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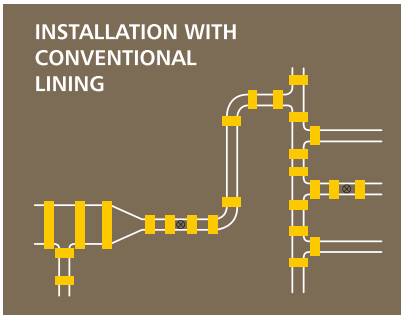

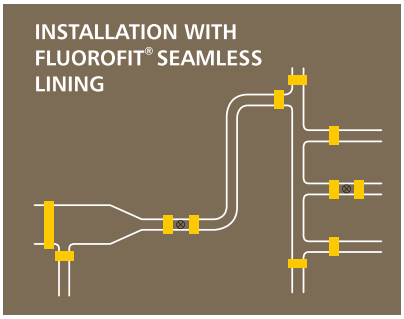

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Validation of Weighing Processes

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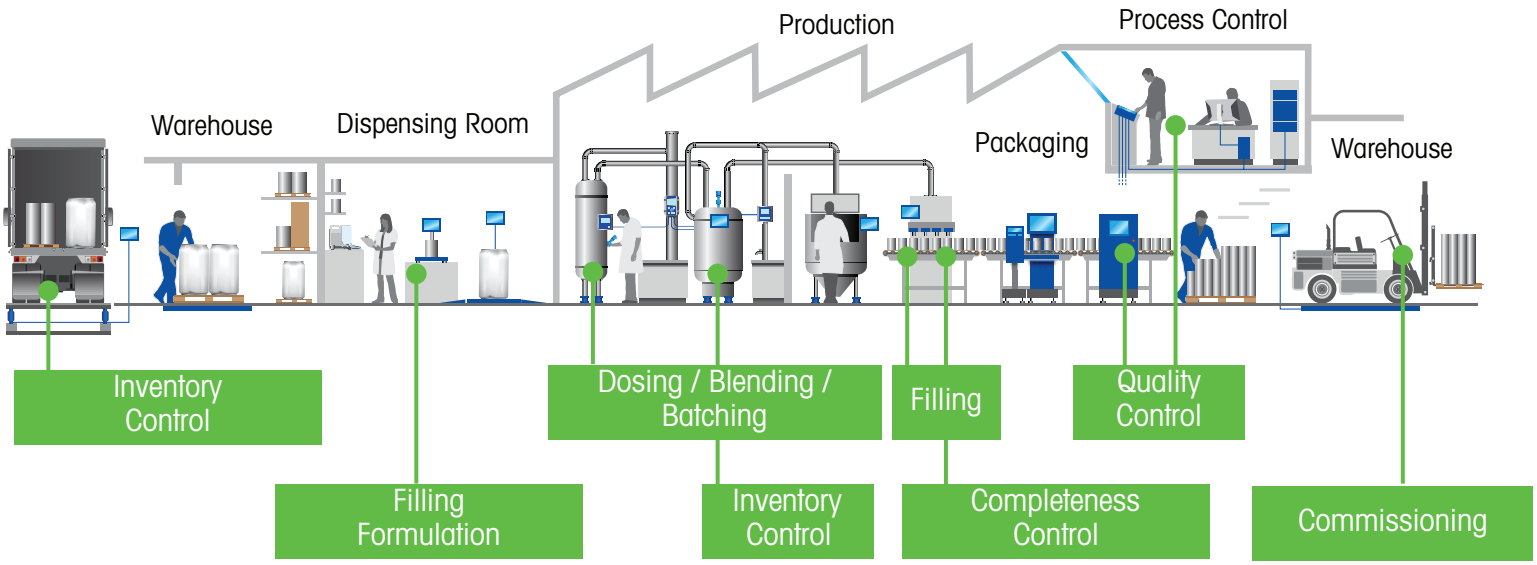

Process validation contributes significantly to ensuring drug quality. Since Weighing has a significant impact on quality, weighing equipment must be qualified and critical weighing processes need to be validated. Mettler Toledo Good Weighing Practice™ (GWP®) provides outstanding support in three main stages- weighing process validation, equipment qualification & continuous process verification.

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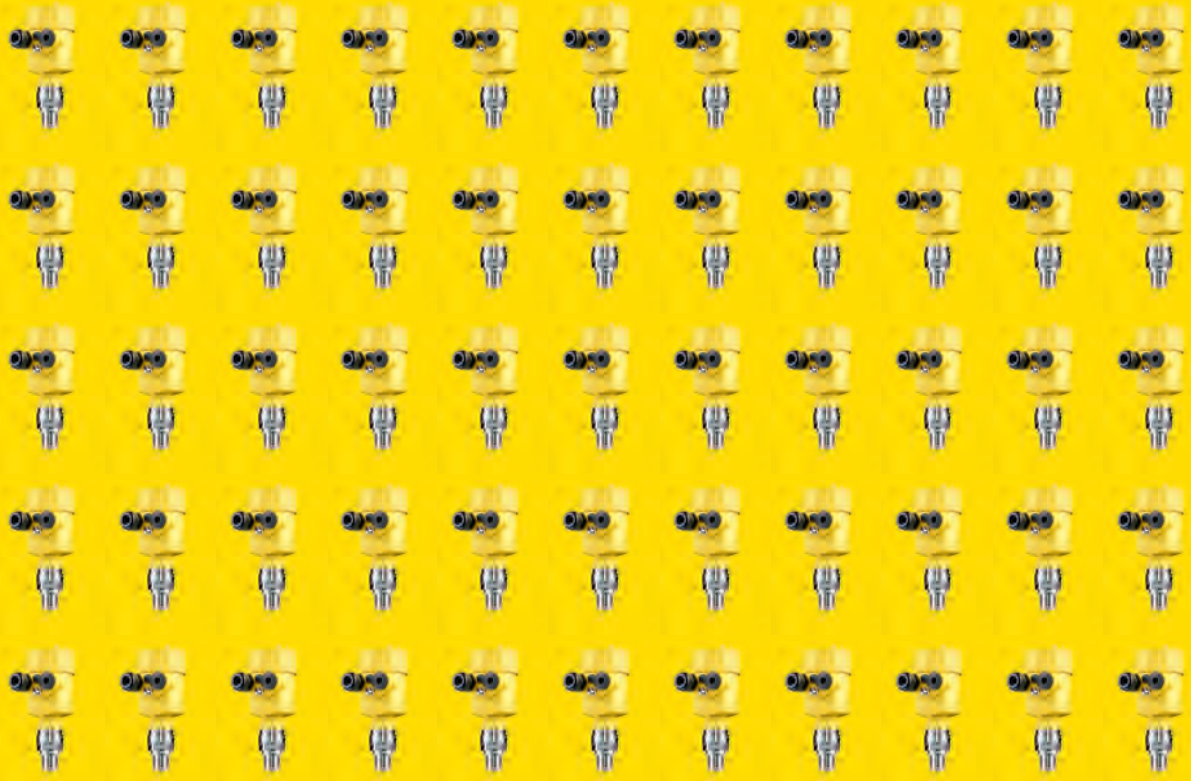
CONTENTS

INTERVIEW

FEATURES

GUEST COLUMN

AD INDEX



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Biocon Biologics Partner Viatris Wins U.S. Court Decisions on Sanofi Appeals for Lantus® Device Patents

Shreehas Tambe, CEO, Biocon Biologics Ltd

Bengaluru, India: Biologics Ltd, a subsidiary of Biocon Ltd. announced that the U.S. Court of Appeals for the Federal Circuit (USCAFC) has upheld the U.S. Patent and Trademark Appeal Board's decisions for unpatentability of five device patents for Sanofi's Lantus® SoloSTAR®, as well as a district court decision on one of these patents. The Patent Trial and Appellate Board (PTAB) at the U.S. Patent and Trademark Office (USPTO) had in April and May 2020 found the challenged claims of U.S. Patent Nos. 8,679,069; 8,603,044; 8,992,486; 9,526,844; 9,604,008 unpatentable. Sanofi had appealed against all these PTAB decisions to USCAFC.

Of these five patents, the 9,526,844 ("the '844 Patent") was also held invalid and "not infringed" by the U.S. District Court for the District of New Jersey. The district court found non-infringement of the asserted claims for the '844 patent and held it invalid for lack of written description. Sanofi had appealed the district court decision for the '844 patent. Since the USCAFC affirmed PTAB's decision for the '844 patent, Sanofi's appeal against the district court's decision is held as moot and thus dismissed.

The Federal Circuit judgments reinforce the continuing efforts of Biocon Biologics and Viatris to break down barriers to patient access for important medicines such as Semglee®. Viatris and Biocon Biologics Ltd. launched their interchangeable Semglee® products (insulin glargine-yfgn) last month, which are the first, and currently the only, interchangeable biosimilars to Lantus®, providing more affordable options for the millions of Americans living with diabetes.

The Semglee® products are available in vial and prefilled pen presentations and are interchangeable for the reference brand, Lantus®, allowing for substitution at the pharmacy counter. Semglee® is indicated to help control high blood sugar in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes.

Shreehas Tambe, CEO, Biocon Biologics, said: "The decision of the U.S. federal court in favour of our partner Viatris, on all the five Sanofi Lantus® SoloSTAR® device patents is a vindication of our long-held position on intellectual property. These developments are very encouraging and will greatly help in breaking down barriers to patient access. With Semglee®, we will be able to

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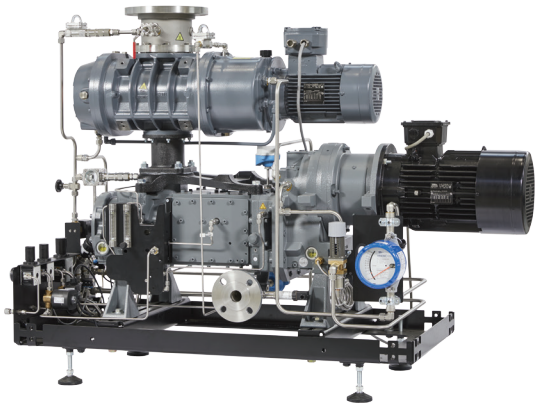

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offer people living with diabetes in the U.S. more treatment options, rationalize cost of therapy and generate savings for the overall healthcare system."

Sun Pharma Receives DCGI Approval for Molxvir® (Molnupiravir) in India

Kirti Ganorkar, CEO (India Business), Sun Pharma Industries Ltd

Mumbai, India: Sun Pharmaceutical Industries Limited and its subsidiaries and/or associate companies announced that one of its wholly owned subsidiaries has received Emergency Use Authorization (EUA) from the Drugs Controller General of India (DCGI) to manufacture and market a generic version of MSD (a trade name of Merck & Co., Inc, Kenilworth, NJ, USA) and Ridgeback's molnupiravir under the brand name Molxvir® in India. Earlier this year, Sun Pharma had signed a nonexclusive. Voluntary licensing agreement with MSD to manufacture and supply a generic version of molnupiravir in over 100 low and middle-income countries (LMICs) including India.

The Drugs Controller General of India (DCGI), based on the review of clinical data of molnupiravir has approved molnupiravir for treatment of adult patients with Covid-19, with SpO2 > 93% and who have high risk of progression of the disease including hospitalisation or death.

"Molnupiravir is an important addition to the portfolio of oral therapies available for treating Covid-19 patients," said Kirti Ganorkar, CEO of India Business, Sun Pharma. "In line with our consistent efforts to accelerate access to new drugs for Covid-19 treatment, we will make Molxvir® available to patients at an affordable price. We are also in the process of launching a toll-free helpline to ensure the availability of Molxvir® to doctors and patients across India. Our endeavour is to make the product available in a week's time."

The recommended dose of the drug is 800 mg twice a day for five days. The duration of treatment of molnupiravir is much shorter compared to other therapies which is a significant advantage as it reduces the pill burden and enhances compliance. Molnupiravir has been developed by MSD and Ridgeback Biotherapeutics. It has been approved by the U.S. Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) for Emergency Use Authorization (EUA). Molxvir® is a registered trade mark of Sun Pharma.

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Yokogawa Enters into Capital and Business Alliance with GlyTech, Inc a Leader in the Application of Glycan Technologies

Tokyo, Japan: Yokogawa Electric Corporation announces that it has invested in GlyTech, Inc., a Kyoto- based company with leading-edge technologies in the synthesis of glycans, which influence cell metabolism and functional changes. The companies will partner with the aim of establishing biosynthesis processes that utilize the structures of glycans and molecules, and building a platform to optimize biopharmaceutical production.

There are high expectations for the future of biopharmaceuticals due to their high efficacy and reduced risk of side effects in comparison to traditional small molecule drugs. A variety of technologies are needed for their development and commercialization, and one of these is technology that enables the high-level control of glycan structure. Glycans perform a variety of functions that include cell-cell interaction and recognition, and play a role in the development of therapeutics for the treatment of a range of medical conditions. As such, it is expected that new biopharmaceuticals will be developed and commercialized and the market will grow if progress can be made in the analysis of glycan functions and in the design, synthesis, and production of glycans for specific applications.

GlyTech is a venture company that has constructed a library of glycans with complex and diverse patterns and structures, and possesses technology for the addition of characterized glycans to biopharmaceuticals that rely on glycoproteins as their active ingredient. In addition to increasing the functionality of glycoproteins, the company has been successful in the production of high purity glycans. By combining this with Yokogawa's abundant know-how and proven track record with quality control, manufacturing execution, and productivity improvement in pharmaceutical plants, the companies look to maximize synergy and accurately control the structure of difficult-to-handle glycans, thus contributing to the quality and stable supply of biopharmaceuticals.

GlyTech CEO Hiroaki Asai says, "For the development of biopharmaceuticals, it is extremely important to control the structure of glycans. However, advanced knowledge and technology are required for the flexible design of glycan number, position, and structure and the rigorous implementation of quality management and maintenance in line with regulatory standards. By working closely with Yokogawa to hold down biopharmaceutical development costs and improve production efficiency, I hope that we will see broad growth in the adoption of innovative biopharmaceutical products."

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Email: **vp@horizonpolymers.com**

Glenmark Pharmaceuticals receives ANDA approval for Bisoprolol Fumarate and Hydrochlorothiazide Tablets

Mumbai, India: Glenmark Pharmaceuticals Inc., USA (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Bisoprolol Fumarate and Hydrochlorothiazide Tablets USP, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg, the generic version of Ziac®1 Tablets, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg, of Teva Branded Pharmaceutical Products R&D, Inc. According to IQVIATM sales data for the 12 month period ending November 2021, the Ziac® Tablets, 2.5 mg/6.25 mg, 5 mg/6.25 mg, and 10 mg/6.25 mg market2 achieved annual sales of approximately $30.3 million.

Glenmark's current portfolio consists of 172 products authorized for distribution in the U.S. marketplace and 46 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

Dedicated National R&D Policy to bolster Indian Pharma Sector

Dubai: The India Pavilion at EXPO2020 Dubai hosted a roundtable, 'India – Pharmacy of the world' as part of the ongoing Health & Wellness week, wherein several government and industry experts discussed the key focus areas including regulatory reforms, pharma exports, ease of doing business, R&D financing mechanisms and clinical trial scenario in India.

In his virtual address, N Yuvraj, Joint Secretary (Policy, Medical Device, Pharma Bureau), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India (GoI) said, "The current valuation of the Indian pharma industry is USD 41 billion, which has the potential to grow up to USD 130 billion by 2030. There is a strong potential for further growth for the industry, but it should be in a holistic manner from across the value chain."

Guerbet in India and 100 Years & Beyond of Lipiodol

Mumbai, India: Guerbet, a global leader in medical imaging, hosted its first India virtual media roundtable, titled 'Guerbet in India and 100 Years & Beyond of Lipiodol.'

Lipiodol is internationally recognized as one of the foremost ethiodized oil that has transformed lives and contributed to huge advances in the treatment of major diseases and debilitating conditions. In India, the drug has been used in fighting liver cancer and disease for decades and continues to make contributions to the management of various diseases.

Lipiodol is a pale yellow/amber-coloured, oil-based, radiopaque contrast agent consisting of iodine that is organically combined with ethyl esters of fatty acids of poppy seed oil. It was first synthesized in

Separation by design

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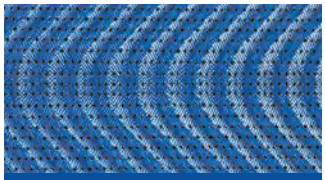

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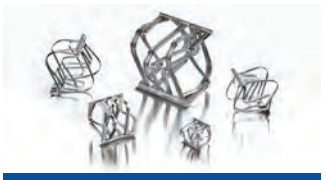

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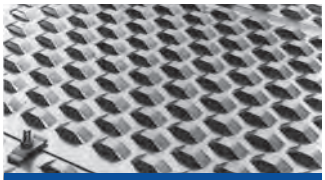

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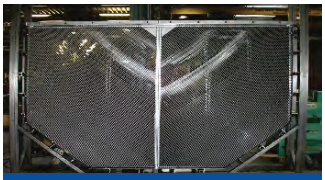

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1901 by French pharmacist Marcel Guerbet initially for therapeutic use. Then in 1921 Lipiodol® (ethiodized oil) was discovered for the use of radiology, till date this injection is a prescription oil-based radio-opaque contrast agent indicated for conventional trans-arterial chemo-embolization (cTACE), diagnosis liver lesions, vascular embolization with medical cyanoacrylate glues, lymphography and endocrinology in adult as well as pediatric patients.

In attendance were Dr. Sanjay Saran Baijal, Chairman of Diagnostics & Interventional Radiology at the Medanta – The Medicity, Dr. Vimal Someshwar, Head of Department, Intervention & Diagnostic Radiology, at the Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Ghosh TP, General Manager, India at Guerbet and Mathieu Elie, Chief Commercial Officer (CCO), Asia Pacific at Guerbet. The panellists discussed Lipiodol's effect on disease management across India and beyond, and its use and future application in the country.

Hester Biosciences Limited Q3 and 9M FY22 Results

Ahmedabad, India: Hester Biosciences Limited announced the financial results of Q3 and 9M of FY 2021-22. The company achieved an improved operational and financial performance in the period as compared to the corresponding period last year.

The company is constantly investing in geographical market expansion and manpower to achieve the budgeted top-line along with expanding the existing

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Rajiv Gandhi, CEO & Managing Director at Hester Biosciences Limited

production capacity, a part of which, will be ready from the next quarter.

Domestic sales have registered a growth of 3% in Q3 FY22, and 24% in 9M FY22. Exports have increased by 88% in Q3 FY22 and 14% in 9M FY22. Overall, the sales grew by 2% in Q3 FY22, and 16% in 9M FY22, as compared to the corresponding period(s).

The revenue during the corresponding previous quarter (Q3 FY21) included a one-time license fee and services of INR 3.31Crore against which there is no income in the current year. This has an impact of 6% on margins during that period. Overall, the sales of vaccines have remained the same in Q3 FY22, but have registered a growth of 16% in 9M FY22. Last year around Q2, Q3 and Q4, there were major disease outbreaks in the poultry industry which led to a spurt in the demand for poultry vaccines. While our vaccines kept the poultry industry immunised from the disease in the last financial year, the over-all poultry health situation has been better this year, thereby registering a normal growth.

The sales of health products have registered a growth of 42% in Q3 FY22 and 49% in 9M FY22. On the account of COVID restrictions during Q3,there was a reduction in the expenses for traveling and conveyance, which has contributed for better margins in that period. ■

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AI Revolutionizing the Diagnostics Industry

Rashi Gupta
CMD-Interlink
Chief Data Scientist and Co-Founder, Rezo.ai.

In current times, Artificial intelligence (AI) is a kind of technology that not only encourages healthier behavior in individuals but also helps with the proactive management of a healthy lifestyle. It puts consumers in charge of their health and well-being. AI has not left any stone unturned to simplify the lives of patients, doctors, and hospital administrators by performing tasks that are done by humans, but in less time and a cost-effective manner. It is efficiently used to diagnose and reduce human errors. Artificial intelligence is reinventing and reinvigorating modern healthcare through machines that can precisely predict, comprehend, memorize and act. AI in healthcare could include tasks that range from simple to complex, everything from answering the phone to medical record review, population health trending and analytics, therapeutic drug and device design, reading radiology images, making clinical diagnoses and treatment plans,

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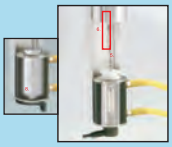
Viscosity Standards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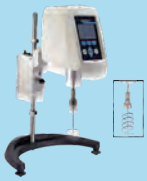
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RHEOLOGY VISCOSITY TEXTURE IN-LINE POWDER MOISTURE GAS

and even talking with patients is made possible by deploying AI through varied modes.

Innovative use-cases of AI in the diagnostics industry:

Artificial Intelligence in Pathology

Path AI is developing machine learning technology to assist pathologists in making accurate diagnoses. In 2015, misdiagnosing illness and a medical error accounted for 10% of total deaths in the US. Incomplete medical histories and volumes of caseloads can lead to serious human errors. Immune to those variables, AI is capable of predicting and diagnosing the disease at an amplified rate than most medical professionals. Other than this, the promise of improving the diagnostic process is one of AI's most exciting healthcare applications across the globe. In a study, it was revealed, an AI model using deep learning diagnosed breast cancer at a higher rate than 11 pathologists.

AI - an intelligent symptom checker

An AI-based symptom and cure checker uses algorithms to diagnose and treat illness. It works with a conversational AI chatbot that listens to a patient's symptoms and health concerns and guides that patient to the correct care based on its diagnosis. In case of an emergency, it can treat patients more quickly avoiding the severity.

AI in hospital administrative applications

There are numerous administrative applications for artificial intelligence in healthcare. Artificial intelligence in hospital administrative areas can prove substantial efficiencies. AI in healthcare can be used for applications like insurance claims processing, clinical documentation, revenue cycle management, and medical records management. Moreover, it also divides the workload of the service providers by Documenting chart notes and patient summaries, writing testing orders and prescriptions, and a few similar responsibilities. AI shows promise in making providers more productive by eliminating these types of manual tasks. It is estimated that by using AI, administrative workflow assistance can result in 51% of time savings for nurses and 17% for physicians which in turn can be utilized for patient care.

Medical AI scheduling software

Healthcare scheduling software allows the clinics and medical practitioners to coordinate an appointment, altering staff scheduling, task delegation, and prioritization. As the appointments are scheduled, canceled, extended, or rescheduled, workflows within the

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organization can automatically adjust to optimize efficiency using online appointment booking portals. Adjusting with the changing demand, schedules can be reframed considering optimal use of time. This can also be used in managing staff shifts or task allocation to the team, which can be accessed from all internet-capable devices while leveraging up-to-date information to everyone in the organization.

Conversational AI chatbots for patient engagement and information retrieval

AI chatbots are programs that simulate human-like conversations using natural language processing (NLP). It enables chatbots to mimic human conversation. They can identify the underlying intent behind the text a real person types, then deliver a response that matches that intent enhancing patient engagement. Also, chatbots can extract patient information using simple questions such as name, address, symptoms, current doctor, and insurance details. Chatbots then store this information in the medical facility system to facilitate patient admission, symptom tracking, doctor-patient communication, and medical record keeping.

Benefits of AI in virtual patient assistance 24/7

The ability of the AI to have asynchronous conversations round-the-clock, where the user can leave and return later to the conversation as per their time availability. The advancements in healthcare have led to an increased ability to handle larger call volumes and deliver a more consistent experience than live agents. AI has played a significant role in developing personalized health plans to deflect complex inquiries to lower-cost, self-service channels that can reduce average handle time and thus, substantially decrease the total handled call volume of call center agents through 'agent assist' functionality. By automating routine customer interactions intelligently with NPL has empowered customers & reduced costs. Health plans can also use AI to proactively detect and manage frauds. Online patient portals provide a personalized experience for patients by addressing the complexities of patients' journeys and healthcare benefits that they can draw. AI also further assists patients' needs with regular notifications and follow-ups to consistently remind them about the virtual care offered.

Post-COVID care and vaccination

To realize the full promise of AI to combat COVID-19, policymakers must ensure that AI systems are trustworthy and aligned. AI has helped in Understanding the virus and accelerating medical research on drugs and treatments, detecting and diagnosing the virus, and predicting its evolution,

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assisting in preventing or slowing the virus' spread through surveillance and contact tracing, responding to the health crisis through personalized information, and learning to monitor the recovery and improving early warning tools. AI has advantages for COVID-19 vaccine rollout. Healthcare organizations can harness machine learning to schedule vaccines, streamline patient communications, and even prioritize access.

AI-Driven therapy and counseling

AI can be utilized to find patterns that may help in unlocking why people develop mental illness, who responds best to certain treatments, and who may need help immediately. Using new data combined with AI will likely help us unlock the potential of creating new personalized and even preventive treatments. Artificial intelligence could be an approach used in individual counseling as soon as it would be convenient, encourage more people to seek help for their mental disorders as it's more seclusive, and it would store more data. The IoT-based wearable devices connected to the internet using Bluetooth or Wi-Fi can be useful in fetching patient data. AI can assist physicians to make better clinical decisions or even replace human judgment in certain functional areas of healthcare, for instance, radiology. The increasing availability of healthcare data and rapid development of big data analytic methods have made possible the recent successful applications of AI in healthcare.

Therefore, in the foreseeable future, AI is long term cost savings for both patients and medical care providers. It can make healthcare both efficient and affordable as it helps in guiding treatment choice, making more efficient diagnoses, helping the patients make better decisions regarding their health, and making important decisions in drug development. It will improve the speed and accuracy of healthcare services, resulting in better care outcomes for patients, improved productivity, and efficiency of care delivery. ■

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How Compressed Air Plays a Crucial Role in the Pharmaceutical Industry

Deepak Pahwa
Director, Delair

As per the Indian Pharmaceuticals Industry report, India holds the 3rd position across the world in pharmaceutical production. The domestic pharmaceutical industry has a network of around 10,500 manufacturing units, with 3,000 drug companies in India. With such broad horizons, there has been a debate that not only large companies, but smaller firms also need to comply with the uncompromised quality of the products. With such a large market share at stake, pharma manufacturers must uphold the highest of standards.

There are several processes involved in the manufacturing of pharmaceutical products where dry compressed air is used in a wide range of production activities. From the creation of medicine formulas to the manufacturing of the final product, quality compressed air is required at every step. Even the Food and Drug Administration (FDA) recommends the use of air compressors to ensure the production of high-quality end products that complies with the industry standards. It would not be wrong to say that air compressors

power a wide range of pharmaceutical applications.

The manufacturing of tablets and capsules involves pneumatic processes, where dry compressed air plays a key role in the mixing of ingredients, granulation, drying, pressing, and various levels of coating to give the required texture, colour, and flavour to the tablet. Likewise, in the manufacturing of liquid medicines, it monitors the balance of ingredients, purification of contaminants, and exact measurement of each formula. It is equally required for the manufacturing of ointments, creams, gels, and syrups.

But just focusing on manufacturing and not paying attention to the packaging can account for a wasteful endeavour. In packaging, compressed air aids in the cleaning and removal of the moisture from the bottles, tubes, or cans to avoid any risk of contamination and increase the shelf life of the product. Moreover, the bottles and cartons required for the shipping and distribution of medicines to the retail outlets are manufactured with the help of pneumatic machines that takes care of cutting, folding, printing, and packaging.

Being crucial to a wide range of intricate processes, it is important to ensure quality compressed air supply. Contaminants of any form like the presence of water/ moisture, dust particles, oil, and solid contaminants in the compressed air systems can adversely affect the air quality which can lead to substandard products.

The pharmaceutical products are highly hygroscopic. They tend to absorb the moisture in the compressed air and undergo physical, enzymatic, microbiological, and biochemical deterioration. This can acutely change the colour of the tablet coating and can even lead to certain chemical reactions. The moisture even causes blisters and breakage of the tablets. In addition to this, moisture-laden compressed air is responsible for the malfunctioning of pneumatic tools and machines. It can account for sluggish and inconsistent valves and cylinder operations. There are high chances of corrosion in pipelines, cylinders, and other components. During winters, there is another concern of freezing in exposed lines. Altogether, moisture can play havoc increase the downtime of the machines and also elevate the maintenance cost of pneumatic machines, tools, or controls.

Therefore, to counter the menace of moisture in compressed air, it is important to deploy efficient dryers for **compressed air treatment in the manufacturing and packaging units of pharmaceutical**

Desiccant Dryer for Pharmaceutical Industry

processes. **Delair,** a company that deals in end-to-end Compressed Air Treatment offer a wide range of refrigeration and desiccant/ adsorption dryers. Both types of dryers entertain the same result but they differ in their principles of drying depending on the specific demand of the particular process.

The refrigeration method is used in processes where the air requirement is between 3° and 6° PDP. In this method of drying the air is cooled down to a nearly freezing point which removes the moisture followed by reheating the air to approximately 10° Celsius below the incoming compressed air at nominal conditions. On the other hand, adsorption or desiccant drying is deployed for extra dry air to achieve PDP below 2° Celsius. It works on the principle of heatless regeneration where the desiccant is employed to adsorb and desorb the water vapour. It delves on the pressure swing principle/purges air to regenerate the desiccant bed.

Therefore, to meet the pharmaceutical air standard, it is imperative to install compressed air-drying systems to avoid any sort of contaminations or disruptions and also ensure the proper functioning of the pneumatic machines. ■

Pharma 4.0: Driving Digitalization in Pharmaceutical Manufacturing

TIYO Kok Fong
Market Manager – Pharmaceuticals & Healthcare,
Asia Pacific, Veolia Water Technologies

Digitalization has driven rapid transformation across many industries, but it has long eluded the pharmaceutical manufacturing sector. Compared to other industries, pharmaceutical and biotech companies have traditionally adopted emerging technologies at a slower pace due to heavy regulations, strong intellectual property constraints, and a well-known conservative culture. However, rapid business environment changes in recent times have driven many in the sector to digitalize their processes.

The Search for the Right Digital Solutions

Many pharmaceutical manufacturers are now looking to move away from traditional decision-making processes, break down organizational and data silos, and to help different functions work together — all while creating better synergies within the company. In essence, the end goal is to help manufacturers improve production flexibility and reduce operational costs and risks, which can be achieved with process analytics.

By choosing the right digital platform to integrate with existing Manufacturing Execution Systems, manufacturers can achieve paperless operations and realize quality, regulatory, operational, and data availability benefits. Such benefits include standardizing procedures, preventing human errors, reducing the need for data entry, and supporting management and manufacturing decisions through data visualizations.

Digitalizing Water Treatment Processes

One way that pharmaceutical manufacturers can effectively implement digitalization is in the area of water treatment. Given their need for a consistent flow of high-quality water, manufacturers can sometimes find water management a challenge, and tend to devote considerable resources to the development and maintenance of water treatment systems.

Compendial water and steam generation systems, as well as the associated process manufacturing controls within the system, require careful review and monitoring as seasonal fluctuations in feed water quality may impact the operation and utilization of the systems and consequently, of product quality.

With the tightening of wastewater discharge limits and the enforcement of environmental regulations in many countries across the Asia Pacific region, the treatment of wastewater (highly charged with TOC, COD, BOD, suspended matter or solvents) and removal of micropollutants before discharging the effluent has also become a key concern for the industry. Many micropollutants like Endocrine Disruptor Chemicals (EDCs) are neither biologically degradable nor absorbable, and are therefore difficult to

remove without the right technology.

Through adopting digital solutions for water management, pharmaceutical manufacturers can be better equipped to overcome daily challenges in managing their water treatment systems and meeting their compliance requirements, while improving the overall efficiency of their systems.

Smart Solutions for Better Optimization

Pharmaceutical companies can benefit from the latest technologies to improve production efficiency and reduce operating costs, without compromising the safety of processes or of product quality. Smart solutions like AQUAVISTA™ can help businesses who desire to integrate a digitalization module to their existing systems to optimize and manage utilities systems.

A cloud-based digital platform, AQUAVISTA™ supports global pharmaceutical manufacturers by optimizing their water and wastewater treatment processes. The platform enriches the users' aggregated data and offers a visualization of the digitalized data to support management and manufacturing decisions. For one industry-leading contract manufacturer in the United Kingdom specializing in handling volatile pharmaceuticals, the integration of the existing Business Management System to AQUAVISTA™ allowed them to achieve a cost-effective and efficient remote monitoring solution, conveniently accessible by multiple engineers on any device. Besides offering automatic color-coded alerts and alarms to enable faster responses to critical issues, the solution also facilitated data collection for predictive maintenance — further supporting the manufacturer in process optimization and improving overall efficiencies.

Through digitalization, pharmaceutical manufacturers can gain more meaningful insights on the treatment processes in their plants. As a result, these businesses achieve greater operational efficiency and quality compliance, while leveraging on existing human capital to bring about a shift towards improved process monitoring, analysis, and optimization. ■

Last-Mile Patient Connectivity, Data-Driven Technologies Set to Spur Growth in Pharmaceutical Packaging

Unmesh Lal
Director, Healthcare & Life Sciences Practice
Frost & Sullivan

The COVID-19 pandemic has revealed supply chain challenges in terms of meeting pandemic- induced demand and showcased weaknesses concerning facing disruptions on a global scale. Despite the manufacturing reboot, supply chain interruptions have created a ripple effect. In addition, the lack of time stamps across the supply chain and the poor tracing of the chain of custody of drugs have reduced the shelf life of existing inventory and increased wastage-related risks. Companies have introduced packaging-related innovation to overcome these challenges. Pfizer has developed reusable GPS-enabled temperature-controlled thermal shippers to maintain ultra-low temperatures. Moderna offers multiple types of packaging to ease transport and distribution, including multi-dose vials, pre-conditioned -20°C shippers, full cases, and full or partial pallets that can be deployed in any healthcare setting.

The rapid development of COVID-19 vaccines has boosted market growth, and many pharma packaging companies have been ramping up their production capacities for glass vials worldwide. For the biopharma industry, positive long-term developments and growth opportunities can outweigh the detrimental short-term impacts of the ongoing pandemic. The industry will witness increased digitalization to build more resilient supply chains to drive flexibility and transparency

across manufacturing, packaging, and documentation across the chain of custody.

Temperature-sensitive Packaging for New-generation Biologics: Products with shorter shelf lives and cold storage requirements.

There has been a continuous growth in the adoption of value-added biologic drugs that are extremely reactive in the global pharmaceutical market and often require advanced primary packaging materials with better functionalities. These products that require cold-chain handling are primarily derived from living cells and include biologics, insulin, vaccines, and CGT. The proper levels of temperature, humidity, pH, sample size, and photo exposure are critical in terms of maintaining the biological activity of the drug substance; otherwise, the high-value product can be rendered useless. Frost & Sullivan's analysis indicates that every year, the biopharma industry loses $35 billion through temperature-control failures across the supply chain.

These sensitive parenteral formulations often require value-added glass and plastic packaging materials with excellent barrier properties, transparency, durability, and drug stability during storage, transportation, and usage. Leading pharma packaging companies such as West Pharmaceutical Services, Gerresheimer AG, BD, and SCHOTT AG have started using innovative premium polymer materials. They offer superior break resistance and ensure minimal interaction with the drug, thereby ascertaining excellent quality drug stability during its shelf-life. Therefore, pharma companies increasingly prefer such materials for high-value packaging of sensitive biologics and countering the challenges of using glass syringes.

The use of active containers with internal refrigeration systems is on the rise; these are coupled with cloud-based monitoring and communication systems for shipment tracking, including vital parameters. Examples include:

- Fisher BioService's cold stations and monitoring towers.
- Cryoport's embedded monitoring devices.
- Skycell's proprietary cellular insulation material with a rechargeable phase-change material.

Additionally, single-use products have also gained popularity in biologics handling due to high capital investments and the risk of cross-contamination in sensitive biological samples. Thus, packaging companies must focus on material and cost innovation for single-use products while considering the impact on the environment.

Environmental Concerns that Demand Sustainable Packaging: Balance between

demand for single- use products and recyclable material.

Efforts to reduce the carbon footprint and waste accumulation are expected to gain momentum in developed economies during the next decade. The trend is anticipated to result in an increased focus on end-of-life analysis, circular economy, and life cycle assessment—the cradle-to-grave concept—that would influence design, production, use, disposal, and recycling of pharmaceutical packaging products particularly plastics.

Moreover, pharmaceutical companies such as Astra Zeneca, BMS, Merck, retailers, & other pharmaceutical supply chain participants have set sustainability goals. Companies are using eco- friendly packing material such as PE or PET made from sugarcane, polylactic acid, and polyolefin laminate or material made from recycled plastic. For example, post-consumer regrind over new plastic saves energy and reduces waste, which pharmaceutical companies consider.

Plastic packaging manufacturers need to increasingly focus on sourcing sustainable alternatives that can improve the recyclability of pharmaceutical plastic packaging materials. For example, Amcor plc, a leading plastic packaging company, is developing the world's first recyclable polyethylene blister packaging product, AmSky™, which, unlike traditional PVC blisters, can offer intrinsic recyclability.

Scalable Smart Packaging for Improved Health Outcomes: Packaging that supports patient adherence, reconciliation, education, and counterfeit protection.

Smart packaging aims to achieve containment, protection, and presentation of drug products with patient-specific information and medication instructions. According to Frost & Sullivan's analysis, the two significant challenges it can address are drug counterfeiting (a market that exceeds $200 billion) and medication adherence (a problem that holds the potential for massive savings). Medication reconciliation concerns can also be addressed through smart packaging. In addition to having information tracking features with embedded alarms, packaging needs to be in the form of a child- resistant but senior-friendly design. Technologies that enable these features include sensors, RFID, programmable alerts, QR codes, NFC, and integrated transmitters. Along with end-user communication, smart packaging can be integrated during the production process for product tracking during manufacturing.

Close collaboration between traditional packers, electronics manufacturers, material providers, retailers/pharmacies, and an ecosystem of innovators is required to achieve scalable and smart packaging.

As the cost of sensors and printable electronics declines, smart packaging will become increasingly affordable.

Companies must explore the immediate opportunity in clinical trial packaging as patient noncompliance (in taking doses) is a significant hindrance to successful trial outcomes. Although small-scale requirements can be met with the current setup, companies will need to simultaneously invest in technologies such as 3D printing that can facilitate scaling-up.

The Way Forward

Last-mile connectivity to patients, embedding data-driven technologies, and rising trends in outsourcing are the primary forces catalyzing growth in pharma packaging according to our analysis. The evolving pharma packaging vendor ecosystem comprises cross-industry collaborations with traditional pharmaceutical companies, contract packaging companies, and smart packaging solution vendors that leverage digital technology. Moreover, the evolving role of third-party logistics providers and cold-chain equipment vendors is disrupting the traditional pharmaceutical packaging value chain. Therefore, local manufacturing deals, supply chain investments, and packaging innovation will play essential roles in the global push for immunization and personalized medicine. ■

Technology-Based Approaches to Building Resilient Pharma Supply Chains

Gaurav Kaushik
Managing Director & CEO
Meteoric Biopharmaceuticals

The ongoing COVID-19 pandemic has not only led to severe disruptions in public health and everyday living, but has also led to a great deal of uncertainty for businesses. When it comes to businesses, it has impacted operations and exposed the frailties and vulnerabilities of supply chains across sectors. The same is true for the pharmaceuticals sector, which has always thrived on timely production, adequate inventory levels, speed-to-market, seamless distribution networks, cost-efficiencies in terms of raw material and freight costs and coordination between several key stakeholders.

In its wake, the pandemic has undoubtedly brought about several disruptions in pharma sector supply chains on a global scale. Both, demand as well as supply-side aspects of the value chain have been impacted. The key obstacles have been in terms of logistics-related impediments, a depleted workforce, the need to operate with low-contact restrictions in place and issues related to timely procurement of inputs and APIs. The unexpected surge in demand for items such as masks, PPE kits, antivirals, vaccines and others due to the pandemic has led to severe shortages and reiterated the importance of enhancing the resilience of existing supply chains within the pharma sector.

Thankfully, forward-looking businesses have been able to successfully leverage and deploy advanced technologies to enhance their supply chain resilience by several notches and wield a competitive advantage. These technologies are leading to several positive outcomes, which apart from enhancing productivity and efficiencies also include infusing intelligence in processes, enabling real-time visibility across operations, facilitating collaboration and dissemination of valuable insights and information across stakeholders, improving distribution and logistics.

Some of the ways in which technology is being leveraged to transform pharma supply chains include -

Drug Discovery & Development and Innovation in Treatment

According to a survey conducted by GlobalData in 2021, more than 70% of pharma sector respondents anticipated drug development to be the area most benefited by the implementation of smart technologies. Indeed, smart technologies like AI are being leveraged to accelerate drug discovery and to develop new innovative methods of treatment. For instance, NVIDIA launched Cambridge-1, UK's most powerful supercomputer, to help British healthcare researchers accelerate and optimize every stage of drug research. Likewise, a series of similar collaborations have also been announced with several other pharma giants. AI accelerates the drug discovery process by a million times. Multimodal AI can be deployed to process multiple sources of health data, discover patterns in diseases and open up new avenues in the prognosis and treatment of patients. Further, AI can also be harnessed for gene editing as well as gene writing to treat genetic disorders.

Industry 4.0 and Smart Manufacturing

Smart Manufacturing involves the combination of interconnected computing devices and sensors into a cohesive network that makes it possible to collect valuable data on a real-time basis, the collection of such data at a central control centre, the processing of such data with the help of algorithms and AI & ML-powered systems and the generation and dissemination of valuable insights to enable quick and critical decision-making through ERPs and other intelligent systems. Within the realm of pharmaceutical manufacturing, this could cover information such as raw materials variability, visibility of material inventory across facilities, manufacturing floor-related information such as environmental conditions, wear & tear of machinery, performance, quality checks, real-time monitoring of operations and much more.

Real-time connectedness, both within and outside the manufacturing facility, makes this a powerful tool in the hands of pharma manufacturers.

Automation of Document Management and Other Key Processes

The process of introducing new formulations and drugs involves significant volumes of documentation. These need to be recorded, reviewed and managed correctly in order to adhere to regulatory requirements. Such documentation is required at pre-clinical, clinical as well as commercialization & post-marketing stages. Automation of such documentation processes can lead to minimization of errors, expedition of approvals, faster speed-to-market, cost optimization and timely compliance with regulatory norms.

Focus on Reducing Exposure to Shocks

India and China collectively account for nearly one-third of the critical components or raw materials within the pharma sector. Expanding the existing network of suppliers is one way to combat such vulnerabilities. Companies can also seek to strike a better balance between just-in-time and just-in-case inventory levels, focus on hardening physical assets to withstand natural disasters and financially support certain essential suppliers. Besides these approaches, there are technologies available to enable quick changes among suppliers and advanced analytics to predict potential challenges better. The resulting ability to reroute components and flex production can help build robust supply chains

Digital Overhaul of Procurement Process

The procurement process has been long overdue for a major overhaul in the case of most pharmaceutical companies. The pandemic situation has provided an opportunity to enhance the risk management and cost-efficiency aspects of the function. The deployment of advanced digital technologies can help centralize decision making and bring together siloed information to gain better visibility into spends and to facilitate better cost control, spend optimization, better supplier management and even product life-cycle management. At the end of the day, such technologies can help sustain the affordability of end-products.

Transparency and Traceability Along the Supply Chain

Blockchain-powered mechanisms to track, update and authenticate the status of drugs & formulations at every stage of its otherwise unseen journey, right from

procurement of raw material to production and eventual distribution among consumers can prove to be critical in the current landscape. They can help address several objectives, including coordination among several stakeholders, inventory management, manpower requirements, order management, shelf-life of medicines, and much more. They can also enhance the process of optimizing production and storage. This not only facilitates accuracy and compliance in procurement, but also enables better coordination among stakeholders, prevents losses due to stagnation of inventory, and ensures cost-reduction, transparency and visibility.

Cold-Chain Management

Cold chain management and logistics are important aspects of the pharma sector supply chain. These help pharma companies maintain a continual stock of materials and drugs from suppliers and for distributors across locations. The shelf life and efficacy of several life-saving drugs hinge heavily on proper cold chain management, at correct temperatures and storing conditions. It is no surprise then, that the global cold chain logistics market, which was valued at around US$ 160 billion in 2018 is estimated to grow to a whopping US$ 585 billion by 2026.

The key factors for the growth of cold storage supply chain management, especially in India, are addressing regulatory issues, product proliferation and infrastructure gaps, among others. There is a need to create awareness about handling temperature-sensitive goods and bridging gaps in refrigeration equipment, warehouse & infrastructure.

New Solutions for Pharma Logistics

The pharma sector thrives on momentum when it comes to the free and seamless movement of materials and end-products across geographies. Shipping and air-cargo solutions have been the mainstay of such free movement. During the course of the pandemic, while ocean freight shippers remained active, air cargoes and even land-based inland logistics have been severely hampered at various junctures due to restrictions. One of the solutions that have emerged to overcome this problem is the introduction of pharma-centric dedicated logistics services by air cargo companies and airlines (e.g., Etihad's PharmaLife service). Likewise, Health Departments of some economies have created consortiums featuring key freight forwarding agencies to facilitate an effective and sustained distribution network for vaccines and other pharma products (e.g., Abu Dhabi Dept. of Health's HOPE Consortium which features freight forwarding leaders such as Aramex, DB Schenker, DHL, FedEx, UPS and many more).

Deployment of Simulation Systems

Simulators are emerging as powerful supply chain planning tools, which provide comparative analytics for various scenarios. These can lead to better decisions such as selecting right alternative sources to meet demand at minimal cost increase, deciding which plant overloading capacity is optimal, determining freight costs, calculating lead times, and much more.

Contract Manufacturing

The pandemic forced several pharmaceutical companies to lean towards contract manufacturing so as to continue providing quality products to their customers in a cost-effective manner. The rapid growth of contract manufacturing can be gauged from the fact that it grew from US$ 935 billion in 2017 to at least US$ 1.2 trillion by 2021. Even as the world gradually marches towards normalcy, many pharma companies are continuing their reliance on contract manufacturing so they can focus on other key aspects of their business. Such an approach helps them increase their overall productivity and efficiency and enhance their margins. Partnering with local manufacturers can also help address speed-to-market objectives.

The Way Forward

Although the pandemic has exposed several chinks in the global pharma supply chain, it has also led to a reality check and provided an opportunity for course correction. The pharma sector will do well to invest in and leverage advanced and smart technologies to reinforce their supply chains and deliver superior outcomes, even in the face of headwinds and general uncertainty. The health, not just of the sector, but also of the human race, will rest in safe hands if these priorities are systematically addressed before the next black swan event rears its ugly head. ■

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‘Upscaling Tech Infrastructure & Validating Robustness of Systems’

Saransh Chaudhary
President, Global Critical Care, Venus Remedies & CEO
Venus Medicine Research Centre (VMRC)

How has the pandemic shaped Venus Remedies stance in the market as a mega Indian Pharmaceutical Research Company?

The pandemic has unleashed an opportunity for the Indian pharmaceutical industry to play an even more important role in global healthcare.

At Venus Remedies, the pandemic tested our manufacturing prowess and supply chain stability with an unprecedented surge in demand for key life-saving drugs. By upscaling our tech infrastructure and validating the robustness of our systems, we kept up with the orders and ensured timely supplies. Faced with an acute shortage of active pharmaceutical ingredients (APIs) from China, we again came out triumphant by leveraging our relationships with long-associated suppliers to secure them. Saving lives was all that mattered, and it demanded an exceptional effort and agility. We decided to incur hefty logistical costs by airlifting key APIs in order to ensure consistent

supplies of drugs during the second COVID wave.

While we have been able to grow significantly over the past two years, we have barely just scratched the surface in terms of our potential and future plans.

How far has Venus Remedies mirrored the market demand and its responses from target customers?

Over the years, Venus established an entrenched presence in the domestic market. The marketing team has, through its consistent efforts, established considerable brand recall among doctors and patients. The company's strategic alliances with leading pharma companies have enabled it to establish a strong presence in more than 75 nations globally, a majority of which are developing nations.

In tune with the rising demand for self-care products, we also launched our consumer healthcare division with the introduction of a nanotechnology-based natural pain management solution called R3SET. We plan to introduce many other disruptive consumer healthcare products over the next five years, covering pain management, gastroenterology, hygiene, stress management and health supplements. Considering the vast potential of self-care through OTC products, we are using digital tools optimally to empower our consumers with health literacy and enable them to achieve better health outcomes through self-care solutions.

With an eye on widening our reach to cater to the growing demand for various products, we have strengthened our redistribution system by building on distribution channel partners. This has helped us improve the availability of products to end-consumers.

Understanding the current market scope and scenario, what are your strategies for expansion in the near future?

We are looking to enhance our share in key global markets. As part of our product strategy, we will alter our product mix to improve profitability and compete with big global players.

We will continue to focus on antibiotics and consumer healthcare products. We will leverage novel technologies that enhance the safety and efficacy of existing antibiotics.

Our goal is to enrich our company's product basket with complex products that help it stand out of the competitive clutter. Our main focus is on value creation. Rather than developing 20 drugs which have flooded the market, we will work on five and be the best in class in them. We want to replace low-margin products with high-value ones. While in the domestic market we will build on institutional business from hospitals and government agencies, we

will extend our global footprint by filing dossiers in key markets for new products and participating in more tenders.

Coming to optimization of our organizational leverage, we believe that human capital holds the key to wealth creation through constant value addition and improvisation. Over the next five years, attracting the best talent to the company remains a key priority. Astute capital investment is also one of our top strategic priorities.

How have you leveraged digital assets for optimizing your reach in integrated care?

At the forefront of technology, Venus Remedies has a comprehensive software system for a pan-India antimicrobial resistance (AMR) surveillance program. Implemented through a vast network of 150 centres across 15 states, including hospitals and research institutes, for data collection and analysis, it has mapped emerging AMR patterns for over 40 antibiotics/combinations for close to 25,000 bacterial strains, which has immensely helped physicians take informed decisions on designing therapy.

We are also taking to e-detailing in our critical care segments. E-detailing will allow the use of tablets instead of printed literature, thus reducing carbon footprint. It will also help enhance the delivery of key scientific content to healthcare providers.

What are some of your major patented research products targeting Antimicrobial Resistance?

As one of India's leading research-driven pharmaceutical firms, we have been relentlessly working on our mission to cater to unmet medical needs in critical care segments like AMR by developing innovative solutions. We recognize the imminent threat posed by AMR and have been working in this area for over a decade.

While our flagship research product Elores, which is under patent protection in 44 countries, has already helped millions of patients, bacteria are becoming increasingly resistant to most last-line antibiotics. As a result, we have been working constantly to develop a platform technology called Renal Guard that aims to significantly reduce nephrotoxicity associated with polymyxin antibiotics. Renal Guard is a platform technology and our first drug candidate, VRP-034, is poised to enter human trials in 2022. ■

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