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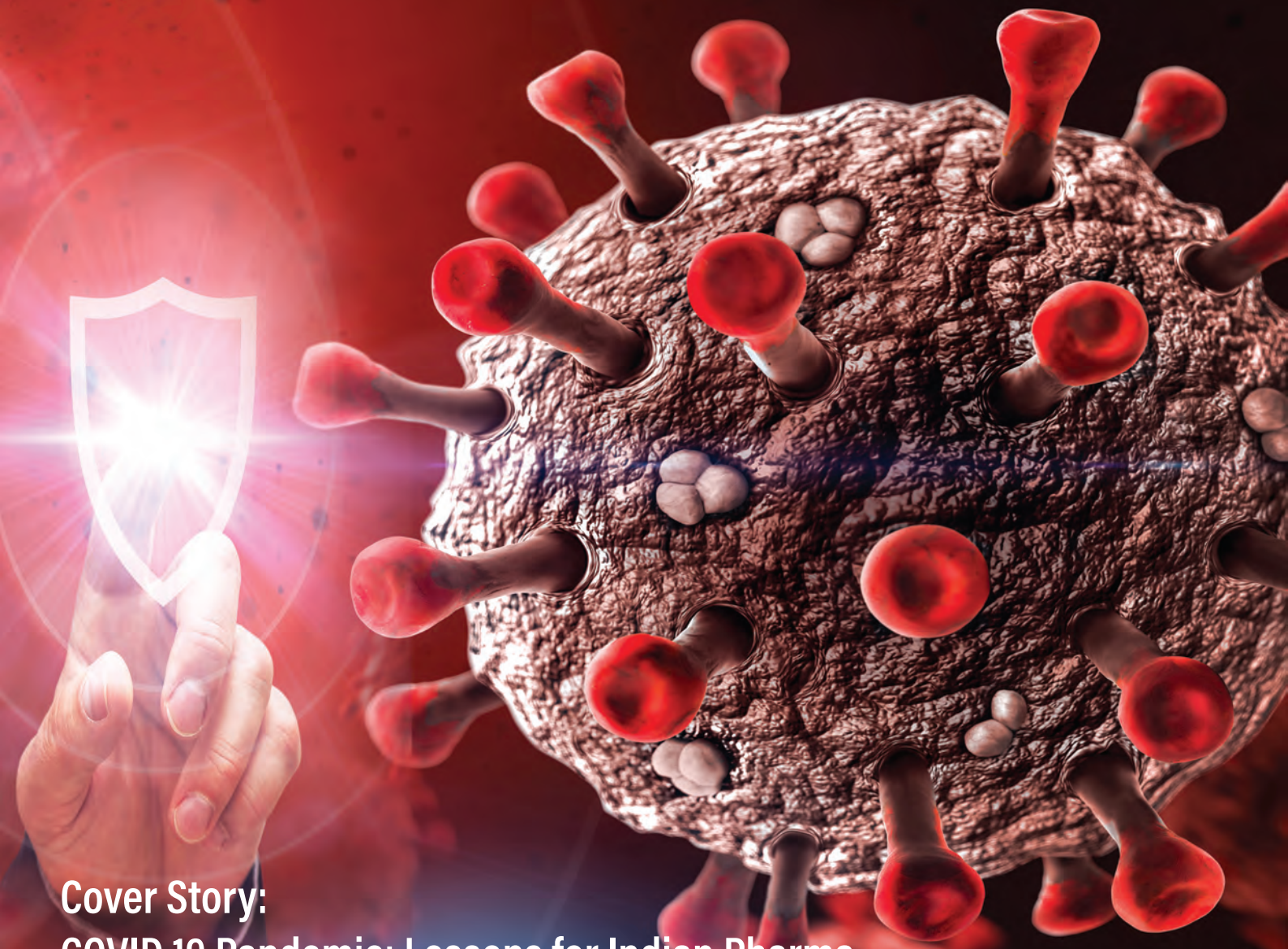
PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES



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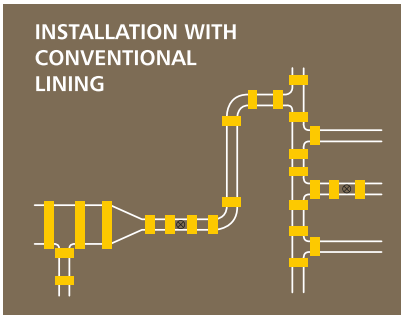

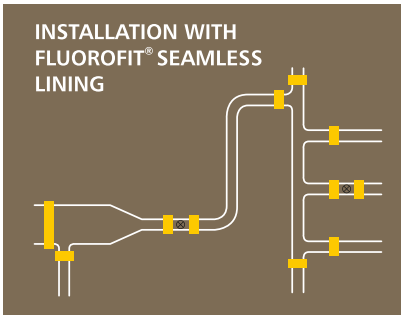

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Sun Pharma reports Q3FY21 results

Dilip Shanghvi, MD, Sun Pharma

Mumbai, India: Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715) reported financials for the 3rd quarter & nine month ending December 31st, 2020.

The company had consolidated sales from operations at Rs. 8,782 crores, growth of 9.2% over Q3 last year. India sales stood at Rs. 2,753 crores, growth of 9.4% compared to Q3 last year, US finished dosage sales at US$ 374 million, growth of 7% compared to Q3 last year . Sales from Emerging Markets were US$ 204 million, up by 4.7% and from Rest of World sales stood at US$ 173 million, up by 11.7% over Q3 last year. The R&D investments were of the order Rs. 560 crores (6.4% of sales) compared to Rs. 527 crores (6.6% of sales) for Q3FY20. Company's EBITDA was at Rs. 2,351 crores, up by 36.3% over Q3 last year, with resulting EBITDA margin of 26.8% . Company earned Net profit for Q3 at Rs. 1,852 crores, up 102.8% over Q3 last year, with resulting net profit margin of 21.1%

Dilip Shanghvi, Managing Director of the Company said, "Our Q3 performance reflects continued profitable business growth in a market that is gradually recovering from the impact of the global pandemic. Most of our businesses have done well over Q3 last year. Our global specialty sales have continued to show an improving trend and have crossed pre-Covid levels. Global Ilumya sales for nine months ended Dec'20 have already crossed last full year's sales."

The company has repaid debt of about US$ 490 million in 9mFY21 compared to the debt as of March 31, 2020. Sale of branded formulations in India for Q3FY21 were at Rs. 2,753 crores, up by 9.4% over Q3 last year, accounting for 31% of total sales. For the nine month, sales were at 7,672 crores, up by 4.5% over same period last year. Sun Pharma is ranked No. 1 and holds approximately 8.2% market share in the over Rs. 145,000 crore Indian pharmaceutical market as per AIOCD AWACS MAT December-2020 report. For Q3FY21, the company launched 27 new products in the Indian market. Sales in the US were US$ 374 million, up 7% over Q3 last year, accounting for about 31% of total consolidated sales. For nine month sales were US$ 991 million recording a de-growth of 11% over same period last year. Sales for nine month last year included a one-time contribution from the special business in US and hence the nine month numbers are not strictly comparable.

Taro posted Q3FY21 sales of US$ 140 million, down 5.1% YoY and net profit of US$ 33 million, down by 51.2% over Q3 last year. For the nine month period, sales were US$ 401 million, down by 14.7% over nine month

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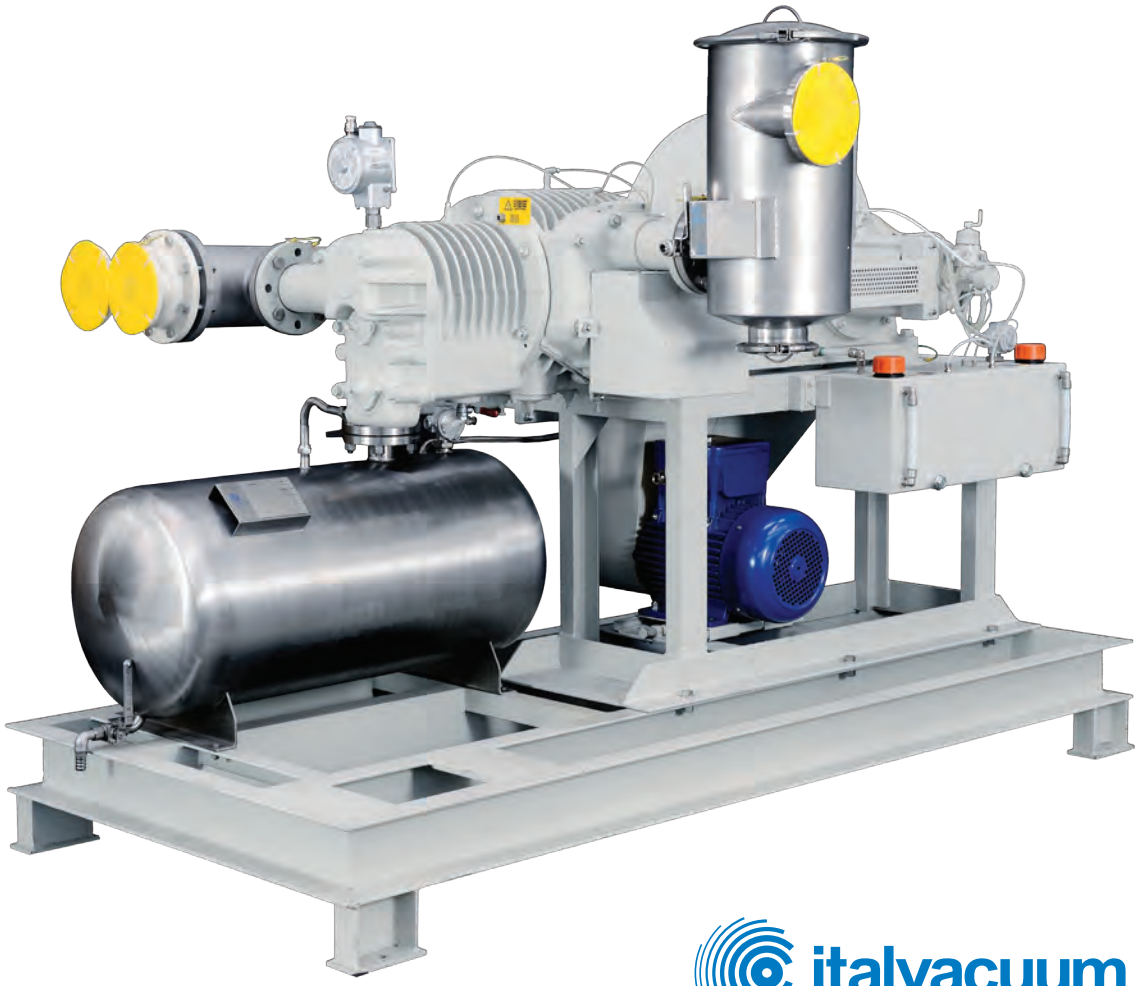

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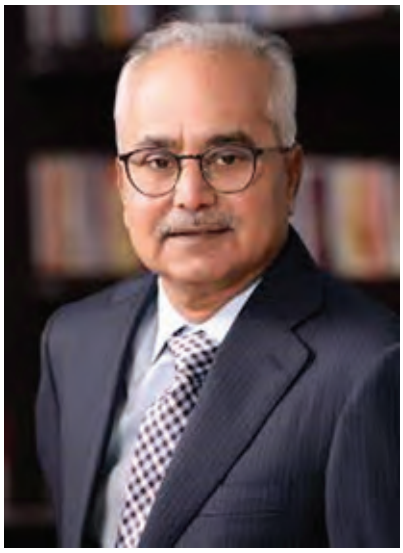
last year. Excluding the one-time settlement charge of US$ 478.9 million, adjusted net profit for 9mFY21 was US$107 million compared to US$ 190 million in 9mFY20. Taro's reported net loss for 9mFY21 was US$ 357 million.

Sales in Emerging Markets were at US$ 204 million for Q3, a growth of 4.7% over Q3 last year. Overall sales in Emerging Markets accounted for about 17% of total consolidated sales for the quarter. For the nine month, sales were US$ 587 million, flat over nine month last year. Formulation sales in Rest of World (ROW) markets, excluding US and Emerging Markets, were US$ 173 million in Q3FY21, up by 11.7% over Q3 last year and accounted for approximately 15% of total consolidated sales. For the nine month, sales were US$ 486 million, flat over the nine month period last year.

For Q3FY21, external sales of API were at Rs. 450 crores, down 10.5% over Q3 last year. For the nine month, API sales were at Rs. 1,515 crores, up by 5.7% over nine month last year. Our API business imparts benefits of vertical integration and continuity of supply chain for our formulations business. We continue to focus on increasing API supply for captive consumption for key products.

Consolidated R&D investment for Q3FY21 was Rs. 560 crores, or 6.4% of sales as compared to Rs. 527 crores (6.6% of sales) for Q3 last year. For the nine month, R&D expense was Rs. 1,593 crores, or 6.4% of sales. Sun Pharmaceuticals has comprehensive product offering in the US market consisting of approved ANDAs for 497 products while filings for 90 ANDAs await US FDA approval, including 22 tentative approvals. For the quarter, 2 ANDAs were filed and 3 approvals were received. Additionally, the pipeline includes 55 approved NDAs while 8 NDAs await US FDA approval.

Dr. Reddy's receives approval to conduct Phase 3 clinical trial for Sputnik V vaccine in India



G V Prasad, Co- chairman & MD, Dr. Reddy's Laboratories

Hyderabad, India: Dr. Reddy's Laboratories Ltd (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) announced today that it has received approval from the Drugs Control General of India (DCGI) to conduct phase 3 clinical trial for the Sputnik V vaccine in India.

The phase 3 study of Sputnik V will be conducted on 1500 subjects as part of the randomized, double-blind, parallel-group, placebo-controlled study in India.

Earlier, the Data and Safety Monitoring Board (DSMB) reviewed the safety data from the phase 2 clinical trial of the vaccine and recommended the phase 3 recruitment. In its

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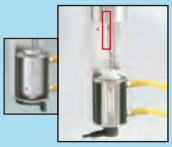
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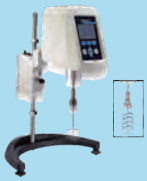
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RHEOLOGY VISCOSITY TEXTURE IN-LINE POWDER MOISTURE GAS

report, the DSMB concluded that no safety concerns were identified and the study met the primary endpoints of safety.

G V Prasad, Co-chairman and Managing Director, Dr. Reddy's Laboratories said, "This is an important milestone in the progress of this pivotal clinical trial of the vaccine. We expect to commence the phase 3 study within this month and will continue to fast-track our efforts to bringing in a safe and efficacious vaccine for the Indian population".

In September 2020, Dr. Reddy's partnered with Russian Direct Investment Fund (RDIF) to conduct the clinical trials of the Sputnik V vaccine and for its distribution rights in India. Sputnik V developed by the Gamaleya National Research Institute of Epidemiology and Microbiology was registered by the Ministry of Health of Russia and became the world's first registered vaccine against COVID-19 based on the established human adenoviral vector platform. The vaccine's efficacy is confirmed at 91.4% based on data analysis of the final control point of clinical trials in Russia. Currently, the vaccine's clinical trials are underway in the UAE, Egypt, Venezuela and Belarus while it has been registered in Algeria, Argentina, Belarus, Bolivia and Serbia for inoculation.

UFlex Chemicals Business Secures India Patent for New Process to Derive Epoxy Ester Resin

Noida, India: The Chemicals Business of UFlex Limited today announced securing of a patent (Patent No 354903) on 'A process for the preparation of Epoxy Ester Resin'

Rajesh Bhasin, Joint President (Chemicals Division), UFlex Limited

in accordance with the provisions of the Patents Act, 1970. This is the first patent for Chemicals business ever in India and it will be considering applying for a global patent in due course of time. UFlex' Chemicals Business is a leading manufacturer of Inks, Coatings and Adhesives for flexible packaging, cartons, labels, and paperboard.

UFlex' new patent will ensure technical advancement in providing a process for resin preparation wherein no waste water treatment is required which is a significant move in the direction of sustainability. Furthermore, Epoxy Ester Resin prepared by this process will be used in radiation curing or energy curing and therefore curing will be faster, unlike the typical Epoxy Ester resin which is thermally cured and takes a longer time besides being uneconomical. With enhanced stability of coating and its chemical resistance attributes a total of 16 claims have been taken under this patent. On securing this patent, Rajesh Bhasin, Joint President, Chemicals Division, UFlex Limited said, "We are extremely

delighted with the continued strengthening of our R&D prowess. The issuance of this patent is another step in the development of a robust portfolio for our business. This is part of our initiative to backward integrate, using our inherent strengths. Such initiatives help us to have greater control on product quality and supply security. This unique achievement is all because of the progressive approach, years of hard work and commitment."

Epoxy Ester resins are known for their use in coatings, paints and adhesives. Before this patent was registered, conventionally Epoxy Ester resin is produced in a two-stage process. The first stage is condensation which generates a lot of salt that is removed through several water washings, resulting in high effluent generation. Typically, waste water contains 50,000-95,000 ppm TDS and 50,000-60,000 ppm COD, which, therefore, requires large capital investment for waste water treatment plants adding to the capital expenditure and operating expense of the process of Epoxy resin preparation. In the second stage of a conventional process, Epoxy resin is converted into Epoxy Ester resin with the esterification process which results in the formation of undesirable Epoxy Ester resin, which has a dark colour and odour.

However, UFlex' newly invented and patented approach arrests the challenges posed in a conventional method as the Epoxy ester produced has no waste water generation, no odour and neither a dark colour which is good for fast curing coatings with efficient cost effective processing.

Epoxy Resins are gaining supremacy over the conventional use of Vinyl Esters and polyesters in the Flexible Packaging industry as well as in Offset printing areas. Epoxy Resins deliver performance attribute in five key areas of offering better adhesion by allowing to bond to the reinforcement or core , superior mechanical properties imparting higher strength and stiffness, improved resistance to fatigue and micro cracking issues , reduced degradation from water ingress. Epoxy Resins have lesser shrink ability by up to 50% in comparison to Vinyl Esters and Polyesters and increased resistance to osmosis which is way better than Vinyl Ester and Polyesters

***ppm- Parts per million; TDS- Total Dissolved Solid; COD- Chemical oxygen demand*

RheinCell Therapeutics Achieves Milestone GMP Certification to Manufacture Cord Blood-Derived iPSCs for Safe and Compliant Cell Therapies

Langenfield, Germany : Life Science Newswire – RheinCell Therapeutics GmbH, a developer and manufacturer of human induced pluripotent stem cells (iPSCs) as starting materials for cell therapies, announced it has received Good Manufacturing Practice (GMP) certification and Manufacturing Authorization. This marks a landmark achievement for RheinCell, which is now among a select few iPSCs manufacturers to have received the critical certification.

The certificate and accompanying manufacturing permit — which were granted following inspection of RheinCell's

manufacturing facilities in September 2020 — confirm that the company's site follows the GMP principles of the European Union for human medicinal products (2003/94/EC), including requirements for chemical, physical, and biological quality control testing.

"We have reached another milestone in the evolution of our company – one that was borne from the foresight of our manufacturing and quality control teams, and the tremendous work of everyone involved in building an efficient production strategy," said Jürgen Weisser, CEO of RheinCell. "RheinCell is now one of very few commercial enterprises worldwide that are certified to produce iPSCs – a critical starting material for stem cell-based therapies – in a regulated and GMP-compliant process and environment."

Heading up the certification efforts was Dr. Katja Aschermann, COO of RheinCell. "At RheinCell, we are proud to implement state-of-the-art, GMP-compliant manufacturing processes to meet the needs of our international customers for ready-to-use, fully characterized clinical-grade iPSC lines," explained Aschermann.

The GMP certification and Manufacturing Authorization pave the way for the company to deliver fully characterized clinical-grade iPSCs that are derived from human cord blood cells for the development of cell-based therapies. Furthermore, RheinCell has the technology, facilities, know-how and processes to manufacture, expand, differentiate and cryopreserve these cell lines according to specific development needs.

Parexel Completes Separation of Parexel Informatics and Medical Imaging Business

BOSTON and DURHAM, N.C.– Parexel, a leading provider of solutions to accelerate the development and delivery of innovative therapies to improve world health, from clinical through commercialization, today announced it has completed the separation of its Parexel Informatics and Medical Imaging business. The strategic move is designed to simplify and streamline Parexel's business strategy and customer relationships while best positioning both organizations for continued, long-term growth and success. As part of the separation, Parexel Informatics will become Calyx.

Parexel will continue to leverage Calyx's Medical Imaging, Clinical Trial Management Systems (CTMS), Electronic Data Capture (EDC), Interactive Response Technology (IRT) and Regulatory Information Management (RIM) solutions moving forward as part of the company's clinical development offerings. Calyx will be privately held by the same ownership group that has owned Parexel since 2017.

"Today's announcement marks a significant milestone as we further position Parexel to expect accelerated growth and performance as a top-tier CRO," said Jamie Macdonald, Chief Executive Officer of Parexel. "We believe the separation will provide Calyx the opportunity to prioritize investments in technology development, customer delivery and customer relationships while enabling the Parexel corporate business to strengthen

its focus on the delivery of innovative clinical development solutions that reinforce our patients-first focus and advance world health." Calyx will be led by Chief Executive Officer Gavin Nichols and the company will be headquartered in Nottingham, United Kingdom, and Durham, North Carolina. The new organization will employ approximately 2,300 employees.

Zydus granted Orphan Drug Designation by the USFDA for Saroglitazar in the treatment of patients with Primary Biliary Cholangitis (PBC)

Ahmedabad, India: Zydus, a leading discovery based, global pharmaceutical company today announced that United States Food and Drug Administration (USFDA) has granted 'Orphan Drug Designation' (ODD) to Saroglitazar Mg for the treatment of patients with Primary Biliary Cholangitis (PBC). Orphan drug designation provides eligibility for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee exemptions and seven-year marketing exclusivity upon FDA approval. This follows the grant of 'Fast Track Designation' by the USFDA to Saroglitazar Mg for PBC in December 2020.

Saroglitazar Mg is a potent and selective peroxisome proliferator-activated receptor alpha and gamma dual agonist. Results of PHASE 2, prospective multicentre randomized double-blind, placebo controlled study to evaluate the safety, tolerability and efficacy of Saroglitazar Mg in patients with PRIMARY BILIARY CHOLANGITIS (EPICS) was presented earlier at the Liver Meeting® 2020, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) [ClinicalTrials.gov Identifier: NCT03112681]. The treatment options are still evolving for PBC and Saroglitazar holds immense potential based on its safety and efficacy profile so far. The global market for PBC treatment is expected to grow at a CAGR of 36.3% from 2018 – 2026 and is expected to reach USD 10.8 bn by 2026 as per Coherent market insights. Speaking on the development, Pankaj R. Patel, Chairman, Zydus Group said, "We are pleased that the USFDA has granted an Orphan Drug Designation apart from the earlier Fast Track Designation to Saroglitazar Mg for the treatment of Primary Biliary Cholangitis (PBC). This underlines the urgent need to address this serious health condition which is an unmet medical need. We are committed in our clinical development efforts to improve the quality of life of patients suffering from PBC with a safe and efficacious treatment."

Albumedix submits Drug Master Files for its products in Japan

Nottingham, UK : Albumedix Ltd. ('Albumedix'), the world leader in recombinant human albumin (rHA), announced the submission of Drug Master Files (DMFs) to the Pharmaceutical and Medical Device Agency (PMDA) in Japan.

Albumedix has submitted DMFs for two of their products in order to further support customers in Japan. The DMF system allows manufacturers, such as Albumedix, to submit

Harriet Edwards, Director of Global Regulatory Affairs Albumedix

detailed confidential manufacturing, chemistry and controls information of their product to PMDA to provide assurance to the regulator that the product is safe, effective and of an appropriate quality for customers to use in their final products. The registered information is necessary for inclusion in applications for pharmaceutical products in which Albumedix products are used.

With these DMF submissions, alongside the enhanced regulatory customer support that Albumedix is able to offer customers, the review process for the customers' end product is made considerably less onerous and assures both the customer and regulators that Albumedix can provide robust and comprehensive documentation, helping customers to alleviate the regulatory burden of product development.

As a non-Japanese company, Albumedix are also required to apply to be accredited by the regulator as approved foreign manufacturers, a process which has also been progressing ahead of the DMF submissions.

Commenting on the DMF submissions in Japan, Albumedix Director of Global Regulatory Affairs Harriet Edwards says, "These submissions are a continuation of Albumedix strategy and ethos; we are dedicated to supporting our customers in all aspects of their product development and beyond when using our products in order to become the partner of choice for advanced therapies worldwide. We are extremely happy to add to the support we currently provide our customers in Japan and believe the submissions further confirm our intent to fully serve the Japanese market. This is a market we have had a presence in for many years and which is currently expanding, especially due to the advance of cell and gene therapies in this territory. The submission of the DMFs in Japan allows Albumedix to provide an enhanced level of regulatory support to these customers as well as an increased assurance of our product safety and quality, particularly for those in clinical development and heading towards commercialisation". Albumedix has already full DMF´s submitted in United States, Canada, Australia, New Zealand and China.

Syntekabio and Hanmi Science Join Forces to Co-Develop New Promising COVID-19 Treatments Using Drug Repurposing Technologies

DAEGEON, Rep. of Korea : Syntekabio (KOSDAQ: 226330), an Artificial Intelligence (AI) and Next Generation Sequencing (NGS)-

based drug development company, and Hanmi Science (KOSPI: 008930), a leading manufacturer of biologics, chemical entities and drugs, have entered into a strategic collaboration to co-develop breakthrough COVID-19 treatments using drug repositioning technologies.

Under the new agreement, Syntekabio and Hanmi Science will investigate the potential efficacy of existing drug candidates against COVID-19, as well as other diseases, utilizing Syntekabio's proprietary AI drug discovery platform — the DeepMatcher™. The drug repositioning and indication expansion research will see the two companies undertaking clinical development activities while also managing regulatory affairs. Data derived from the research will be used to enable the development of a digital therapeutics platform for clinical practice. Furthermore, Syntekabio and Hanmi Science will work together to drive clinical development of Syntekabio's proprietary COVID-19 treatment — the Zafirlukast-sulfinpyrazone combination therapy.

"We are confident that our collaboration with Hanmi Science will enable us to accelerate clinical trials and drive critical developments for new promising COVID-19 treatments", said Tyson Kim, CEO at Syntekabio. "Both Syntekabio and Hanmi Science bring a full breadth of high-value capabilities to this partnership to deliver significant outcomes."

The DeepMatcher™ is based on Syntekabio's proprietary AI platform for small molecule drug candidate discovery. The solution is a 3-dimensional structure-based deep leaning model that searches for the most optimal compound structures that exhibit high binding affinity. The structural flexibility of the protein-compound complex is considered to enhance predictive power, while secondary and off-target analysis is also conducted.

"Multiple therapeutics and vaccines have already received emergency use authorization from regulatory agencies, and Syntekabio's in-silico simulation solution would be an optimal approach for drug repurposing," added Jongyoon Lim, CEO at Hanmi Science. "This project will be supported by the Lightspeed Task Force initiated by Hanmi Science, and will mark the first time medical contents are presented using the digital therapeutics capabilities of the task force."

The Hanmi Science Lightspeed Task Force was formed on January 5, 2021 with the aim to create innovative business models to help in the fight against COVID-19. It brings together the Hanmi Pharmaceutical Group, Syntekabio, and other biotechnology companies such as Bioapp, Herings and EvidNet. Herings, a digital therapeutics platform company, will be in charge of clinical trial design, while Syntekabio will be leading the in-silico drug repurposing.

AstraZeneca is recognised as a Top Employer 2021 in South Africa and Kenya

JOHANNESBURG, South Africa : The 2021 Top Employers have been announced and AstraZeneca (www.AstraZeneca.com) has been recognised as a Top Employer in South Africa and Kenya. Being certified as a Top Employer showcases an organisation's

dedication to a better world of work and exhibits this through excellent HR policies and people practices.

The Top Employers Institute programme certifies organisations based on the participation and results of their HR Best Practices Survey, covering topics such as People Strategy, Work Environment, Talent Acquisition, Learning, Well-being and Diversity & Inclusion and more.

Top Employers Institute CEO David Plink says: "Despite the challenging year we have experienced (which has certainly made an impact on organisations around the globe), AstraZeneca has continued to demonstrate the power of putting their people first in the workplace. We are proud to share this year's announcement and congratulate the organisations who have been certified in their respective countries through the Top Employers Institute programme."

Barbara Nel, Country President African Cluster (South Africa, Sub Sahara and French Speaking Africa), says: "None of what we have achieved this year would have been possible without the tremendous efforts of all our teams, despite personal challenges faced. Achieving the Top Employer certification is testament to each individual within our region working with absolute determination and passion to make a difference, to each other and around the world. The distinction is a reaffirmation of our commitment to continue to work hard at building our inclusive culture, supported by enabling people-focused practices and policies, because this is how we will make the most of our strengths."

ENPICOM introduces an end-to-end solution for fast and efficient antibody discovery

's-Hertogenbosch (The Netherlands) : ENPICOM BV, an innovative bioinformatics software engineering company, announces a major release of its ImmunoGenomiX (IGX) Platform featuring the new Antibody Discovery Module (ADM). This solution will allow scientists in biopharmaceutical companies and academia, as well as service providers working in the antibody discovery field, to make the most of their Sanger and NGS data and independently perform complex analyses.

In recent years, antibody discovery workflows have started relying more on sequencing data and in-silico analysis to identify the best candidates. However data integration, analysis, and visualization can be challenging and require diverse expertise, including immunology, protein biology, and bioinformatics. In close collaboration with over 50 industry leaders, ENPICOM has pinpointed the bottlenecks and challenges in the antibody discovery process and validated the new product designed to solve these. Today, ENPICOM introduces a set of specialized IGX Platform Apps engineered to rapidly identify a diverse set of promising antibody candidates from integrated sequencing data.

"By conducting thorough interviews with a large group of industry leaders, we gained a deep understanding of the specific pain

points and needs in the market." explained Jos Lunenberg, co-founder and Chief Executive Officer at ENPICOM. "We learned exactly what researchers need, and as a result, can offer something truly unique: a validated solution, tailored to the specific needs of antibody developers. This allows researchers without extensive bioinformatics expertise to independently perform their discovery analysis and stay focused on what matters the most – their research."

"Extensive product discovery efforts have led to the identification of several new analyses and data management features that are key to the workflow of antibody developers." commented Nicola Bonzanni, co-founder and Chief Product Officer at ENPICOM. "With our new module built on top of the powerful IGX Platform core, we empower scientists to discover and perform in-depth analysis on drug candidate sequences in the context of therapeutic antibody development."

The two new Apps developed for the ADM release are IGX-Cluster and IGX-Branch. IGX-Cluster groups sequences based on user-defined parameters such as CDR3 similarity, gene usage, and CDR3 length. It effortlessly performs large clustering tasks in the cloud and supports a wide variety of workflows for both paired and unpaired receptor chains. Subsequently, IGX-Branch creates interactive visualizations to prioritize clusters and pick antibody candidates for follow-up analysis through information-rich phylogenetic trees.

ENPICOM's IGX Platform is a professional tool to manage, analyze, integrate, and visualize immune repertoire sequencing data in a single environment. Technology-agnostic and code-free, it enables scientists to securely and effortlessly analyze immune repertoires. Together with the two new Apps introduced today, it provides an ideal setup for crucial tasks like candidate selection and hit expansion, thus creating a versatile system to discover promising antibody candidates. Other prominent new features released today include revamped receptor profiling workflows and vastly improved metadata importing. The earlier announced collaboration with MiLaboratories has resulted in a new MiXCR App, fully embedded in the platform. ■

From the Desk of Guest Editor

Subobh Priolkar
CEO, Wincoat Colours & Coatings Pvt Ltd.

Every year has a few defining moments, but the past months have contained so many world-changing, paradigm-shifting developments. Many are convinced 2020 should be treated as zero year, and looking back to the beginning of the year, the events of 2020 have defied prediction.

While economies have gone down and industrial sectors have suffered huge losses, one sector that has emerged as the savior is the pharma/biotech/life science sector. Though the global pharmaceutical markets are in the midst of major discontinuities, the Indian pharmaceuticals industry is in the process of reworking its business and growth strategies to completely leverage its deep expertise in the manufacture of drugs, highly skilled scientists, and low-cost manufacturing.

We have tried to cover all facets of the profession with representation from Professional associations, Industry leaders from Pharma as well biologics sector. We have covered services sector like contract services as well as IP services. To add International perspective, we have one Industry leader from across the globe.

It will be interesting to understand various perspectives from the leaders on the performance during the year filled with challenges. As we are aware, Indian Pharmaceutical Industry did overcome challenges and was in forefront of not only supply but also introducing drugs effective against Covid 19. In fact, they have done excellent job in passing cost efficiency to the customer by reducing the cost and impacting affordability of population of India.

I thank all the contributors who readily agreed to contribute in spite of their busy schedule.

I would also like request feedback and comments from you about your views on the performance of the last year.

Wish you a good 2021.

Regards

Subodh Priolkar

"Crisis often fuels disruptive, accelerated innovation"

Video Link: https://youtu.be/fh2N1Ys8r5c

Ashish Pal, Managing Director, MSD Singapore & Malaysia

COVID 19 Pandemic:
Lessons for Indian Pharma

The health crisis in the form of COVID 19 that dawned upon in early 2020 continues to impact healthcare system. The global pandemic has demonstrated the importance of safeguarding public health, globally. Post the rapid spread of the COVID-19 in March 2020, many countries came to a standstill with the imposition of lockdowns. Countries around the globe took measures such as social distancing, restrictions on movement, travel, and social gatherings to curb the profound impact of the pandemic on public health and the economy. While the world was grappling with a global pandemic, the Indian pharmaceutical industry emerged as a dependable partner by supplying uninterrupted life-saving drugs not only in India but across the globe and demonstrated tremendous commitment towards patient welfare.

Sudarshan Jain
Secretary General
Indian Pharmaceutical Alliance

The COVID-19 Challenge

The global pandemic not only posed challenges to the pharma industry but also presented the industry with several opportunities. The industry proved itself to be a reliable partner by supplying life-saving medicines in India and across the world even during a time where restrictions made it challenging to engage in manufacturing and distribution. With the announcement of a nation-wide lockdown in India, the government collaborated with pharmaceutical organizations and industry experts to wade through the challenges of the pandemic. Some key learnings derived from the pandemic in the last year are:

Collaboration is Key

In March 2020, when the lockdown was first announced the manufacturing and distribution was highly interrupted and manufacturing capacities came down to less than 20 percent of their original capacity. This was due to various reasons such as workers from the cities and towns returned to their hometown, shutting down of ancillary and related operations, forbidding workers to reach their places of work due to lockdown, and obstructions in the imports from China. In these trying times, supply of medicines is fundamental need of the hour for which smooth functioning of manufacturing operations is critical. The industry experts and the government acknowledged this early and accordingly, classified pharmaceutical manufacturing, distribution, ancillary and support operations as essential goods and services, which helped the industry to function. By the end of May 2020, the manufacturing capacity rose to 70-80 percent due to cooperation between the government, trade associations, ancillary industry and other industries. This cooperation included feedback at periodic intervals, unified efforts and regular dialogue between the government and the stakeholders of the industry.

Need for Resilience in Supply Chains

The Active Pharmaceutical Ingredient (API)/Key Starting Material (KSM) consequent supply disruptions were observed in February 2020 which highlighted the Indian pharma industry's reliance on imports from a single source. The global pandemic

and this new challenge did not stop the need to secure the supply of APIs and KSMs. In March 2020, the Government of India announced a new policy in the wake of this challenge to incentivize domestic production of APIs/KSMs. The sustained engagement between the API and formulation manufactures and the Government ensured the focus to be on creating scale and long-term survival of the industry. There was no drug shortage reported in India. The pandemic has certainly brought forth the significance of a diverse and resilient supply chain.

Best Practices Protocols

In the early days of the pandemic, pharma companies faced a challenge regarding safety practices for employees due to the sudden and fast spreading of COVID 19. The Indian pharmaceutical companies came together to formulate best practices and guidelines to ensure the safety of employees. It provided an all-encompassing list of precautionary safety practices to be deployed by pharmaceutical manufacturers against the COVID-19 crisis. Indian companies collaborated to prepare a code of conduct for the manufacturing processes in the pharmaceutical sector for when a person is reported to be infected by the virus. The objective of this protocol was.

1. To ensure the safety of the manufacturing and other personnel at the plant premises
2. To minimize the risk and possibility of an outbreak within the plant premises
3. To ensure that patients across therapy areas are protected and ensured uninterrupted supplies through continued manufacturing operations without compromising personnel safety

The Indian Council of Medical Research (ICMR) had endorsed the protocol upon being shared with them. This protocol has been used in the industry and has strengthened the safety measures.

Vaccines and Repurposed Medicines

COVID-19 had a turbulent effect on the pharmaceutical industry as it posed a wide array of challenges and required solutions to be delivered with pace and efficiency. The industry responded with swift solutions by assessing possible

uses of the available drugs (repurposed drugs) and researching more innovative approaches. Indian pharma companies have taken a stride forward in developing indigenous vaccines which are currently undergoing clinical trials to be tested for efficacy and safety. This current trend of R&D in India needs to be continued even after the pandemic ends. The Indian Pharmaceutical Industry's Vision 2030 can only be realized if innovation is prioritized.

India and vaccine challenges

During the initial phase of the pandemic, various stakeholders worked effectively and collaborated to bring effective medication and treatment options such as the antivirals Remdesivir and Favipiravir, mAbs medicine, and even older medicines such as the corticosteroid dexamethasone. The government, regulatory authorities, pharmaceutical companies, and ancillary industries are working continuously to deliver safe and efficacious vaccines. Indian pharma companies have proven competence in large-scale manufacturing and distribution of generics and are capable to manufacture and distribute vaccines. With a robust supply chain system, they can facilitate patient-centric distribution channels that enable last-mile delivery. of such

The Way Forward

The Indian pharmaceutical industry has been committed towards increasing accessibility and availability of affordable medicines not only in India but also across the globe. Given the scale and reach of Indian industry, it has a vital role to play not only in vaccine for COVID 19 but beyond it. This is an opportune time to move ahead of the short-term goals and focus on the long-term perspective of making stable and conducive ecosystem for the industry to work and innovate. The aim should be to bring in simplified regulatory system that will improve the value of competition and enforce growth in quality and encourage innovation. The global pandemic poses an opportunity for India to augment India's role as "Pharmacy of the World" and be the largest volume producer in the world. ■

2020- Year of Importance to the Pharma Profession & the Pharma Industries

J Jayaseelan
Founder & Director, Delvin Formulations Pvt. Ltd.
Vice President – Industry Division IPA
Chairman- IDMA (Tamilnadu, Kerala, and Puducherry)

Year 2020 is a very challenging year for the entire world particularly on two fronts, one is on the economic front and the other is on the health care front.

Pharmaceutical industry was expected to outperform in spite of many hurdles and issues. Particularly Indian pharma industry had a lot to contribute not only to save the domestic people but for those living in over 200 countries. In month of December 2019 when the pandemic was spreading across the globe from china, the first blow came for the Indian pharma industries.

Yes, the government withheld exports of certain categories of products like antibiotics, vitamins etc. Because of this ban, export-oriented industries got struck and at the same time countries buying medicines from India cried. We witnessed the then American president called our prime minister for want of hydroxychloroquine tablets. Many other countries' leaders also approached our government to release the ban on exports. A very rare situation which reinforced the importance of Indian

pharma industries as the pharmacy of the world. Later once the export ban was removed the Indian pharma industries worked overtime to meet the needs of the global medicinal requirement.

On the other hand, the industries faced huge challenges because of the lock down. Initially the government locked all industries including pharma industries. Thanks to various industry bodies like IDMA, IPA etc. which explained the importance of the continuous functioning of pharma industries without which there would be drug security issues in the country. Similarly, there was a surge on the requirement of hand sanitizers and the surgical masks. The industry responded very aggressively and they met the domestic need at the right point of time. The industries had a lot of teething issues in operating the plant because of the lock down, lack of transport, workers fear of pandemic, shortage of workers, shortage of packaging materials and raw materials etc. Thank god, the Indian pharma industry sustained all these challenges very professionally and ensured that the country is self-reliant on drugs and medicaments. This was not only achieved for India but also for those 200 countries which are importing medicines from India.

Because of this pandemic, the community understood the importance of the pharma industries and the pharmacists who make and dispense medicines. Many doctors and hospitals closed their services during this pandemic but no pharmacists closed their shop. They were the saviors for the community and people who suffered with other ailments apart from COVID-19. The prime minister's visit directly to three vaccine making pharma companies reflected the importance of pharma industries during this pandemic year 2020. Overall, the pandemic has challenged many industries, particularly the pharma industries. We should be proud of our Indian pharma industries which withstood the challenges and protected our people. ■

"With the slow-down in production leading to shortages, the need for self-reliance has increasingly become clear"

Prashant Nagre
CEO, Fermenta Biotech Limited

Every year typically has a few defining moments and year 2020 has defied perceptions and predictions. COVID has caused disruptions in all sectors. Pharma sector has been jolted too but there is hope that things will ease and growth will resume. Your views and predictions for the coming year for the pharma sector.

Like other industries, the pharma sector has been impacted by the effects of the pandemic and subsequent lockdown. Global supply chains have been hit, with logistical impact causing stock outs, transportation issues and delay in deliveries of raw materials. Many companies have also seen internal challenges with their workforce being affected by the virus. However, operational resilience has been the way forward, with companies evolving with the changing times into more agile versions of themselves.

In the coming year, I anticipate greater utilization of technology by the industry, and a movement from treatment to preventative health. The global pandemic

has brought into play the need for improved health and wellbeing that is here to stay.

The pandemic has thrust the Pharmaceutical industry into the global spotlight. But it quickly became evident that to return to anything resembling normal, the world would need diagnostics, drugs, and vaccines. So is it safe to say that this is 'Year of pharma'? Your views

I would call it the Year of Healthcare: be it diagnostic, preventive or therapeutic. With growing focus on health and wellness, products catering to these areas will be in the spotlight. The consumption pattern would depend on the 3 A's: Affordability, Accessibility and Awareness. Many surveys have revealed that consumers are increasingly paying attention to the importance of nutrition in the prevention and treatment of diseases. The sharp increase in the cost of quality health care in the last few decades has widened the market for preventive healthcare based on a growing recognition that a small cost today can potentially avert expensive treatment, especially important given the low penetration of medical insurance in India. However, affordability still remains a challenge, with consumers at the bottom of the pyramid unable to afford preventive care.

Global pharmaceutical markets are in the midst of major discontinuities. The Indian pharmaceuticals market, along with the markets of China, Brazil and Russia, are expected to spearhead growth within these markets. Compared to others, Indian pharmaceuticals markets has characteristics that make it unique. How these characteristics will help India leverage the challenges to opportunities?

India is the third largest pharma industry in the world, in terms of volume, manufacturing 20% of generic drugs and 60% of vaccines produced globally. In order to remain competitive with other global players, it must also look at innovative measures of improving cost-efficiency through continuous improvement of the production processes. This is a time when we are at a crossroads in our position as one of the leading global pharma industries, and in order to cement our place, we must also utilize our scientific expertise to vertically integrate to deepen our value chain as well as horizontally expand to diversify into allied categories such as preventive healthcare products, which are the solutions to tomorrow's problems.

You are the largest manufacturer of Vitamin D and other products. How does the year reflect on the performance of your organization - specifically with your focus on global markets?

With over five decades of experience in Vitamin D, Fermenta possesses

proprietary technology for the manufacture of its flagship product, catering to more than 300 customers across 50 countries worldwide, with more than 70% of revenues arising from exports. Given our standing as one of the leading global players in Vitamin D, we are proud of the role our product plays in maintaining the health and immunity of communities across the world. Bone strength is just the tip of the iceberg when it comes to the health benefits associated with Vitamin D across all life stages, which range from its potential role in heart and mental health to management of lifestyle disorders such as diabetes. With increased consumer awareness and scientific advocacy on the role of Vitamin D in immune support and respiratory health, we envisage an increase in the number of new formulations containing Vitamin D to grow in the times to come. In light of its widespread deficiency, increased consumption of Vitamin D through fortification and supplementation is the need of the hour.

Did you develop new marketing tools or new initiatives to engage your customers worldwide?

Our wholly-owned international subsidiaries in Germany and the US have been incorporated recently, and have brought us closer to our customers than ever before. During the global lockdown scenario, we consistently communicated with our valued clientele to keep them updated about the situation. We also continued to engage our customers digitally through virtual meetings, online expos and exhibitions as well as through other digital channels. This principle of customer proximity lies at the heart of our enduring relationships, making us not just suppliers but strategic partners in their success story.

Biotech start-ups launched in spite of the pandemic. Notable start-ups in 2020 included new firms tackling coronaviruses and brain diseases. Will India's motto of 'Make in India' help the start-up ecosystem? Your comment on unleashing entrepreneurial spirit through policy stability and ecosystem.

With the slow-down in production leading to shortages, the need for self-reliance has increasingly become clear. Make in India schemes such as the bulk drugs parks are expected to incentivize local manufacturing. Considering that the world is now a changed place, companies must revisit their strategies such that they increase their control on value chains. It is the era to think global by way of marketing products and services but act local in terms of manufacturing and operations. In the long term, as economies of scale catch up, they should also be able to export the surplus products. Collaborations between the industry, academic and government will also be mutually beneficial, with knowledge sharing and pooled resources being the way forward for fostering an environment of innovation.

Despite the cut in production in China, India is far behind its neighbour when it comes to export of APIs or Active Pharmaceutical Ingredient. According to Pharmexcil, in 2018/19, India imported Rs 17,400 crore worth of APIs from China and exported APIs worth around Rs 1,600 crore. This shows India still has to cover a long distance in substantially reducing its China dependence. The govt. has announced many schemes like PLI to manufacture APIs in India. Do you foresee Industry making good use of these multiple schemes and make India Atmanirbhar?

The volatility in global supply chains has exposed the wide need-gap of the Indian pharmaceutical industry, which is heavily dependent on external sources of APIs. With the government policies of Production Linked Incentives for manufacturing key starting materials, drug intermediates and active pharmaceutical ingredients will definitely provide a much-needed impetus for indigenous manufacturing. Even as imports of raw materials continue, this scheme will also push the industry to manufacture cost-effectively in order to be competitive globally.

At Fermenta, we have inculcated the spirit of self-reliance into our strategy, and recently initiated manufacturing of cholesterol, the key starting material for production of Vitamin D. This backward integration has propelled us into a niche category of sustainable suppliers of Vitamin D globally.

This period has shown us India can innovate – be it vaccine research, or the Feluda Corona Test kits, or the ventilators by IIT Kanpur. How can Indian industry redefine and repurpose innovation? How innovation in the pharma industry and business models would assist industry to grow?

In order to maintain its tag of the "Pharmacy of the World", the industry must take steps to develop demand-driven products through incubation centers in association with research institutes. Open innovation is the key for growth, which requires partnerships between ingredient manufacturers and formulators for a cross-pollination of consumer-centric technologies. For example, in the dietary supplements category, less is more for consumers, and hence, decreasing dosages requires bringing in technologies for increasing bioavailability and absorption. Palatability remains a key concern of consumers, which can be achieved through innovative delivery formats manufactured through alliances. ■

The Game of Survival

Mahendra Mehta
President, Indian Pharma Machinery Manufacturers' Association (IPMMA)

The year went by was a year which the world never experienced before and there were no gurus to guide based on any study or experience on how to handle the business scenario in a situation of Pandemic. The one guru mantra was that just SURVIVE. Each one of us had to find their way to survive as everything came as a shock and unpredictable situations like lockdowns, economy on a grinding halt, limited workforce, no public transport, just essentials etc.

Meeting the high expectations of the mankind

Our Industry is a part of the essentials and the whole mankind was hoping that we don't let them down during this crisis. Everyone was looking up to the Pharma Industry to come up with a vaccine soon and get back to normalcy. On the other side, to improve the immunity and health, the pharma industry had to work out ways for seamless supply of medicines. India had to keep up to its

image of Pharmacy of the World and they proved rightly so.

Pharma Industry depends upon machines and its uninterrupted services for smooth functioning. The challenges were multifold and dynamic which kept on evolving through each phase of lockdown. In 2020, it was a chain reaction where one challenge led to another. In such scenario, pharma machinery sector was trying their best to provide the required support to manufacturing activities. One positive outcome of this pandemic is that pharmaceutical companies and machinery & tool suppliers developed a very good understanding and started to work together as one team in mitigating the challenges.

Adaptability and Agility are the two key factors that drove the entire pharma machinery industry to deliver value even in critically challenging times. Pharma machinery industry has proven its business agility by giving its full support to the pharma industry in meeting the medicines needs of the masses.

Minutely looking at all the changes brought about by this pandemic, first would be - Communication. Right from sales meet, presentation, client meetings, reviews, daily and review meetings, even board meeting, everything was on the virtual platform. With 30 percent permissible workforce on the shop floor, more than 70 per cent of us were working from home. The need for agility in every aspect of business was so very well engraved and taught to us by the pandemic that even the basic aspect of communication needed adaptability to the New Normal way of working.

Adapting to digitalization

This virtualization of communication was just the beginning of the digitization. Soon enough the industry realized that the time has come to build efficiency through digitization, automation and improving productivity. If that happens, then even in the lean period in spite of challenges, one can run business very efficiently and smoothly. It's not about AI or automation replacing workforce but how the digital technologies can augment the human world to innovate and improve efficiency for the next generation of our manufacturing businesses. There is a strong need to leverage digitization, connect, communicate and collaborate. The technology is at our disposal, we need to leverage it optimally.

Needless to say, since the supply chain and logistics was severely hit, the pharma machinery industry had a tough time dealing with multiple issues at hand. However, the industry emerged strong with the timely support from government for delivery within state

borders and also processing shipments and containers at the ports. Our members provided full support for fighting this pandemic with flexibility in adopting to change and helping medicines reach those needy patients at the other end of the supply chain.

Building self- reliant industry

The pandemic year 2020 has once again rung the alarm bell on the perils of excessive import dependence on a single country for bulk requirements of Active Pharmaceutical Ingredients (APIs) used for the production of formulations. The Union Cabinet adopted a decision in March 2020 for the promotion of domestic production of APIs and intermediates. With government support through suitable amendments in existing policies, the Indian Pharma industry is heading towards import self- reliance, now known as Atmanirbhar Bharat which could be considered as a sub-set of the bigger vision Make in India. We at IPMMA support the initiative looking at the larger picture.

Although this year gave us a push towards digitization, it also gave us a fair picture of how we can move on a faster pace by implementing Industry 4.0 framework, adopting high-end technology like 3D printing, machine learning, IIOT, Augmented reality, Artificial intelligence and more.

Along with the technological and operational aspects, one more developmental aspect that was highlighted during this time was – Up skilling of people. Without a doubt, for meeting the rigorous compliance that too during additional challenges is very difficult without up skilling people with the right training, knowledge and hand-holding. IPMMA has taken definitive steps towards up skilling in pharma machinery industry in joining hands for skill development initiative by our government.

The vaccine trials are in progress at various stages globally and multiple vaccines are proving to be successful. It will again be for India to manufacture those vaccines in huge volumes and supply across the globe with proper logistics including the cold chain storage facilities. IPMMA member companies are working hand in hand with vaccine manufacturers to ensure that all required machinery and spares are made available on priority so as to have uninterrupted manufacturing. The traceability of the shipment from the manufacturer to the consumer and tracking of the results will be very important to capture the data on its efficacy and development of further Vaccines in future.

Transformation is the key

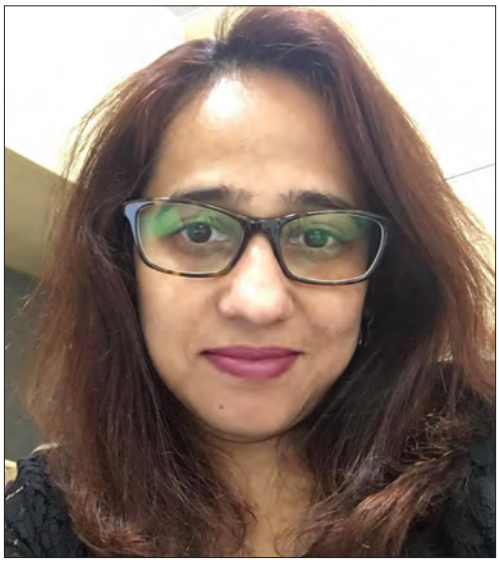
The Indian Pharma industry has shown phenomenal growth and it

will continue to grow rapidly in years to come. However, we need to move ahead implementing all our learnings from such challenging situations. We at IPMMA strongly believe, with such strong learning and agile approach, we can definitely surmount any challenge in our way. We are proud of our Indian pharma machinery fraternity who have proved their mettle by delivering value during the pandemic year 2020 and once again proved that we are the backbone of Indian pharma industry to maintain our status of 'Pharmacy of the World.'

Without any hesitation, I will label the IPMMA members as 'COVID-19 Warriors' in support of smooth running of pharma industry and in service to the mankind in general. Indian government should make a note of this significant contribution by pharma machinery sector.

The experience and views during pandemic are completely different from those of the post Covid-19 duration. Earlier it was anxiousness for life to resume to normalcy, however, now it's time to gear up. The year 2020 was almost completely engulfed with the pandemic and its intrinsic impact. Pre Covid-19, we always worked on Survival of the fittest, now post Covid-19 it will be the survival of the adaptable and agile. ■

"COVID as a situation has only helped the Pharma Industry to better itself"



Dr. Bharati Nadkarni
Founder, Appropriate IP Services

COVID has put the industry on a transformational journey – looking back what is your opinion on how the Indian as well as Global pharma sector has progressed?

I look at COVID as a situation that only helped the pharma industry to better itself. Apart from the fact that the research teams moved aggressively to find cures – synthetic drugs as well as the vaccines – we have seen tremendous progress across functions within the pharma industry. For example, a mRNA vaccine was in the making for several years, but we only managed to get it approved for human use for, and because of, COVID. This development will, I am sure, help us foray into seeking approval of the mRNA vaccine in other disease conditions.

The supply chain function has reached heretofore unknown levels in terms of efficiency, as regards times taken and volumes delivered, while battling unprecedented logistics challenges. These

new practices have helped lay down new standards that are here to stay, and will only benefit us in the future.

For better or worse, the Indian Pharma industry was forced to reduce its reliance on raw materials and intermediates for active pharmaceutical ingredients from China, pushing the Indian generics industry to work towards being vertically integrated, or depending on Indian companies for the supply. This necessity led to development of in-house processes that have been significant in improving the state of the art, as well as in generating active ingredients that are economically viable. In turn, this has led to development of infrastructure and capacity building within the industry.

COVID pushed Indian companies to seek joint ventures with foreign companies, and we also saw significant collaborative efforts in research & development, manufacturing, technology transfer, regulatory approvals and marketing support between companies. These relationships will extend beyond COVID related matters and will carve out new paths in the Pharma world.

It was also very heartening to see the Pharma companies come out to meet their corporate social responsibility. Whether all of this would have happened so quickly, without COVID necessitating it, is a question no one can answer. But what is heartening is that these positive changes are here to stay.

In response to the global race to combat the Covid-19 pandemic, the World Health Organization embraced a proposal to create a voluntary pool to collect patent rights, regulatory test data, and other information that could be shared for developing drugs, vaccines, and diagnostics. Intellectual property is a fundamental part and it works as an incentive for those who innovate and therefore Companies who are investing billions to find a solution for COVID-19 are against it. What is your views on this?

This is a very valid question, but also one that has no single answer. While Intellectual Property Rights are granted to an inventor so that she (or her organization) can recover the expenses on the drug discovered by excluding others from commercializing the same, giving those up would be tantamount to charity. Therefore, giving up patent rights is in stark contradiction to the purpose of creating the rights. There have been situations – and the Patent Laws of several countries do also have the provision for compulsory licenses (where a government decides to set the patent rights aside in order for the drug to be made available to the larger population in a situation of national emergency), there have been

very few such licenses granted across the globe – just one in India so far, for Sorafenib. We have also seen companies dedicating their patent rights, or licensing them out voluntarily to other companies so that the global supply volumes can be met with, such as for example, Gilead's licensing-out of its Remdesivir patents.

During COVID, we did see the WHO rallying the cause, seeking nations and Pharma companies to pool their knowledge and efforts and support towards finding cures and symptomatic relief. We saw joint ventures arising out of the same, and also significant knowledge sharing about the virus, its details, diagnosis, treatment and the precautions to be taken. This knowledge pooling certainly helped fasten the research towards the cures. However, as regards IP, while the WHO can only suggest dedication or licensing of patent rights, it really is for the individual countries to step in to decide how the IP must be treated in a situation such as COVID, because IP is after all a territorial right. The country must decide the severity of the situation to consider and declare it as an emergency, and must have law regarding compulsory licenses or equivalent provisions, as well as machinery in place to implement that law. This also needs to be supported by the individual country's abilities, capabilities and capacities to meet its needs, so that when the patent rights covering the drug needed in the emergency are licensed out compulsorily or dedicated or shared, the same are effectively used to supply the drug.

So in my opinion, since the IP rights are granted by the government of a country, the government must step in to address a situation where the rights may be misused in a manner that harms the people of the country. Fortunately, what we have seen in this current phase is that companies have come forward to collaborate and license patents, and we have not seen IP rights being used in any negative manner. Probably that is why the governments did not need to step in to compulsorily license the IP. IP rights, while creating a monopoly, are an incentive for investment into research and development, and taking them away in situations that are short of a national emergency will not be setting the right precedence. So it is also important, as I mentioned before, to make sure that the compulsory licenses are effectively used to meet the need for which they were granted, are not misused in any manner. Maintaining those checks and balances is the government's responsibility.

Governments have been waiving common Intellectual Property laws in pursuit of a treatment for Covid-19, overriding patent protections and allowing sales of generic drugs. This is a concerning move for Pharma companies

struggling to navigate unclear rules, but could it change the R&D landscape forever?

There is a need to maintain the delicate balance relating to IP rights. Taking away IP rights by way of compulsory licenses, or by compelling inventors to dedicate their patents, and not ensuring that those compulsory licenses meet their purpose (meeting required volumes), would be unfair to the rights holder. Ideally, if the inventor can meet the volumes needed by the country, a compulsory license may not be necessary. Similarly, if the required volumes are met with through collaborative efforts of the inventor with one or more licensees, the need for a compulsory license may not be met with. Again, it is the duty of a government to make sure that the IP rights do not get in the way of protecting its own people, in a situation such as COVID, and it must proactively work to forge collaborations and/or licenses, if these are not seen happening between the parties. We have seen a few issues being raised across several countries about the maintenance of these balances, and its important that rights of all parties are maintained. It is also important to define situations that will mandate such IP licenses. It is of course necessary for the rules around these to be laid out clearly. I think its fair to say that a lot remains desired about that clarity today.

Having said that, I don't see the landscape changing. The world of R&D, the IP rights arising out of it, the business prospects related to the IP rights, and the evolution of the state of the art through these IP rights, is very well-established. The generic Pharma industry learns a lot from the IP created by the innovators, and in turn, the generic industry generates its own IP around secondary innovations, typically focused on cost and volume advantages. Multinational companies will always work to seek IP rights in markets of their interest, as long as they see fair treatment, and lawful decisions.

The Pharma industry, as a rule, tends to be fiercely protective of its intellectual property (IP) and indeed sees patents as key to innovation. You need to balance patent protection against the fact that the patent owners have a monopoly and therefore the opportunity to raise prices. What are the impacts and how will this affect the industry?

Indeed patents are key to innovation. They add to the state of the art and improve our understanding of various aspects of the pharma industry. While it is cliched to say that patents create a monopoly that allows innovators to raise prices indiscriminately, that is not true. The patent laws of all countries provide equal opportunities to challenge patents, should a third party find them to be not inventive enough, or

obvious or if they find a legal reason that demands the right be taken away from the inventor(s). Patent offices and Courts across the globe have been handling such patent challenges and have been doing a fair job of pulling down patents that are not eligible, or that should not have been granted in the first place. Similarly, competition laws in most countries now monitor pricing, and question price rises as well as settlements arising out of patent challenges. There are, therefore, mechanisms in place in most markets now for checking such misuse of patent rights, and/or monopolization of the markets.

The impact on the industry is that the generics industry has taken up patent challenges and pulled down patents, thereby bringing generics to market earlier than expected. The incentives associated with these challenges, such as those in US and other countries like China, South Korea, means that the generics industry starts working on patented products way ahead of time. It has helped improve the overall standard of products and processes, and has also helped ensure that patent ever-greening is kept under control – and the obvious advantage is that patients receive affordable healthcare.

A message for our readers on Intellectual Property and its role in the Pharma industry.

We already discussed a lot of aspects and the impact of IP on pharma industry. It can be best summed up with stating the fact that Intellectual Property is like any other immovable property or asset. It needs to be created and used with a vision and purpose to take the organization forward. The goal may be to ensure monetization within the 20 years term of the IP, or it may be to license out the IP and earn continued royalties/benefits on it, or then to sell the IP to earn a premium on the investment in research & development. In every situation the return on investing in IP is always very high. The quid-pro-quo requirement in IP ensures that the state of the art improves with every IP filing. Patents have been hugely important in improving and sharing knowledge. In the last 40 years we have seen intelligent commercialization of IP, such as in the Hatch-Waxman ANDA process in US, joint-ventures that allow partners to collaborate and market products across geographies, cross-functional fertilization and utilization of ideas such as in drug-device combination products, and we will see more in the days ahead, what with AI and ML making its way into the pharma world. The protection provided by IP also provides recognition and further motivation to the scientific community. Patents and patentees will only gain more importance in the next decade in pharma industry. ■

The Evolution of Law & Ethics in Pharma Sector:
Statutory Framework in India - Part II

In the last issue, author dealt with some statutory regulatory. We will continue to look at the remaining legislation that has contributed to the significant growth of this pharma sector.

Mr R. S. Raveendhren
Advocate, High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.

The Relationship between Law & Development

Laws play a pivotal role in shaping a country's economy. Robust trade and commerce requires good regulatory policies and a legal framework that is in tune with emerging challenges. In a developing economy like ours it is important that the legal framework is constantly evolved.

The Indian pharma market is the third largest in volume and thirteenth largest in value. It has been able to establish itself as a major manufacturing and research hub thanks to the foresight of our lawmakers. It is true that law and business are not exclusive of each other; neither can stay in isolation.

The Indian pharmaceutical market today has generic drugs that constitute 70 percent of its market. Over-the-Counter (OTC) drugs are 21 percent and patented drugs share a humble 9 percent.

Growth of Indian pharma sector is impressive keeping in mind the following milestones that we have been able to achieve in a short span of time:

- Our pharmaceuticals export was US$ 20.70 billion in the year 2019-20;
- We are amongst the top three pharmaceutical markets for our estimated growth in the next couple of years;
- We are the largest supplier of generic medicines globally sending out 20 to 22% of the global export volume;
- Our total export between April 2020 and November 2020 was US$ 15.87 billion and in November 2020 alone it was a whopping US$ 1.99 billion;
- India has exported US$ 3.89 billion of Bulk Drugs & Drug intermediates in FY20 and remaining US$ 2.52 billion in FY21;
- India has the most competitive manufacturing costs in the world that is lower than the USA and most countries in Europe.

It will not be an exaggeration to say our practical legal framework and our enthusiasm is the perfect impetus for our significant growth.

The Drugs & Cosmetics Rules, 1945

The Drugs and Cosmetics Act, 1940; Drugs Act and the Drugs Rules, 1945 regulates import, manufacture, licensing, testing, distribution and sale of drugs in India. Under the Act, every drug meets quality standards before it is

- Imported
- Manufactured
- Imported
- Stocked
- Sold & / or
- Distributed

The product must display ingredients in

the prescribed manner on the label or the container and must pertain to all other standards prescribed under its rules. It lays down general standard about drugs manufactured in form of tablets, capsules, liquid orals, injections and ointment.

Schedule Y of the Act:

Schedule Y of this Act governs clinical trials in India. It is quite interesting to note that National Human Rights Commission [NHRC] of India in the year 2013 constituted a committee to frame guidelines on the clinical trial of drugs. It was as fallout of several incidences of malpractices by pharmaceutical companies while conducting clinical trials on human subject in Hyderabad in 2011.

The NHRC guidelines reiterate the spirit of Rule 122 DAA, Rule 122DD, and Rule 122 DAC of good clinical practices. NHRC incidentally is the first human rights organization to have intervened and exercised its powers to regulate clinical trial through separate guidelines.

Schedule M of the Act:

Different countries call their clinical guidelines differently. USA and Japan use Regulations whereas it is termed as Directives in the European Union, U. K chooses to call it Guides, Australia, Codes and some Southeast Asian Countries refer to it as the WHO Code. In India, we call it the 'Good Manufacturing Practices' or GMP. Whatever the nomenclature, they all mean the same.

GMP in our country is extensively dealt with in Schedule M of the present Act. It classifies various statutory requirements that are mandatory for drugs, medical devices and other categories of products as per the current legislation.

The Schedule M protocol is revised in harmony with the WHO and US-FDA protocols. The revised protocol include detailed specification on infrastructure and premises, environmental safety, health measures, production, operation controls, quality control assurance, stability and validation studies including the plant and equipment and the minimum recommended areas for installation of certain categories of drugs. The requirements specified under Schedule M are mandatory for all pharmaceutical units in operation with effect from July 1, 2005.

Schedule T

The schedule prescribes Good Manufacturing Practices followed in the manufacturing of Ayurveda, Siddha and Unani medicines.

The Narcotic Drugs & Psychotropic Substances Act,1985

The Act concerns with the control and regulation of operations relating to Narcotic Drugs and other Psychotropic Substances. It regulates the use of chemicals and chemical formulations used to prepare drugs and the precautions

observed by pharma companies while handling and manufacturing of such drugs.

Environmental Regulations

In India, regulation and enforcement of environment protection and safety is governed by three major central regulations:

- Water (Prevention and Control of Pollution) Act, 1974,
- The Air (Prevention and Control of Pollution) Act, 1981, and
- The Environment (Protection) Act, 1986.

The main purposes of these legislations is to regulate prevent and control pollution by the setting up inter alia national and regional Pollution Control Boards (PCBs) which checks and enforce standards and norms in relation to air, water pollution and other kinds of wastes causing environmental damage.

Also, the Environment (Protection) Act, 1986 also prescribes rules for the management and disposal of hazardous industrial wastes as governed by Hazardous Wastes (Management and Handling) Rules, 1989 and Bio- Medical Waste (Management and Handling) Rules, 1998. Further all proposals for setting up, expansion and modernization are evaluated in terms of environment assessment impact by the Ministry of Environment and Forests which accords necessary clearance for projects after evaluation of Environment Impact Assessment.

The issue of management, storage, and disposal of hazardous waste is regulated by the Hazardous Waste Management Rules, 1989 made under the EPA, 1986. Under the rules, the PCBs have the power to grant authorization for collection, treatment, storage and disposal of hazardous waste either to the occupier or to the operator of the facility.

A similar regulatory framework is also in place for the purposes of bio-medical wastes under the Bio-Medical Waste (Management and Handling) Rules, 1998. The Public Liability Insurance Act 1991 imposes liability on the owner or controller of hazardous substances for any damage arising out of an accident involving such hazardous substances.

A list of all hazardous substances under the Act is notified from time to time in the government's gazette publication. The owner or the handler requires insurance against liability. Any transgressions that are fined are sent as contribution towards the environment relief fund. . ■

XSR Precision Balances - Go Beyond Weighing

METTLER TOLEDO'S XSR large platform precision balances are ideal when you have high sample throughput and tight deadlines. Even under the toughest conditions, you can rely on XSR to get the job done – quickly, and without errors.

Weighing methods can be saved in the integrated method library providing fast access to daily tasks and ensuring consistency between users. All results and task parameters are saved automatically to the results notepad and can be easily transferred to a PC via USB or Ethernet. Transcription errors are eliminated.

With ease-of-use, fast performance and secure data handling, XSR balances fit comfortably into your workflows.

Benefits and Features:

Extremely Durable

The new Monobloc™ weighing cell delivers fast and precise results. Integrated overload protection and the full metal housing safeguard the weighing cell and help ensure a long balance lifetime.

Ergonomic Operation

Placing the display at eye-level on the adjustable ErgoStand™ saves space and eliminates excessive bending of the neck. The touchscreen display simplifies operation and has large bright figures which are easy to read.

Error-free Data Transfer

You no longer need to record results by hand or spend time typing in data. Simply transfer task parameters and results to a PC or software application via USB. Large volumes of data can be transferred quickly and without error.

Easy to Clean

XSR precision balances have been designed to withstand harsh chemicals, dust and dirt. Smooth surfaces and rounded edges make the whole balance easy to clean.

About METTLER TOLEDO

METTLER TOLEDO is a leading global manufacturer of precision instruments.

The Company is the world's largest manufacturer and marketer of weighing instruments for use in laboratory, industrial and food retailing applications. The Company also holds top-three market positions for several related analytical instruments and is a leading provider of automated chemistry systems used in drug and chemical compound discovery and development. In addition, the Company is the world's largest manufacturer and marketer of metal detection systems used in production and packaging. Additional information about METTLER TOLEDO is available at **www.mt.com** ■

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Italvacuum: Your Vacuum drying specialist from more than 80 years

Come Join us at Chemtech digital edition from 23 to 26 February!

Italvacuum is one of the leading manufacturers of vacuum pumps, as well as a world-wide reference point in the engineering, manufacture and supply of vacuum dryers, ensuring top-tier performances for the treatment of wet powders from filtering and centrifuging processes.

Considering the importance of the use of Italvacuum installations, that are quite often exploited in the production of Active Pharmaceutical Ingredients (APIs), Fine Chemicals and Intermediates, the company mission has always been to provide the customers with the utmost in quality, innovation and safety.

Italvacuum manufacturing capabilities include a wide range of original and patented equipment and systems, complying with the main international regulations (ATEX, UL, PED and ASME) and with the latest FDA and cGMP norms, including:

- Saurus939®, vacuum pump available in single stage, double stage and double stage model with one or two volumetric compressors
- Multispray Cabinet Dryer®, tray vacuum dryer with C.I.P. (Clean in Place) Multispray® patented fast-washing system
- LaboDry®, laboratory-scale tray vacuum dryer
- Bi-Evolution Dryer®, bi-conical rotary vacuum dryer available with a wide range of accessories
- Criox® System, rotary vacuum dryer / powderer with electric lump-breaking units
- Planex® System, patented horizontal vacuum dryer with ZeroFriction® planetary movement eccentric agitator
- CosmoDry® System, horizontal vacuum dryer with concentric agitator available with a wide range of accessories.

Italvacuum is able to provide turn-key installations and also tailor-made equipment and systems, according to customer's process requirements. Italvacuum presence all over the world, with a continually growing number of installations in every continent, is a tangible sign of the company's reliability.

A vacuum pump that guarantees best performances, ensuring total recovery of extracted solvents, even in severe operating conditions. A simply designed machine, that combines traditional robustness and reliability with the most evolved technology. Resistance, strength and consumption of oil virtually eliminated thanks to the innovative LubriZero® system. A solution which guarantees perfect operation and optimum results with total respect for the environment. Saurus939® has no fear of aggressive and corrosive solvents, powders and condensates, nor distillation by-products. But above all it does not fear confrontation because it is designed and manufactured to work 24 hours a day with a constant excellent performance and minimum operating costs, thanks to a low-energy motor, negligible oil consumption and easy, immediate maintenance. Powerful, efficient, but absolutely safe: Saurus939® guarantees optimum safety through the whole process and complete purity of the final product. In other words, ensures an uncontaminated vacuum. Saurus939® has a wide range of use and could be employed in different sectors: Chemicals,

Vacuum pump - Saurus939®

Pharmaceuticals, Cosmetics, Oil & Gas, Plastics & Rubber, Bioscience and Waste Management. The processes are drying, reaction, distillation, crystallization, filtration, evaporation and polymerization.

Multispray Cabinet Dryer®, a consolidated ever evolving technology

Best results, ergonomics, safety and flexibility for any product batch. These are the qualities that have always characterised Multispray Cabinet Dryer®, result of Italvacuum consolidated experience in process applications in the pharmaceutical, chemical, cosmetic and food industries.

But that is not all, because the important added value that differentiates Multispray Cabinet Dryer® from conventional tray dryers is that it guarantees total cleanliness of the inner chamber and all heating plates, in compliance with

Multispray Cabinet Dryer® detail

the latest FDA and cGMP standards. In fact, thanks to the C.I.P. (Clean in Place) Multispray® patented fast-washing system, the equipment can be completely cleaned in just a few minutes, minimizing washing liquid consumption.

Multispray Cabinet Dryer® can be used in any type of application, as there are two available versions: the fixed plate and the removable plate ones. The latter is particularly indicated for multiproduct usage. Also, for the production of highly Active Pharmaceutical Ingredients (High Potency APIs) and for Research & Development activities, Italvacuum has developed the laboratory-scale vacuum dryer LaboDry®.

Criox® System, powdering while drying

An international great success patent, which consists of a rotary vacuum dryer / powderer, counting more than 400 units installed in more than 30 countries world-wide.

The central body is made of a double cone chamber, characterized by smooth surfaces without edges and sharp corners. During the rotation, this structure helps the total and continuous revolution of the mass to be dried and allows a homogenous and delicate mixing. The double cone shape of the rotary chamber would not be effective in itself if it did not contain inside the two powerful electric lump breaker units – which are a peculiar characteristic of the Criox® System – allowing for the increase of the product surface exposed to the evaporation and to enhance the agitation efficacy of the system. The lump-breaking units not only break down the eventual pre-existing agglomerates in the wet powders thus preventing the forming of lumps, but they also allow for grinding and powdering during the last drying phase, limiting the use of the mill. This helps having bulk products ready for bagging or powders with checked final particle size distribution, where the next operation is

Italvacuum's facilities in Borgaro T.se (Italy) – Criox® Systems

often limited to a sifting phase. Criox® is versatile and profitable: specific solutions have been studied for the products automatic loading and unloading and also in order to wash, to clean through and to inspect the plant before changing the batch. This means the opportunity to pass quickly from one product campaign to another, as production demands.

CosmoDry® System, the evolution of the species

An innovative horizontal vacuum dryer, the result of highly advanced research by Italvacuum and of a careful analysis of the production requirements of the most demanding customers.

Power, load flexibility, drying speed, easy unloading, maximum quality of dried product. All important and fundamental values, but Italvacuum went even further. The great innovation of CosmoDry® System as opposed to conventional horizontal vacuum dryers is in the particular structure of the agitator: the inner parts can be dismantled in different parts, quickly and easily. Which means very easy internal cleaning, maintenance and inspection: a mix of qualities guaranteeing that the machine is always kept in perfect working order and optimize the production processes, making CosmoDry® System also the perfect solution for multi-product applications.

Planex® System, a revolutionary drying philosophy

A patented machine which is conquering the most demanding operators from all around the world, by guaranteeing results that were unthinkable with conventional vacuum dryers, both horizontal and vertical ones.

Planex® System is a horizontal vacuum dryer with an eccentric agitator featuring two independent movements, allowing it to simultaneously revolve around its own axis and to rotate tangentially to the drying chamber, ideal for the production of Active Pharmaceutical Ingredients (APIs).

The combined rotations of the agitator and its small size compared to the drying chamber diameter, ensures the perfect mixing of the entire batch, and allows

consuming at least three times less energy than conventional dryers with concentric agitators. This means a threefold reduction in mechanical and thermal stresses on the batch – analysis carried out by the Department of Materials Science and Chemical Engineering of the Polytechnic University in Turin. As a result, even the most delicate temperature-sensitive products are treated with maximum care.

But there is more. Planex® System, thanks to its agitator's ZeroFriction® planetary movement, prevents the product from being rubbed against the drying chamber walls and thus heating up due to friction, a typical problem in conventional paddle systems. In addition, the rotation of the paddles tangentially to the chamber walls, conveys the product into the small clearance between the agitator and the chamber surface, preventing lumps formation and guaranteeing an even more effective drying and a controlled final particle size distribution, which is impossible to achieve with conventional dryers. Thanks to the agitator movement controlled by the "Stop & Swing" program, it is also ideal for drying small batches.

Italvacuum customer services: from Pilot Trials to Project Engineering right through to a comprehensive After Sales Service

Customer care, for Italvacuum, means supporting the customer from the very first contact. Italvacuum offers the opportunity to conduct pilot drying trials and involves

Pilot Trials

the customer in system design and manufacturing. Once the system is up and running, Italvacuum also provides all the technical support the customer may need to ensure year after year of fault-free operation.

Pilot Trials

The Italvacuum facility comprehends a full range of pilot systems for carrying out semi-industrial and laboratory scale drying tests on customer's products.

Project Engineering

Outstanding technical know-how and a thorough knowledge of the needs of the chemical and pharmaceutical industries have enabled Italvacuum engineering services to build up unparalleled expertise in vacuum processes.

After Sales Service

With highly qualified personnel, Italvacuum After Sales Service provides the following assistance: 1) Scheduled Preventive Maintenance; 2) Technical Assistance; 3) Service Parts; 4) System Upgrading and Overhaul.

Italvacuum in India

Concerning sales strategy, Italvacuum can count on a world-wide network of highly qualified agents. For the promotion of vacuum pumps and vacuum dryers in India, Italvacuum cooperates with Vacuum Drying Technology India LLP, which is based in Mumbai. With a very competent staff, Vac Enterprises India LLP is able to understand every customer's process requirement. This is also due to the training provided to all the salesmen and technicians, that are constantly updated with regular courses at Italvacuum headquarters.

The difficult historical period didn't stop Italvacuum's activies. Italvacuum has been able to continue production, today as in the past months, in full respect of the safety of its employees, scrupulously following the safety guidelines and will continue to cope with the current orders.

A heartfelt thanks to all of the Customers and to all the company staff in the offices and workshop, and also a special thanks to Vacuum Drying Technology India LLP, without whom none of this would have been possible.

For the first time, this year Italvacuum is going to attend the brand new event of Chemtech online exhibition.

Come and join us!! ■

Contact Details

Website: www.italvacuum.com

Clean Room Vacuum Cleaners

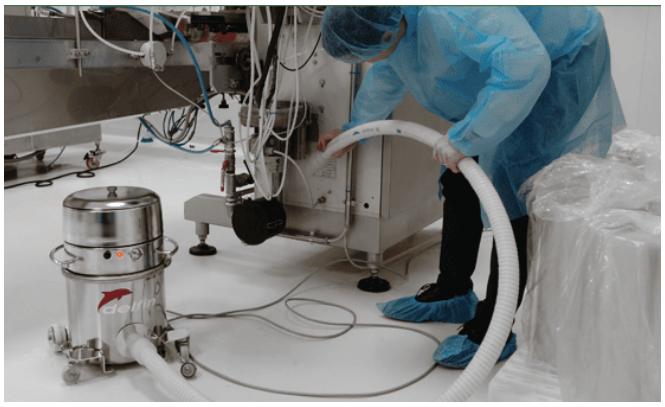
ROOTS
ADDING VALUE

Range of Root Multiclean Ltd. Clean Room Vacuum with Autocleavable Tank and Accessories Kit

CONTAMINATION : Contamination refers to products that has been made impure with another substance. Avoiding product contamination is a key factor especially in any Food, Pharmaceutical industry, where highly polluting particles are often released during the production and packaging processes. It is therefore essential for cleanroom vacuum cleaners with stainless steel equipment and H14 HEPA filters.

CLEAN ROOM ENVIRONMENTS: A clean room is an area in which the concentration of airborne particles is controlled and used in a manner to minimize the contamination inside the room, in which other parameters like temperature, humidity and pressure are controlled.
Our Team of specialists are keen to visit your facility and conduct a thorough site survey in order to provide customised proposal, based on conditions prevailing at the site.
In over 25 years of our glorious journey, we are driven by the commitment to add value through innovation, quality, service and

LC 1000D



- Compact Dry model
- Safe bag available with safety cap
- Single phase through flow motor.
- Up to 4 stages of filtration
- U15 absolute filter available
- AISI304 stainless steel construction
- AISI316 stainless steel for components in contact with material 5 liters of capacity
- Suitable for ISO4 cleanrooms

LC 1100WD

- 40 litres liquids capacity
- 25 liters solids capacity Suitable for ISO6 cleanrooms
- Suitable for ISO4 cleanrooms with U15 upstream filter equipped

thereby building sustainable long-term business partnerships. Roots Multiclean Ltd touches lives of People across the world & fulfills the dream of billions of people for a cleaner environment. ■

- Wet and dry model
- Single phase bypass motor
- Up to 6 stages of filtration U15 absolute filter available
- AISI30 stainless steel construction
- AISI316 stainless steel for components in contact with material

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Diversity in Pharma & Biotech

“It is critical for Pharma Industry to align with cultural intelligence & cultural diversity”

Video Link: https://youtu.be/xH30reOAfr0

Smita Holey, Associate Vice President - International Strategic Business Unit at Cadila Pharmaceuticals Limited

“Number of women in top leadership is discouragingly low”

Video Link: https://youtu.be/vOryWku8LB8

Milva D’Aronco, President & **Sanobar Syed,** Executive Lead, Women Leaders in Pharma

"Diversity is not just about gender, race or colour but it is the diversity of thoughts and experiences which are truly valuable"

Dr. Nivedita Parwatkar
Head of Clinical Operations
Transformative Pharmaceutical Solutions LLC

When the editorial team of Pharma Bio World reached out to me regarding the article about my journey in pharma for PharmaBio World (PBW) for their special edition on diversity in Pharma & Biotech my first thought was, I am just starting.

I am thankful and would love to share this amazing ride with you all.

I am Dr Nivedita Parwatkar a practising medical doctor tuned into clinical researcher currently heading Clinical Operations for Transformative Pharmaceutical Solutions LLC a company determined to drive breakthrough innovation in the pharmaceutical industry. I am a proud mom of two beautiful boys who fill my days with love and laughter.

Inspiration to shift from Medicine

After practising medicine in India and abroad for about seven years I shifted to the pharmaceutical industry.

Practising medicine was a very satisfying experience when I could treat the sick who came to my clinic. However, I wanted to reach out to the larger population. Developing newer medicines to treat the untreatable diseases, alleviating pain, sufferings of many is what made my transition to the area of drug development.

I started my journey at ground level dealing with clinical studies at hospitals, interacting with patients and physicians, seeing the patients getting better. Here I would like to share one of my rewarding experiences. We were working on developing a drug for treating refractory epilepsy. We had a sweet 14 years old enrolled in the study whose life was nothing but chaos with multiple epilepsy attacks in a single day. The days of her bubbly childhood were replaced by being confined at home and miserable sufferings. After being on the study drug for 4 months the frequency of her seizures came down drastically. She was able to attend school, play with her friends and enjoy her childhood. I still cannot forget the gratitude and joy in her mother's eyes. It was priceless.

So, I continued my journey from managing the clinical studies at the sites to moving on to managing multiple studies and portfolios. Being the only employee in Pune city, to expanding the team to 20 plus members and we became the most sought-after team in the company. It was my dedication and hard work and certainly the encouragement and appreciation I received from my bosses that made me take on newer and bigger responsibilities. All this time I was continuously juggling my responsibilities as a wife, a mother and a professional. Honestly, my kids were young and needed me more, so I wasn't overly ambitious in my career at that time. Looking back, I am happy with the choices I made.

Entering the new world of Pharma

Then came a big decision of moving to another city with expansion of work scope from India only operations to global operations. Joining a new team for one of the best pharma company's which was created to drive innovation. The decision was not easy. Thanks to my family and their support during the transition, this opened a whole new world to me!!

I worked with the very first team in the Pharma industry to implement risk-based monitoring for a large portfolio.

The rewarding experience of visiting USFDA in person was a dream fulfilled that many aspire to in the pharma world. I participated as a Subject Matter Expert in front of FDA Director and 20 plus inspectors. It was a moment of pride to receive the nod of approval from the highest authorities for what you have created!

The journey moved forward when I was asked to head clinical operations for my current organisation. There was a definite risk involved of leaving a secure position in top five of the pharma companies and joining a start-up. However, the company was formed by someone I always looked up to as a professional and as a leader. He showed faith in me by offering me the exciting opportunity and I knew we as a team of likeminded professional would succeed. We were a new company with a lot of ideas and pharma industry experience. I wore different hats every day from writing SOPs, to creating training to building teams. We challenged the current processes. We questioned the status quo. We developed new processes and deployed new technologies. Using Artificial Intelligence and voice technology in Clinical Operations ,all this to reduce the time to get newer drugs to patients and to reduce the drug development cost with improved quality. It was challenging but it was also very engaging and satisfying. As a result, I have seen things develop from an idea to the reality in just weeks. However, we still have a lot to do.

Building valuable relationships

It has been an exciting and rewarding growth in both my professional and personal spheres. Working with various multicultural and multilingual teams has expanded my horizon. I have always been a people's person. My colleagues maintain that my office space is the noisiest and fun place in the group. I have met some amazing people on this journey who made a significant impact on me as a person. I have worked with great teams whom I attribute my success to. Connecting with teams and stakeholders beyond work has resulted in developing some really good friendships without whom this journey would not be as interesting and joyous. I believe that being honest, transparent, and open in my communications are the reasons for these valuable relationships.

To me, diversity is not just about gender, race or colour but it is the diversity of thoughts and experiences

which are truly valuable. I bring a lot of diversity to my teams as a result of the different roles I play in life; a woman, a mother and a doctor. As a woman, I am strong yet sensitive. As a mother, I am a problem solver, multi-tasker, very proficient in financial planning and resource and time management. It is a fine balance one learns between being a nurturer and an enforcer especially when you have two children who are high energy and multi-talented. As a medic, I understand the human anatomy and physiology which helps me make a more meaningful contribution to the entire drug development process and understand patient psychology. This is the diversity I bring to the table.

Forging new paths

Pharma industry has operated in its traditional old ways for many decades now. However, the recent pandemic has forced it to find newer processes, technologies and different ways of working. The pharmaceutical industry is slowly embracing these changes. I would truly like the industry to adapt quickly to new technologies and find processes that get drugs faster to the markets at reduced costs making it more affordable to most of the population. Along with my team, we will continuously strive to embrace these changes and forge new paths to achieve these goals.

I truly love my job. I thrive on challenges. I am blessed to share that I have always been encouraged and never faced any discrimination in this industry. I was always given equal opportunities and respect.

My final message to my fellow women; keep growing in your knowledge and experience, do not shy away from taking risks, recognize your inner potential and tap into its full strength and finally and most importantly, it is ok to make your kids and family as your priority. Your career will still grow as you have a lot to offer! ■

“There are three kinds of Organizations: Organizations that make things happen, Organizations that watch things happen and Organizations that wonder what happened.”

Lakshmi Achuta, MRQA
Strategic Advisor (Biotech, Pharmaceuticals & Medical Devices)

I am often asked by many, what did I do (and achieve) in one single Organization (or Group) for 26 years! As I look back on the journey undertaken by myself, I would like to share a snapshot of how it evolved with very crucial milestones which made me move out of comfort zone and complacency; and importantly taught me how to build a world class Organization.

Having a passion for Biotech and Enzymology, I joined Biocon after completing my post-graduation (M.Sc. Applied Botany, specializing in Medicinal & Aromatic Plants, Bangalore University) in QA laboratory as an Enzyme Analyst in 1993. This gave me an opportunity into the functioning of the Biotech industry. Being a novice and straight from college, I was trained on relevant requirements through a very rigorous training programme. Ms. Kiran Mazumdar Shaw

was a role model, a visionary who provided us with impetus to achieve with a bigger picture in mind and cognizant of international practices. Culture of the organization was such that the onus and accountability rested on the individual – there was no gender discrimination whatsoever, with competent women heading Quality and R&D; and as an individual, we were responsible, empowered and accountable. A slide in the Corporate presentation slide deck that impacted me majorly and ingrained in me was:

'There are three kinds of Organizations: Organizations that make things happen, Organizations that watch things happen and Organizations that wonder what happened.' This was followed by the attestation - **We are an Organization that make things happen'**

The path of transformation

As the Organization was evolving, we as a team came together in a very collaborative manner setting aside our differences, to achieve many major milestones that transformed the Organization. Considering an Organization's path for transformation, opportunities were available for taking up various projects.

Subsequently, in a year after I joined, in 1994, when Biocon became India's 1st Biotech company to be certified for ISO 9001, the certification process provided me an insight into Quality Management System (QMS). I expressed my interest in taking it further and was given the opportunity to implement / upgrade / digitize the Quality Systems thereon which enabled me to embark on a different journey other than the initial one on Enzymes. This gave me a platform to interact with various stakeholders within and outside the Organization. I realized that I had an aptitude and flair for the whole process of Management Systems, viz., interpreting compliance standards, concepts, training, auditing and so on. I accepted more opportunities in implementing green field projects over the years – viz., integrating cGMP, ISO 17025, NABL, CAP, etc. It is interesting to note that the quality management concepts were evolving in this phase world over.

After post-graduation, I had to set aside my aspiration of pursuing higher studies owing to lack of financial stability at home and take up employment to support the family. During the course of work, I wanted to study further. There were various options available – MBA,

PhD, etc. Considering my passion for Management Systems, I pursued and successfully completed MS in Quality Management, a collaborative program with Indian Institute of Quality Management (IIQM), Jaipur and BITS, Pilani in 2004 via distance learning. It was very challenging phase for me because I was pregnant for the first time during the entire course work along with my full-time job and I was implementing ISO 9001 for Syngene! I was able to achieve this with the support from my family (mother & husband), my seniors and colleagues at work.

The inflection point

An inflection point came in 2004, when I was given the responsibility of implementing Environment, Health and Safety Management System (EHSMS) for Group Companies - Biocon, Syngene and Clinigene – a very crucial phase, much bigger platform and an even bigger responsibility. This definitely made me move out of the comfort zone of Quality and take on the challenge. All activities had to be mapped to the minute details (viz. risk register, legal and compliance register, sign boards, emergency routes, enable a dedicated emergency telephone line with call being mapped to important people, training of housekeeping staff in colloquial language and so on), management and stakeholders (of various business verticals and vendors) had to be advised / counselled, trained, documents prepared & reviewed – very importantly the system had to be integrated with the existing QMS. This was an enormous change management process considering the diverse and complex activities handled by the Group Companies with about 1000+ employees. Very crucial lessons learnt included involvement of people by creating the EHS Core team with representatives of each department and communicating to them the expectations; this ensured review and ownership of practices and any updates whilst enabling cultural transformation. In change management and cultural transformation, it is very imperative that mindset of the stakeholders to be aligned and transparency in the process. Process was akin to working on different pieces of the puzzle to make it a whole. Nonetheless, the implementation resulted in successful certification outcome with no major non-conformities in 8-9 months.

I continued to handle QMS and EHSMS for few more years, implementing it in new facilities and new standards. The next opportunity and career milestone

were unexpected and came in 2007, after I returned to work post my maternity leave for my second child. It came with a mandate to implement Quality Systems for Clinical Trials and harmonization of Quality Systems for Clinigene in its transformation as a full service CRO. This was when I took a very crucial decision of moving out of Biocon into Contract Services space – a different sector altogether. I had to strategize the implementation and harmonization of Quality Systems to ensure that it was current and relevant to industry best practices. Many were skeptical whether the strategy would even be implemented let alone work. It was implemented in a phased manner over a span of two years and it yielded in a harmonized Quality System. We were able to face the first European inspection for the clinical study conduct which resulted in a favorable outcome followed by other International regulatory inspections.

Move to Syngene ensued in 2012, where in projects handled were related to CSV, Business Continuity & Disaster Recovery, Due diligence audits along with that of research, development and medical device quality systems. Tenure in Corporate Quality & Regulatory Compliance provided a platform for formalizing and implementing Policies for Data Integrity, Quality Governance framework, whistleblower mechanism among others.

Overcoming the roadblocks

As an individual and as a woman, we do come across various roadblocks, resistance to change and exposure to new arenas / ideas / concepts. These question our self-worth, ideals, challenge us to unknown territories – we need to gear up for it with fortitude and scale up our expertise. Very importantly, we need to groom ourselves and our subordinates. There are lot of talented men and women, both young and old - but it is those who persevere with resilience spirit who are for the long haul. Working mothers and fathers need support of extended family; seek someone who will give a patient hearing; and supportive organization practices. As I pursue being a Strategic Advisor today, it provides me a wide scope of assignments to taken on with the aim to enable Organizations and individuals to achieve their goal; and hence, the opportunities continue. ■

“Knowledge and process behind making an ‘informed decision’ is the key to success of any new drug discovery program”

Sonali Das
Associate Research Director, Research Informatics
Syngene International Ltd.

After earning a Ph.D. in Molecular and Cellular immunology, I spent 6 years as a Post-Doctoral Research Fellow at the University of California, Santa Barbara, USA, to gain further insights into the molecular basis of viral infections. All through my academic life, from undergraduate studies to postdoctoral research, I enjoyed scientific research to decipher the unknown and published the work in reputed international journals and present it in front of the scientific community in multiple international conferences and workshops.

Developing specialised skill set

My present role demands ingenious thought-provoking problem-solving skills. However, being a part of the service industry, I find that I need to exercise a slightly different skill set, to help lead a concerted effort to solve problems for advancing discovery programs. Perhaps my academic mentors would be

(pleasantly) surprised to see me leading a successful business endeavour and providing solutions for clients rather than being a group leader of an academic research laboratory. However, being a leader at the intersection of cutting-edge science and business facing the challenges of finding a drug is addictive!

Armed with a decade's worth of curiosity-driven research experience and training at the world's premier research laboratories, I joined a Bioinformatics start-up in Bangalore in 2006. There, our dynamic, multi-disciplinary team of researchers created a patented platform that aids drug discovery research during Lead Optimization stage of drug development. A long association with the project, as a project lead, helped me gain a deep understanding of drug discovery research and provided me opportunities to interact with leaders in the field as mentors, colleagues, and clients.

A little over four years ago, I moved to Syngene International Ltd. where I got an opportunity to partner with global pharma leaders to apply findings of basic research from various fields of biology towards new drug development. Along with my team of biologists, toxicologists and bio-informaticians, our expertise help biopharma organizations make informed decisions in their early-phase drug development pipeline and optimize resource utilization. It gives me great satisfaction when a client provides feedback on how our analysis helped them arrive at the best decision. My team and I have been working in this space for long, and it has been a very rewarding and productive experience.

The biopharma world is constantly seeking cost effective ways to reduce drug target attrition. Our experience with our clients (pharma, biotech & animal health care sector) has shown that comprehensive in silico assessment, deployed effectively, can form the base for a practical strategy for any discovery and innovative research.

Avenues & opportunities available for female employees

2020 Women in the Workplace study conducted by McKinsey and LeanIn. Org evaluated the growth in women representation in senior decision making portfolios from January 2015- January 2020. While for SVP (senior-vice-president) positions the growth is from 23 to 28% only, in the C-suite it is from 17 to 21%. In healthcare, women remain underrepresented in the Pharmaceuticals and Medical Products (PMP) industry, with few women holding seats in the C-suite.

However, have we ever wondered what is common in the US Vice President-Elect, CRISPR-Cas9, and Covid19 vaccine! These are examples of the awesome power of talented women striving to make the world a better place to live. The expression of joy reflected on the face of a young girl while watching Kamala Harris's speech after the 2020 US Presidential elections results were announced says it all – now the little girl believes that even she can be a future US President! Two exceptional scientists, Emmanuelle Charpentier and Jennifer Doudna discovered the CRISPR-Cas9 technology that has the power of transforming the way genome manipulation is being done and are now the 6th and 7th women of 186 Nobel prize winners in Chemistry! Gita Patel, another immigrant from India, leads an "all-female" team on developing a Covid19 vaccine for the US-based company Novovax and one of the most promising vaccines under trial. The list goes on. One of the most influential and successful business entrepreneurs in World Pharma is the founder of the Biocon-Syngene group of companies in Bangalore is our beloved Dr. Kiran Majumdar Shaw.

As a leader of a vibrant group of scientists, predominantly women with PhD and postdoctoral experience from reputed educational institutes across the world, I am optimistic and looking forward to a future where women power is progressively advancing pharma growth in both business and R & D.

Message to reader

Having garnered more than 25 years of experience in basic and industrial research in the frontier areas of science that interface chemistry and biology, I wish to share the knowledge and process behind making an "informed decision", which is key to the success of any new drug discovery program. Working on customized solutions to scientific problems is something that keeps me motivated. I get utmost satisfaction to see my junior colleagues growing, gaining confidence, and making key contributions to achieving organizational goals, under my leadership. Identifying and nurturing the unique skillsets of each of my team members is an aspect of my role that I particularly enjoy. The challenge of continuously delivering enhanced value to our clients while working within the demanding timelines of the industry is what drives me every single day! ■

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“For me success means getting a meaningful outcome of a job I undertake rather than an output”

Lakshmi Seetharama
Senior Manager, Project Management
Syngene International Ltd.

At Syngene, I work with both male and female colleagues in the Project Management department. All genders have unique qualities which make them better at work in the project management sector. My personal inspiration are my mother, grandmother & aunts who were adept at managing monthly groceries, organising small Poojas to big weddings, their skills in holding members of the family together despite their varied interests, managing communications with multiple people right from the milkman to everyone who visits the house. In a project management parlance, these activities are called as stakeholder management, communication management, costing and budgeting, schedule management, making complex things simple etc. The other reason for becoming inspired by these people are they never got tired by doing the same over many years and yet did things differently by bringing lessons learnt from their experiences. You sum it all and bingo! You see a project manager.

Role of women in Syngene

Dr Kiran Mazumdar Shaw herself is a great inspiration for all of us at Syngene. There are other great women leaders but something in common at Syngene is the following:

Inclusivity: We are treated at par with other gender and given equal opportunity. They have always encouraged me to think freely and inspired me to think differently. My voice is heard and my opinions matter in the forum I speak and that instils confidence in me.

Integrity: Integrity is our core value at Syngene. Through good, bad and difficult times our leaders here stay composed, fair and stayed true to their principles. This is something that inspires me to work here as high standards of Integrity are practised.

Empathy: From ensuring safe transport services to reach back home to providing forum to preventing sexual harassment on site, Women are given safe place to work. This makes my family feel safe when I am in office or on the move.

What drives my success?

For me success means getting a meaningful outcome of a job I undertake rather than an output. I am self-driven, resilient, thirsty for learning, and passionate about my work. At my work here in Syngene, I am given good opportunities to excel in an area that I am good at. I have led a team of project professionals to write a process document under the mentorship of my manager. The outcome of the process document is uniform practise of project management across all departments at Syngene. My colleagues who have shown faith in my capability and helped me to achieve success are a worth mention here. Such encouraging environment always drives success. ■

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