolidation.

Regulatory compliance

For pharma companies, regulatory compliance is a part of doing business. Government regulations such as FDA CFR 21 part II, Eudralex Annex 11 and GAMP 5 require companies to ensure the security and accuracy of their electronic records, as well as prove compliance with GMP. In addition to having to comply with governmental authorities, pharma companies also have to submit to audits from business partners and customers.

Failure to comply with or meet the standards of any of these requirements can have catastrophic consequences for a pharma company's business and reputation.

With a legacy approach to labelling, meeting federal or international requirements often required a lot of manual overhead and paperwork. Adopting a modern label management system and digitising label storage reduces manual processes, improves label quality and streamlines compliance procedures. Modern label management does this by enabling centralisation, label lifecycle management and audit trails.

Pharma companies that have implemented a modern label management system have found that their data quality has improved and the time and effort spent on compliance have reduced dramatically. This is achieved through consolidating existing label files into a series of intelligent universal templates, which, in turn, dramatically simplifies label management and reduces the number of change requests.

Having one solution for all of a pharma company's labelling and direct marking also aids its compliance with regulations by keeping all relevant data in one place so that track and trace is far easier to achieve.

The FDA itself has moved from requiring paper evidence, with its vulnerability to human error, to electronic methods of validation using computer technology to ensure safety and security. The best modern label management systems now allow companies to demonstrate who printed a label, which label was printed, and which printer the job was sent to, while tracking exactly when each step occurred. These systems allow business users to design, review, approve and control label data from a document management system, providing approvals, time stamps, maintenance of records and electronic signature capture.

Implementing a modern label management system also places pharma companies in the best position to respond to future requirements, such as serialisation. Increasingly, each pack of tablets, each bottle of medicine and each box of any pharma product will have a unique serial number, enabling it to be tracked and traced. This is partly an anti-counterfeiting measure and also assists in improving safety and accountability in the industry.

By using one label management solution for both labelling and direct marking printers, pharma companies will be able to meet the demands serialisation will place on their business. Through printing barcodes for individual boxes, cases, pallets or any other pharma packaging, regulatory requirements can be fulfilled and products tracked and traced.

Summary

To ensure that a pharma company is fully compliant with relevant regulations, future-proofed against likely new developments, safeguarded against action from regulators, able to demonstrate traceability and in line with current best practice, it is vital to adopt a modern label management system which can fulfill these criteria and protect the enterprise.

Drug recalls have increased more than 65% over the past ten years. Source: GS1

Maintaining safety standards

One of the main goals behind the regulations governing the pharma industry is ensuring consumer safety. For example, part of the intention behind the DQSA regulations is to reduce potentially costly and life-threatening errors and oversights. The regulations are the latest development in a long-standing process through which the FDA and the equivalent organisations in the European Union have sought to protect public health. Errors in prescriptions or doses due to inaccurate labelling can cost billions of dollars and thousands of lives. Thus, product identification standards have been drawn up in order to ensure patient safety through obligatory validations, audit trails, electronic signatures, copies of records and record retention.

This places labelling standards at the heart of pharma companies' efforts to maintain safety standards, eliminate errors and guarantee accuracy. A modern label management system should be efficient, accurate, able to operate without paper versions of records and designed to work across an entire organisation, managing the complete label lifecycle.

This approach, where data is controlled and managed throughout the label lifecycle, is especially relevant for pharma companies, as products move from the factory to distribution and through various packaging iterations. Keeping track of the progress of a product so that it remains safe and can be delivered to its intended destination is of critical importance. Labeling is an integral part of this process.

Beyond issues of human health, pharma companies have to beware of the threats from counterfeiters and from agents diverting pharma products. A label management system that includes a central document management system helps with the fight against these twin issues, since it is easier to secure label files and provide multiple levels of role-based security to limit access to data.

Summary

To ensure label accuracy and protect patient safety, pharmaceutical companies are best placed if they adopt a modern label management system that can manage the entire label lifecycle, offer complete transparency throughout the label production process and facilitate quality control procedures.

Reducing costs

With tighter margins across the pharma sector, cost saving has become a central issue in the industry. Also here a modern label management system can be of assistance by helping companies create faster, more efficient operations throughout their production process, from manufacturing to order fulfillment.

For example, if a large-scale manufacturer is able to label its goods more quickly, accurately and with better traceability, it will also be able to ship these goods and sell them more quickly.

In addition to the direct cost savings that can be achieved through efficiency measures, a modern label management system helps to reduce and eliminate the losses caused by unplanned production delays and product re-working as a result of labelling errors.

50 per cent of pharma recalls are due to errors in product labeling or packaging artwork. Source: Xtalks
The average cost to distribute a recall notice is $8 million. Source: GS1

In other cases, costs can be reduced simply through minimising label variations and preventing duplication. By moving from printer code or printer-specific label formats to universal intelligent label templates, KRKA, a European generic pharma company, was able to eliminate a high volume of duplication, creating significant cost savings through saving hundreds of hours spent on label change requests.

There is a common-sense calculation to cost savings in label production: if a company has a decentralised labelling operation, each facility that ships products to customers must update its label templates whenever a new element is introduced. This will include adding new fields to a label template, adding new barcodes and so on. In many cases, IT staff will be involved in these changes, at a high cost to the organisation. Alternatively, label design and amendment may be sub-contracted to an outside agency, with further cost implications and potential time delays.

By contrast, a centralised, modern label management system helps to reduce direct and indirect costs through minimising the labour, time and expertise required to maintain label formats, make changes and create new labels. The repetition and redundant effort present in a decentralised labelling operation can be eliminated, freeing up IT staff for more productive work and saving hundreds or even thousands of man-hours, along with vast amounts of money.

Summary

Prevailing market conditions are placing pressure on pharma companies to reduce their operating costs. Introducing a modern label management system increases operational efficiency, makes the best use of internal resources and reduces label errors, thereby saving time and money and mitigating the risks associated with quarantines and recalls.

Agility

Customers and the markets in which they live are becoming increasingly involved in how products are labelled and shipped and are, in many cases, placing demands on pharma companies that they cannot ignore. Added to this are the demands of meeting local and regional requirements for labeling that international pharma companies must face.

To adequately meet the demands of so many different stakeholders, pharma compa-

nies need to be agile and capable of meeting new requirements quickly. Modern label management systems enable this responsiveness and help companies manage the complexity of location-specific labeling requirements, while maintaining consistency and efficiency.

A modern label management system will include a centralised document management system and the capacity to scale standardised processes across an extended global supply chain. Such a system should also be able to connect with MES and ERP systems and facilitate data integration programs. Adopting this approach will make a labelling system more responsive to enterprise demands.

Many manufacturers today contract some of their production to third parties. Whether companies choose to integrate contractors into their ERP system, or elect to extend their labelling platform to contractors via web printing, a modern label management system will ensure that the labelling process remains consistent across all sites.

Summary

Where labels are being printed at a number of different locations, adopting modern label management means that products can be launched faster, compliance with new regulations can be achieved more easily and return on investment can be increased. Pharma companies can become more agile, as they are able to accommodate change requests more easily and quickly across a wide range of sites and throughout the supply chain.

Supply chain management

Effective supply chain management is a central element of 21st century commercial life. Pharma companies have to collaborate with business partners in even more complex ways, across geographical and product boundaries. Deploying a modern label management system can help them achieve consistency and efficiency in these partnerships.

Using the latest generation client-side web printing labeling technology, suppliers can be given access to a company's centralised label management system, meaning that whatever they supply comes correctly labelled and ready for distribution or integration into another production process. This saves time, eliminates a potential source of error and cost and ensures consistency across the supply chain.

As KRKA, mentioned earlier, noted, "We optimised inbound logistics and supplier collaboration, and improved master data management, by extending labeling beyond the enterprise to suppliers and sub-contractors."

Centralised labelling systems make the whole extended supply chain more responsive to change requests and deter diversion and counterfeiting through advanced labelling techniques.

By making use of web-enabled technology, modern label management systems also improve internal collaboration by making it easier to deploy the system to business users across departments, offices and sites. Using a browser-based interface enables shop-floor users to access and print centrally-managed labels and data, thus improving label and brand consistency while reducing mislabelling. Having a web-based system is also the best way to manage a multiuser environment, and provides the transparency, tracking and access control highly-regulated environments require.

Summary

By implementing a modern label management system, pharmaceutical companies can enable collaboration and ensure consistency both internally and externally. Modern label management enables all relevant users to have access to the same, centralized labeling system and utilises web-based technology to manage complex, multi-user environments.

Centralisation

Since the dawn of globalisation, every international company has had to deal with the global vs local dilemma: to what extent should a company centralise or localise key operations? For pharma companies, centralisation means being able to improve consistency, accuracy and accountability. However, the vast amount of local or regional regulations and requirements can make centralising labelling a challenge. Pharma companies also seek to mitigate the risk of downtime in their production operations by spreading production centres, and their data and labelling functions, between different locations. Thus, there is also a compelling argument to be made for decentralising labelling.

A modern label management system allows for both options, enabling pharma companies to select the configuration that best suits their business, products and processes. Modern label management systems adapt to the IT layout of the company in question. If a company has a centralised ERP (SAP) system, then they will most likely choose a centralised label management system. If they have decentralised MES, then they can use the same system to decentralise label management, while still benefiting from some aspects of centralisation.

Summary

A modern label management system will be able to offer as much or as little centralisation as any pharma company is ready to adopt. By selecting a system that is flexible and customisable, companies can succeed in establishing 'one single source of truth' in their labelling systems, while still supporting local and regional variations in labeling templates.

Conclusion

As this white paper has outlined, implementing a centralised, modern label management system offers pharma companies the opportunity to make profound improvements to their business processes, reaching far beyond label production.

When successfully implemented, a modern label management system can yield dramatic results, including:

- Increased efficiency and streamlined compliance
- Greater label consistency and customer responsiveness
- Label template consolidation and a reduction in change requests
- Improved governance for label content and layouts
- A scalable platform for future growth

Agility, accuracy and compliance will be hallmarks of successful pharma companies going forward. To compete and thrive in an increasingly complex and challenging marketplace, pharma companies will have to rethink their processes and find ways of accomplishing more with less. This transformation starts with implementing a modern label management system.

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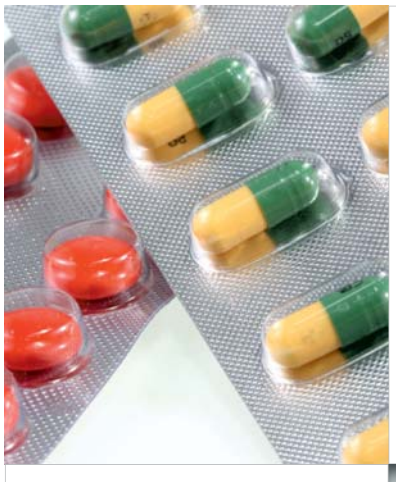

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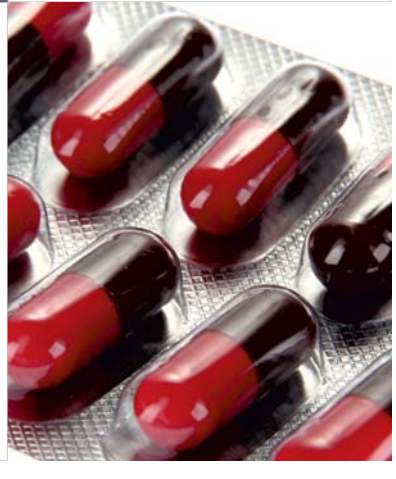

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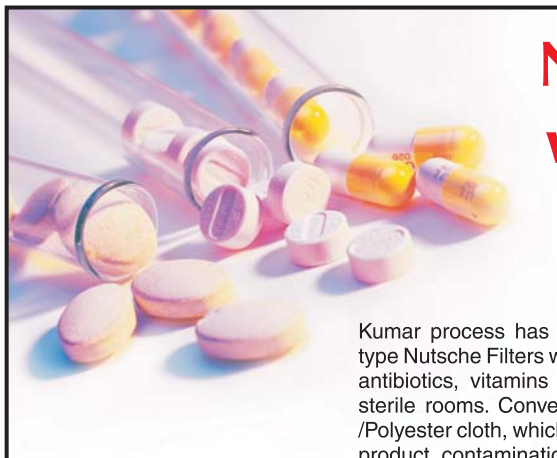

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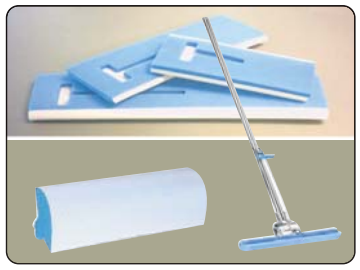

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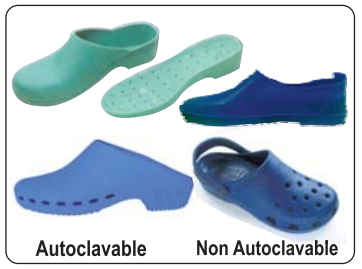

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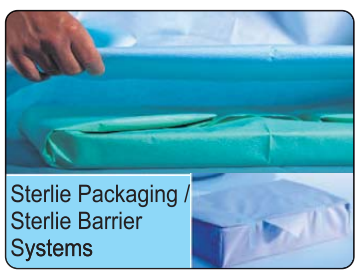

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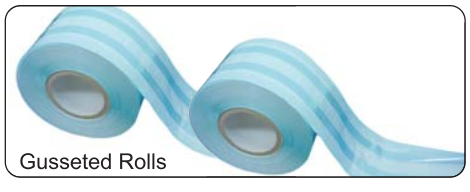

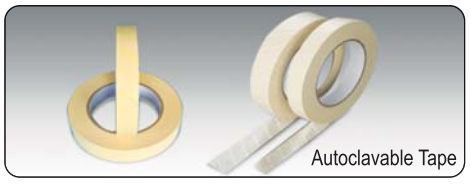

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Biocon appoints Siddharth Mittal as its CEO and Joint MD

He takes over from **Dr Arun Chandavarkar** who retired as Chief Executive Officer & Joint Managing Director of Biocon on November 30, 2019

Biocon has announced that Siddharth Mittal will take charge as Chief Executive Officer and Joint Managing Director of the Company starting December 1, 2019. Mittal has been serving as Biocon's Chief Financial Officer (CFO) since August 2014. He took over from Dr Arun Chandavarkar who retired as Chief Executive Officer and Joint Managing Director of Biocon on November 30, 2019, after 29 years of service.

Kiran Mazumdar-Shaw, CMD, Biocon, said, "I am very pleased to welcome Siddharth as CEO and Joint MD of Biocon. Siddharth's strong leadership qualities, comprehensive understanding of various aspects of the business, deep financial insights and robust operational experience make him an excellent fit for the role of CEO to lead Biocon through its next phase of growth. I am confident that in this new role he will build immense value for Biocon and its stakeholders."

> Mittal has been a core member of the leadership team at Biocon since May 2013 and has global experience in strategic finance and general management

Mittal said, "I am honoured to take over as the CEO & Joint MD of Biocon, which has a strong legacy as an innovation-led biopharma company. It is at an inflection point where it is well-positioned to create value for its shareholders by unlocking the potential of various business segments. Post the creation of Biocon Biologics as a wholly-owned subsidiary, I now look forward to generating value for our stakeholders by focusing on our Small Molecules business with an aim to further strengthen our portfolio of complex APIs and generic formulations in key global markets."

Mittal has been a core member of the leadership team at Biocon since May 2013. He has over 20 years of global and diversified experience in the fields of general management, strategic finance and accounting, mergers and acquisitions, taxation etc.

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Bombay College of Pharmacy receives FICCI Award for Excellence in Research

The award was received by **Prof Krishnapriya Mohanraj**, in-charge Principal, from Union Transport Minister Nitin Gadkari

Mumbai-based Bombay College of Pharmacy (BCP) has been awarded Special Jury Mention for 'Excellence in Enabling Research Environment' at the 6th FICCI Higher Education Excellence Awards 2019 held in New Delhi recently.

The award was received by Prof Krishnapriya Mohanraj, in-charge Principal, from Union Transport Minister Nitin Gadkari, among other dignitaries present on the occasion.

"We are proud to receive this honour from FICCI. The award is a testimony to the world-class industry-academia research taking place at BCP. The award is significant as it places a huge emphasis on scientific research within academic institutions," said Prof Krishnapriya Mohanraj. The official tabulator for the awards was the consultant EY.

Numerous research projects are at forefront in BCP in domains impacting healthcare and society. BCP has been recognised for the award for the following representative research projects among many being conducted at the institute. Investigation on liver enzymes assessing drug metabolism, a research thrust under the leadership of Dr Krishna Iyer and partially funded by Bristol Myers Squibb (BMS), represented the category on partially funded project by the industry. Dr Mala Menon developed a targeted nanoliposomal platform for inhalation therapy of TB with complete internal financial support. National

Facility for Research and Training (NFRT) for testing of drugs, pharmaceuticals and nutraceuticals has been established with an aid of Rs 5.87 crore under Drugs and Pharmaceuticals Research Programme funded by Department of Science and Technology, Government of India. The facility is a state-of-the-art research and training centre with high end sophisticated hyphenated mass spectrometry instruments.

This facility is established with the grant awarded to Dr Vaishali Shirsat and Prof Krishnapriya Mohanraj. Development of nanotechnology platforms that can aid treatment of HIV to improve maternal health was undertaken by Prof Mangal Nagarsenker, and involved collaboration between University of Helsinki (Finland), University of Jena (Germany) and University of Porto (Portugal). The project was a showcase in

category of projects partially funded by an International Agency. Further, other faculty members have also undertaken efforts in advancing research in field of waste water management, veterinary medicines, herbal drug technology, green initiatives and waste disposal.

Cumulative research efforts of faculty and students at BCP have culminated in 91 publications in various national and international journals of repute, 99 presentations at various conferences and 36 awards during the past three years. The college has received a funding of around nine crores through government and industry funding in the same period.

"Some of the future initiatives of BCP include setting up of a pilot plant that would aid technology transfer, scale up research projects, and offer solutions for challenges faced by industry. We also plan to expand the existing Innovation Cell to involve and motivate students even at UG level to work upon novel ideas and offer solutions for unmet societal needs," said Prof Mohanraj. BCP is endowed with eminent faculty, state-of-the-art infrastructure, industrial and international collaboration and research grants have contributed to research holistically, by creating and nurturing innovation for public health and well being of common public. BCP has also conducted many technology development programmes. External accolades like this on a national platform bear a testament to a vibrant research environment at BCP.

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