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Interview

Prof (Dr) Hilary Thomas

Partner and Chief Medical Officer - Healthcare and Life Sciences Advisory and Global Centre of Excellence, KPMG

BLUEPRINT FOR 2019

Pharma leaders and experts share their views on the trends and aspects which will shape the sector's machines, methodologies, processes, and workforce

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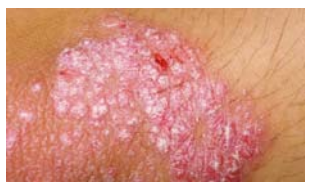

PHARMA ALLY

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Where is the patient in the e-pharmacy debate?

The tug of war between brick and mortar chemists and online pharmacies (or e-pharmacies), which has been on for at least the last three years in India, promises to heat up once again. Two high courts of the country, Madras followed by Delhi, have responded to petitions with bans on online sale of medicines. On December 20, the Madras High Court suspended its interim order banning online sale of medicines until the Union Government releases rules governing e-pharmacies.

While the Ministry of Health and Family Welfare released the draft rules for the operations of e-pharmacies in India on August 28, the Madras High Court still felt the need to prod the regulator, the Central Drugs Standards Control Organization (CDSCO), to notify rules for the online sale of medicines at the earliest and no later than January 31, 2019.

Larger e pharmacies like 1mg, NetMeds, and four other players petitioned the Madras High Court that its interim stay order should only apply to unauthorised companies. Thus seeking to differentiate themselves from the rest of the pack, by contending that they have their licences in place.

The truth is, does the ordinary consumer know how to check the antecedents of an e- pharmacy before she books an order? In this case, the consumer is either a relative of a patient or a patient herself. Most often, the purchase is done in a hurry and under stress. Thus the empowerment of having a choice, which is touted as a advantage by e-pharmacies, rings somewhat hollow if it is not 'informed' in the true sense of the word.

Most e-pharmacies have attracted successive rounds of funding to fuel their growth, and are thus now in a position to splurge on branding campaigns across broadcast and print. To further this frenzy, the pro-online pharmacy stance of the CDSCO has encouraged them to believe that it is only a matter of time before the regulations will be notified. And hence, the dash to the finish line to grab the mind space of the consumer, hoping that it will convert, in time, into market share.

But objections from traditional chemist store associations like the Tamil Nadu Chemists' and Druggists Association (TNCDA) and the umbrella association, the All India Organization of Chemists and Druggists (AIOCD) should also be seriously considered. While self-regulation looks good on paper, will everyone follow it? It is an open secret that even where we have strong regulation in place, we falter on the implementation and monitoring of these policies. Between knee jerk reactions like bans and policy diktats, it is the patient who is left high and dry in the e-pharmacy debate.

e-pharmacies cannot be considered a mere extension of the e-commerce boom, simply because the patient cannot tell the difference between counterfeit or sub-standard purchases. In extreme cases, it may even be too late

Also, e-pharmacies have not been able to garner more than one per cent share of the pharma distribution business. Which means that there is enough room for all kinds of models - offline, online as well as hybrid models – in India. The customer will ultimately vote with her wallet and discounts will not work beyond a certain point. Moreover, India is not a homogeneous market and what works in urban or Tier 2 cities might not work or be viable in smaller towns, especially rural India.

With so many grey areas, we need more debate and discussion on this issue. What's clear is that e-pharmacies cannot be considered a mere extension of the e-commerce boom, simply because the patient cannot tell the difference between counterfeit or sub-standard purchases. In extreme cases, it may even be too late. Let's hope that 2019 sees all stakeholders, especially the patient community, working towards a more nuanced solution.

Some cheer for the sector comes from a recent report based on a CRISIL webinar. The report expects the Indian pharma sector's revenue to rebound to 11-12 per cent over fiscal years 2018-2020 , from 3.5 per cent in fiscal 2016-18. However, this growth needs a commitment to look beyond generics. Biologics will be the next buzz word, with about $65 billion worth of biologic patents expected to expire in the US over the next five years.

As 50 per cent revenues come from exports, the report predicts that companies will focus on acquisitions to establish footholds in targetted export markets, especially the US. This was a clear trend in 2018, with seven acquisitions, clocking a total deal value crossing $2 billion till September 2018, all of which were geared towards this goal. Will companies succeed in turning these predictions into facts?

VIVEKA ROYCHOWDHURY *Editor*
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PRE EVENTS

Pharma Packaging and Labelling Congress 2019 to be held in Hyderabad

The event will be a platform for packaging leaders, experts and veterans to congregate, confer and converse on the current and future trends in the industry, their growth drivers and the challenges

Organised by *Express Pharma*, PPL Conclave 2019 will be held at Novotel Airport, Hyderabad from February 22-24, 2019. It is 'the' platform for packaging leaders, experts and veterans to congregate, confer and converse on the current and future trends in the industry, their growth drivers and the challenges. It is also a great medium to form meaningful alliances which will fast-track progress in the pharma packaging industry.

Various factors including novel formulations, personalised medicines and stringent legislations is constantly shaping and transforming the pharma industry, globally and in India. As a result, pharma packaging too is evolving as an increasingly complex and multi-faceted task.

Hence, the pharma packaging industry will have to design and develop innovations which serve multiple purposes ranging from enhancing patient experience and keeping pace with changing regulatory environments to making products tamper-proof, fighting counterfeits and improving logistics security.

The need to develop and deliver tailored, distinct packaging and labelling solutions is an imperative one. But, it will have to meet the ever-growing expectations of stakeholders without compromising on profit margins. Therefore, the Pharma Packaging and Labelling (PPL) Conclave, is back this year with the theme, 'Future-proofing pharma packaging'.

This year, experts and veterans at the event will examine the fast transforming landscape for pharma packaging to understand and predict trends and happenings which will influence pharma players and impact future demands in packaging. They will explore proactive approaches to develop more agile, compliant and innovative packaging solutions to deliver significant value to businesses and consumers alike.

PPL Conclave 2018 would also examine the role of technology in developing intelligent packaging solutions to serve the needs of the product as well as meet supply chain requirements. It will facilitate industry leaders to look beyond short term measures and develop strategies strategies to adapt to future legislations, both in the markets they currently cater for, and the markets they intend to enter in the future. Thus, the event will empower experts and industry leaders to enhance preparedness in dealing with future requirements of the ever-changing pharma industry.

Suggested topics

- Impact of global trends on Indian pharma packaging industry
- Driving patient-centricity with packaging innovation
- Rethinking primary packaging for regulatory compliance
- Dose accuracy and efficacy with packaging
- Green packaging for sustainability and progress
- Pharma packaging for competence, compliance and communication
- Advancements in pharma packaging technology
- Smart packaging and its potential

Thus, for the 100+ leading pharma packaging professionals attending the event, the two-day event will give an opportunity to

- Get updated on the advancements in India's pharma packaging sector
- Demonstrate your pharma packaging capabilities
- Showcase your innovative packaging solutions
- Gain insights from thought leaders of the pharma, biotech and packaging industries
- Acquire access to solution providers with cutting-edge packaging technologies
- Discuss on the role of packaging in gaining a competitive edge
- Network with the who's who of the pharma packaging industry

EP News Bureau

MEDINSPIRE to be held at DY Patil University, Navi Mumbai from February 14 to 17, 2019

The summit will host 70+ international speakers, 400+ national stalwarts

THE INAUGURAL edition of MEDINSPIRE, an international multidisciplinary medical summit, will be held at DY Patil University, Navi Mumbai on February 14 to 17, 2019. The summit will be a platform to understand the dynamic field of medicine and its convergent, rapidly developing technologies and ideologies and their potential in advancing healthcare. The summit will be a platform for medical professionals across the globe to assimilate diverse concepts through a blanket-approach summit that can potentially transform the healthcare landscape globally.

The summit is going to host 70+ international speakers, 400+ national stalwarts, 30+ medical specialties. The expected number of delegates is 10,000. The Healthcare Management track in MEDINSPIRE will be an opportunity to learn and interact with the leaders who govern the $280 billion industry in the country. It encompasses topics focussing on super specialty business, quality, manpower retention, financial planning, medico-legal, operational excellences.

MEDINSPIRE seeks to stimulate an exchange of knowledge with the best-in-class international speakers and global stalwarts whilst providing evidence-based learning through a variety of methods like simulation workshops at Asia's first simulation-based medical training facility and hands-on training workshops to name a few. The distinguishing factor of this summit lies in its multi-disciplinary nature, its vast variety of learning opportunities under proficient guidance and the one-of-a-kind expansive 72-acre medical industry interaction spread.

Competitions will be held on business model, medical legal case studies, organ donations, and inter college debate.

EP News Bureau

POST EVENT

India's pharma API industry discusses green chemistry concepts

A two-day conference by Green ChemisTree Foundation points to industry's gradual growing response towards GC&E practices and the overall advancements in its implementation

A TWO-DAY conference and EXPO on 'Advancing Implementation of Green Chemistry and Engineering in the Indian Pharma Industry' was recently organised by Green ChemisTree Foundation in collaboration with the ACS-Green Chemistry Institute's Pharmaceutical Roundtable (GCIPR) in Hyderabad.

The main objectives of the conference were to provide subject-specific interactions on topics pertinent for green chemistry and engineering (GC&E) integration in the pharma API industry and to facilitate learning of green chemistry implementation strategies and practices from successful case studies.

The conference was attended by over 200 senior representatives from industry, solution providers, government bodies, regulatory agencies, industry associations and media. Scientists from Hetero Research Foundation, GVK Biosciences, Laurus Labs and Natco Pharma attended the one-on-one meetings.

The conference was organised in collaboration with ACS-Green Chemistry Institute's Pharmaceutical Roundtable (GCIPR); and supported by Telangana State Pollution Control Board (TSPCB). Companies including Bristol Myers Squibb India, Laurus Labs, Hikal, Natco Pharma, GVK Biosciences and Pfizer India Healthcare served as industry partners. The Bulk Drug Manufacturers Association of India (BDMA), PHARMEXCIL, and Pharmaceutical Supply Chain Initiative (PSCI) supported the Conference as Associate Partners, whereas the Research and Innovation Circle of Hyderabad (RICH) was on-board for the first time to serve as the Knowledge Partner to the conference. Continuing the strong support and active involvement of past years, *Express Pharma* continued was one of the conference media partners this year as well.

Dignataries at the inauguration included (L-R) Dr Juan Colberg, Senior Director, Pfizer, US; Dr David Constable, Science Director, American Chemical Society – Green Chemistry Institute; RK Agarwal, Managing Director, Nakoda Chemicals; Prof S Dayanand, Dept of Animal Sciences, School of Life Sciences, University of Hyderabad; Dr Guy Humphrey, Distinguished Senior Investigator, MSD, US; and Nitesh Mehta, Conference Convener and Co-Founder – Green ChemisTree Foundation and founding director of Newreka Green Synth Technologies

While a Pharma Leadership Summit and workshop on biocatalysis was held on the first day, the second day had the GCIPR workshop on Essential Tools & Techniques and a seminar on Ready-to-Implement Tools, Technologies & Solutions. The structure and content of the conference provided a conducive platform for solution provider companies to engage in focussed interactions with the industry participants across the two days.

The conference was inaugurated and attended by senior representatives from pharma industry, industry associations, government and regulatory bodies including Telangana and Andhra State Pollution Control Boards. Their presence indicated their endorsement of GC&E practices while their messages to the audience emphasised the role of each stakeholder towards accelerating GC&E implementation in Indian pharma API industry. Gracing the inaugural dais were Dr Juan Colberg, Senior Director, Pfizer, US; Dr David Constable, Science Director, American Chemical Society – Green Chemistry Institute; RK Agarwal, Managing Director, Nakoda Chemicals; Prof S Dayanand, Dept of Animal Sciences, School of Life Sciences, University of Hyderabad; Dr Guy Humphrey, Distinguished Senior Investigator, MSD, US; and Nitesh Mehta, Conference Convener and Co-Founder – Green ChemisTree Foundation and founding director of Newreka Green Synth Technologies.

Pharma Leadership Summit

The objective of the Pharma Leadership Summit was primarily to bring together leaders from the Indian pharma industry to collectively engaging in various aspects of GC&E implementation – from identifying opportunities, to recognising gaps, getting acquainted to collaborative models and enabling platforms, to exploring emerging tools and solutions for advancing the implementation of GC&E practices in the industry.

The session commenced with two keynote addresses by Dr David Constable, Science Director, ACS– Green Chemistry Institute, who shared a global perspective on GC&E implementation and sustainability in the pharma industry; followed by Sai Sethuram, Head, Product & Portfolio Development, Pfizer Healthcare, who spoke on the importance of sustainability in the Indian pharma industry for emerging as a robust and sustainable supplier to the global pharma industry.

The talk by Dr Guy Humphrey, Distinguished Senior Investigator, MSD (Merck) US, shared insights on the business-case for green chemistry and how over the years, Merck has been strategically and systematically investing in the field of green chemistry for their products. This outlook was reinforced by Dr Rajappa Vaidyanathan, Group Director and Head, Chemical Development and API Supply, Bristol Myers Squibb, in his talk, wherein he elaborated on various case-studies citing examples on how BMS has been integrating the application of green chemistry principles in early phase development processes.

Dr Sudhir Nambiar, President – R&T, Hikal spoke on his company's journey towards GC&E implementation,

and outlined the events leading from identification to implementation of GC&E practices at Hikal. This was pertinent as Hikal is the first Indian pharma company which is now on-board with the ACS-Green Chemistry Pharmaceutical Roundtable (GCIPR) as a Member Company.

This session was followed by Dr Vilas Dahanukar, R&D Director, Bioxera Research India who pointed out various gaps and opportunities of implementing GC&E practices in the pharma sector, further emphasising the need to develop a mind-set for greener and simpler processes, and newer approaches to problem solving.

Speaking in the last session of the summit, Dr Juan Colberg, Senior Director, Pfizer, US spoke about green chemistry and manufacturing technologies at Pfizer. He remarked that the challenges in resource and environmental sustainability requires more efficient and benign technologies for chemical processes and emphasised that the importance of manufacturing products through green chemistry means that these can potentially addresses such challenges.

Workshop on bio-catalysis in pharma API industry

The objective of this workshop was to have focussed deliberation on exploring the real-time potential of bio-catalysis in pharma API synthesis. The content of the workshop was designed to expand the technical understanding of bio-catalysis, while also learn from successful case-studies and explore relevant bio-catalytic solutions vis-à-vis the pharma API industry's challenges and requirements.

The session commenced with a keynote address and half-day technical workshop by subject expert, Prof Nicholas Turner, Professor of Chemical Biology, School of Chemistry, Manchester Institute of Biotechnology, UK. In his session, he provided an introduction to biocatalysis in the pharma industry, illustrated with examples the various biocatalytic pathways that can make manufacturing of pharma APIs greener, and posited a need to increase application of biocatalysis in discovery chemistry.

The next session was conducted by Dr Guy Humphrey, Distinguished Senior Investigator, MSD (Merck), US, who discussed the role of biocatalysis in green and sustainable development. He opined that enzymes specificity, selectivity, ability to be evolved are key propertiesthat create aspirational opportunities and the answer to the chemist's question "do you have an enzyme that can do x, y or z?" is no longer 'Yes' or 'No'. It's increasingly 'Yes' or 'Not yet'. The biocatalysis case-studies as presented by Dr Humphrey were reportedly shared for the very first time in a public forum and the workshop participants were fortunate to be able to learn from these very exciting projects being done at Merck, US. Similarly Dr Juan Colberg shared relevant case-studies from Pfizer to illustrate the advantages of bio-catalysis in pharma synthesis while Dr Ishwar B Bajaj, Senior Scientific Manager, Biocon shared case-studies on the application of biocatalysis in syntheses of complex APIs.

In the last session of the workshop, presenters shared

pharma API relevant technologies and solutions in the bio-catalysis space. Suresh Kumar from Advanced Enzymes Technologies, discussed the viability of enzymes as "Green Catalysts in the Pharma Industry," and presented case-studies where AET enzymes have shown break-through results in complex API synthesis. The last presenter, Saravanan Jothi, Iosynth Labs, deliberated on white biotechnology and its application in chiral synthesis. He stated that bio-catalysis is an effective tool for achieving chiral purity, which is critical in the pharma industry.

Besides the presentations, participants at the workshop also continued with offline interactions and focussed discussions in the break hours with experts like Prof Nick Turner present throught the conference.

GCIPR workshop on essential tools and techniques

The workshop was designed to facilitate learning from the collective efforts of GCIPR towards performing several PMI benchmarking exercises of chemical processes across different development stages over the last one decade within the member companies of the Green Chemistry Institute's Pharmaceutical Roundtable (GCIPR). The workshop highlighted on how smarter decisions on solvents (including water) and raw materials using the solvent and reagent selection guides can result quickly in significant reductions of wastes, and enhance greener and more sustainable processing.

The first session was conducted by Dr Guy Humphrey, who introduced the objectives and background of the GCIPR model, and set the context for sustainability in the pharma industry. He stated that GC&E enables lowest cost API production, helps mitigate supply-chain risks and presented examples on how GCIPR catalyses innovative approaches to improving process efficiency in the sector.

This was followed by a session by Dr David Constables on PMI metrics, with extensive examples and hands-on exercises. After a detailed introduction on the solvent and reagent selection guides, he demonstrated how R&D teams could integrate these tools on a day-to-day basis.

Industrial experts like Dr Bhuvaneshwari Sridhar, Head of API & R&D, Pfizer Healthcare India, Dr Rajappa Vaidyanathan, Group Director & Head, Chem Dev & API Supply, Bristol-Myers Squibb, India and Dr Guy Humphrey, Distinguished Senior Investigator, MSD (Merck), US shared relevant and real-time examples of integrating GCIPR tools and techniques in making conventional synthesis 'greener'.

Mehta, Conference Convener and Co-founder, Green ChemisTree Foundation, concluded the session by acknowledging the GCIPR for their generous support and partnership in forwarding the "Green Chemistry Initiative for Pharma Industry" in India over the years. He also reiterated the importance and relevance of the GCIPR tools and techniques for the pharma industry in India.

Tools, technologies and solutions in GC&E

The seminar on 'Ready-to-Implement' Technologies and Solutions, was designed to bring together GC&E solutions at the door-step of participating companies. Combined with case-study presentations and demonstrations, the presentations in the seminar introduced emerging tools, technologies and environmental solutions which have the potential to address industry's immediate environmental and process-related challenges. The seminar was categorised into two distinct categories, with the first half being dedicated to tools and technologies applicable at the R&D stage and the second session about those available for process, manufacturing and operations stage.

The first session was commenced with a keynote address by Dr Rakeshwar Bandichhor, Director and CoE Chemistry Head – API R&D, Dr Reddy's Laboratories who provided a consolidated insight into the array of GC&E tools and techniques which R&D teams can incorporate at various process-development stages. The next presenter, Dr Satya Lakshmi Oruganty, Director – LifeSciences – Enterprise Analytics and Intelligence, PerkinElmer, further discussed the various lab informatics tools as developed and offered by PerkinElmer.

The talk by Dr Sivakumar, Technical Services Manager, Johnson Matthey, discussed the use and applications of homogenous hydrogen and through case studies and examples highlighted how optimised homogeneous catalytic system can offer safer, milder conditions (lower temperature and/or pressure), increased chemoselectivity and functional group tolerance (e.g. to halogens). He also explained how these catalysts help in creating simpler work-up procedures and most importantly help in reducing waste generation (as compared to hydrides).

The next presenter, Virendra Chouhan, GM, Equinox Software & Services discussed an innovative Multi Batch Distillation System (MBDS) software technology for carrying out distillation using a stand-alone advanced and effective tool. The MBDS is a user friendly tool developed by Equinox in association with Stochastic LLC (US). He shared examples highlighted the functioning of this tool, and how it can handle both batch and continuous distillations.

Prathamesh Kulkarni, from ACS International India discussed the CAS' SciFinder Tool, which is a research discovery application that provides integrated access to the world's most comprehensive and authoritative source of references, substances and reactions. With the help of case studies, he explained the functioning of CAS SciFinder Tool to find green synthetic routes for API molecules, various green reactions and 'green' solvent reactions; and various other parameters as required.

Dr Shailaja Donempudi, Senior Principal Scientist, CSIR-Indian Institute of Chemical Technology (CSIR-IICT) in her talk briefly shared the journey of 75 years and the focus areas as evolved over the years at IICT. She also shared various case-studies and examples where-in the institute demonstrated development of sustainable and robust 'green' solutions in the areas of multistep and asymmetric synthesis, flow chemistry, parallel synthesis, biotransformations, bench scale level to pilot plant facility, technology for organo-fluoro chemistry, reactors for gas and liquid phase reactions, photochemical reactions, and supercritical carbon dioxide extraction.

> The objective of the Pharma Leadership Summit was primarily to bring together leaders from the Indian pharma industry to collectively engaging in various aspects of GC&E implementation – from identifying opportunities, to recognising gaps, getting acquainted to collaborative models and enabling platforms, to exploring emerging tools and solutions for advancing the implementation of GC&E practices in the industry

The second session on GC&E solutions and technologies for process manufacturing and operations level, included four presentations, starting with Pratas Baruah, National Sales Head – ACC Geocycle who spoke on the efficacy of 'co-processing' as a sustainable and compliant waste management solution for the pharma API industry. Dr Prashant Waske, Mettler Toledo, presented Mettler Toledo's expertise in offering process safety and process optimisation engineering solutions while Ankur Turakhia discussed a 'green' approach to ZLD, Sugam Pariyavaran Vikalp's innovation ZLD solution of "Constructed Geological Filter System".

The last presentation in the seminar was by Megha Shanbhag, Business Development Manager, Newreka Green Synth Technologies who discussed their Recycle-Source solutions for API and the pharma industry. He elaborated on the current reality of this industry generating multiple effluent streams with widely differing quantities and characteristics. Taking into account this reality, Newreka's platform technologies are developed for recycling effluent streams in early stage pharma synthesis, particularly for those API molecules which are high in volume and thus high in effluent. With relevant examples and successful case-studies, she shared Neweka's platform technologies and the customer-friendly business model.

The conference was followed by one-day workshop for teachers and students on "Essential Tools and Guides for Green Chemistry Education and Research," held at K J Somaiya College of Science and Commerce, Mumbai.

4th Grand Edition of Nutrition & Wellness Awards 2018 held in Mumbai

THE 4TH Grand Edition of Nutrition & Wellness Awards 2018, recently held in Mumbai, felicitated achievers under various domains including research and development, manufacturing, packaging, distribution and other support services in the areas of active ingredients, procedures, practices, technologies, and finished products. The following companies were felicitated including winners and winning companies like GSK, Dabur, Nestle India, Abbott Nutrition, Influx Healthcare, Saffron Formulations, Roseate Medicare, MITS Healthcare, 4care Lifescience, Aimil Pharmaceuticals,

Achievers under various domains including R&D, manufacturing, packaging, distribution and other support services were felicited

Tsar Health, Danone India, Sanger Genomics, GM Nutrition, Aero-Chem Neutron, Sundyota Numandis, Nysa Lifesciences, Vrihaan Pharmaceuticals, Deccan Healthcare, Walpar Healthcare, Prabodh Dhavkare - Nitrro Bespoke Fitness, Vinod Channa, Healthyhey Foods, Brukem Life Care amongst others in the presence of top dieticians, nutritionists, doctors and industry stalwarts. Key dignitaries like Bhai Jagtap (MLA Maharashtra State), Shyna Sunsara (United Nations 2018), actors Harshwardhan Rane, Sandhya Shetty and Anaida Parvaneh were a part of this grand evening. Subhasree Ray, Corporate Dietician, Milind Doshi, Co-Founder, Sanger Genomics, Paavni Jella, Director, Vie Foods and Dr Priya Karkera Paediatric Nutritionist. Panelists who took part in the panel discussion were Arnavaz Kollah, Certified Reebok fitness instructor, Dt Kanchan Patwardhan consultant Nutritionist & Dietician, Shweta Bhatia, Reg. Dietician, panelist Mission Fit India and Alok Shirodkar, CEO, Krunch Today.

EP News Bureau

India Pharma Week debuts in Delhi

Key stakeholders and professionals of the pharma industry congregated to network and celebrate the industry under one giant umbrella through avant-garde events

INDIA PHARMA Week, a week-long event including premier shows such as CPhI and P-MEC India, was held recently at India Expo Centre, Greater Noida, Delhi-NCR. It organised more than seven events and activities pertaining to business, knowledge, leadership, innovation, recognition and networking in the field of pharma. It kick-started with a Pharma Leaders Golf in Mumbai. Later, a series of interesting and engaging activities such as Pharma Connect Congress, Women in Pharma, India Pharma Awards, Networking Evening, the CPhI & P-MEC India Exhibition and a closed-door CEO Roundtable, among others, were held in Greater Noida.

It was attended by key stakeholders and professionals of the pharma industry congregated to network and celebrate the industry under one giant umbrella through avant-garde events. Reportedly, this year's edition witnessed participation from more than 1,600 exhibitors from over 42 countries. Special pavilions by Pharmaceuticals Export Promotion Council of India (Pharmexcil), China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCMHPIE) and China Council for the Promotion of International Trade (CCPIT) were also part of the expo. The organisers expect the shift to Delhi-NCR region will further foster a comprehensive pharma ecosystem.

Yogesh Mudras, Managing Director, UBM India, in an earlier interview with Express Pharma had said, “Given the stupendous growth of the show, and the infrastructural and travel logistics hitch in Mumbai, we felt it would be extremely beneficial to have a bigger, consolidated venue that offered the entire spectacle under one umbrella. Besides, the Delhi-NCR region has become the heart of India for holding some of the biggest events in the country. Being in close geographical proximity to policy makers, consulates and government bodies, the show is poised to enhance the industry’s community building efforts.”

Key highlights at IPW

CPhI & P-MEC: CPhI and P-MEC India, held from 12 – 14 December 2018, was attended by the movers and shakers in India’s pharma machinery, technology and ingredients industry for a competitive advantage. It has become South Asia’s leading pharma meeting place covering every step of the supply chain from drug discovery to finished dosage.

The organisers, this year, was looking at recruiting young talent, conducting knowledge sharing sessions comprising eminent industry stalwarts and producing a special White Paper Report on the challenges of the sector that will be prepared based on the recommendations of the top CEOs of pharma companies and presented to the Prime Minister’s Office.

India Pharma Awards and Networking Night: The India Pharma Awards, in its sixth year, celebrated the advances and achievements of the Indian pharma industry on December 12, 2018. The Awards nominations were judged and evaluated by a jury panel including industry veterans such as Bhalchandra G Barve, Joint Managing Director of Blue Cross Laboratories; Lion Daara B Patel, Secretary-General IDMA; Sunil Bambarkar, Managing Director, Gattefosse India; Subodh Priolkar, CEO, Wincoat Colours & Coatings; SM Mudda, Director Global Strategy, Microlabs and Dr RB Smarta, Secretary, HADSA. Reportedly, this year over 65 nominations were

received from companies such as Cipla, Dr Reddy's Laboratories, Abbott Healthcare, Fermenta Biotech, Parle Global Technologies, ACG and Clariant Healthcare Packaging. The Process Advisors, EY helped the jury select the winners of this year's edition who were formally recognised and rewarded at the India Pharma Awards and Networking Night.

Pharma Connect Congress: With the theme of 'Ideate. Innovate. Integrate', the Pharma Connect Congress helped create a platform for the leaders and game changers to come together and strategise to make India the next major hub of end-to-end drug discovery. Held on December 12, 2018 the topics of discussion included 'Transforming the Pharma Industry Architect Through Collaborations', 'Strategies to Strengthen Regulatory Policies in India', 'Role of Digitalisation in Transforming the Pharmaceutical Sector' and 'Leveraging Latest Innovations in Technology' amongst others.

Daara B Patel, Secretary-General, IDMA; Suresh Pattathil, CEO, Ferring Pharmaceuticals; Ashok Bhattacharya, Executive Director, Takeda Pharmaceuticals India; Krishna Prasad, Director, Contract Operations Quality Assurance – Consumer Healthcare, APAC, Pfizer; Kamal Mehta, Sr. VP - Formulations R&D, Jubilant Generics; Manish Gumber, Director & Lead – India Portfolio Planning, Cipla; Vipul Kumar Gupta, Associate Director – Corporate Affairs (India Regulatory) at Cipla; Dr Ravi Sekhar Kasibhatta, Senior VP - Clinical Research, Lupin Pharma; Dr BM Rao, VP and Head Corporate Quality Control, Dr Reddy's Laboratories; Dr Shubhadeep Sinha, Senior VP - Department of Clinical Development & Medical Affairs (CD&MA), Hetero Labs; Arani Chatterjee, Senior VP, Clinical Research, Aurobindo Pharma; etc were some of the dignitaries at the Pharma Connect Congress this year.

CEO Roundtable: It is one of the marquee events of India Pharma Week. In the third edition, held on December 12, the exclusive, closed door CEO Roundtable was attended by a gathering of eminent CEOs of leading pharma companies to discuss issues pertinent to the industry. The organisers informed that recommendations from the thought leaders will be made into a White Paper Report and presented to policy makers of the nation.

Women Leaders in Pharma: This summit acknowledged the significant and continued contribution of women to the pharma industry. Scheduled for December 13, 2018, it brought together women leaders and gamechangers on a common platform to share their success stories, experiences and knowledge. The third edition of Women in Pharma featured interesting sessions such as Balancing Life and Work' and 'Strategies to make our organisations More Diverse and Adopting Inclusive Leadership' amongst many more.

Tanaz Buhariwalla, Director for IDA Ireland; Rina Chokshi, Global Leader for Regional and Field Marketing, DuPont Nutrition and Health; Bhavna Saxena, IPS Special Commissioner; Jyotsna Ghoshal, Senior Director – Corporate Affairs, MSD; Savindu Kudrigikar, Business Director-South Asia etc; DuPont Nutrition and Health Division (N&H) etc were some of the women leaders at the event. Thus, it was a convention of Indian and global companies, attended by the who's who of the pharma industry.

EP News Bureau

Goa Pharma Summit discusses India Pharma Inc's trajectory as a global supply destination

Under the theme, 'Unlocking India Pharma Inc's true potential, experts share their success story and discuss the way forward on making Goa an ideal pharma hub

EXPRESS PHARMA, in association with Goa Pharmaceutical Manufacturer's Association (GPMA), recently organised the Goa Pharma Summit. The theme for the summit was 'Unlocking India Pharma Inc's true potential'. The event was attended by more than 70 delegates from the pharma industry who have their base in Goa. Speakers emphasised on the advantages and opportunities which the state beholds for pharma companies.

Experts and veterans of the industry addressed critical issues such as Building on India's cost advantage; Innovation strategies for the next decade; Leveraging technology to future-proof key processes; Learning from international best practices; Embracing digital for accelerated growth; Exploring strategic alliances to enter newer markets; Building stronger quality systems for improved compliance; Tackling price controls and protectionism and Evolving regulatory landscape.

The conference began with a lamp lighting ceremony by Jyoti Sardesai, Director, Goa FDA, who was also the Chief Guest, and Mahesh Gurnasinghani, Secretary, GPMA. In the Chief Guest's address, Sardesai highlighted that regulatory compliance in the state and informed that pharma products manufactured in Goa have crossed the ₹10,000-crore mark, thanks to its conducive business environment.

The first speaker of the event, Gurnasinghani shared GPMA's Vision and Mission to make Goa a major supply destination. He spoke on various advantages which the state offers such as great connectivity, good talent, a conducive business environment, and others for the pharma sector.

Panel discussion on India Pharma Inc's trajectory as a global supply destination: The Goa Advantage

Mahesh Gurnasinghani, Secretary, GPMA

Jyoti Sardesai, Director, Goa FDA

He also mentioned that Goa is upgrading many facilities and measures are being undertaken to provide more value to the players such as improving its logistics chain, upskilling the resources and building more capacities and others."

The next speaker at Goa Pharma Summit, AV Kiran, Associate Director, Sanofi, spoke on innovation strategies for the next decade. He gave an overview on how India Pharma Inc is evolving and elaborated on how incremental innovation and disruptive innovation both, have significant role on furthering pharma industry's progress. He said, "Meeting unmet needs will be pivotal in creating an innovation strategy. Innovation should be customer-focussed."

Veena Jayaraman, Sales Leader, Beckman Coulter Life Sciences, India briefed the audience on her company's offerings for the pharma sector.

Ramanuj Samal, Application Specialist, Beckman Coulter Life sciences, India spoke on particle characterisation and stability study of formulation.

Manohar Rao, Business Development Manager - Pharma, South Asia, Perkin Elmer spoke on implementing key USP recommendations with analytical and informatics solutions. He also said that his company can be the perfect partner for any pharma needs.

Ankur Ailawadi, Director, Svam Packaging, informed about the company's recent collaboration with Japanese packaging firm Toyo Aluminium KK to bring in advanced technology in order to tackle the menace of spurious drugs. He further briefed the delegates on how the company has been able to handle

packaging requirements of pharma companies.

Vinay Pandey, Business Development Manager, Polymer Technologist: Pharma Tubing Division, Ami Polymer, spoke on the right selection of polymer tubing and various polymer solutions available for pharma companies.

This was followed by a panel discussion on India Pharma Inc's trajectory as a global supply destination: The Goa Advantage. The panel discussion was moderated by Arun Naik, MD, Merit Pharmaceuticals. The panelists were Anant Naik, General Manager Quality, Unichem Laboratories; Mahesh Gurnasinghani, Director – MS&T, Teva Pharmaceuticals; Pareen Dashottar,Vice President & Site Head – Formulation Operations, Glenmark Pharmaceuticals; and Sagar Adichwal, Regulatory Project Manager, Sanofi.

The discussion began with the moderator's overview on Goa's journey as a pharma destination and urged the panelists to share their views on opportunities for Indian Pharma Inc as a global supply destination; Innovation strategies for the next decade; Leveraging technology to future-proof key processes; Building stronger quality systems for improved compliance and Evolving regulatory landscape.

Gursinghani highlighted the need to face challenges and use of automation and innovation to maintain cost. He believes that greater opportunities will unfold in the future for the Indian pharma sector which will enable it to surpass greater heights and retain India's position as a preferred global supply destination for the world.

Dashottar shared his views on leveraging technology to future-proof key processes. He said, "People are very resistant to adopt technology even now in the pharma industry. We need to have a more proactive approach and befriend technology for progress."

Naik spoke on the importance of quality and emphasised that it is essential to change obsolete practices to improve quality standards. He said that Goa can be instrumental in bringing better quality standards as the resources in the state are educated and are more inclined to work towards excellence.

Adichwal gave a brief understanding on how changing regulatory requirements will shape the pharma industry and various steps taken by government will help India Pharma Inc meet global standards and continue to be a preferred supply destination of pharma products.

Dr Robin Isyas, Sales Manager - Sales Manager - South Asia, Middle East, Africa, Anton Paar talked on how to achieve total control in the pharma industry. He was followed by Prof Sanjay Pai, Goa College of Pharmacy, who spoke on forging successful industry-academia partnerships. Education in pharma needs to be more industry-oriented training at academic level, advised Dr Pai.

The last speaker of the event was Ramanuj Samal from Beckman Coulter Life Sciences India. He elaborated on PAT 700 TOC: Low cost of ownership with improved compliance. A networking dinner concluded the event. It was well received by all the attendants.

EP News Bureau

EVENT BRIEFS

14 MEDINSPIRE

28 Acrex India 2019

MEDINSPIRE

Date: February 14 to 17, 2019
Venue: DY Patil University, Navi Mumbai
Summary: The inaugural edition of MEDINSPIRE, an international multidisciplinary medical summit, will be held at DY Patil University, Navi Mumbai on February 14 to 17, 2019. The summit will be a platform to understand the dynamic field of medicine and its convergent, rapidly developing technologies and ideologies and their potential in advancing healthcare. The summit will be a platform for medical professionals across the globe to assimilate diverse concepts through a blanket-approach summit that can potentially transform the healthcare landscape globally. The summit is going to host 70+ international speakers, 400+ foreign speakers, 30+ medical specialties. The expected number of delegates is 10,000. The Healthcare Management track in MEDINSPIRE will be an opportunity to learn and interact with the leaders who govern the $280 billion industry in the country. It encompasses topics focussing on super specialty business, quality, manpower retention, financial planning, medico-legal, operational excellences.

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ACREX INDIA 2019

Date: February 28 to March 2, 2019
Venue: BEC Mumbai
Summary: The event will focus on building automation (BMS) and indoor air quality (IAQ). The mega event will witness participation from more than 25 countries including Belgium, China, Czech Republic, Egypt, France, Germany, Italy, Japan, Korea, Malaysia, Saudi Arabia, Singapore, Spain, Switzerland, Taiwan, the Netherlands, UAE, the UK, Ukraine and the US.

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BLUEPRINT FOR
2019
Pharma leaders and experts share their views on the trends and aspects which will shape the sector's machines, methodologies, processes, and workforce

Pharma Trends in 2019: The rise of outsourcing

Vivek Sharma, CEO, Piramal Pharma Solutions (PPS), predicts that outsourcing will be a central cog in the future pharma supply chain as it evolves from a transactional need to a strategic function

As pharma companies lever external capabilities to drive growth, outsourcing has now become a key component of the drug development and drug manufacturing supply chains. As customers demand scale, reach, and breadth in capabilities, Contract Development and Manufacturing Organisations (CDMOs) have begun to consolidate, to obtain both, proximity to clients and the end markets, through a network of global sites. This extended footprint has also allowed CDMOs to become full-service providers that offer end-to-end capabilities.

By establishing strategic partnerships with CDMOs, both large and small companies can now focus on their core competencies, lever external capacity and specialised expertise with no capital investment, control costs, while rapidly accelerating programmes towards commercialisation. These partnerships help mitigate the risk and costs associated with drug development, by extending the runway for the capital invested. With new drug approvals on the rise - the FDA approved 50 NMEs by November 2018, second only to 53 NME approvals in 1996 - signalling a robust clinical development pipeline, these external collaborations provide the bandwidth needed to drive these approvals to successful launch.

On the other side, by developing these preferred relationships, CDMOs are now migrating from a 'vendor-customer' model to a 'partnership' model, one that can be both sustainable and rewarding. CDMOs now are providing platform solutions that can assist customers in taking programmes from Concept (discovery) to Commercial launch. As the future needs of pharma companies evolve into personalised medicine, niche therapies, fast track programmes, and novel delivery systems, CDMOs are now investing in these future needs on the strength of these strategic partnerships. Other areas of collaboration include CDMOs taking over the manufacturing of late life cycle commercial products, by levering their superior scale and cost structure, allowing pharma companies to increase profitability while allocating their internal capacity to newer, higher-value drugs.

The comparison between small molecules and biologics is also an on-going discussion in the industry. A lot is happening in the biopharma market with the advent of cell and gene therapies. As compared to small molecules, biologics offer high margins and long term value to the companies. Manufacturing of biologics is a complex process and a multi-discipline activity. Therefore, most big pharma companies have invested in biologic manufacturing facilities to manufacture their biologic drugs in-house. This helps them retain full control over the supply chain and

quality of the product while ensuring security of supply. CDMOs are, in some cases, unable to fulfil requirements that demand flexibility and small volumes for biologic molecules. Therefore, one evolving trend is for pharma companies to virtualise their small molecule portfolio while retaining large molecule manufacturing in house. Small molecules continue to dominate the FDA approvals as almost 70 per cent of NMEs being approved over the last five years are small molecules. We expect that the small molecule outsourcing trend will continue to strengthen in the coming years as companies continue to streamline their manufacturing footprint.

In line with the focus on biologics, Antibody Drug Conjugates (ADCs) are now in the news again with the recent wave of third generation ADCs that are site specific and are homogenously conjugated. This has led to an increase in the clinical trial of ADCs with almost 600+ clinical trials on going worldwide. With close to 17 drugs, that are either approved, or are in late stages of clinical development, the ADCs therapeutics market is anticipated to grow at a CAGR to 19.4 per cent between 2017 and 2030 with an estimated value of $8 billion in next five years. The global market for antibody drug conjugates is expected to be driven by the advancement in medical technology, rising incidence of cancer, and an increasing demand for biologic therapies. Unlike conventional chemotherapies that also damage normal tissue, ADCs target only cancer cells and hence the majority of the antibody drug conjugates under development are for oncological indications propelled by the availability of monoclonal antibodies targeting different types of cancer. Some market players are also looking outside the oncology domain to develop antibody drug conjugates, though such drugs are limited in number and are in the preclinical stage of development.

An ADC manufacturing/fill finish facility is a substantial investment, which is why most ADCs are manufactured at CMOs. Most smaller companies, and even some larger companies, do not have enough of a pipeline to justify the level of facility investment needed for ADCs and/or cannot keep the facility fully utilised. In addition, the supply chain for manufacturing ADCs is complex, including linker/toxin manufacture, antibody manufacture, conjugation/QC/stability testing, and fill finish. As a result, most pharma companies have opted to outsource the manufacturing of their ADCs with approximately 70 per cent of all ADC manufacturing activities conducted by CMOs.

In summary, we expect outsourcing to be a central cog in the future pharma supply chain. It has become a 'must have' from a 'nice to have' as pharma firms seek to extend their capital runway, while focusing on their core competencies. Consequently, Outsourcing has evolved from a transactional need to a strategic function. Working with a limited number of supplier-partners helps firms optimise costs and management time, while ensuring that these partners focus on investing capital to meet their future needs. We at Piramal continue to invest in the future requirements of our customers, and now offer a customised suite of integrated solutions that can drive programs from Concept to Commercialisation. Our range of offerings, breadth of capabilities, geographical reach, and integrated network of sites has propelled us to become the 'Partner of Choice' for several pharma and biotech companies. We expect these trends to continue as the industry focuses on developing breakthrough medicines, rapidly and cost effectively, for the one person we are all focussed on the patient.

Future of pharma innovations and R&D in India

Dr Anwar Daud, Managing Director, ZIM Laboratories, gives an insight about the innovation trends to look out for in 2019 in the pharma sector

Innovation is the key to success for any business. Innovation and research in various business sectors is driven by factors specific to the business. In pharma, currently innovation is driven by following three factors:

Firstly, competition in the generic market has become ferocious with the entry of many players, both, big and small. In the US, about 50 per cent of the market is controlled by three major retail companies and therefore they increase pressure on pharma companies to lower their prices. In developed countries, healthcare is provided through insurance companies and these companies are not ready to pay for premium for products without any tangible clinical benefits. In short, everybody is looking for affordable healthcare. So, pharma companies are required to direct their research efforts to develop the products that addresses unmet medical needs and provide them at affordable cost in order to sustain with high profits.

Secondly, in many of the otherwise lucrative markets for Indian pharma companies, government policies are changing to encourage local manufacturing and to promote generics products. This is causing massive disruption in the business. Pharma companies either need to set up their manufacturing plants in such markets or are required to bring highly innovative products with high technology barriers in order to survive through such government policies.

Thirdly, availability of pharma products on e-commerce platforms has shifted decision making power to patient from physician and supply chain push. Social media is additionally altering psyche of consumer through awareness campaigns and subtle promotional messages. In such scenario, only truly innovative products will sustain and grow.

The crux of discussion is innovation is indispensable.

Trends of innovation among global pharma companies

Biologicals

Biologicals and gene therapy based drugs are large molecules that constitute effective mode of treatment for complex diseases like cancer, HIV, arthritis, psoriasis or Crohn's disease etc. The first approved biological drug was biosynthetic human insulin in 1982. After that there was a long period before any new biological was approved. Overall, EMA has authorised more number of biologicals since 2006 than US FDA. In US recently the number of approved biologicals is increasing to about 25-35 per cent of the total approved drugs. Research in biologicals require a specific skills that are different from those required for small molecules. Therefore, number of global players in this category is limited.

New/additional indications

Use of existing drugs for new or additional indications is explored as a cost effective method for innovation and increasing lifecycle of a product. Since all such drugs have tested safety profile, therefore, the review process is also shorter. This option also provides patent protection in some cases. To quote examples, Amantadine, originally an antiviral drug was later approved for the treatment of Parkinson's disease, Montelukast, an established antiasthmatic is being explored for its use in Alzheimer's patients and Tadalafil an ED drug is also approved for treatment of benign prostatic hyperplasia.

New route of delivery

Establishing new route of delivery for existing molecules brings about significant clinical benefits and provides an edge over the competitors. Generally, injectables are converted to nasal/buccal/sublingual formulations as non-invasive means of delivery or oral products are designed to be delivered by nasal/ buccal/ sublingual routes. Such products overcome some serious limitations of the existing products like poor bioavailability, slow onset of action, to get faster onset in case of emergency, reduction in dose etc. Zolmitriptan nasal spray, Midazolam nasal spray, Desmopressin sublingual tablets, diazepam buccal films are some of the examples in this category of innovation.

New dosage forms

Sometimes simply changing the dosage form brings significant incremental advantage to the product and extended patent protection. For example in the case of switch from Suboxone sublingual tablets to films resulted in reduced dose and better safety and in case of Cholecalciferol oral films it increases efficacy. Most of the times new dosage forms are developed to target special need patient population like paediatric and geriatric etc. These innovative features are received very well by both physicians and patients.

New technology for old products

Innovations are done to produce existing products with new technologies. These new technologies overcome limitations of existing products. Spritam orally disintegrating tablet is manufactured using 3D printing technology. The advantage of this technology is to prepare very fast dissolving tablets for

AREA OF PHARMACEUTICAL INNOVATION

Biologicals	Natco (imatinib, Glatiramer) Dr Reddys (Imatinib, E7777)
New route of delivery	Lupin (Testosterone transdermal gel) Sun Pharma (Desmopressin Nasal spray)
New dosage form	Orally disintegrating Films (Dr Reddys, Zim Lab, Shilpa Therapeutics
Niche products	Sun Pharma (Cinacalcet, Oxycodone, sodium Oxybate) Lupin (Sodium Oxybate) Dr Reddys (Cinacalcet) Cadila (mesalamine)
Fixed dose combinations	Sun Pharma (Abiraterone/ Methylprednisolone) Lupin (Mesalamine)
Modified release profile	Lupin (Ranolazine ER) Cadila (Dexmethylphenidate ER) Natco (Budesonide EC)

high dose drugs. This is not possible with conventional lyophilisation or low compression processes. Another example is "Melt dose technology" that yields controlled release products with better bioavailability. With the help of this technology, poorly soluble drugs can be developed into extended release with predictable release profiles. Envarsus XR is based on this technology.

Innovation in packaging

Most of the innovations in this segment addresses the area of child resistance, senior friendliness, adherence, overuse/misuse etc. For some drug categories these issues are very serious therefore, such additional attributes to the package are absolute necessity and clinicians prefer them over the conventional products. There are products available in the market like blisters with child lock (ecoslide RX), unit dose pediatric products (Pedia Care), bottle caps that record the time between doses(RX Timer Cap) or sets the time for next dose and tablet dispensers with biometric facility (Zalviso).

New fixed dose combinations

Several fixed dose combinations are approved every year with the aim to reduce number of pills and increase compliance to treatment regimen. Ertugliflozin L-pyroglutamic acid/ Metformin hydrochloride; Aspirin/Omeprazole; Tezacaftor/ivacaftor are some of the recently approved combinations that established their efficacy in the clinical trials or could convince drug authorities for their utility.

Current trends and future of innovation in Indian pharma

Indian pharma industry holds a very strong position in the global pharma market since long time. With 304 ANDAs approvals in the year 2017, generic products are basic expertise of Indian pharma industry. The wave of price erosion of generic products has struck Indian pharma badly resulting in big loss of revenues. Many Indian pharma realised this in time and switched the gears to development of R&D based products. Having skills for development of generic products, developing niche and complex generics products is relatively easier for Indian pharma industry. Recently, there is increase in filings of complex generics by Indian pharma players. Table 1 summarises the area of pharma innovation and Indian companies focusing on these areas.

Indian companies have very strong future in developing products based on alternate route of delivery, new dosage forms, modified release profiles and fixed dose combinations. Some companies are working in the area of niche products and biologicals. Although, number of biotech companies is limited in India and currently these companies are focussing on development of off patent biologicals but, there is a huge scope of development in this sector. With very supportive Government policies, development of biotechnology parks and funding to novel ideas will strengthen the position of Indian pharma industry in the global biological market.

Top 10 Indian companies have filed about 45 complex generic products in 2017. These companies have very strong pipeline of complex products. Many medium and small R&D based companies are also working on focused R&D programs and offering their share of complex products to the global pharma market. Considering need of innovation, pharma companies are increasing their R&D spending and investing in systematic research based activities for development of innovative products. This will not only keep them ahead in the competition but also will set an example that timely change in the strategies is must to sustain and move ahead in the business.

Building human capital – 2019

Sumit Kumar, Vice President, NETAP asserts that pharma sector cannot achieve the expected growth if it doesn't invest in building talent

Jonathan Haskel & Stain Westlake in their famous book called 'Capitalism without Capital' mentions about rise of phenomena in 21st century about investment by developed economies in intangible assets than in tangible assets for a long-term success. Countries, companies, investors and managers are exploring avenues to create intangible assets to grow their economies, businesses and portfolio. In 2004, Harvard Business Review came out with an influential paper stating that talent, capability and skills constitutes intangible assets and are far more valuable for an organisation than their tangible assets. Often, employees are considered as tangible assets as they can be seen in their physical form, but more than just the warm bodies, its actually their abilities, talent and skill that is an asset for an organisation. You can replace a talented employee by back filling the position; however the capability of that employee cannot be replaced. It needs to be created.

As economies are realising the value of human capital, pharma sector is exploring avenues to create such capabilities. Pharma sector is the sought after sector for employment. It currently employees about three million people and is expected to add over a million people in next four years. The fact that sector is backed by favourable regulatory amendments and economic improvement has put the sector on a fast growth trajectory. The sector is also witnessing adoption of technology in all aspects of business to bring in cost efficiency and productivity enhancement. As technology is overpowering

As economies are realising the value of human capital, pharma sector is exploring avenues to create such capabilities. Pharma sector is the sought after sector for employment. It currently employees about three million people and is expected to add over a million people in next four years

the sector, the need for talent is also getting specific and specialised. Also, pharma retail which is predominantly unorganised is witnessing a paradigm shift as organised players are entering this segment and setting up pan India chain of pharmacies. With all this expected growth, sector which employs 2.6 million people currently is projected to go upto four million by 2022.

Pharma sector as a whole is witnessing a transformation and as the sector evolves it needs massive investments in human capital to cater to current needs and to prepare capabilities for tomorrow. While technology, regulatory reforms, foreign investments, etc. will support the growth, investment in human capital cannot be ignored. World over, pharma giants have invested in formal structured training to develop talent. Apprenticeships have been widely used by these giants for training as it gives on-the-job exposure which is best suited to create capabilities. It helps build cognitive skills which are essential at work place. In India, the trend of blended apprenticeship training is catching up which is a combination of on the job and off the job training programmes to create a productive work force. Customised curriculum is being curated as per the National Skill Qualification Framework to fit the organisation's needs. Under blended apprenticeships, trainees can be groomed as per the needs of the organisation and the industry. Performing real work under on the job training makes the person proficient in the craft.

For talent creation, apprenticeships works best in long rung as it is a cost effective way to build a consistent supply chain of talent which supports future growth of the organisation. Employers are realising its benefits as it supports their overall growth strategy. Organisations are investing in blending learning which is more output focused resulting in productivity enhancement. As jobs are becoming complex and

job roles more specialised, it's the integration of different form of class rooms i.e. on the job, online, on site and on campus which makes the learning impactful and output productive. Technology is overpowering the learning form as well and is witnessing adoption by many organisations. Augmented reality, machine learning and web technology is being widely used for talent development and enhancement. The trend of blended learning is catching up for sure in last few years. There are has been an increment in of 60 per cent in apprentices' addition by the sector and the number of employers doing apprenticeships has more than doubled. The trend which was started by the large enterprises in the sector is now catching up with smaller and medium ones as well due to its success. The growth rate looks impressive but in times to come it will settle to around 35-40 per cent. The potential is huge for the sector to skill people through blended apprenticeship program and create much larger pool of employable candidates. Since some of the skills acquired are traversal in nature, the output could be employed in any related industry and job roles. Hence, apprenticeships can over the concerns of unemployability of the youth of the country and bridge the skill deficit in the industry.

As employers are preparing capabilities through blended learning, retention of talent is a mammoth task for employers. Hence talent engagement becomes an essential part of human capital strategy. Many employers are trying innovative techniques to engage with their workforce by adding value to their livelihood. Sponsoring or subsidising higher education is one such initiative which is catching up. Usually such benefits are offered to the upper cadre of the workforce; apprentices and employees at bottom of the pyramid are devoid of such benefits. Offering higher education connectivity to this segment fulfils their education aspirations and enhances earning power. Offering such benefits enable employers a continuous engagement with their workforce that leads to better business returns.

Role of human capital cannot be ignored when counting the assets, be it at a country level or at an organisational level. The mark of a successful economy is its skilled manpower. Similarly, talent creation, upgradation and retention are essential for any organisation's success. Pharma sector cannot achieve the expected growth if it doesn't invest in building talent. The process of upskilling and reskilling needs to be continuously explored to create a consistent supply chain of talent.

A mixed landscape in 2019

Pushpa Vijayaraghavan, Director, Sathguru Management Consultants, predicts that pharma in 2019 will be a mixed landscape of transformational innovation, value chain shifts and tapered growth with continued pricing pressure

Most regional Indian new year celebrations include a sweet, sour and tangy dish to denote multiple facets of life as we step into another year with optimism and hope. When viewed with a wider strategic lens, the pharma journey in 2018 and what we expect in 2019 couldn't be more poignantly reflective of this reality and how multi-dimensional the evolving dynamic is:

Transformational promise of next-gen healthcare

As a generation, we have the privilege of witnessing the transformation of healthcare into next generation of possibilities. Cost of sequencing being reduced to a fraction of erstwhile levels has opened up wide possibilities for pharma and diagnostic companies as well as healthcare delivery overall, but the true clinical and commercial potential is yet to be realised. 2019 will continue to witness great strides in personalised care - use of genomics and proteomics to deliver therapeutic solutions with higher efficacy though more targeted care for stratified population subgroups. We will continue to revel in the potential of immuno-oncology and other high impact areas of science that now have high level of scientific and investment depth. Finally, we are most excited about the transformative potential of pipeline innovations in gene therapy and gene editing. While 2018 was the landmark year for approvals, 2019 will be the landmark year for market adoption, evolution of more sustainable pricing models, and strengthening of global pipeline in this controversial yet highest potential pursuit within the healthcare domain.

Reality of cost burden and changes in value chain

While we push the boundaries on therapeutic possibilities, we continue to grapple with the burden of healthcare costs across the world. This is resulting in multiple tectonic shifts - a significant reshaping of power across the value chain as well as intensifying pricing pressure across product categories. The generics segment will have continued stress from such pricing pressures and the 'new normal' pricing levels are here to stay. Competition levels of the post-GDUFA regime will continue and will rationalisation is at least couple of years away. Greater emphasis on value-based pricing is expected around the world. Pricing and negotiation power is likely to tilt with re-scripting of the value chain in the most important target markets. Greater integration across stakeholders is expected to continue and the momentum triggered by the active M&A landscape (CVS-Aetna, Cigna-Express Scripts, United Health-Avella, Amazon-Pillpack) is only expected to intensify. Information islands will shrink with such integration across care providing and paying entities paving the way for more optimised healthcare delivery costs but also higher negotiation power in the payor ecosystem.

India Pharma Inc: Looking beyond generics

As the crowned pharmacy of the world, the Indian pharma industry has been reeling under the global pricing pressure, especially in the US, the largest target market by value. Leading generics companies have concentrated portfolio expansion focus on a smaller set of relatively complex formulations. As Indian companies court success in such turbulent times, we expect them to have higher selectivity on portfolio products, deepen appetite for partnerships and prioritise agility in path to market. Simultaneously, the gradual shift to specialty pharma will further evolve. Several Indian majors have laid the foundation by identifying therapeutic areas for strategic focus (ophthalmology, oncology, dermatology, CNS et al) and are actively scouting for partnership opportunities. We anticipate these diversification investments to get more aggressive in 2019 and be the primary M&A driver for larger Indian pharma companies. 2019 will witness portfolio development for US specialty business and will also have precursor commercial investments to build front end capability to detail products to clinicians. We foresee big ticket M&A activity being limited and opportunistic, and deal landscape shaped largely by portfolio expansion dovetailing growth aspirations.

Other key trends

While the complex generics and specialty strategy is executed in regulated markets, we foresee the same overall mantra of quality over quantity being applied even in the RoW markets. In this segment, we expect geographic consolidation and more intense quest for success in fewer markets. 2019 also holds promise of being the year when Indian formulation exports to China could take centre-stage as the latter has relaxed import duties on several high value oncology formulations.

The domestic market has high promise of growth and chronic segments will continue to the kingpin. Appetite for brand acquisitions will continue to be high and growth will be driven by both organic market expansion and portfolio expansion. As aggregated procurement programs such as the Amrit pharmacies are expanded to support Ayushman Bharat implementation, 2019 could even be the year when a viable solution for healthcare access in the Indian context could emerge and price control could gradually be rendered redundant. The foundation of aggregated procurement model with direct bids from pharma companies could be the most significant change in the domestic turf pushing market boundaries and expanding access to care in a sustainable manner.

Lastly, we expect greater focus on operations rigor, quality, digitisation and data security across pharma companies focused on regulated markets. Business continuity risks associated with regulatory observations are the single largest threat still faced by industry; and significant management attention and investment is anticipated to be guided by the intent to better manage this risk. Health of the industry lies in the operational backbone and preventive focus will take centre-stage.

INTERVIEW

A race to the bottom on price must not mean low quality, high volumes

Professor (Dr) Hilary Thomas, Partner and Chief Medical Officer - Healthcare and Life Sciences Advisory and Global Centre of Excellence, KPMG in the UK gives **Viveka Roychowdhury** a glimpse of some of the trends to watch out for in 2019

> Pharma companies need to be more agile and able to acquire, divest and change more rapidly in terms of nimble operating models

With governments in key markets like the US, UK and EU becoming more focussed on reducing the healthcare burden of aging populations, what are the challenges facing Indian life sciences companies?
Cost pressures mean that cutting costs will be very important – and it is simpler to cut the cost of drugs rather than the complexity of making savings across the system. Therefore there are pricing challenges which will feed through to Indian companies doing business in the US and EU.

How can Indian life sciences companies move from a pure generics volume play in key markets like the US, etc to a more differentiated value proposition?
There needs to be a focus on quality in order to compete globally and there will need to be a focus on how outcomes and value based pricing/ funding models would apply.

Governments, and consumers, want high quality patented medicines at low cost of generics. How can Indian pharma companies meet these two seemingly paradoxical demands?
Again – focus on quality to justify better prices but also understand where value can be created taking advantage of the lower cost base in India.

The government in India is hoping that generics will improve access to medicines through schemes like Ayushman Bharat. But how can they make this an economically viable proposition for pharma companies, both Indian as well as MNCs who might want to participate in such schemes but also have to answer to shareholders?
This will inevitably create a tension and achieving both of these will require navigating a tightrope. It will be important not to compromise on quality so a race to the bottom on price must not mean low quality, high volumes.

What trends do you see unfolding in terms of future business and operating models and strategies that will be or are being adopted by Indian companies to navigate these challenges?
Pharma companies need to be more agile and able to acquire, divest and change more rapidly in terms of nimble operating models. Partnering – with smaller companies, CROs, academia and start-ups will be of increasing importance to speed up the move from discovery to licensed drugs.

With thinning margins, what will be the fate of pharma R&D? Will we see more pharma companies divesting, partly or fully, their R&D portfolios and if so to what kinds of players?
Inevitably – see our R&D 2030 Thought Leadership – R&D will be the product of more collaboration and insourcing rather than keeping R&D in house as has historically been the case.

How can stakeholders incentivise R&D into disease areas where not much research is being done (like for tropical diseases etc)?
In some areas – such as developing antibiotics – there has been a failure of the model as we do not see enough new molecules coming through. However, going forward more and more diseases will be 'rare' due to greater personalisation thanks to scientific advances.

Is creating a common pool of R&D lead molecules, part of the answer?
I'm not sure this is scientifically feasible as we are identifying more specific targets - however immunology is becoming increasingly important.

What are the trends in oncology treatment globally and what role can Indian pharma companies play to fit this need? Any examples? Genetic testing holds opportunities but also risks for Indian players. How can this be tackled?
Oncology is a huge area of opportunity globally – growing as we understand more about the molecular profile of disease, the flip side is that smaller numbers of patients will be suitable for more therapies (see our The Future of Oncology Thought Leadership) Genetic testing and genomics are a large part of this opportunity. If Indian companies can keep pace with the science and partner appropriately then they can de-risk this area.

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Monitoring product safety beyond clinical trials – Industry practices

Dr J Vijay Venkatraman, Managing Director & CEO, Oviya MedSafe, details on the need to foster adherence to good pharmacovigilance practices within the industry to ensure its future progress

Medicinal product safety monitoring is an ongoing activity that starts long before a product is introduced into the market and continues until the product remains available in the market. In clinical trials, only a few hundreds to thousands of carefully selected people get involved for a fixed period of time. The safety data from clinical trials may therefore not necessarily suffice to assess how safe the product would be in the long-term when it will be used by millions of consumers in the real world. A medicinal product may appear to be safe and well-tolerated in the pre-marketing phases which may result in it gaining marketing approval too but the real safety profile of the product will be understood only after it has been used by large numbers of patients over a longer period of time and in different parts of the world. For this to happen, it is imperative for product safety data to be collected, organized, analysed and reported in a proper manner in the post-approval scenario also.

The term 'Pharmacovigilance', defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem, is generally used in the context of safety monitoring beyond clinical trials. While the pharma industry is not the only stakeholder of pharmacovigilance, it is the primary stakeholder that is mandated by regulation to monitor the safety of the medicinal products it manufactures and/or markets. Although regulations may significantly vary between countries, they are usually derived from overarching guidelines which have garnered considerable acceptance across the globe. This article aims to provide an overview of the various pharmacovigilance processes in vogue in the industry without specific reference to the regulations of any particular country/region.

Pharmacovigilance system in the industry

Once a medicinal product is approved for marketing, it is the responsibility of the manufacturer/marketer to implement a pharmacovigilance system within their organisation. In addition, they must proactively assess and manage the risks associated with the product throughout the lifecycle of the product.

In the post-marketing scenario, the following processes are followed for purposes of regulatory compliance in the context of pharmacovigilance:

Adverse Event (AE) Handling

Collection of safety information

Pharmacovigilance commences with collection of safety information from various sources such as patients, consumers, healthcare professionals, company partners/ employees, e-mails, phones, fax, letters, journal publications, clinical trials, surveys of patients or healthcare providers, regulatory reports, social media, etc. Published medical and scientific literature articles are particularly considered as important sources of safety information and therefore a periodic (usually monthly) search and review of literature databases is mandated by the pharmacovigilance requirements in many countries. These sources will also give information like frequency of adverse drug reactions (ADRs), patients with highest risk of ADRs, effects in chronic and long-term use, drug-drug interactions, drug-food interactions, misuse or abuse of drug products, medication errors, etc. Each of these reports needs to be evaluated for its causal association with the product and needs to be communicated to the appropriate regulatory agencies either as an Individual Case Safety Reports or as part of Aggregate Reports within the specified timelines.

Dr J Vijay Venkatraman

Individual Case Safety Reports

Individual Case Safety Report (ICSR) is a format and content that is used for the reporting of one or more suspected adverse reactions in relation to a medicinal product that occurs in a single patient at a specific point of time.

One of the fundamental principles of single case reporting is the determination of validity. During the triage phase, the case report will be checked for validity against the four minimum criteria: an identifiable patient, an identifiable reporter, a suspect drug, and an adverse event. If any of these elements are missing or unknown, the case report will not be qualified as valid. Hence, it is the responsibility of the company to take up the appropriate measures to find out the missing data element. Once the missing element is found, the case report will be qualified as valid. Further, the seriousness and expectedness assessments will play a major role in determining the reportability of ICSRs to the relevant regulatory authority. The process flow of the steps involved in single case processing is provided below:

Signal detection

A signal is essentially a hypothesis of a risk with a medicine, with data and arguments that support it, and derived from data from one or more of many possible sources. According to the World Health Organization, a 'signal' is 'reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously.'

Usually, more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information. Generally, unexpected ADRs or new aspect of a known ADR, specific adverse reactions like Steven Johnson syndrome or toxic epidermal necrolysis or some severe hematological conditions like agranulocytopenia or aplastic anaemia that do occur naturally and do have other causes but are very often associated with drug therapy, are considered signals. Reports with these kinds of reactions need to be analysed to understand if there is a reasonable possibility that the suspect drug has caused the clinical conditions.

The process of signal management must systemically

Figure – 1 –Pharmacovigilance processes followed in the industry

address the following steps:

All steps taken and recommendations made must be accurately tracked and documented at every stage. There are resulting legal obligations which must be fulfilled in an accurate and timely manner but the ultimate goal is to confirm or refute whether there is some new issue with the safety of a medicine so that action might then be taken to reduce the risk.

Periodic reporting

Periodic reporting is otherwise known as aggregate reporting. It provides the broader view of safety profile of the medicinal product and helps to evaluate the safety of the medicinal product in a periodic manner. It is the compilation of safety data for a particular period of time and submitted to the regulatory authorities at defined time points by the company in both pre-approval and post-approval phases of the product.

A pre-approval aggregate report is known as Development Safety Update Report (DSUR) and post-approval aggregate reports include Periodic Safety Update Reports (PSUR) / Periodic Benefit Risk Evaluation Reports (PBRER), Periodic Adverse Drug Experience Report (PADER, which is US-specific) and Addendum to Clinical Overview (ACO) in many regions including in Europe.

An aggregate report helps to evaluate the benefit-risk profile of the medicinal product and to identify the safety information that would require further investigation of the product in order to optimise the use of the product or make changes to the medicinal product label. Depending on the significance of benefit/risk profile of the product, the company may need to implement a Risk Management Plan to protect public health.

Risk management

A Risk Management Plan (RMP) is a document that describes the current knowledge about the safety and efficacy of a medicinal product. It is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise the risk relating to medicinal products including assessment of the effectiveness of those interventions. It is ensuring that the benefits of the medicinal product exceed the risks by the greatest achievable manner for the individual patient and for the target population as a whole.

In many countries, risk management plan is required as part of the medicine's approval and renewal process and to retain the marketing approval status. Risk management plan includes the information on the medicine's safety profile and how the medicine's risks will be prevented or minimised in patients and describes the plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine. Also, the scope of risk management also includes the effectiveness of risk minimisation measures.

Communication of safety information

Communication is interactive exchange of information and opinions concerning risk and risk-related factors among regulatory authority, HCP and consumers. Safety communication is a broad term covering different types of information on medicines, including statutory information as contained in the product information (i.e. the summary of product characteristics (SmPC), package leaflet (PL) and the labelling of the packaging) and public assessment reports.

Safety communication aims to providing timely, evidence-based information on the safe and effective use of medicines, promoting changes to healthcare practices (including self-medication practices) where necessary, changing attitudes, decisions and behaviours in relation to the use of medicines, supporting risk minimisation behaviour and facilitating informed decisions on the rational use of medicines. In addition, high-quality safety communication boosts public confidence in the regulatory system.

Communication tools and channels have become more numerous and varied over time, offering the public more information than was previously

possible. Relevant communication tools and channels should be considered when issuing a safety communication in order to reach the target audiences and meet their growing expectations. Different communication tools and channels are direct healthcare professional communication (DHPC), press communication, website, bulletins and newsletter, social media and other online communications.

The primary target audiences for safety communication issued by regulatory authorities and the company should be patients, carers and healthcare professionals who use (i.e. prescribe, handle, dispense, administer or take) medicinal products. Effective safety communication enables them to take adequate actions to minimise risks and to give clear and useful information to their patients. This ultimately promotes patient safety and confidence in the regulatory system. Both healthcare professionals in clinical practice and those involved in clinical trials should be provided with appropriate information on any safety concern at the same time.

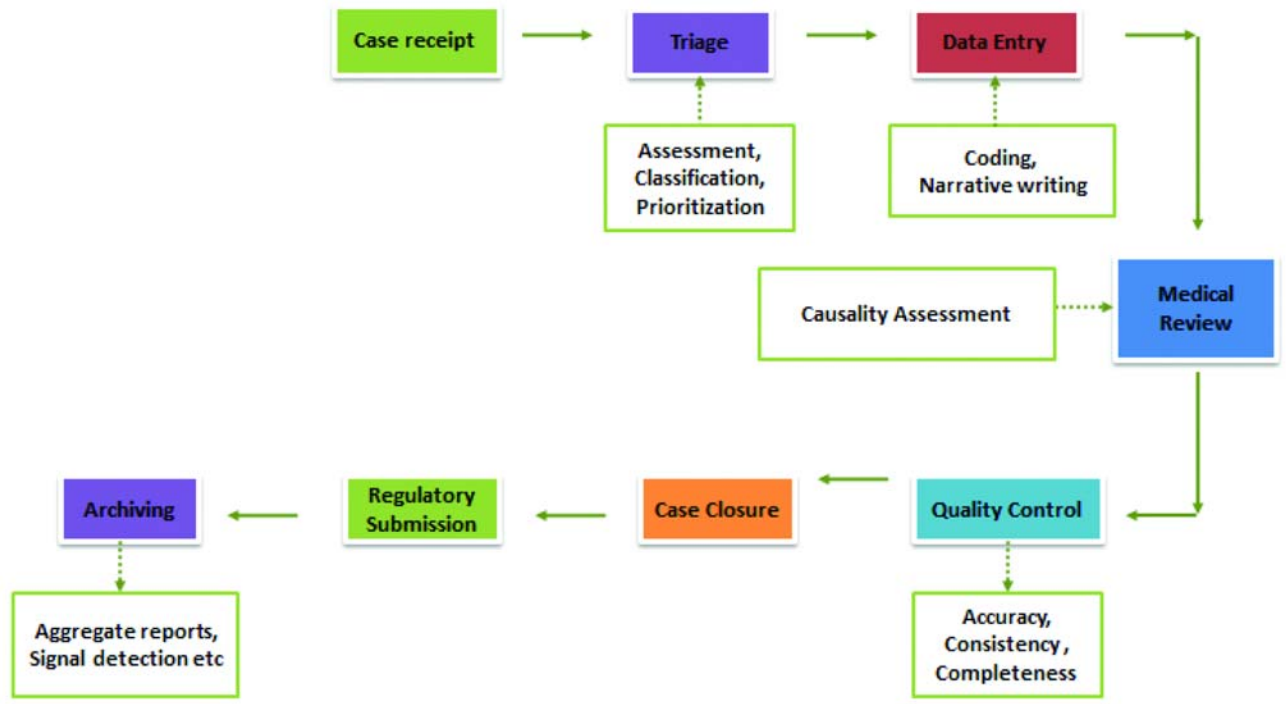


Figure – 2 – Process flow of ICSRs

Regulatory consequences

Since the industry practices described above are primarily targeted towards regulatory compliance, it becomes important for us to see how the regulatory agencies respond to the safety information submitted by the industry. A regulatory agency may choose to order the manufacturer/ marketer to do any of the following, based on the gravity of the safety issue:

- An update to the product information – warnings and contraindications;
- Restriction to the approved indication/population;
- Conduct of a post-authorisation safety study (PASS);
- Perform risk minimisation activities – if risk is acceptable / preventable; and
- Suspend/withdraw the medicinal product – if risks outweigh benefits.

Conclusion

The pharma industry is necessitated by regulation to carry out a wide range of pharmacovigilance activities with the sole aim of ensuring that the benefit-risk ratio of a medicinal product is always in favour of the patient who is treated with the concerned drug. Time and again, there have been several cases in which hitherto approved medicines with extraordinary efficacies had to be recalled from the market after review of the real world safety data which got accumulated post-approval. This clearly establishes the vitality of the need for fostering the further growth of good pharmacovigilance practices within the industry and for furthering the adoption of such practices among all players in the industry.

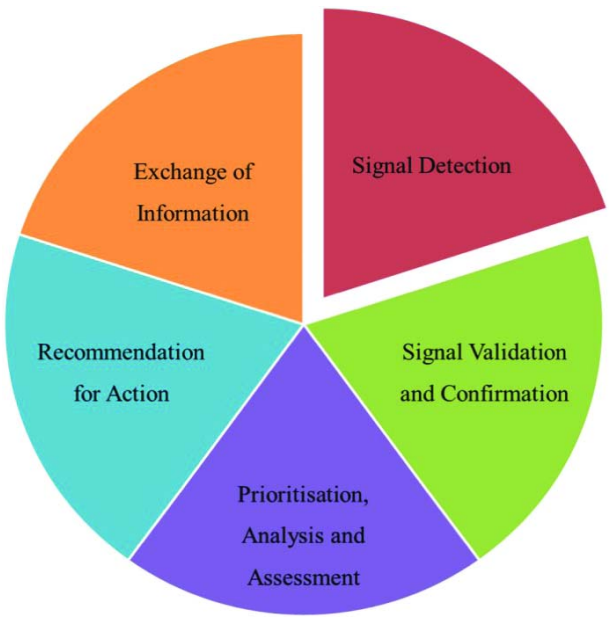


Figure – 3 – Process of signal management

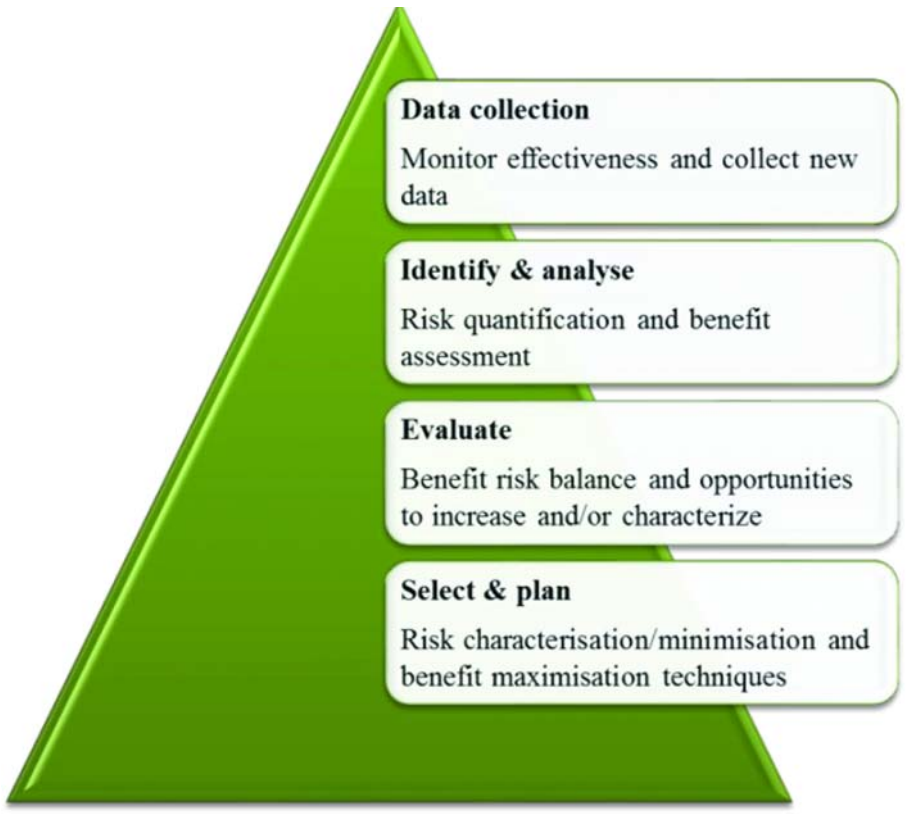
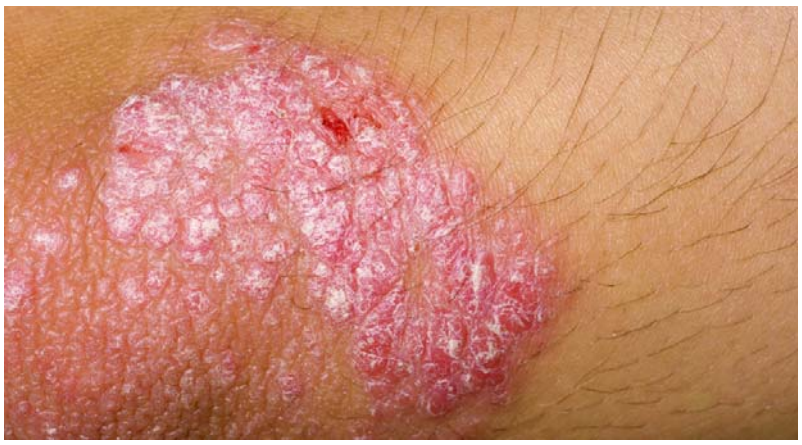


Figure – 4 – Risk Management Cycle

UPDATES

J&J says its psoriasis drug superior to Novartis treatment: Study

Psoriasis is a chronic condition that causes an overproduction of skin cells, resulting in inflamed, red lesions or plaques, which can be itchy and painful



Johnson & Johnson (J&J)said its drug, Tremfya, was found to be more effective than a rival medicine from Novartis in reducing the severity and affected area in adults with moderate-to-severe plaque psoriasis in a late-stage study.

After 48 weeks of therapy, 84.5 per cent of the 1,048 participants treated with Tremfya showed 90 per cent improvement in disease symptoms, as measured by the Psoriasis Area Severity Index, compared with 70 per cent on Novartis's Cosentyx, J&J said.

J&J is positioning Tremfya as a better alternative to Cosentyx as it seeks to take market share away from Novartis' drug, which was launched two years ago and is among the top-selling treatments in the $11 billion global psoriasis market.

That market is expected to double to $21.11 billion by 2022, according to US consultant Grand View Research.

With $2.1 billion in sales in 2017, Cosentyx has become one of the top revenue earners for Novartis and is expected to make up for falling revenue from its blood cancer treatment, Gleevec, whose patent expired two years ago.

On a media briefing following the release of J&J's trial results, Novartis said it expected the data to have "limited clinical relevance" and no impact on plans to expand the Cosentyx label.

J&J also said Cosentyx demonstrated quicker effectiveness than Tremfya during the study.

"These results imply that Cosentyx remains a good option for moderate-to-severe psoriasis patients that want to achieve more rapid skin clearance," brokerage Jefferies wrote in a note following the results.

"We see Cosentyx secure as a mainstay psoriasis therapy."

Psoriasis is a chronic condition that causes an overproduction of skin cells, resulting in inflamed, red lesions or plaques, which can be itchy and painful.

About 7.5 million Americans live with plaque psoriasis, of which 20 per cent have moderate-to-severe form of the disease, J&J said.

Tremfya, first approved in July 2017 as a plaque psoriasis treatment in the US, is also being tested as a for psoriatic arthritis and Crohn's disease.

Reuters

Delivering a baby increases, then lowers, risk of breast cancer: Study

Researchers found that the breast cancer risk peaks 4.6 years after a woman's most recent birth but then begins to fall

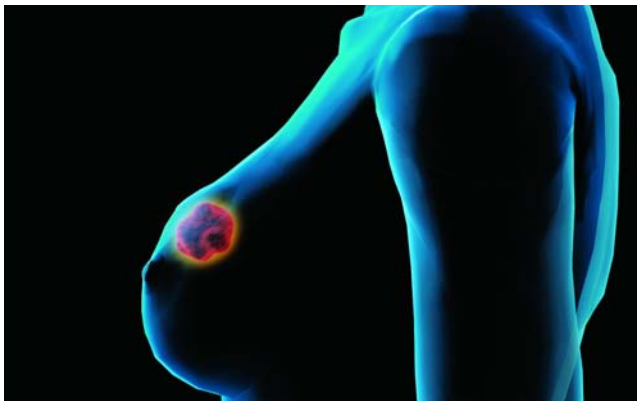
HAVING A baby temporarily increases the risk of breast cancer by about 80 per cent compared to the risk in women who have never given birth, researchers behind a new study have concluded.

But the 80 per cent-higher breast cancer risk is not as scary as it first sounds because "fortunately, breast cancer is uncommon in young women," chief author Dr Hazel Nichols said.

Nichols and colleagues found that the breast cancer risk peaks 4.6 years after a woman's most recent birth but then begins to fall. After another 19 years, the risk returns to the same level as a woman who has never given birth. And from there, it continues to drop.

By 34.5 years after birth of the youngest child, the breast cancer risk is 23 per cent lower than the risk in women who had never been pregnant.

While a 45-year-old woman who had never given birth had a 0.62 per cent chance of being diagnosed with breast cancer up to that point in her life, the breast cancer odds for a woman



of the same age who had given birth in the past three to seven years were only slightly higher, at 0.66 per cent.

Similarly, by age 50, the odds of being diagnosed with breast cancer were 1.95 per cent for the childless women and 2.20 per cent for women with a recent pregnancy, a difference of only one quarter of a percentage point. Women who had given birth to their first child before age 25 did not have any elevated risk at all.

"This should not dictate when women decide to have their children because while we are seeing this extra risk after childbirth, this is a period of time when risk overall is exceptionally low," said Nichols. "This is not translating to a large number of additional breast cancers."

Mia Gaudet, Scientific Director for epidemiology research, American Cancer Society, agreed. The findings "shouldn't change women's behaviour with regards to when a woman decides to have a first child," Gaudet said.

"It may perhaps change how and when a woman begins to be screened for breast cancer," added Gaudet, who was not involved in the study.

The conventional wisdom has been that pregnancy and childbirth protect women from breast cancer, but that belief had come from looking at the cancer rates among women age 60 and older. In fact, half of women with breast cancer are diagnosed before age 62.

The new findings, reported in the *Annals of Internal Medicine*, come from combining data from 15 studies of nearly 890,000 women of varying ages across three continents. They confirm what smaller studies have suggested.

With the aggregated data, "we got a rich picture not only of when women have their children but whether they had a family history of breast cancer, whether they breastfed their children, and the type of cancer that developed," said Nichols. "We are not the first to see the short-term increase in risk after childbirth, but we are now able to see whether or not other factors like breastfeeding your children make a difference. When it came to breastfeeding, it did not."

But Gaudet of the Cancer Society said the breastfeeding conclusion is questionable because the Nichols study only looked at whether breastfeeding ever occurred.

That's important because "prior studies have shown that it's the duration of breastfeeding, not whether they ever breast fed or not" that's key, she said. Those studies show that breastfeeding lowers the breast cancer risk.

The Nichols team also found that women with the most children and those who had children later in life had highest risks.

Having a family history of breast cancer doubled the odds of a breast tumor compared to other mothers.

The higher risk for mothers is probably due to the fact the breast tissue divides rapidly during pregnancy, increasing the likelihood that a copying error will be made in the genetic code, said Nichols of UNC's Lineberger Comprehensive Cancer Center in Chapel Hill, North Carolina.

Reuters

AstraZeneca's Imfinzi fails to meet main goals in head and neck cancer study

The study, known as 'EAGLE', did not improve overall survival compared with standard chemotherapy in patients with the hard-to-treat disease

ASTRAZENECA'S immunotherapy treatment Imfinzi did not meet the main goals in a late-stage study for advanced head and neck cancer, the London-listed drugmaker said.

The study, known as 'EAGLE', did not improve overall survival compared with standard chemotherapy in patients with the hard-to-treat disease, the company said.

The results come after AstraZeneca warned last month that its immunotherapy treatment Imfinzi did not meet the main goal of improving survival rates for patients with the most advanced form of lung cancer, putting pressure on its shares.

AstraZeneca has been seen as having a head start in the race for cancer treatments, and Imfinzi was aiming to be the new standard of care in treating early inoperable stage III lung cancer.

"While these results are disappointing, we remain committed to evaluating the potential of Imfinzi and other innovative medicines for patients with head and neck cancer," said Sean Bohen, Chief Medical Officer, AstraZeneca.

The trial was conducted at 169 centres across 24 countries including the US, Europe, South America, Japan, Korea, Taiwan, Israel and Australia, AstraZeneca said.

Reuters

Roche-AbbVie cancer drug gets accelerated FDA approval

The drug, developed in partnership with AbbVie, was approved for patients with acute myeloid leukemia

ROCHE HOLDING said its cancer drug, Venclexta, received accelerated approval from the US Food and Drug Administration as part of a combination treatment for newly diagnosed patients with a form of leukemia.

The drug, developed in partnership with AbbVie, was approved for patients with acute myeloid leukemia (AML) aged 75 or older, or those ineligible for intensive induction chemotherapy.

"Many people with acute myeloid leukemia are unable to tolerate standard intensive chemotherapy, and the Venclexta combination regimens represent important new options for these patients," said Sandra Horning, Chief Medical Officer, Genentech, a unit of Roche. Venclexta has been previously approved for forms of chronic lymphocytic leukemia, and a late-stage study recently showed that it helped reduce the risk of disease worsening when used with Roche's cancer drug Gazyva. AML, the most common type of the aggressive blood cancer in adults, has the lowest survival rate for all types of leukemia, the company said. The American Cancer Society estimates about 19,520 new cases of the cancer in the US this year.

Reuters

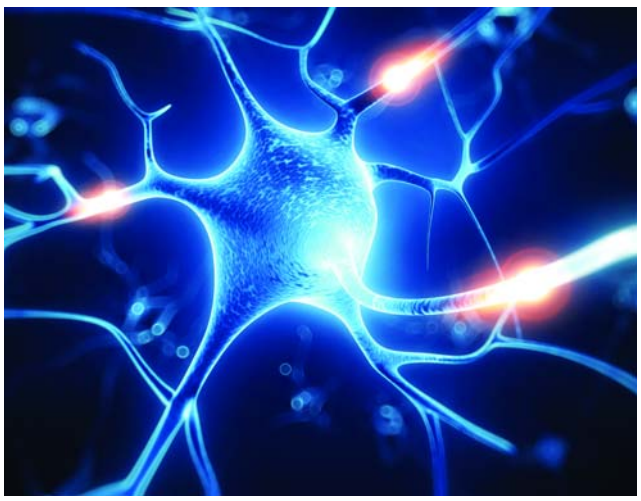
Zebrafish help unlock mystery of motor neurone disease

Trialing 1,000 drugs on mice models would take more than 10 years, however trialling 1,000 drugs on zebrafish would take only a couple of months

SCIENTISTS FROM the University of Sheffield have successfully created zebrafish that carry the complex genetic change known to cause the most common genetic form of motor neurone disease (MND).

The breakthrough will help to accelerate pioneering research and experimental drug trials to tackle the degenerative disease.

Until now, research to better understand how the disease occurs and the trial of experimental drugs has been conducted on fruit flies or mice models. This has had limited success due to the difference between the human brain and the fruit fly brain, and the time and cost implications of using mice models.For the first time, researchers from the University of Sheffield's Institute of Translational Neuroscience (SITraN) have successfully created the complex aspects of human C9-ALS/FTD pathobiology in zebrafish models.



This pioneering breakthrough is essential for studying the underlying mechanisms of MND and frontotemporal dementia (FTD).

MND, also known as Amyotrophic Lateral Sclerosis (ALS), is a devastating neurogenerative disorder that affects the nerves – motor neurones – in the brain and spinal cord that tell your muscles what to do. The messages from these nerves gradually stop reaching the muscles, leading them to weaken, stiffen and eventually waste. The progressive disease affects a patient's ability to walk, talk, eat and breathe. MND affects 5,000 adults in the UK and there is currently no cure.

Approximately 10 per cent of MND cases are inherited but the remaining 90 per cent of MND cases are caused by complex genetic and environmental interactions which are currently not well understood – this is known as sporadic MND. The most common known genetic cause of MND and FTD is a hexanucleotide expansion within the first intron of the C9orf72 gene. In this gene there are hundreds and thousands of repetitions of the sequence GGGGCC in patients with MND. This mutation is the largest genetic cause of MND and also the most predominant form of sporadic ALS.

Dr Tennore Ramesh, from SITraN at the University of Sheffield, said: "Using zebrafish models for MND research means that we can accelerate studies and our understanding of the devastating disease and other neurological conditions.

" Zebrafish are transparent you can record results of studies much quicker and easier – the research is much less invasive."

"Trialing 1,000 drugs on mice models would take more than 10 years, however trialling 1,000 drugs on zebrafish would take only a couple of months."

"This will enable us to accelerate research into clinical trials in humans quicker than ever before."The four year project, which was led by Dr Ramesh in collaboration with leading researchers from SITraN including Professor Dame Pamela Shaw, Vice-President and Head of the Faculty of Medicine, Dentisry and Health at the University of Sheffield, is published in the journal *Acta Neuropathologica Communications*. The study was funded by the MND Association.

EP News Bureau

INTERVIEW

‘Our primary focus is to reach out to customers who have more specific needs’

Bio-Techne empowers researchers in life sciences and clinical diagnostics by providing high-quality reagents, instruments, custom manufacturing, and testing services. **Chuck Kummeth**, President and CEO, Bio-Techne reveals more about the company’s growth prospect in India in conversation with **Sanjiv Das**

What made you think of setting up shop in India? Why is this the right time to do so?
We have been doing business in India for over 30 years and this has been through our distributor channels. We are well aware of the important role that India plays in both academic life science research but also in the clinical space with both research, trials and drug manufacturing. As pharma continues to focus more on the use of biologicals as therapeutics it was important for us to be closer to the end user. Opening our own office was the logical next step.

Tell us more about your new office in Pune? How is it going to help you fulfil plans for India and global ambitions?
Our office in Pune currently has four representatives. Our primary focus is to reach out to customers who have more specific needs and would benefit from having a direct dialogue with our company. We can also develop products on a custom basis and this would be another reason where our India customers would benefit from meeting with representatives that are very knowledgeable about our product lines and product development capabilities.

Tell us about your new innovations both for the domestic and the global market?
Bio-Techne products have continued to address our customers’ workflow; from research reagents for the life science industry, to automation in the protein analysis area to molecular tools and diagnostic assays to assess transcriptomics. These are all key workflows that customers need as they develop products that can serve the local as well as larger the global market.

What will be your future plans for the Indian market? How do you plan to raise investment for it?
We will continue to invest in personnel and infrastructure in a manner that will allow the India business to grow and become a much more significant revenue generator for our corporation.

Who are your Indian clients? How is the Indian market different from the global market?
Our customers in India are represented by academics who continue to make pivotal discoveries and elucidate complex biological pathways to better understand the immune system and associated pathologies in the fields of oncology, neurology, inflammation and others. As these ideas mature and translate into potential diagnostics and therapeutics we can continue to serve more industrial customers in the biotechnology and pharmaceutical markets who are in need of biomarkers to stratify their patient population to understand who would most benefit from a newly developed drug or the better appreciate a drug’s full spectrum of effect.

> As pharma continues to focus more on the use of biologicals as therapeutics it was important for us to be closer to the end user

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VENDOR NEWS

Adents Prodigi cloud serialisation solution chosen by French pharma company

Cloud solution enables cristers to easily exchange serialisation data with supply chain partners and move beyond compliance to improve business practices

ADENTS, A leading provider of versatile and easily deployable serialisation and track & trace solutions, had its Adents Prodigi cloud serialisation solution chosen by French pharmaceutical company Cristers to ensure compliance with the EU Falsified Medicines Directive (FMD) and provide beyond-compliance ROI. Jointly developed with Microsoft and powered by Azure, Adents Prodigi allows for secure data exchange and helps leverage the power of serialisation data to improve business practices.

Cristers markets generic and OTC products, and is a French Lab owned by a cooperative of pharmacists. Holding a marketing authorisation for more than 400 products, Cristers differentiates itself with clear and handy packaging to facilitate communication with patients.

While searching for a serialisation solution that would ensure compliance with the FMD, Cristers also sought a means of enabling easy exchange of serialisation data with its supply chain partners, including contract manufacturers and logistics providers. Additionally, Cristers wanted a solution that would aid in the onboarding of more than 30 European partners – including CMOs, vendors and third-party logistics providers – and facilitate connection with a diverse set of Levels 3 & 4 serialisation solutions.

Adents serialisation solutions are designed to help companies gain simplified speed to compliance with regulatory requirements.

The Adents Prodigi cloud-based Level 4 traceability solution met all of Cristers' needs. The solution centrally manages regulatory requirements, provides an easy onboarding process to connect multiple trading partners, and facilitates significant business improvements by enabling companies to utilise the massive amounts of data generated during the serialisation and track & trace process.

"Adents Prodigi solution was the best native cloud Level 4 solution that offers us scalable and cost-efficient IT architecture in addition to a quick and easy partners onboarding," said Hervé Abou, Head Pharmacist of Cristers.

"Our pre-qualified software saves time during the validation phase, provides ultimate data security, and offers tremendous advanced analytics capabilities – enabling companies to move beyond compliance to improve business practices," added Christophe Devins, Founder and CEO, Adents.

EP News Bureau

Lonza, Sartorius Stedim Biotech modify relationship for supply of cell culture media

Sartorius Stedim Biotech will continue to offer Lonza media and buffer products but under a non-exclusive agreement

LONZA AND Sartorius Stedim Biotech (SSB) have modified their current agreement for supply of cell culture media by mutual accord. The agreement, signed in 2012, gave SSB exclusive sales and marketing rights for certain media and buffers developed and manufactured by Lonza for use in biopharmaceutical manufacturing processes. Lonza retained sales for research-based products, among others.

Under agreements signed, SSB will continue to offer current and future Lonza media and buffers on a non-exclusive basis as part of its extensive portfolio of products for cell-based development and manufacturing. Lonza Pharma & Biotech resumes sales and marketing of all its media products for both manufacturing and research. Customers of both companies will continue to be able to source media products for their specific needs.

"We have a long-standing and productive partnership with SSB, and we will continue to work together to provide solutions for customers as they bring medicines to patients," said Marc Funk, COO, Lonza Pharma & Biotech. "As new generations of complex biologics move toward commercial production, media is no longer viewed as a consumable but as a critical part of the package we offer customers developing next-generation therapies, so we are investing accordingly in this area."

"Our collaboration over the past years has greatly benefited our customers and both companies. The adapted agreement now reflects the dynamics of this rapidly evolving market, providing additional strategic flexibility for both partners," commented Reinhard Vogt, Member of Sartorius Stedim Biotech's Executive Committee.

Both companies have also entered into a further long-term agreement for supply of equipment and consumables. Under the new agreement, SSB will be a preferred supplier for specific Lonza projects. As Lonza increases its capacity for small-scale manufacturing, notably through the recently announced IbexTM Design and Develop in Visp (CH), strong partnerships are key to offering the best solutions for customers.

Lonza is currently investing in its media business and will open a new R&D facility in Rockville, MD (USA) by the end of 2018. Supporting the nearby Walkersville, MD (USA) site, the new R&D centre will drive innovation in media formulation. As biologic-based medicines – including next-generation antibody-based therapeutics and cell and gene therapies – become increasingly complex, media formulations need to be tailored to specific processes. The new centre will ensure a strong platform for current and future growth and provide new solutions for customers.

EP News Bureau

Rockwell Automation, PTC launch collaborative offering to drive digital transformation across industrial enterprises

New FactoryTalk InnovationSuite to accelerate digital transformation strategies for greater productivity through simplification of complex processes in industrial businesses

ROCKWELL AUTOMATION and PTC announced that they have launched FactoryTalk InnovationSuite, powered by PTC, a software suite that enables companies to optimise their industrial operations and enhance productivity by providing decision makers with improved data and insights. The new suite delivers complete visibility of operations and systems status from one source of information inside the organisation. The collaborative offering is the first to integrate technologies from both companies following the strategic partnership announcement in June.

FactoryTalk InnovationSuite, powered by PTC, improves connectivity to operational technology (OT) devices on the plant floor, natively supporting the rapid, scalable, and secure connection of the most commonly used industrial equipment. Combined with data from information technology (IT) applications and systems, decision makers can now gain a complete digital representation of their industrial equipment, lines, and facilities from anywhere in the enterprise.

"Our offering is unique in its ability to improve how companies capitalise on the IIoT by combining expertise from industry, technology, and plant-floor professionals," said John Genovesi, incoming senior vice president, Enterprise Accounts & Software, Rockwell Automation.

> FactoryTalk InnovationSuite improves connectivity to OT devices on the plant floor, natively supporting the rapid, scalable, and secure connection of the most commonly used industrial equipment

"We're moving the needle on how leading-edge technology is applied in industrial environments," said Catherine Knicker, Head of Strategic Alliances, PTC.

Included in this collaborative offering are the FactoryTalk Analytics and MOM platforms, as well as PTC's ThingWorx Industrial IoT Platform, which includes industrial connectivity from Kepwareâ, and the Vuforia augmented reality solution. Key features of applications within the new collaborative offering include:

- Intuitive, user-friendly interfaces that give users a view of the operations by combining data from multiple IT and OT sources and tailored to their role. An operations manager, for instance, can view overall performance of a facility, or multiple facilities, before researching the performance of specific equipment or factors impacting OEE.

- Automated advanced analytics of IT and OT sources transform massive amounts of raw data into actionable or proactive information to improve performance and reduce the impact of downtime. Leveraging powerful artificial intelligence (AI) technology to simplify complex analytical processes, users can now proactively respond to issues ahead of any critical failures.

- Augmented reality (AR) delivers more efficient and effective ways of looking at digital information within the physical world. AR enables more efficient training, wider knowledge sharing, and better first-time fix rates. Through the bundled offering, maintenance, for example, can receive digitized work instructions containing real-time performance and service history information so technicians can better diagnose and fix equipment correctly the first time.

EP News Bureau

ERT enhances its clinical trial imaging team

David Raunig brings decades of pharmaceutical research experience

ERT, A global data and technology company that minimises uncertainty and risk in clinical trials, announced the addition of David Raunig to its team of scientific and technological imaging experts. The science team is a key component of ERT's rapidly growing advanced technology imaging solution, which has been used in more than 500 clinical studies to date.

Raunig brings 20+ years of experience integrating current medical, scientific and statistical techniques into the collection and analysis of imaging data during the development of new medical products. Previously, Raunig held senior leadership positions with global pharmaceutical and clinical research organisations, including Bristol Myer-Squib, Icon Medical Imaging, and Pfizer.

"ERT's innovative imaging solution is overcoming the challenges many drug developers face when using traditional imaging approaches to support safety and efficacy endpoints during clinical development," said Raunig. "I'm thrilled to join this team of forward-thinking scientists and to be part of the solution that delivers the highest quality imaging data to worldwide clinical trial sponsors and CROs."

> Raunig is responsible for driving the quality of ERT's imaging solution by integrating regulations, operations and statistics into the conduct of clinical trials

Raunig is responsible for driving the quality of ERT's imaging solution by integrating regulations, operations and statistics into the conduct of clinical trials. He joins an established scientific team who apply their 160 collective years of imaging experience to ensure ERT's advanced technology imaging solution reduces human error, complies with global regulations, and accelerates clinical development.

"David's significant experience in pharmaceutical research complements ERT's expertise in managing our customers' most complex imaging challenges and delivering greater efficiencies throughout clinical research," said Tim Kulbago, Vice President, Imaging at ERT. "We're pleased to welcome him to the ERT imaging team."

EP News Bureau

VALUE ADD

K2VITAL DELTA: The K2-7 stability solution for India

Jim Beakey from Kappa Bisoscience, gives an insight on how Indian manufacturers have an exceptional opportunity for lower cost higher quality K2-7 solutions

VITAMIN K2-7 is vital for bone and cardiovascular health. K2-7 activates osteocalcin proteins which integrate calcium into bone, and matrix Gla proteins (MGP) which bind excess calcium to protect the heart. Calcium is also a common prescription for bone health, and heart-friendly magnesium is often paired with K2 as well.

Unfortunately, standard unprotected K2-7 is not stable when combined with mineral salts or in high-alkaline environments. Unprotected K2-7 degrades relatively rapidly, and products are likely to miss label claim before the end of shelf-life. Kappa Bioscience developed microencapsulated K2VITAL DELTA as a solution. DELTA leverages a patented double-coating of the MK-7 molecule which restricts oxygen exposure.

K2VITAL DELTA is now available in India as a complete stability solution with the grant of a registration certificate and first-of-its-kind drug import license. DELTA ensures K2-7 quality and potency and reduces costs by requiring less overages. The opportunities for India were recently demonstrated as part of a global market study.

Kappa Bioscience conducts an annual K2 quality study by testing consumer products for K2 label claim. Recent testing included 17 products purchased in India. Each included K2-7 and calcium or magnesium salts. Results demonstrated opportunities for Indian manufacturers to reduce costs and improve quality. Specifically:

- Fewer than half of Indian products contained the K2-7 amount claimed on the label claim. One product was also found to contain high levels (32 per cent) of non-bioactive cis MK-7. In effect, only 41 per cent of Indian K2-plus-minerals products tested met K2 label claim.
- Three products measured 96 per cent to 99 per cent of K2-7 label claim at the time of the testing. However, because unprotected K2 can degrade at a rate of approximately 40 per cent (with Ca) to 99 per cent (with Mg) in six months, it can be questioned if these products would meet K2 label claim at full shelf-life.
- Very poor quality was found in 29 per cent of Indian products tested. These demonstrated both low K2-7 content and high amounts of biologically inactive cis MK-7. Three products contained zero bioactive K2-7.
- In a surprise finding, Indian products that met label claim generally demonstrated excessive K2-7 amounts (i.e. overages far higher than the global average). It is unclear if these overage amounts were the result of an intended strategy to offset K2 degradation (to promote shelf-life), or an unplanned by-product of manufacturing. It does indicate that Indian manufacturers likely spend more to manufacture K2 products than the global average.

In sum these results indicate that Indian manufacturers have an exceptional opportunity for lower cost, higher quality K2-7 solutions. Hundreds of global products demonstrate that K2VITAL DELTA delivers 99.7 per cent all-trans quality and higher product profitability. Less overage with Ca or Mg salts reduces costs while ensuring stability, shelf-life and potency.

Are you ready for Brexit?

Chemical companies need to be prepared for various outcomes affecting the chemical industry in a post-Brexit UK. An insight by DKSH

ON MARCH 30, 2019, the UK will leave the EU and become a third country ("Brexit"). As there is still no certainty that there will be a ratified withdrawal agreement in place on that date, or what it will entail, the EU Commission expects that the UK's withdrawal will undoubtedly cause disruption to many industries, including chemical distribution.

In a worst-case scenario ("no-deal Brexit"), it is currently envisaged that REACH could cease to be applicable to the UK from March 30, 2019. Due to the current status of the negotiations, this scenario grows more likely. In this scenario, the UK would be considered a "third country": based outside the EU under the REACH regulation and unable to act as a registrant. In addition, current REACH registrations made by entities based in the UK would no longer be valid.

DKSH acts as a distributor and importer in the UK and also has suppliers located in the UK. In order to overcome any potential business disruption and anticipate the future regulatory environment in the UK, DKSH has established a "Brexit Task Force" consisting of regulatory affairs, business and management representatives. This task force meets on regular basis to prepare and monitor all regulatory and business process plans and resourcing to ensure business continuity to our customers.

If you have any questions regarding DKSH's preparation for Brexit, please contact DKSH Regulatory Affairs Europe at *brexit@dksh.com*

B&R Automations: Precise control of temperature processes

New software component for easy access to temperature control

With mapp Temperature, B&R offers temperature control that combines maximum usability and powerful control algorithms. Integrated simulation capabilities allow virtual commissioning in minutes. mapp Temperature also provides heating current monitoring.

With mapp Temperature, it is possible to define zones and groups for temperature control. A zone is a unit consisting of an actuator, a temperature process and a sensor for measuring the temperature. Multiple zones can be combined into a physical group and controlled and optimised together. This gives the user maximum flexibility and scalability to meet any temperature control requirement.

Autotuning and integrated simulation

If applications cover a wide temperature range, simple tuning is often not sufficient to optimally adjust the parameters. mapp Temperature therefore includes a multi-stage autotuning process. The user can define several operating points and optimise them individually. The integrated simulation capability enables simple virtual commissioning without any hardware. This option makes it possible to test the application's logic, error handling and HMI system in advance to significantly accelerate on-site commissioning.

Heating current monitoring

B&R's temperature control system also offers heating current monitoring to enable early detection of faults through predictive maintenance. By monitoring the current of the heating elements, it is possible to react to a fault at an early stage without stopping the entire process. This ensures a high level of operational reliability and helps prevent extended downtime.

B&R shapes the future of OPC UA over TSN

The unified communication standard of the Industrial IoT has been chosen

OPC UA over TSN will be the unified communication standard of the Industrial IoT. Standardization and ongoing development of OPC UA at the field level will take place under the umbrella of the OPC Foundation. This represents a long awaited answer to the market's demand for vendor-agnostic, interface-free industrial communication.

B&R has been a main player in the initiative to develop and standardize OPC UA over TSN for communication at the controller and field level. The company plays a leading role in the corresponding standardisation organisations: OPC Foundation, IEC/IEEE and VDMA. B&R also actively participates in testbeds such as those conducted by the Industrial Internet Consortium. "We're working to make sure that both builders and operators of industrial machinery see real benefits from harmonised communication as soon as possible," says Stefan Schönegger, vice president of strategy and innovation at B&R. In addition, B&R's parent company ABB has been appointed to the board of the OPC Foundation.

18x faster

OPC UA over TSN will enable plug-and-produce networks that are easy to administer and configure. Network stations will communicate up to 18 times faster than with any protocol available on the market today. This opens up new possibilities in areas such as tightly synchronised motion and control applications.

OPC UA over TSN will also meet the requirements of future

IoT applications. The technology supports networks comprising tens of thousands of nodes and benefits from bandwidth extensions to the Ethernet standard. Even large volumes of data – such as those generated by integrated machine vision applications – can be handled with ease.

The fusion of IT and OT

OPC UA enables seamless, transparent communication from the sensor to the cloud. The worlds of IT and OT merge to form a unified network, fulfilling a key requirement of all Industrial IoT applications. Both OPC UA and the TSN Ethernet extension are managed and developed by independent organisations, making OPC UA over TSN a truly vendor-agnostic protocol. "In terms of communication, machine builders and operators are no longer bound to specific suppliers," explains Schönegger.

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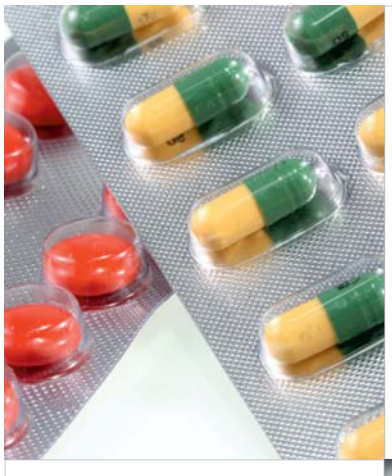

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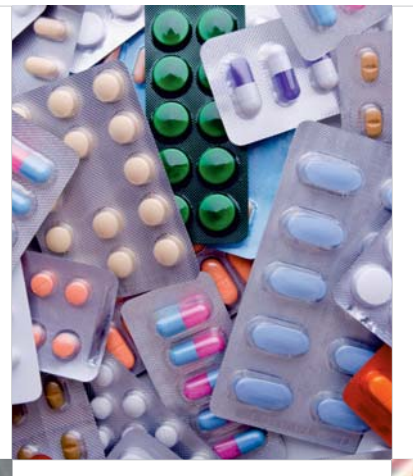

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INTERVIEW

‘We promote diversity and inclusion amongst all our clients’

Qwazent has been able to bring in leaders and healthcare practitioners from different countries for different countries. **Deepali Jetley**, Managing Partner, Qwazent Health Search in a conversation with **Usha Sharma** reveals more about hiring women in the lifesciences industry

Tell us the objective of Qwazent Health Search and its functioning mechanism.
Qwazent was conceived with a unique idea of serving the talent acquisition and management need of the entire healthcare industry. Executive search practice was next to negligible, especially in healthcare delivery systems. Qwazent Health Search has been one of the pioneers in establishing this practice in the industry and is trying to further evolve the sector by bringing in and shaping up leaders from different sectors into this industry. We are an all women organisation and believe that we bring a 360 per cent perspective in fulfilling the need of our clients. We are long-term custodial of people who we place and our deep process make sure that we bring best fit people for our client. We have built a ‘phygital’ model of search wherein we analyse extensive data, profile matching and supplement the same with personal interaction prior to bringing the candidate to a potential hirer.

Why is the company’s focus mainly on the healthcare industry and how did it become a trusted advisor for healthcare enterprises?
Healthcare industry in India has been growing at a phenomenal pace however, there is no firm which focuses specially on talent gap – there are many firms which are generalist in nature and can fulfill the general need of healthcare providers. We have invested the last two years in building teams, network and technology wherein we can find and fulfill specialised needs of healthcare service providers. Our relentless focus, diligent pursuit on delivery quality has helped us to earn the trust of our healthcare clients.

How do the methods of hiring top-level management differ from mid-level management? What are the challenges in each segment?
To be very honest, these days it’s not drastically different. Organisations are super conscious in hiring mid-management personnel as well. Ultimately it’s this management that’s going to form leaders of tomorrow. Thereby, our strategy and process remains the same for both levels. Just a little more sensitive towards top management hiring and involvement by senior consultants would be the only striking difference at our end. Professionalism and ethics seem to be dying down across levels thereby facing the same set of challenges across segments. Misinterpretation of profiles, lack of commitment, material objectives are some of the common traits that makes it hard for us to look for genuine candidates. Moreover, healthcare is a very small knitted industry, so at top-level management hiring, lot of times it’s the same pool of candidates shuffling from one place to another. We are forever on the look-out for leaders from other sectors who could fit the bill for our clients who are willing to experiment and bring innovation in their business.

How to convince passive candidates for job switch?
That’s been our forte. There is no set formula and is purely case to case basis but formulating a strong pitch by evaluating and understanding the role thoroughly from different stakeholders and thereby customising that pitch to an individual’s personal circumstances and eco-system is what helps us in convincing passive candidates.

What services do you offer for the pharma sector? Do you have plans to offer any value added services?
Besides the CXOs, we have been handling some of the niche positions like Head Quality, Head Regulatory Affairs, Head Investor Relations etc. wherein it’s a limited pool again and it’s about pitching and convincing the candidate even if he/ she is not seeking a change.

We do offer other value added services to our clients like Compensation Benchmarking, Organisational Restructuring and Cultural and Organisational Transformation. Besides, we are also helping organisations with diversity and inclusion.

Why are there considerably less women in the pharma industry? What efforts will your company put in for scaling up the numbers?
One of the reasons we decided to make Qwazent an all female employee firm is to establish among our clients that women are equally effective if not

superior to their male peers. Now we have seen the trends are changing and more females are emerging in the sector. I remember we were trying to fill an extremely niche position in sterile injectable space wherein it was a limited pool of just about three to four relevant candidates and we were able to successfully close the position with a female leader.

We promote diversity and inclusion amongst all our clients and we have been able to place females across multiple positions in the sector. Currently our male vs female placement ratio is 70:30 and it's our constant effort to bring it at par.

The company is an expert in cross-border hiring, brief us on it? (kindly provide segment wise details like sector, countries etc.)

That's again our forte wherein we have been able to bring in leaders and healthcare practitioners from different countries for different countries. Would like to quote a few case studies here:

- Placing Indian doctors and management personnel in countries like Bangladesh, Sri Lanka, Nigeria, South Africa, Democratic Republic of Congo, Uzbekistan, UK etc. largely for a healthcare delivery system
- We got a Sri-Lankan management professional for an Indian medical device company to head the country
- We were able to get a female HR leader from Finland for a strategic acquisition there by an Indian medical technology and diagnostic company
- We helped a NYSE listed Pharma company with their Head Investor Relations from the US.
- We helped a diagnostic company in Dubai get their Lab Director from Germany
- We helped a hospital in the Democratic Republic of Congo get a team of doctors from Tunisia and Morocco.

What role will the company play in scaling up health personnel for making a success of Ayushman Bharat?

Ayushman Bharat has come as an evolving point for Indian healthcare industry and we all will be witnessing multiple changes in the system, including the Human Resources side of it. We are helping our clients in healthcare delivery systems standardise compensation across levels including that of medical practitioners. This is going to be a key factor to make it a win-win situation for both, organisations and the government. We are extending our full support to our clients in bringing about this cultural shift and bringing doctors in-tune to this model.

Do you see the positive impact of brain drain in pharma or healthcare and how effective is it?

Yes, definitely there's been a positive impact across the healthcare sector. We know for sure that Western markets are definitely evolved and are known for their practices and innovation. With the US FDA playing an active role in the pharma sector, it now helps us bring back those candidates to India from the US who are well acquainted and have thoroughly experienced the functioning of this committee. Similarly, doctors who had migrated to serve the US or NHS in the UK are now willing to come back to India and serve their own nation with the expertise and advanced practices they have gathered from their respective countries.

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RECOGNITION

Vinod P Shah, International Chairman, SPDS, bags recognition from AAPS

Shah has conclusively demonstrated his vision, passion, and commitment to advancing treatments and cures that improve the quality of life for all global citizens

AMERICAN ASSOCIATION of Pharmaceutical Scientists (AAPS) has recently honoured Vinod P Shah, International Chairman, Society for Pharmaceutical Dissolution Science (SPDS), with the Global Leader Award.

Shah has made significant and long-lasting research contributions to the pharmaceutical sciences field working in regulatory, standards-setting, and academic communities both in the US and globally. His 30-year tenure at the FDA and his subsequent work as a volunteer for many professional societies, including AAPS, FIP, USP, and SPDS resulted in a lifetime of notable achievements and awards. He is the author/co-author of more than 300 scientific publications and co-editor of four books and a theme issue of the AAPS Journal.

From conducting workshops and conferences in the areas of bioequivalence and dissolution throughout the world to being a key organiser and thought leader, Shah has conclusively demonstrated his vision, passion, and commitment to advancing treatments and cures that improve the quality of life for all global citizens.

"Shah's leadership and efforts in organising and conducting international workshops have had a significant and a broad impact in the availability of high quality drug products, and benefit to patient's in needed therapies internationally. He has improved

the quality of drug products worldwide by investing significant amounts of time and effort in making regulatory workshops available throughout the world. His tireless efforts have garnered good will for AAPS and FIP globally and have improved drug product quality, which has benefitted patients throughout the world" stressed nominator and Leslie Z Benet, Founder, AAPS.

The AAPS Global Leader Award recognises a leader working in pharmaceutical science, technology, engineering, or education whose contributions to the pharmaceutical sciences community have resulted in an outstanding positive impact on education and/or public health. AAPS recognises these leaders both as a means to support their work, and to encourage pharmaceutical scientists around the world to keep driving toward treatments and cures that improve life for all global citizens.

AAPS is pleased to recognise Shah as a scientist who has the vision, passion, and commitment to advance the development of drugs and therapies that assist in addressing today's global health challenges.

EP News Bureau

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