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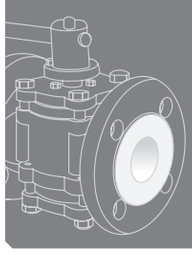

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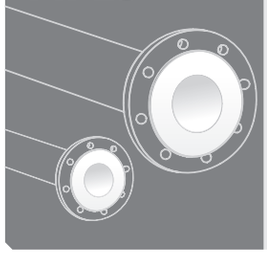

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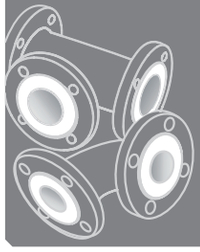

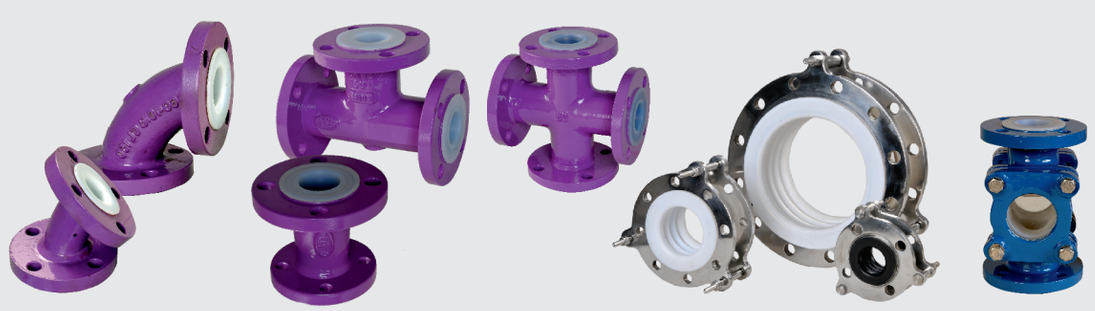

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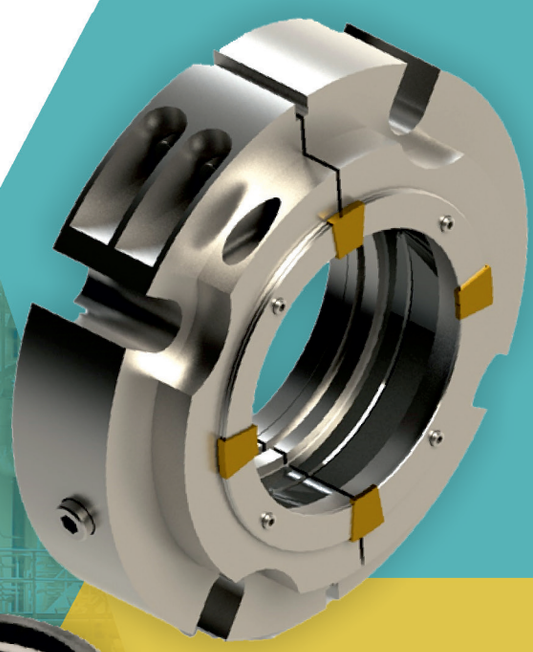

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India's Generic drug prescription mandate faces challenges: Fitch

Mumbai, India: New Indian government guidelines mandating physicians prescribe only generic drug names face execution challenges and an immediate impact on pharma companies' profitability in the domestic market is unlikely, says Fitch Ratings. The ratings stated that domestic pharmaceutical market is mainly a 'branded generics' market in which pharma companies sell off-patented drugs under their own brand names with varying prices among competitors. Branding and marketing activities remain important in pharma companies' sales strategy, considering less stringent quality and testing standards than other regulated markets such as the US. Pharma companies employ sizeable sales teams in India as part of their outreach to physicians who are the primary decision-makers amid low insurance coverage.

"Presence in the domestic pharmaceutical market aids the credit profiles of most of the leading Indian pharma companies, considering the healthy long-term growth potential, adequate profitability and the diversification benefit. A sizeable erosion in branded generics sales share will affect Indian pharma companies' profitability, as sharply lower average prices will outweigh potential benefits from lower marketing costs. Even so, we think the new guidelines are unlikely to trigger an immediate shift away from branded generics," stated Fitch. Fitch believe the implementation faces practical challenges, as India's less stringent drug quality norms may lead to variability in drug quality and efficacy among various manufacturers. The mandate may shift the decision-making process about the choice of drug manufacturer from physicians to pharmacists who may not be adequately qualified or lack alignment with the interests of patient safety and drug efficacy. A national association of Indian physicians has already requested the government defer the new guidelines, citing the challenges it will pose on physicians in ensuring patient safety and treatment efficacy.

.Glenmark Pharma to divest 75 per cent in Glenmark Life Sciences to Nirma for ₹ 5,651 crore

Mumbai, India: Glenmark Pharmaceuticals Limited, a research-led, integrated, global pharmaceutical company has entered into a definitive agreement with Nirma Limited to divest 75% stake in its subsidiary, Glenmark Life Sciences Limited, at a price of ₹ 615/- per share for an aggregate consideration of ₹ 5,651 crore, subject to closing adjustments. Glenmark Pharma own 7.84% in GLS after the divestment. The transaction is subject to customary closing conditions precedent, including receipt of regulatory and shareholder approvals. Pursuant to the transaction, Nirma Limited will make a mandatory open offer to all public shareholders of GLS.

Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals Ltd

Commenting on the divestment, Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals Limited said, "We are pleased to announce this strategic transaction with Nirma Limited, which marks a significant milestone in shaping an independent growth trajectory for GLS. This deal aligns with our strategic intent of moving up the value chain to become an innovative/brand ledorganization, with continuous focus on our core therapeutic areas of dermatology, respiratory and oncology. It also presents an opportunity for us to strengthen shareholder value through deleveraging and enhancing our overall return profile."

Speaking on the announcement, Dr. Yasir Rawjee, Managing Director and CEO, Glenmark Life Sciences Limited said, "Today's announcement marks the next step in the journey of the company, one that will accelerate growth and help create more value for our stakeholders in the long term. We will continue to operate as an independent API company under the new ownership of Nirma Limited. I see this as an opportunity to further strengthen our position in the API industry and continue the growth trajectory." Glenmark Pharma will continue to focus on consistent growth across its key markets whilst having a strong emphasis on return ratios with net cash positive balance sheet, ultimately creating value for its shareholders.

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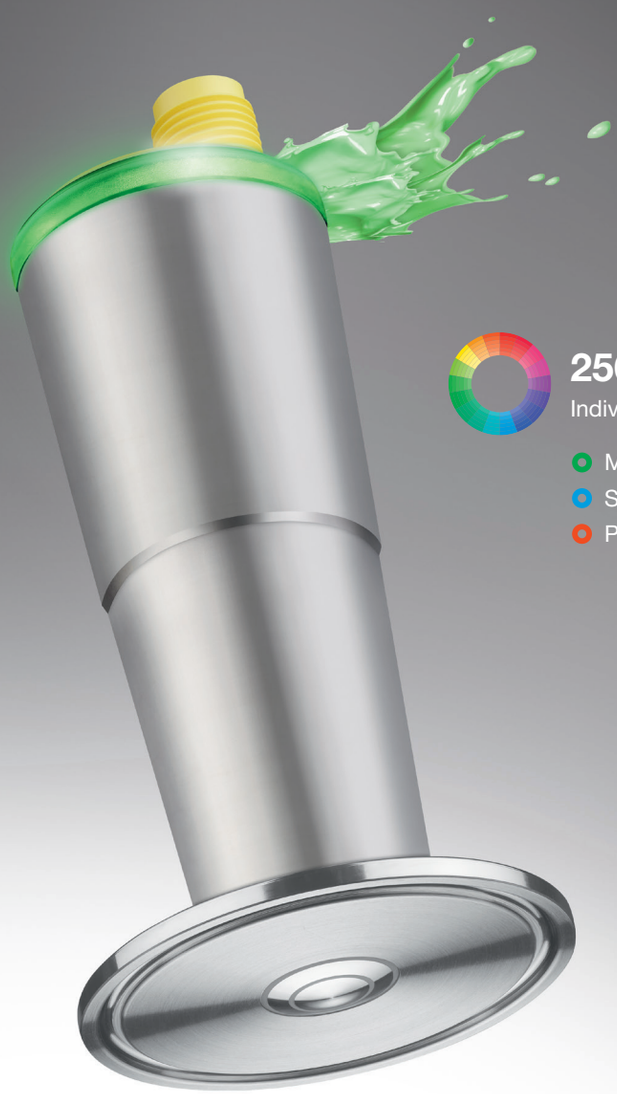

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Looking Forward VEGA

Biocon acquires Eywa Pharma's New Jersey facility for USD 7.7 million

Bengaluru, India: Biocon Limited, an innovation-led global biopharmaceutical company, announced that its step-down, wholly-owned subsidiary, Biocon Generics Inc., has acquired Eywa Pharma Inc.'s oral solid dosage manufacturing facility, located in Cranbury, New Jersey, U.S., effective 1st September, 2023. The facility is acquired for a total consideration of USD 7.7 million. As part of the acquisition, the existing workforce of the facility will transition to Biocon Generics Inc. The facility has a potential for capacity expansion up to 2 billion tablets/capsules per year. Siddharth Mittal, Managing Director and CEO, Biocon Limited said, "The acquisition of this US FDA approved facility, our first in the U.S., will complement Biocon's existing manufacturing capabilities and strengthen our foothold in the United States. The acquisition will also enable us to add oral solid dosage capacities for new products earlier than originally planned and ensure continuity of supply through the diversification of our manufacturing infrastructure. Our focus will be on integrating the acquired facility expeditiously and expanding our portfolio in the region."

Venus Remedies gets Saudi marketing approval for Enoxaparin in pre-filled syringes

Saransh Chaudhary, President, Global Critical Care, Venus Remedies

Mumbai, India: Venus Remedies Ltd, a leading exporter of affordable generic drugs with presence in more than 80 countries, has received marketing approval from Saudi Arabia, the largest pharmaceutical market in the Gulf Cooperation Council (GCC) region, for its product Enoxaparin in pre-filled syringes. Venus Remedies has an annual capacity of producing more than 5 million units of Enoxaparin, a widely used anticoagulant that prevents blood clots, at its robotic line. Having secured marketing authorisations from Saudi Arabia for six antibiotics meant for intensive care units and three oncology products, Venus Remedies has so far sold more than 12 million units of drugs in the $7.8-billion Saudi Arabian pharmaceutical market (as in 2021), which is expected to grow to USD 13.1 billion by 2031 at a 10-year CAGR of 5.4 per cent. The marketing approval for Enoxaparin from Saudi Arabia, the leading country in the Gulf region in terms of quality benchmarks as well, is expected to soon pave the way for grant of marketing authorisations to Venus Remedies for the drug from other countries in GCC and Middle East and North Africa (MENA) regions where the submissions have already been made and consider the Saudi Food and Drug Authority (SFDA) as a reference authority. Enoxaparin plays a crucial role in addressing the grave concern of blood clot formation in patients suffering from deep-vein thrombosis, acute coronary syndrome, heart attacks and pulmonary embolism. Cardiovascular diseases are a major health issue In Saudi Arabia, which account for 145 deaths per 1 lakh population, highlighting the urgent need to mitigate clot-related complications.

Hailing the achievement, Saransh Chaudhary, President, Global Critical Care, Venus Remedies Ltd, said, "The approval of Enoxaparin in pre-filled syringes is not merely an addition to our product portfolio; it's a pivotal component of our FY26 strategic vision. Enoxaparin's approval fortifies our commitment to innovation and our focus on PFS solutions, optimizing patient convenience and safety. Already established as a leading supplier of crucial antibiotic products in Saudi Arabia, this approval positions us to further anchor our leadership, expand our influence, and magnify our impact across the GCC and MENA regions." Saransh also indicated that Venus is awaiting marketing approval from Saudi Arabia for another six-seven oncology drugs anytime soon. These additional approvals will enable the company to build a high-value portfolio of soon-to-be off-patent products in the GCC region. Venus Remedies Executive Director Akshansh Chaudhary said this major milestone would not only help the company reach new markets, but also strengthen its reputation as a trusted provider of high-quality medicines. "Among the world's top 10 fixed-dosage injectable manufacturers, Venus Remedies will make the most of this opportunity," he said.He further highlighted that the marketing authorisation for Enoxaparin from Saudi Arabia comes as an evident outcome of the Good Manufacturing Practices (GMP) certification granted to the company by the SFDA for all its production facilities at its unit in Baddi, Himachal Pradesh six months ago. The first-time approval from SFDA for pre-filled Enoxaparin syringes and general injection facilities followed a stringent inspection and extensive audit of the company's facilities.

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Cipla Medpro South Africa to acquire Actor Pharma (Pty) Ltd

South Africa, India : Cipla South Africa, a 100% owned subsidiary of Cipla Limited signed a binding term sheet with Actor Holdings (Pty) Limited to acquire 100% of the issued ordinary shares of Actor Pharma (Pty) Limited. This development underpins Cipla's commitment and investment in its over the counter (OTC) business and supports its journey to be a leading healthcare player in South Africa. This is a strategic acquisition for Cipla South Africa to unlock the future growth opportunities and leverage cost synergies in the South African market. Actor was founded in 2009 and has quickly grown to become the 5th largest, privately owned, OTC player in the South African private market. Actor specializes in OTC and generic medicine, where they have established strong consumer brands, and identified niche prescription markets in categories of Women's health, Nasal, Cough & Cold and Baby & Child. In addition, Actor has an exciting and innovative pipeline and in its last financial year (FY23) delivered revenue of R234 million, on the back of strong double-digit growth. Commenting on the acquisition, Umang Vohra, Global MD & CEO, Cipla Limited said, "This is in line with our strategy of strengthening our OTC and wellness portfolio. We believe this is an excellent opportunity to leverage our existing marketing capabilities, unlock future growth opportunities and optimize the performance of our pipeline". Paul Miller, CEO, Cipla South Africa said, "This is a unique opportunity that helps to build Cipla's OTC portfolio, providing the business with a more balanced revenue contribution between the prescription and over-the-counter business and continue to provide additional quality medicines for consumers". Lynton Lomas, shareholder of Actor said, "We are delighted to transact with a company of Cipla's stature. With the focussed approach of their commercial team, we are excited to see Actor grow from strength to strength in future". The transaction is expected to close in the next three to four months, subject to the negotiation and signing of the definitive transaction agreements (which are expected to be concluded imminently) as well as receiving regulatory approval from South Africa's Competition Commission.

IndiaRF to acquire API and CRAMS business of Ind-Swift Laboratories

Mumbai, India: The Board of Directors of Ind-Swift Laboratories Limited on September 6th 2023 approved a business transfer of its active pharmaceutical ingredients ("API") and contract research and manufacturing services ("CRAMS") business to Synthimed Labs Private Limited ("Synthimed"), a portfolio company of India Resurgence Fund. IndiaRF, a leading Indiafocused investment platform promoted by Piramal Enterprises Limited and Bain Capital, will acquire the business for a consideration of ₹. 1,650 crores.

Ind-Swift is amongst the top ten independent merchant API businesses in India in size, with two manufacturing sites in Punjab and Jammu, and a combined reactor capacity of ~700 KL catering to both regulated and unregulated markets. The API business has strong market and cost position with diverse therapeutic presence across the US, Japan, Korea, EU, Brazil and India. Ind-Swift reported a consolidated revenue of ₹ 1,207 Cr and consolidated EBITDA of ₹ 256 Cr in FY23. Shareholder and regulatory approvals are required for the completion of the transaction. Synthimed will also acquire an intermediate manufacturing facility from the promoter group.

N R Munjal, Chairman and Managing Director of Ind-Swift on this occasion said "Ind-Swift is amongst the largest independent API players in India and has had the track recording of developing API molecules with customer centric approach and has created high quality facilities. We are delighted that IndiaRF, which has a pedigree and track record in transforming businesses across varied sectors, will support and invest in the growth of the business. We are grateful to our team and wish them the best to scale the business to newer heights under the IndiaRF's stewardship."

Zydus receives final approval from USFDA for Zinc Sulfate Injection

Ahmedabad, India: Zydus Lifesciences Limited stated that it has received final approval from the United States Food and Drug Administration (USFDA) for Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package Vials (USRLD: Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL)). Zinc Sulfate Injection is indicated in adult and paediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. The drug will be manufactured at the group's formulation manufacturing facility at Jarod. Zinc Sulfate Injection USP, 10 mg/10 mL (1 mg/mL), 30 mg/10 mL (3 mg/mL), and 25 mg/5 mL (5 mg/mL) Pharmacy Bulk Package Vials had annual sales of USD 17.1 mn in the United States (IQVIA MAT June 2023). The group now has 377 approvals and has so far filed over 444* ANDAs since the commencement of the filing process in FY 2003-04.

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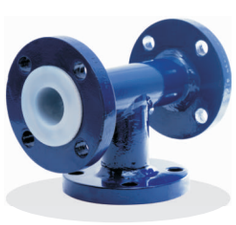

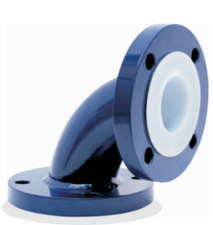



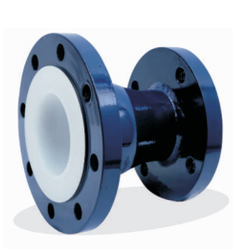
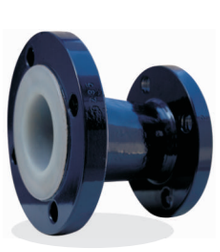


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Lupin acquires Brands ONDERO and ONDERO MET to expand Diabetes Portfolio in India

Nilesh Gupta, Managing Director, Lupin

Mumbai, India: Global pharma major Lupin Limited announced the acquisition of diabetes brands ONDERO and ONDERO MET, from Boehringer Ingelheim International GmbH (Boehringer Ingelheim), including the trademark rights associated with these brands. Lupin has been marketing ONDERO® and ONDERO MET since 2015 in the Indian market as part of a comarketing agreement with Boehringer Ingelheim India. In India, an estimated 77 million people above the age of 18 years have Type-2 Diabetes, while nearly 25 million are pre-diabetic, at higher risk of developing diabetes in the future. ONDERO (Linagliptin) and ONDERO MET (Linagliptin + Metformin) are the gold standard in diabetes management. This acquisition strengthens Lupin's commitment to providing superior treatment options for patients navigating the complexities of diabetes.

"Lupin is at the forefront of providing quality pharmaceutical products to patients. With the acquisition of ONDERO and ONDERO MET, we continue to offer a wide portfolio of products to enable access to medication for patients, and further consolidate our position as a market leader in the anti-diabetes segment," said Nilesh Gupta, Managing Director, Lupin

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Transcell, Quantiphi collaborate to develop an innovative drug discovery and testing solution

New Delhi, India: Hetero Biopharma, an innovative leader in biosimilar development and a dedicated R&D-driven company known for delivering biosimilar drugs, is driving a paradigm shift in chronic ailment treatment. Together with Transcell and Quantiphi, Hetero Biopharma is exploring integrating DART's advanced technology into its operational processes.

Transcell and Quantiphi collaborated to develop an innovative drug discovery and testing solution known as Digital Animal Replacement Technology (DART). DART harnesses human Microphysiological Systems and uses artificial intelligence and machine learning-powered digital prediction models to effectively help eliminate the need for animal testing in pharmaceutical development. These models are integrated into modular assays that predict the safety and efficacy concerns of pharmaceuticals and biopharmaceuticals intended for human use. One standout aspect of DART is its seamless integration into existing workflows, enhancing end-user engagement. This empowers users to assess the safety and efficacy of their assets, providing human-relevant data even before clinical trials commence and sometimes during the routine batch testing stage.

Within the developmental cycle of biosimilars, a strategic approach involves a progressive evaluation of biosimilarity and efficacy equivalence. This includes the consideration of conducting animal studies when necessary and appropriate, based on remaining uncertainties. This approach aims to efficiently tailor study requirements. "We began working with Hetero Biopharma's leadership team to offer non-animal DART residing modules for human cardiotoxicity and immunogenicity-like key assessments. Advantage in adopting DART, which is anti-thesis to contract testing model," said Transcell Founder & CEO, Dr. S Dravida, who is leading the group representing the DART implementation opportunity.

Director of Hetero Biopharma Dr. Bala Reddy said evaluating the value of animal studies to support regulatory approval of biosimilars is becoming more important. "In light of guidelines from various regulatory agencies that encourage alternative approaches to animal testing, innovative technologies like Transcell's human Microphysiological Systems in combination with AI & ML-based in-silico modeling, provide opportunities to develop better and more predictive scientific tools to safeguard the environment and human and animal health." Quantiphi Co-Founder Asif Hasan said DART embodies Quantiphi's commitment to propel bio/pharmaceutical research and development with hight ethical standards.

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Marksans Pharma receives USFDA approval for Guaifenesin ER Tablets (OTC)


Mark Saldanha, MD & CEO, Marksans Pharma

Mumbai, India: Marksans Pharma Ltd, one of the fastest-growing pharmaceutical companies in India, has received final approval from the US Food and Drug Administration ("FDA") for its Abbreviated New Drug Application ("ANDA") for Guaifenesin Extended-Release Tablets, 600 mg and 1200 mg (OTC). The Guaifenesin Extended-Release Tablets, 600 mg and 1200 mg (OTC) are bioequivalent to the reference listed drug (RLD), Mucinex Extended-Release Tablets, 600 mg and 1200 mg, of RB Health (US) LLC. Guaifenesin extended-release tablets help to loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. The company expects to launch the product immediately. Commenting on the approval, Mark Saldanha, Managing Director of the Company said "We are delighted to announce the approval, which further strengthens our growing Cough and Cold OTC portfolio in the US. We are confident in tapping the market opportunity of the product and remain committed to working diligently towards sustaining this momentum in the coming quarters."

JB Chemicals gets US FDA nod for Doxepin Hydrochloride Capsules

Mumbai, India: JB Chemicals and Pharmaceuticals Ltd announced that US FDA has approved JB Pharma's Abbreviated New Drug Application (ANDA) for Doxepin Hydrochloride Capsules USP, 10 mg, 25 mg, 50 mg, 75 mg, and 100 mg, the generic version of Sinequan (Pfizer), which is indicated for the treatment of anxiety, depression, and other target symptoms of psychoneurosis.The drug will be manufactured at JB Pharma's formulation manufacturing facility in Panoli, Gujarat. Doxepin Hydrochloride Capsules had an estimated annual sales of USD 23.90 million in the United States (IQVIA MAT Jun' 2023).

BDR Pharmaceuticals International launches Dalbonova Injection


Raheel Shah, Director of BDR Pharmaceuticals

Mumbai, India: BDR Pharmaceuticals International announce the launch of Dalbonova Injection. A revolutionary medication for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible strains of Gram-positive microorganisms. This ground breaking drug will be available as a 500 mg injection and marks an important milestone in the field of anti-infective medicines in India.

Dalbonova revolutionizes medical treatment with its single-dose therapy for acute bacterial skin and skin structure infections (ABSSSI) in patients of all ages, including newborns. This innovative approach simplifies treatment, eliminates the need for hospital admissions, and reduces the risk of hospital-acquired infections. Unlike traditional methods involving multiple infusions over days, Dalbonova's dosing regimen offers remarkable convenience and effectiveness. Patients can opt for a potent single-dose of 1500 mg or a comprehensive two-dose regimen of 1000 mg followed by 500 mg after one week, catering to individual needs. Raheel Shah, Director of BDR Pharmaceuticals said, Dalbonova Injection is set to provide significant benefits to adult and pediatric patients suffering from ABSSSI. With its innovative approach, BDR Pharmaceuticals aims to enhance patient care and accessibility while making the treatment more affordable for Indian patients. This advanced treatment will not only save valuable time but also reduce the overall cost burden associated with traditional treatment approaches.

BDR Pharma remains determined to improve patient lives and advance cutting-edge treatments with the introduction of Dalbonova Injection, the company strives to provide a game-changing solution for individuals battling Acute bacterial skin and skin structure infections (ABSSSI). India is ensuring that patients receive the finest care possible by funding cutting-edge research, encouraging partnerships, and consistently enhancing the nation's medical infrastructure. It is also significantly time and cost savings. With this BDR aims to introduce innovative medicines first time in India in

Anti-Infective segment and also make them affordable for Indian patients.

According to the latest data from the World Health Organization (WHO), in 2023 there were an estimated 11.5 million cases of Acute bacterial skin and skin structure infections (ABSSSI) in India. This represents a 15% increase in the number of cases from 2022. The male-to-female ratio for ABSSSI in India is 1.2:1. This means that men are about 20% more likely to develop ABSSSI than women. Children under the age of five and people over the age of 65 throughout India have the highest incidence of ABSSSI. The incidence of ABSSSI varies by area in India as well, with Gujarat, Rajasthan, and Uttar Pradesh, to mention a few, having the highest rates. Certain population groups in India, such as those with diabetes, HIV/AIDS, and poverty, bear a disproportionately high burden of ABSSSI.

Torrent Pharmaceuticals gets EIR from US FDA for Dahej facility

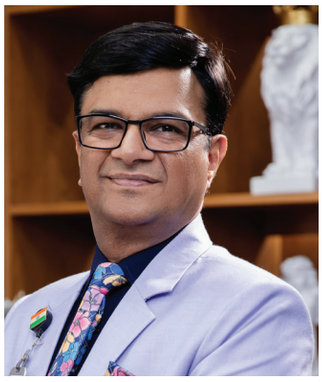
Ahmedabad, India: Torrent Pharmaceuticals Limited has announced that the US drug regulator US Food and Drug Administration (US FDA) has issued an Establishment Inspection Report ("EIR") for the company's manufacturing facility at Dahej, Gujarat, and that the inspection has been successfully closed by the US FDA. Based on the March 2019 Inspection outcome, the Dahej facility was placed under "Official Action Indicated (OAI)" by the US FDA. The drug regulator had conducted re-inspection of the site in May 2023 from 17-May-23 to 25-May-23 and issued Form 483 with 2 observations. The updated classification of site is VAI (voluntary action indicated) which indicates that Torrent will start to get approval of filed ANDAs. This will further enhance the company's prospects and foster growth in the US market with its new product offerings. The Dahej facility manufactures APIs and formulations for Torrent Pharma's international markets.

Strides receives USFDA approval for Mycophenolate Mofetil for Oral Suspension

Bangalore, India: Strides Pharma Science Limited announced that its stepdown wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for Mycophenolate Mofetil for Oral Suspension USP, 200 mg/mL, from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), CellCept for Oral Suspension, 200 mg/mL of Roche Palo Alto, LLC. (Roche). The approval bolsters the Company's Mycophenolate Mofetil portfolio, which already includes numerous products in which the Company is a market leader. The Mycophenolate Mofetil for Oral Suspension has a market size of ~US$41 Mn per IQVIA. The entire Mycophenolate Mofetil range of products for the company has a cumulative market opportunity of ~US$145 Mn per IQVIA.

The products will be manufactured at the company's facility in Bengaluru. The company has 280 cumulative ANDA filings (including the recently acquired portfolio from Endo at Chestnut Ridge) with USFDA, of which 260+ ANDAs have been approved. The company has set a target to launch ~ 60 new products over three years in the US.

Akums Drugs and Pharmaceuticals sets new standard Diabetes Care with DCGI-approved Vildagliptin SR and Metformin SR Tablets



Sanjeev Jain, Joint Managing Director, Akums Drugs & Pharmaceuticals Ltd

New Delhi, India: Akums Drugs and Pharmaceuticals Limited, India's eminent contract drug manufacturer, unveils a pioneering solution in the fight against diabetes – Vildagliptin SR and Metformin SR tablets. Designed to cater to patients with type 2 diabetes mellitus who have found inadequate control with metformin monotherapy, this revolutionary combination promises effective glycemic control and represents a remarkable advancement in diabetes treatment.

Vildagliptin SR and Metformin SR tablets merge the potent mechanisms of vildagliptin and metformin to offer patients a comprehensive approach to managing their glycemic levels. Vildagliptin, a well-tolerated oral dipeptidyl peptidase-4 inhibitor, stands out for its unique mechanism of action that prevents the degradation of glucagon-like peptide-1 (GLP-1). By doing so, it leads to reduced glycaemia, stimulates insulin secretion, and inhibits glucagon secretion in a glucose-dependent manner. This distinctive mode of action not only ensures effective glycemic control but also significantly reduces

the risk of hypoglycemia and weight gain, making it especially suitable for elderly patients. Metformin, a trusted and established medication, plays a pivotal role in diabetes management. Its mechanism of action centers around altering cellular energy metabolism, resulting in reduced glucose absorption from food, decreased glucose production by the liver, and heightened responsiveness to insulin. These attributes combine to make Metformin a potent glucose-lowering agent, further enhancing the efficacy of the Vildagliptin-Metformin combination.

Sanjeev Jain, Joint Managing Director of Akums Drugs & Pharmaceuticals Ltd, expressed his enthusiasm for the launch, stating, "Our mission at Akums is to provide innovative solutions that elevate patients' quality of life. The introduction of Vildagliptin SR and Metformin SR tablets marks a leap forward in diabetes management, offering patients a safe and efficient means to control their glycemic levels."

Sandeep Jain, Joint Managing Director, provided additional insight, saying, "Our dedicated research and development team has worked diligently to create a product that meets the intricate needs of diabetes patients. The synergy of Vildagliptin and Metformin in sustained-release tablets not only demonstrates efficacy in reducing HbA1c and plasma glucose levels but also offers a weight-neutral profile and minimal risk of hypoglycemia. This launch underscores our steadfast commitment to delivering healthcare solutions of the highest quality."Vildagliptin SR and Metformin SR tablets are available in four strengths: 50 mg/500 mg, 50 mg/1000 mg, 100 mg/500 mg, and 100 mg/1000 mg. These tablets have been granted regulatory approval by the Drug Controller General of India (DCGI), attesting to their safety and efficacy for patient use. With the introduction of Vildagliptin SR and Metformin SR tablets, Akums Drugs and Pharmaceuticals Limited demonstrates its dedication to driving innovation in healthcare. As a leading contract drug manufacturer, Akums remains committed to delivering innovative solutions that cater to the evolving needs of patients, contributing significantly to their well-being and improved quality of life.

Eugia Pharma receives USFDA approval for Icatibant Injection, 30 mg/3 mL (10 mg/mL) Single-Dose Prefilled Syringe

Hyderabad, India: Aurobindo Pharma Limited announce that its wholly owned subsidiary company, Eugia Pharma Specialities Limited, has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Icatibant Injection, 30 mg/3 mL (10 mg/mL), Single-Dose Prefilled Syringe, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD) FIRAZYR (Icatibant Injection) by Takeda Pharmaceuticals USA Inc. The product is being launched in September 2023. The approved product has an estimated market size of around US$ 137 million for the twelve months ending June 2023, according to IQVIA.This is the 166 th ANDA (including 9 tentative approvals received) out of Eugia Pharma Speciality Group (EPSG) facilities, manufacturing both oral and sterile specialty products. Icatibant Injection is indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

Ipca Laboratories receives VAI status from US FDA for Piparia (Silvassa) facility

Mumbai, India: Ipca Laboratories stated that it has received voluntary action indicated (VAI) classification from the United States Food and Drug Administration (USFDA) for its Piparia (Silvassa) manufacturing unit. The company stated that have received a communication from US FDA that they have determined the inspection classification of this manufacturing facility as "Voluntary Action Indicated (VAI). "Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP)," the company said. Earlier on 27th April, 2023, the company had intimated to you about US FDA inspection of our Piparia (Silvassa) formulations manufacturing facility from 18th April, 2023 to 26th April, 2023, which inspection resulted into 3 observations under USFDA Form 483."This classification means that the facility was found to be adhering to a minimally acceptable state of compliance with regards to current good manufacturing practice," the company said.

Gland Pharma receives EIR from USFDA for Dundigal facility

Mumbai, India: Gland Pharma announced that it has received an Establishment Inspection Report (EIR) from the United States Food and Drug Administration (USFDA) for its Dundigal facility located near Hyderabad in Telangana. Gland Pharma has grown over the years from a contract manufacturer [HK1] of small volume liquid parenteral products, to become one of the largest and fastest growing generic injectables manufacturing companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia,

India and other markets. The company operate primarily under a business to business (B2B) model and have an excellent track record in the pharmaceutical research and development, manufacturing and marketing of complex injectables.

Granules India receives accreditation certificate of Foreign Drug Manufacturer from PMDA

Hyderabad, India: Granules India Limited stated that it has received the Accreditation Certificate of Foreign Drug Manufacturer from Pharmaceuticals and Medical Devices Agency (PMDA), Japan for its Jeedimetla facility, located at Jeedimetla, Quthbullapur Mandal, MedchalMalkajgiri District, Hyderabad, Telangana. The certification has been received for accreditation categories of non-sterile Drugs, Packaging, Labelling and Storage of Drugs. Jeedimetla facility manufactures Active Pharmaceutical Ingredients (API) and Pharmaceutical Formulation Intermediates (PFIs). The company has received the approval from Brazilian Health Regulatory Agency (ANVISA), for compliance with the guidelines of Good Manufacturing Practices for its Bonthapally facility, located at Bonthapally Village, Gummadidala Mandal, Sangareddy District, Hyderabad, Telangana. Bonthapally facility manufactures Active Pharmaceutical Ingredients (API).

Dr. Reddy's Laboratories announces launch of Saxagliptin and Metformin Hydrochloride ER tablets in U.S.

Hyderabad India: Dr. Reddy's Laboratories Ltd, announced its launch of Saxagliptin and Metformin Hydrochloride Extended-Release Tablets in the U.S. market, a therapeutic equivalent generic version of KOMBIGLYZE XR (saxagliptin and metformin hydrochloride extended release) tablets, approved by U. S. Food and Drug Administration (USFDA).Dr. Reddy's Saxagliptin and Metformin Hydrochloride Extended-Release Tablets are supplied in a strength of 2.5 mg/1000 mg in bottle count of 60 and strengths of 5 mg/500 mg and 5 mg/1000 mg each in bottle counts of 30. Dr. Reddy's Laboratories Ltd. is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC.

Ajanta Pharma receives USFDA approval to market Topiramate extended-release Capsules

Mumbai, India: Ajanta Pharma Limited, a speciality pharmaceutical formulation company, has received final approval from the United States Food and Drug Administration (USFDA) to market Topiramate Extended-Release Capsules, 25 mg, 50 mg, 100 mg and 200 mg. Topiramate is the generic version of Supernus Pharmaceuticals Inc's Trokendi XR. As per the settlement with the innovator, Ajanta can launch Topiramate on February 1, 2026 or earlier under certain circumstances. Ajanta has received 50 final ANDA approvals, out of which 41 are commercialized. Ajanta also holds 2 tentative approvals and 22 ANDAs are awaiting US FDA approvals. Ajanta Pharma is a speciality pharmaceutical formulation company having major focus on branded generic business across India, Asia & Africa. Company has ground presence in each of these 30+ countries. Many of the company's products are 1st to market and are leading in their sub-therapeutic segments. This business contributes 73% in total revenue.

Sathgen Therapeutics completes dosing of the first two cohorts of healthy volunteers with MSP008-22

Samir Somaiya, Chairman and MD, GBL and Executive Co-Founder, Sathgen Therapeutics

Mumbai, India: Sathgen Therapeutics, a division of a chemical conglomerate in India - Godavari Biorefineries Limited (GBL), announced that they completed the dosing of the first two cohorts of healthy volunteers in a Phase 1 clinical trial with their novel chemical entity (NCE), MSP008-22. The clinical development of this drug is supported and managed by Clinexel Life Sciences, a leading clinical research organisation in the pharmaceutical sector. The clinical trial is headed by Dr. Shrinath Kshirsagar and his able Clinical Trials & Research Unit Team. Sathgen is a clinical-stage novel therapeutics venture focused on bringing therapies for

difficult-to-treat diseases like cancer and viral infections. Their goal is to bring this drug, MSP008-22, as a solution to a range of viral infections. Developed under the leadership of Dr. Sangeeta Srivastava, Executive Director, GBL, and CSO, Sathgen Therapeutics, the lead molecule has shown outstanding effectiveness and safety against COVID-19 in preclinical development. This NCE has widespread anti-viral potential due to its ability to inhibit both viral entrance and replication.

Professor Sendurai Mani, Associate Director (TO), Legorreta Cancer Center at Brown University and Scientific Co-Founder, Sathgen Therapeutics stated, "Viral diseases present limited treatment options and can lead to life-altering pandemics. MSP008-22 has the potential to address this unmet critical clinical need to treat numerous diseases caused by viruses."Samir Somaiya, Chairman and MD, GBL and Executive Co-Founder, Sathgen Therapeutics highlighted the company's commitment to research and its goal in discovering therapies for viral infections. He expressed, "Our lead program, MSP008-22, progressing through clinical testing for the drug's safety profile will mark an important milestone in our efforts to help patients with viral diseases." Professor Prashant S. Kharkar, Institute of Chemical Technology (ICT), and Consultant, Sathgen Therapeutics emphasized the urgency of finding effective drugs against present and emerging viral infections. He said, "MSP008-22 is a promising drug candidate with great potential to combat viral diseases and associated pandemics. Its excellent efficacy and safety profile make us highly enthusiastic about its prospects."

Dr. Deepa Arora, CEO, Clinexel expressed optimism about the Phase 1 study (NCT05532293) results of MSP008-22 in healthy volunteers. She stated, "The successful completion of the first cohort without any serious adverse events indicates the drug's non-toxic and safe nature. This trial will pave the way for further development efforts to combat the viruses that afflict the world today."

ABB India bags automation contract from Reliance Life Sciences

Bengaluru, India: ABB India has secured a major automation contract from Reliance Life Sciences (RLS), to automate their new manufacturing plants in Nashik, Maharashtra. RLS' 160-acre facility at Nashik will house manufacturing plants for plasma proteins, biopharmaceuticals, oncology pharmaceuticals, and vaccines. Large-scale biotechnology production presents distinct and complex process and automation challenges.

These processes adhere to strict regulatory guidelines to ensure product quality, and ABB's System 800xA solution reduces manufacturing errors and ensures high-quality yields. It interfaces seamlessly with various skid systems and is used extensively for seamless operator interaction, batch control, and production information on the factory floor.

"We are proud to partner with Reliance Life Sciences on this critical project. This collaboration will reinforce our position in the pharma and life sciences market, where, as a technology provider, we see tremendous potential for growth and innovation," said G. Balaji, SVP, Head of Energy Industries, ABB India. "With India rapidly progressing as a prominent biopharmaceutical manufacturing hub, we find ourselves well-poised to ride the wave of the industrial revolution driven by the adoption of automation in these segments, which is pivotal for large-scale production with quality assurance.

Enzene Biosciences inaugurates R&D facility in Pune

Enzene Biosciences facility

Pune, India: Enzene Biosciences Ltd., a leading biopharmaceutical company offering integrated Contract Development and Manufacturing (CDMO) services for Biologics, has announced the inauguration of its cutting-edge research and development (R&D) facility in Pune. Enzene's new R&D facility, spanning over 75,000 square feet, is equipped with an open lab set-up that promotes cross-departmental collaboration, efficient communication, and knowledge sharing. This facility marks a significant milestone in the company's commitment to fostering innovation and advancing the frontiers of biotechnology. The facility showcases Enzene's dedication to advancing scientific research and development, offering fully integrated services from Cell Line Development to Fill & Finish across a wide range of modalities. By breaking down traditional barriers, Enzene aims to facilitate seamless cross-functional interactions, which are proven to spark

creativity and drive innovation. Strategically located in the Chakan Industrial Area of Pune, represents a major investment in the pursuit of scientific excellence. Within the new R&D facility, Enzene has established specialized departments, including Cell Line Engineering (CLE), Drug Product Development (DPD), Purification Process Development (PPD), Advanced Analytical Technology (AAT), and Bioanalytical Assay. These departments bring together a team of highly skilled scientists and researchers with affiliations to esteemed institutions like Massachusetts Institute of Technology, University of Tennessee Medical Centre among others and prior experience at globally renowned companies.

Mankind Pharma launches 120 Premium DMF Quality Drugs for Indian Patients

Rajeev Juneja, Vice Chairman & Managing Director, Mankind Pharma

New Delhi, India: Mankind Pharma, a leading pharmaceutical company announced the introduction of 120 DMF (Drug Master File) Quality Medicines in the Indian market. Committed to delivering exceptional healthcare solutions at affordable rates, Mankind Pharma's initiative aims to ensure universal access to medicines of international c-alibre. The company's commitment to offering premium healthcare solutions that cater to all strata of society is reinforced by this ground-breaking initiative. India stands as a global leader in offering generic medicines that adhere to the stringent DMF quality standards set for Active Pharmaceutical Ingredients (APIs). Mankind Pharma takes a pioneering step by introducing DMF quality API in the Indian market, which is manufactured in a USFDA-approved plant. Thus, the final medicine is always one of the best quality with better efficacy. DMF Quality API represents a pinnacle of excellence that surpasses conventional standards.

The medicines in the USA comply with stringent USFDA's norms for quality, safety and effectiveness; defined by DMF (Drug Master File). The Drug Master File (DMF) has all the information on an API (Active Pharmaceutical Ingredient/Raw material for medicine). It provides all the information on the manufacturing, stability, quality, packaging, purity and impurity profile for authorities to ensure that medicines have the best quality and efficacy. DMF quality API is purer than normal API because it follows US pharmacopeia and is manufactured in USFDA-approved plants for medicines that are of best quality and efficacy.

Rajeev Juneja, Vice Chairman & Managing Director, Mankind Pharma says, "Introducing over 120 DMF Quality Medicines reflects Mankind Pharma's unwavering commitment to delivering healthcare solutions of exceptional quality. At Mankind, we believe that every Indian, irrespective of their economic background, has the right to get medicines of International quality. As we launch this comprehensive range, we aim to bridge gaps in healthcare accessibility, ensuring that every individual in India can access medicines that are of the highest USFDA approved standards. This initiative resonates with our motto of 'Serving Life,' and underscores our dedication to enriching lives through accessible and reliable healthcare".

The company's commitment to offering premium healthcare solutions that cater to all strata of society is reinforced by this ground-breaking initiative. Mankind Pharma is one of the largest pharmaceutical company in India, which focuses on the domestic market with its Pan India presence. Mankind operates at the intersection of the Indian pharmaceutical formulations and consumer healthcare sectors with the aim of providing quality products at affordable prices."

Cabinet approves foreign investment of up to ₹ 9589 crore in M/s Suven Pharmaceuticals

Mumbai, India: The Cabinet Committee on Economic Affairs chaired by the Prime Minister, Narendra Modi approved the FDI proposal for foreign investment of up to ₹.9589 crore in Suven Pharmaceuticals Limited by Berhyanda Limited, Cyprus. The approval is for acquisition of up to 76.1% equity shares of Suven Pharmaceuticals Limited, a public limited Indian pharmaceutical company listed on the National Stock Exchange of India Limited and the Bombay Stock Exchange Limited, by Berhyanda Limited, Cyprus, by way of transfer of shares of from existing promoter shareholders and public shareholders through mandatory Open Offer. The aggregate foreign investment may increase up to 90.1% in Suven Pharmaceuticals Limited.The proposal has been evaluated by SEBI, RBI, CCI and other relevant agencies.The approval has been granted after examination of the proposal by Departments concerned, RBI and SEBI and is subject to the fulfillment of all rules and regulations as applicable in this regard.

The entire investments in foreign Investor Company, Berhyanda Limited are held by Advent Funds, which pool investments from various Limited Partners (LPs). The Advent Funds are managed by Advent International Corporation, an entity incorporated in USA. Advent International Corporation, set up in 1984 has made investments of about USD 75 billion in 42 countries. Advent India started investments in India since 2007 and so far it has invested about Rs 34000 crores in 20 Indian companies across healthcare, financial services, industrial manufacturing, consumer goods and IT services sectors.

The approved investment aims to generate new jobs, capacity expansion of the Indian company through investments in plant & equipment. Association with Advent Group is expected to provide larger platform to Suven Pharmaceuticals Limited by expanding business operations; achieving operational excellence; enhancing productivity and accelerate growth; improve the environment, health and safety standards of Indian Company; and bring in global best practices in management as well as excellent training opportunities to existing professionals.The Government has put in place an investor-friendly Foreign Direct Investment (FDI) Policy regime for pharmaceutical sector in order to bring in global best practices through technology, innovation and skilling for accelerated economic growth and development; supplement capital for up scaling domestic productivity, increase competitiveness and employment generation amongst other benefits.

As per the extant FDI Policy, 100% foreign investment is allowed under automatic route in greenfield pharmaceutical projects. In brownfield pharmaceutical projects, FDI upto 74% are allowed under the automatic route and Government approval is required for investment beyond 74%. Total FDI inflows in pharmaceutical sector has been Rs.43,713 crore during last five years (from 2018-19 to 2022-23). The sector has witnessed significant growth in FDI of 58% in the last financial year.

Caplin Steriles receives EIR from US FDA

Tamil Nadu, India: Caplin Steriles Ltd, a subsidiary of Caplin Point Laboratories Ltd, announced that it has received the Establishment Inspection Report (EIR) from the United States Food and Drug Administration (US FDA) for its injectable and ophthalmic manufacturing unit located near Chennai. The unit underwent an inspection from US FDA during May 22nd ~ May 31st and the inspection classification was determined by the agency as Voluntary Action Indicated (VAI). Commenting on the achievement, Mr. C.C. Paarthipan, Chairman said:"This is the fourth US FDA audit at this site and we're pleased to receive the EIR with a satisfactory outcome. Our commitment to maintaining the highest levels of compliance at all our units remains steadfast. The receipt of EIR will help in receiving continued ANDA approvals for this unit, which is an important growth engine for us".

Caplin Point Laboratories Limited is a fast-growing pharmaceutical company with a unique business model catering predominantly to emerging markets of Latin America and Africa. Caplin Point is one of the few companies to show consistent high-quality growth in Revenues, Profits and Cash flow over the last 15 years. The Company has state of the art manufacturing facilities that cater to a complete range of finished dosage forms. The Company has also entered regulated markets such as US through its Subsidiary Caplin Steriles Limited.

Sun Pharma enter into licensing agreement with Pharmazz Inc.

Mumbai, India: Sun Pharmaceutical Industries Limited announced that one of its wholly-owned subsidiaries has entered into a license agreement with Pharmazz Inc., (Pharmazz), a U.S. based biopharmaceutical company to commercialise a first-in-class innovative drug, Tyvalzi (Sovateltide) in India. Developed by Pharmazz for potential global use, Sovateltide is indicated for treating cerebral ischemic stroke.As per agreement terms, Sun Pharma is granted rights for marketing Sovateltide in India under the brand name Tyvalzi (Sovateltide). Pharmazz will be entitled to upfront and milestone payments, including royalties.

Kirti Ganorkar, CEO – India Business, Sun Pharma said, "The Phase 3 clinical trial for Tyvalzi conducted in India demonstrated statistically and clinically meaningful improvement in neurological outcomes in ischemic stroke. Tyvalzi is a first-in-class innovative drug which can help improve the quality of life of stroke patients. The drug can be administered within 24 hours for the treatment of ischemic stroke. The current treatment options provide a narrow time windowof 4-5 hours limiting its use in most patients."

Dr. Prof. Anil Gulati, M.D., Ph.D., inventor, CEO, and Chairman of the Board of Directors of Pharmazz, said: "It is a significant step for Pharmazz to partner with Sun Pharma, the largest pharmaceutical company in India. For patients with cerebral ischemic stroke, I believe Sun Pharma is the best partner for Pharmazz to market Tyvalzi (Sovateltide), an innovative, first-in-classnovel treatment for cerebral ischemic stroke, in India."

Indian pharma Industry to sustain 8-10% revenue growth in FY24: ICRA report

Mumbai, India: Despite several disruptive events over the last few years, the Indian Pharmaceutical Market (IPM) witnessed a healthy CAGR of 9.7% between FY2014 and FY2023, according to ICRA report.

The report said that the growth in recent years has largely been supported by price increases and new product introductions even as volume growth has been negative or 2-3% at best. ICRA expects growth for its sample set of 25 companies, which account for ~60% of the overall Indian pharmaceutical industry to sustain at 8-10% in FY2024. This is likely to be supported by continued price increases, new product launches and rising penetration of healthcare services in semiurban and rural areas.

Acute therapies, accounting for 62-65% of the IPM, have continued to outpace growth in chronic therapies since FY2022. However, the trend is expected to reverse going forward. With increasing incidence of lifestyle diseases and given the long duration of medicine courses for chronic diseases, the growth of chronic therapies in the IPM is expected to be higher than that of acute therapies. At present, revenues from drugs under the National List of Essential Medicines (NLEM) constitute ~17-18% of the IPM, with some companies deriving ~30% of revenues from the NLEM drugs. The price increase granted for drugs under the NLEM has been higher at 12.1% for FY2024 due to sharp WPI inflation. This is the second consecutive year of double-digit price increase allowed for NLEM drugs.

The NMC recently released new norms for doctors that require them to only prescribe generic drugs instead of certain brands. These changes support the GoI's focus on driving generic prescriptions to reduce healthcare costs for patients. However, this could impact the branded generic formulations for manufacturers over the long term, stated ICRA report.

Biocon Board appoints Peter Bains as Group CEO

Bengaluru, Karnataka: Biocon's Board has approved the appointment of Peter Bains as the Group CEO, with effect from September 18th, 2023. He will be reporting directly to Biocon Group Chairperson, Kiran Mazumdar-Shaw. Bains has accordingly stepped down from his role on the Biocon Board as an Independent Director with immediate effect, to assume this strategic executive responsibility.

Welcoming this appointment, Ms Kiran Mazumdar-Shaw said, "Biocon is entering a dynamic phase of growth for its 3 core businesses, Biocon Biologics, Biocon Generics and Syngene, and for the Group as a whole.I am delighted to welcome Peter back to the Biocon Group in the role of Group CEO. Siddharth Mittal, CEO & MD Biocon Ltd, Shreehas Tambe, CEO & MD Biocon Biologics Ltd. and Jonathan Hunt, CEO & MD Syngene International Ltd. will continue to have independent charge of their businesses and will work with Peter to strengthen synergistic strategic leadership at a Group level to maximise the combined value of all 3 businesses.Peter has a unique fit and profile for the role having both extensive global leadership experience and success across the biopharmaceutical field and a comprehensive understanding of the Biocon Group, having led Syngene for 5 years, taking it through its very successful IPO in 2015.I am confident that this appointment will serve the integrated business objectives of the Biocon Group of companies and deliver added value to all stakeholders."

Neuberg Diagnostics announces merger of Neuberg Supratech and Neuberg Anand

Chennai, India: Neuberg Diagnostics Private Limited, a prominent player in the diagnostics sector with a global presence, announce the merger of Neuberg Supratech Reference Laboratory, Ahmedabad, and Neuberg Anand Reference Laboratory, Bangalore, into Neuberg Diagnostics Private Limited. This merger has been facilitated through an NCLT court-based process, further solidifying Neuberg Diagnostics' position as a frontrunner in the diagnostic industry. With a strategic vision to streamline operations and enhance efficiency, this merger brings together two prominent entities under the canopy of Neuberg Diagnostics Private Limited. The amalgamation has resulted in consolidating more than 80% of the overall group revenues within a single entity, setting the stage for Neuberg Diagnostics to achieve remarkable milestones.

Neuberg has positioned itself at the forefront of innovation in Personalised medicine by establishing centers of excellence, including Neuberg Centre for Genomics Medicine (NCGM), Neuberg Centre for Proteomics & Metabolomics (NCPM), Neuberg OncoPath, Jeenomics by NCGM for Transplant Immunology, and Neuberg Anand Academy of Laboratory Medicine (NAALM). NCGM has emerged

as a prominent player in the Genomics Segment within South Asia, the Middle East, and Africa, and it maintains a direct presence in North Carolina USA to harness the latest advancements in Genomics Medicine. Dr. GSK Velu, Chairman and Managing Director of Neuberg Diagnostics, expressed his enthusiasm regarding the merger, stating, "This merger marks a significant step forward in our journey to provide unparalleled healthcare solutions. By integrating these renowned laboratories, we reinforce our commitment to delivering excellence in diagnostics and patient care."

The merger is projected to contribute to Neuberg Diagnostics' ambitious target of achieving gross revenues exceeding ₹1,000 crores (USD 120+ Million) as a group in the current fiscal year. With this united front, the company can leverage its enhanced capabilities to expand and offer an extensive range of cutting-edge diagnostic services to patients across India and beyond.Neuberg Diagnostics also reshaped its senior management team as part of the merger. Dr. Sandip Shah has been elevated to the role of Joint Managing Director at Neuberg Diagnostics. His exceptional leadership qualities and strategic vision are poised to be pivotal in the company's continued growth. Dr. Sujay Prasad is promoted to Chief Medical Director of Neuberg Diagnostics. Dr. Sujay's unparalleled medical expertise and steadfast dedication will guide the clinical services with the highest quality and patient care standards.A Ganesan, will continue with his role as Vice Chairman of Neuberg Diagnostics. He will play a vital role and be actively engaged in the business expansions.

Commenting on these appointments, Dr. GSK Velu stated, "Our leadership team is the cornerstone of our success; with me, Mr. A Ganesan, Dr. Sandip Shah, and Dr. Sujay Prasad on the board of directors, Neuberg boasts of one of the most experienced leadership team at the board level with combined diagnostics experience of over 120 years. It will elevate Neuberg Diagnostics to new standards of excellence." Neuberg Diagnostics has set its sights on the future with plans to launch an Initial Public Offering (IPO) in the latter part of 2024 or the early months of 2025. This move aligns with the company's growth strategy, enabling it to attract additional resources for expanding its operations and maintaining its position at the forefront of diagnostic innovation.

Takeda reiterates the need of equitable access to healthcare for universal impact

Mumbai, India: Takeda Biopharmaceuticals India Private Limited (formerly Baxalta Bioscience India Pvt Ltd) – a global values-based, R&D-driven biopharmaceutical leader in innovative healthcare solutions presented an industry perspective on equitable access to healthcare during the 5th edition of the Confederation of Indian Industry (CII) UP Health Summit "Empowering Wellness: Transforming Lives for a Healthy Future". The summit serves as a crucial platform for bringing together policymakers, industry leaders and experts to deliberate on pressing healthcare challenges and opportunities.

Michelle Erwee, Global Head of Access to Medicines, Takeda said, "At Takeda, we are committed to accelerating global, equitable access to our medicines and vaccines. Whilst we know every individual, country and community often face their own barriers to access, availability of medicines, capacity within local healthcare systems, and affordability are common challenges that require a collaborative and innovative approach. We acknowledge that the Government of India continues to prioritise initiatives aimed at enhancing the accessibility and equity of health services, and we remain open to collaboration in order to advance access to medicines for patients in need."

Ruchi Sogarwal, Head of Corporate Affairs, Takeda India added, "The Government of India has implemented value-based healthcare measures through large-scale initiatives such as Pradhan Mantri Jan Aarogya Yojana and Ayushman Bharat Digital Mission to improve and scale the delivery of healthcare services to all. Specifically in Uttar Pradesh – the most populus state of the country - the government is taking transformative measures to advance healthcare infrastructure and eliminating barriers to care across patient pathways. We believe India's G20 Presidency will give a fillip to its initiatives to boost healthcare access while the success of our government schemes could inspire other nations across the globe to emulate this model."

Through collaborative efforts and innovative solutions, Takeda India aims to continue driving progress and access to quality healthcare, in line with its purpose of Better Health and a Brighter Future for people around the world.

NEC selected by AMED for design of a universal vaccine that is effective against influenza virus strains

New Delhi, India: NEC Corporation has been selected to participate in a vaccine/new modality research and development project beginning in FY2023. NEC was selected following its submission of a research project titled "Development of universal vaccine design technology using computational science" in response to a public call for proposals by the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), which operates under the Japan Agency for Medical Research and Development (AMED).During this research project, NEC will utilize cutting-edge AI technologies in order to identify immunogenic regions that are effective against a wide range of influenza virus strains and to design a universal vaccine.

Research on universal vaccines that are broadly protective against mutating viruses are being conducted around the world in preparation for future pandemics. However, it is likely to take a considerable amount of time for universal vaccines to be put to practical use. As such, expectations are high for the utilization of AI and other computational science approaches to shorten the vaccine development period and reduce associated costs.

Specifically, in Japan, the "Strategy for Strengthening Vaccine Development and Production Systems" was formulated in June 2021 as part of a long-term national strategy to develop and produce vaccines domestically. Later, in March 2022, SCARDA was established within AMED for the purpose of strategically funding research to bolster R&D and production systems for vaccines. With the vision of using in-house AI technology for designing universal vaccines, NEC submitted a proposal in response to SCARDA's public appeal and was selected for the program.

In this research project, a universal vaccine will be designed for influenza using a proprietary computer analysis technology based on several state-of-the-art AI technologies. Specifically, the genomic and genetic information of influenza viruses will be analyzed to search for and identify immunogenic regions, and verification tests will be conducted. NEC will then aim to design a vaccine based on these results within a year of the project initiation and to obtain a non-clinical PoC in the near future. This research and development will be carried out in collaboration with Specially Appointed Professor Keiko Udaka of Kochi University.

This research will move forward using cutting-edge AI and computational science to identify protein regions that are effective for vaccine designs. Moreover, NEC will utilize these research results to develop and put to practical use universal vaccines in collaboration with other partners having modality in order to effectively deliver benefits to patients.

"We are pleased that our proposal has been selected by SCARDA for the development of universal vaccine design technology through industry-government-academia collaboration. Amid expectations for the early development of vaccines, computational science, including AI technologies, is extremely important and can drive meaningful advances within the pharmaceutical industry. Going forward, NEC will continue contributing to global health and the provision of better vaccines by utilizing cutting-edge technologies," said Masamitsu Kitase, Corporate Senior VP and Head of the Healthcare and Life Science Division at NEC Corporation.

"Having worked together with NEC for many years on the development of a peptide immunotherapy for malignant tumors, I am truly looking forward to partnering with the company on the development of a universal vaccine for the influenza virus through this SCARDA program," said Keiko Udaka, M.D., Ph.D., Specially Appointed Professor, Department of Immunology, School of Medicine, Kochi University. "I anticipate that AI and ICT will contribute to not only better vaccine development but also preemptive measures aimed at containing pandemics."

IIT Kanpur signs MoU with Sensa Core

Kanpur, India: The Indian Institute of Technology Kanpur (IITK) signed a memorandum of understanding (MoU) with Sensa Core Medical Instrumentation Pvt. Ltd. for mass manufacturing and sales of a novel point-of-care technology developed at the institute for rapid analysis of bilirubin in human blood/serum along with its three variants. The inventive technology developed at the National Centre for Flexible Electronics (NCFlexE), IIT Kanpur, by Professor. Siddhartha Panda, Department of Chemical Engineering, and Dr. Nishant Verma, discloses the fabrication of a non-enzymatic electrochemical sensing strip that can simultaneously detect the direct and total bilirubin in a single drop of blood, and provide the concentrations within a minute. The technology licensing agreement was formally signed between IIT Kanpur and Sensa Core in the presence of Professor.

Abhay Karandikar, Director, IIT Kanpur; Prof. Ankush Sharma, PIC, Innovation & Incubation; Professor. Siddhartha Panda (Inventor), and Dr. Ravi Kumar Meruva, Licensee & Founder/CEO of Sensa Core Medical Instrumentation Pvt. Ltd. The company, based in Hyderabad, has been a leading manufacturer of Ion-selective Based Electrolyte Analyzers, Arterial Blood Gas Electrolyte Metabolite Analyzers, Glucose Test strips and Hemoglobin Test Strips. With this MoU, they plan to expand their portfolio by including Bilirubin Test strips as a part of point-of-care testing and screening.

Professor. Abhay Karandikar, Director IIT Kanpur, said, "Developing effective point-of-care technologies for enriching the healthcare system has been a priority at IIT Kanpur. This novel sensor makes detection of bilirubin levels in blood easier, and it would revolutionize the processes leading to the detection of certain health conditions. The incorporation of a unique five-electrode configuration would allow the detection of direct and total bilirubin on a single strip, simultaneously. Through this MoU, we hope to cater to the healthcare sector in effectively marketing this invention for better utility of all."

The non-enzymatic electrochemical sensor is specifically designed for accurate detection of bilirubin levels in clinical samples. Bilirubin is a pigment in our blood, detecting the level of which can help diagnose certain health conditions, such as Neonatal jaundice. It is a prevalent clinical condition, affecting roughly 60% of full-term and 80% of preterm new-borns with a mortality rate of 7.3 per 1000 live births in India. The conventional methods of detection have limitations. The developed sensor is portable, affordable and can be directly applicable for blood sample analysis without the need for any preliminary processing steps. This sensor is expected to be used for bedside testing, in diagnostic laboratories, and even in health screening centers.The sensor incorporates a unique five-electrode configuration that allows simultaneous detection of direct and total bilirubin on a single strip

Parexel appoints Gwyn Bebb to lead Oncology clinical development

Mumbai, India: Parexel, one of the world's largest clinical research organizations (CROs) providing the full range of Phase I to IV clinical development services, announced the appointment of Gwyn Bebb, BM, BCh., Ph.D., as Senior Vice President and Global Therapeutic Area Head – Oncology. In this role Dr. Bebb will lead the research and development of new cancer treatments for biopharmaceutical customers worldwide. "The complexities of oncology require agile, multifaceted teams to push the boundaries of drug development and deliver groundbreaking treatment options for patients with cancer," said Amy McKee, M.D., Chief Medical Officer and Head, Oncology Center of Excellence. "Dr. Bebb's depth of expertise in oncology drug development and proven experience in leading cross-functional teams in academia position him as an expert resource for customers and a natural leader for our global oncologist team."

Dr. Bebb is a licensed medical oncologist with more than 20 years' experience in academia and the clinical research and biotechnology industries.

Most recently, he was a Clinical Research Medical Director at Amgen in both early- and late-stage oncology drug development where he shepherded a biphasic T cell engager to a confirmational Phase III trial. His experience also includes serving as a professor in the Department of Medicine at the University of Calgary (Alberta, Canada), where he established the Precision Oncology Experimental Therapeutics (POET) program and directed the Clinical Trials Unit at the Tom Baker Cancer Centre. While at the University of Calgary, Dr. Bebb founded and directed a provincial lung cancer database (the Glans Look Lung Cancer Database) to examine the association between real world patient outcomes and molecular markers being studied in his research lab. His experience also includes clinical practice as a Medical Oncologist focused on lung and gastrointestinal cancers.

"There is tremendous unmet medical need for patients with cancer representing an important priority for our customers and Parexel," added Peyton Howell, Chief Operating and Growth Officer. "We're pleased to continue expanding our expertise and leadership in this important therapeutic area and others — reinforcing our unwavering commitment to patients.". ■

Identification of counterfeits & security

Dinesh Pilgaokar, Executive Vice President & Chief Customer Officer, Bar Code India talks about the Identifying counterfeits and ensuring security in pharmaceutical manufacturing. He also spoke about how QR codes serves as a fundamental strategy for preventing counterfeiting and enhancing product traceability.

Identifying counterfeits and ensuring security in pharmaceutical manufacturing are critical aspects to safeguard public health and maintain the integrity of the pharmaceutical supply chain. The alarming threat of counterfeit medicines stands out as one of the significant difficulties this industry must overcome. It has the power to compromise patient safety and the well-deserved reputation of pharmaceutical businesses.

Counterfeit drugs have far-reaching and detrimental impacts on public health and the pharmaceutical industry's reputation. Counterfeit drugs can contain harmful or toxic substances that cause adverse reactions, severe side effects, and allergic responses. This can worsen health conditions and cause unnecessary harm to patients. Public trust in the healthcare system and medical practitioners can erode when patients experience unfavourable health outcomes due to counterfeit drugs. This mistrust can have lasting effects on the entire industry.

In the face of such dire consequences, implementing efficient mechanisms becomes essential for preventing counterfeit medications and enhancing security within the pharmaceutical supply chain. Counterfeit drugs pose significant risks, including ineffective treatment, harmful side effects, and even death. A combination of technologies, processes, and regulatory efforts is necessary to ensure the security and authenticity of pharmaceutical products throughout the supply chain.

Ensuring patient safety, maintaining top-notch quality assurance, adhering to stringent regulatory standards, and efficiently managing the pharmaceutical supply

chain all hinge on one vital aspect: traceability. Traceability enhances security where manufacturers can monitor the movement of pharmaceutical products at every stage, ensuring they adhere to predetermined routes and conditions. This prevents unauthorised parties from introducing counterfeit products. If a pharmaceutical package is tampered with, traceability systems can provide alerts, allowing for quick removal of compromised products from the supply chain. With accurate traceability data, manufacturers can quickly identify affected batches and execute targeted recalls, minimising the impact on public health.

Serialisation leveraging rfid/barcodes/QR codes serves as a fundamental strategy for preventing counterfeiting and enhancing product traceability. It involves assigning unique serial numbers or codes to individual products during manufacturing. These codes are then recorded and tracked throughout the supply chain, creating a digital fingerprint for each item. This transparency enables faster identification of irregularities and more effective product recalls or quality issues management. Implementing serialisation demonstrates a company's dedication to producing and delivering genuine, safe products, fostering consumer trust and confidence.

Blockchain technology, provides a powerful solution to this challenge. It provides a decentralised, immutable ledger system that makes transactions safe and transparent. Its distributed design ensures that no single entity controls the network, making it impervious to fraud and manipulation. Blockchain's immutable and transparent nature enables recording every transaction and movement of products within the supply chain. This traceability ensures that the authenticity and origin of products can be easily verified, reducing the risk of counterfeit goods entering the market. Thus, adopting blockchain has become imperative, given the increasing need for trust in today's interconnected business ecosystems.

Utilising hardware to detect counterfeits and boost security encompasses various technological solutions to validate product legitimacy. Renowned for its prevalence in tracking, RFID tags can help trace and validate goods across the supply chain. Furthermore, barcodes and QR codes hold information about where the product comes from and when it was made. This further helps people ensure that things are genuine. A Unique Identification (UID) is imperative for an efficient supply chain. It is fundamental to have the UID from inception to the manufacturing or storage process linked to batch details and other essential details as stipulated by the supply chain.

The decision to employ a specific technology, QR code or RFID, can be influenced by factors such as the criticality and cost of the drug. A validation process must be introduced at every juncture to ensure the accuracy and completion of the preceding steps. This involves utilising digital credentials through an enterprise mobile device capable of seamlessly scanning and interpreting QR codes or RFID tags. This approach expedites the progression towards digitisation and augments the return on investment, encompassing the freshly implemented infrastructure and extending to cover expenditures such as ERP systems, QMS, or LIMS.

The infusion of digital data streams, interlinked machinery, condition monitoring, and control mechanisms collectively work harmoniously to optimise product quality while concurrently minimising errors. Using special codes on the packaging that connect to previous batches is important for a stronger supply chain. Thanks to advanced printing and camera tech, fast packaging is no longer a problem. This sets the stage for a clear and strong supply chain soon.

By combining these identification and security measures, industries can safeguard against counterfeits, fraud and unauthorised access. As technology evolves, staying abreast of innovative solutions is essential to maintaining a resilient defence against these threats. ■

Author

Dinesh Pilgaokar
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Role of Artificial Intelligence in the BioPharma Industry

Artificial intelligence (AI) is a leading force in today's technological disruptions, reshaping and significantly impacting various industries and sectors. In the pharma and life sciences, AI is particularly promising, as it transforms drug discovery, enhances patient experience, improves patient outcomes, and generates new revenue streams.

With machine learning algorithms, vast data sets and computational power – AI is driving the shift towards greater customer-centricity through Direct-to-Customer business models achieved through customer engagement and personalization for increased customer satisfaction and sustainable growth. Moreover, AI is also fueling innovation for driving operational excellence across the entire value chain through automation and predictive analytics. Additionally, AI also empowers the biopharma sector to become more resilient towards economic uncertainty, external threats, supply chain disruptions and frequent regulatory changes.

The following sections of this article provide a comprehensive view of pertinent use cases across key business outcomes for the biopharma industry

AI for Operational Excellence

Artificial Intelligence (AI) is playing an increasingly significant role in pharmaceutical operations, revolutionizing various aspects of how the industry functions. Here are some key areas where AI is making an impact:

- Drug discovery and development
- Pharmacovigilance
- Manufacturing and quality control
- Supply chain optimization
- Employee Experience

Drug discovery and development: AI can play a vital role in the entire life cycle of drug development, starting from discovery to manufacturing. It can help identify potential drug targets by analyzing huge amounts of biological data to find molecules / proteins or genes associated with diseases. It can predict chemical compounds for their potential usage as drug candidates and simulating them to design the new drugs with reduced side effects and improved efficacy. Clinical trials these days enabled via AI help identify suitable patients, optimize protocols, and predict the trial outcomes.

Pharmacovigilance (PV): Pharma companies conduct PV to detect, assess and prevent adverse effects of drugs or any other possible drug-related problems. Sophisticated AI algorithms extract useful information from huge amount of health-related data to increase the success of a medicinal products (i.e. through assessment of the risk and effectiveness of medications).

Supply Chain Optimization: AI algorithms optimize pharmaceutical supply chains, ensuring efficient distribution and reducing waste. Leveraging advanced, intelligent technologies, including predictive analytics, can help track the state of the drugs throughout the supply chain and take proactive interventions before any issue arises. AI enabled predictive maintenance that provides insights about operational equipment helps the business in effective monitoring of compliance, quality, or safety-related issues as that is a common challenge for biopharma companies.

Manufacturing and Quality Control: Robotics and automation enabled using AI, can improve efficiency in pharmaceutical manufacturing, reducing errors and enhancing consistency. AI enabled Quality control systems can detect defects and anomalies in drug production, ensuring product safety and compliance.

Employee Experience: Generative AI based virtual assistants can be used to assist employees in their day-to-day activities. Chatbots can act as a single point of contact for employee queries, fetching from various enterprise knowledge bases trained on organization's policies, procedures, manuals, and other business documents. Virtual assistants are widely successful in areas such as Procurement, payroll, HR, finance and IT helpdesks.

AI for customer centricity

There is a huge shift happening in biopharma companies, that has focused on selling through healthcare professionals', to directly engaging with the end customer. The recent pandemic further boosted this shift away from traditional fragmented patient journey towards a digitized patient experience through value-based "Care-as-a-service".

This paradigm shift has driven many mature healthcare and pharmaceutical companies to invest in strategic transformation aligned to technology enabled D2C business models that help in deriving value through customer (/patient) engagement and not just the attributes and features of a medicinal product. Over time the benefits for the user will take the form of a frictionless patient journey from early or timely diagnosis to OPD experience, diagnostics, treatment planning, medication management, health monitoring and disease management. The transformed digital value chain will also cover all patient experience

providers including the government, pharmaceutical manufacturers, hospitals, doctors, health coaches, insurance companies, pharmacies and fintech.

Artificial intelligence plays an increasingly important role in enabling the patient journey through omnichannel care, real-time monitoring using wearables, personalized healthcare etc. Innovation at early stages and understanding the customers' behavior can improve market coverage, customer satisfaction and mitigate risk of failure. Generative AI will expedite the adoption of innovations such as robo-advisors, virtual health coaches, healthcare chatbots etc. Healthcare and Pharmaceutical organizations also gain immensely from using the true potential of AI to optimize their outreach through efficient and effective health-trend and behavioral analysis. Personalized content such as high-quality recommendations, gamification techniques etc., help improve user engagement and stickiness through improved health scores i.e., achievements against patient-defined objectives. The benefits of such technological innovations also support in expanding the horizon of our regulators and government institutions, towards improving healthcare access in rural and underserved communities.

AI for Organizational Resilience

Being one of the hyper-growth sectors, the risks faced by Pharma sector are also fast evolving. Some of these risks include cyber-attacks and security threats, pharma frauds, and regulatory non-compliances, etc. Hence, there is a clear need for pharma companies to resort to technology as a key enabler for resilience.

A resilient enterprise is characterized by agile organization, self-sufficient teams and adaptable leadership aided by right technology enablers to anticipate, prepare, respond, and adapt to adverse changes and sudden disruptions in internal/ external environment.

The key to using Artificial Intelligence (AI) for improving operational resilience lies in its capability to continuously monitor data patterns and indicators to detect emerging risks and deviations from accepted norms or best practices. AI enables organizations to leverage predictive analytics, which can anticipate the potential impact of an event and help plan for contingencies. This proactive risk management approach empowers organizations to implement effective mitigation strategies and ensure business continuity and minimal impact in the face of uncertainty.

AI algorithms can sift through massive volumes of data from various sources, including social media, news feeds, IOT sensors, network devices etc. to provide comprehensive and close-to-real time insights into vulnerabilities and possible frauds. Advanced algorithms for behavioral analytics can analyze individual activities to predict abnormal patterns in human behavior that can adversely impact BAU.

AI/ML can also be used to spot any abnormality in the midst of normal business operations to send early warning signals ensuring necessary security controls are activated in time to mitigate any threat. For example, organizations utilize AI enabled access management platforms to automatically develop and maintain security policies that help enforce zero trust security models to protect applications and networks from malicious threats.

To maintain compliances with constantly shifting regulations, pharmaceutical companies need tools that enable them to discover, highlight, and extract key data within regulatory documents. Generative AI models can help interpreting and summarizing regulatory documents and, also in accessing the necessary compliance related data from systems and documents which otherwise need significant human resources.

For instance, these models can help companies

automate compliance of their drug development programs with the latest global regulatory requirements. Another use case is where Biopharma companies routinely interact with health care professionals (HCP) through contractual arrangements such as for paying a standard fee for participation in an event or provision of services. These contracts are subject to comprehensive regulatory and legislative scrutiny across the globe. Companies can use various supervised AI techniques for image recognition and unsupervised techniques such as NLP and NLG, to support in compliance monitoring to such contracts, company policies and local regulations.

While the advantages are numerous, there are increasing concerns surrounding the social, ethical and medico-legal impact of use of AI for biopharma industry. There are important aspects around clinical safety, information security, algorithm bias etc. that should be considered while using such technologies.

The improvement that such technologies bring to pharma businesses, can be overshadowed by inordinate impact of socioeconomic and geopolitical magnitude of inaccurate medical predictions, improper drug formulations, loss of sensitive health data and compounding of social inequities. Organizations need to define Responsible AI principles that architect and deploy AI models, systems, and platforms that are trustworthy, fair, and explainable by design. It is imperative to establish Responsible AI governance structures should be built having industry-wide and national scale for improving confidence and trust such emerging technologies. ■

Author

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"We are planning to expand our global footprint by entering at least six new countries."

Sargham Dhawan Bhayana
Director
Planet Herbs Lifesciences

Sargham Dhawan Bhayana talks about the company's expansion plans and global footprint. She also spoke about the market dynamics, research and development segment, strategy going forward, market dynamics and product launches.

Brief us about the expansion plans.

Through these research and analysis efforts, we have identified and evaluated different expansion scenarios, considering factors such as market dynamics, customer demand, regulatory environment, and competitive landscape. The quantification of the expansion opportunities involved a rigorous assessment of market potential, revenue projections, cost implications, and risk analysis.

We are planning to expand our global footprint by entering at least six new countries. This expansion will enable us to tap into new markets, diversify our customer base, and capitalize on emerging opportunities. We will conduct thorough market research and analysis to identify the most promising regions for expansion, considering factors such as market demand, regulatory environment, and competitive landscape. These collaborations will help us establish a strong foothold in each new market and expedite our growth trajectory.

To achieve our growth target, we will also focus on operational efficiency and scalability and will optimize our internal processes, streamline workflows, and leverage technology to drive productivity gains.

By strengthening our local presence, establishing strategic partnerships, implementing targeted marketing campaigns, and optimizing operational efficiency, we are confident in our ability to achieve these goals and drive sustained growth for our organization. Our expansion plans have been formulated through a robust process that integrates inputs from internal specialists, external key opinion leaders, and thorough secondary research. By employing modeling techniques and financial projections, we have assisted our client in assessing the commercial value and feasibility of different expansion scenarios. Our goal is to provide them with valuable insights to make informed decisions and maximize the success of their expansion efforts.

Comment on your research and development segment.

We are investing in top talent acquisition, forming a diverse R&D team in various fields. Strategic partnerships with leading institutions and startups provide access

to cutting-edge research and expertise. We prioritize investing in advanced infrastructure and technologies, equipping our R&D team with state-of-the-art tools for efficient experimentation and prototyping. Our culture of innovation includes internal programs that empower employees to propose and develop ideas, fostering a thriving ecosystem of creativity. Aligning our R&D efforts with market needs allows us to drive impactful research and development. Through these efforts, we aim to drive breakthrough innovations in the pharmaceutical industry, develop cutting-edge products, and maintain a competitive position in the market.

Brief us about the launch of a revolutionary pill called X Hangover?

X Hangover is an all-natural solution designed to alleviate the symptoms of a hangover. This product has been thoroughly tested, ensuring its safety, reliability, and clinical effectiveness in a Convenient Pack of 6 Tablets. In today's lifestyle, where social interactions are increasingly prevalent, alcohol often plays a role in various settings such as work functions, family gatherings, house parties, and clubs. As a result, preparing for the following day and the potential challenges that lie ahead can be quite demanding. It is crucial to maintain mental and physical stability during such times. Packed with carefully selected ingredients like Pueraria Lobata from Japan & China, Silybum marianum from Europe and Asia, Menthax piperita, Salix alba, and ß-Carotene, our product effectively detoxifies the liver and kidney while providing relief from acidity and nausea.

What are the company's plan to expand reach in the offline segment.

We have successfully established franchises in several regions, including Kerala, Bihar, Punjab, Chandigarh, and Port Blair. One of our core strengths lies in contract manufacturing, and we are proud to collaborate with esteemed brands such as Sun Pharma, ARI Healthcare, Nutramarc Sports Nutrition, Ten ABZ Sports Nutrition, Albert David, Venus Remedies, and more. In addition to our domestic operations, we have also ventured into the international market with exports to Dubai and Sri Lanka. We are currently in the process of expanding our export activities to reach even more markets around the globe and are in conversation with companies for contract manufacturing in India and worldwide.

Please elaborate about the new initiatives for Planet Herbs Lifesciences?

We have implemented several new initiatives with a focus on longer-term, transformative solutions. These initiatives demonstrate our commitment to innovation, sustainability, and patient-centricity, positioning us as a leader in the industry. We have introduced green manufacturing processes, reduced our carbon footprint, and implemented initiatives to minimize waste and promote recycling. By adopting environmentally conscious practices, we align our operations with global sustainability goals and contribute to a greener future. Digital transformation plays a crucial role in our initiatives. Planet Herbs Lifesciences has embraced cutting-edge technologies to enhance various aspects of our business. Advanced data analytics optimize our research and development processes, accelerate drug discovery, and improve clinical trial efficiencies. Innovative digital solutions, such as telemedicine platforms and personalized applications, enhance engagement. These initiatives reinforce our commitment to improving lives, advancing healthcare, and shaping the future of medicine.

How Planet Herbs Lifesciences sources its ingredients from natural and sustainable sources?

All Products manufactured are having only positive effects as they are ensured to be free from heavy metals and pesticides and are sourced from the most authentic suppliers from across the world. The patients can take all these medicines, for a long period without side effects in chronic ailments.

What is your growth target for next year?

Our growth target for the next year is to significantly expand our market presence and reach. One of the key strategies, we are implementing is doubling our offline team, allowing us to enhance our local operations and customer engagement. By increasing the size of our team, we aim to strengthen our on-the-ground capabilities, improve customer support, and drive business growth. ■

Fuelling Scientific Progress: The crucial role of Skill Development in the scientific community

Dhananjay Singh
Head – Science and
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Merck Life Science

Dhananjay Singh speaks about the role of skill development programs in industry academia. He emphasizes upon encouraging young researchers to embark on their upskilling journey in life sciences industry.

The Indian pharmaceutical and life science industry stands on the precipice of an extraordinary technological revolution, propelled by the unstoppable forces of globalization and the growing global reliance on Indian pharmaceutical exports. In the realm of scientific progress and discovery, the relentless march of innovation demands nothing less than a workforce armed with the precise skill set to master the intricate and perpetually evolving landscape of research. India, renowned for its exceptional prowess in life science research, now faces an indisputable imperative: skill development is not just an option but an absolute necessity to ensure that the scientific community remains at the very forefront of global innovation.

According to a report by Randstad Sourceright, a striking 33% of C-suite and human capital executives in the life sciences and pharmaceutical sector emphasize talent scarcity as a formidable challenge. To maintain a competitive edge in this volatile, uncertain, complex, and ambiguous (VUCA) industry, there can be no doubt that upskilling and reskilling talent is not merely beneficial but imperative. Despite India's substantial population of scientists, engineers, and entrepreneurs, combined with its robust demographic advantage, companies must embark on a resolute journey to cultivate the talent of tomorrow. This commitment extends beyond business interests; it underscores a resounding societal responsibility to empower individuals and communities with the skills needed to thrive in this dynamic and ever-evolving landscape.

Merck Lifescience facility

The Demand for specialized Skills

India's life science research sector has unmistakably risen as a global powerhouse, leaving its mark in pharmaceuticals, biotechnology, genetics, and environmental sciences, to name just a few. This thriving ecosystem owes its success to the seamless convergence of exceptional talent and abundant resources, transcending industry boundaries.

As scientific exploration broadens its horizons and ushers in new frontiers, researchers must go beyond traditional academic knowledge. To thrive and remain truly relevant, scientists must not only grasp but fully master revolutionary technologies. For example, they must harness the boundless potential of big data and demonstrate unwavering proficiency in AI and ML for comprehensive data analysis and profound insights. In this ever-evolving landscape, adaptability and expertise in these pivotal skills distinguish the leaders who spearhead pioneering scientific breakthroughs and drive relentless innovation.

Essential soft skills

Beyond technical proficiency, the modern scientific community places an undeniable premium on soft skills. Proficiency in effective written and oral communication stands as a cornerstone, facilitating the sharing of research findings and fostering collaboration across interdisciplinary teams. In tackling scientific challenges, the ability to solve problems takes centre stage. Furthermore, adeptness in project management is indispensable, ensuring the streamlined organization and efficient execution of research initiatives. These non-technical proficiencies are steadily gaining prominence within the scientific workforce and serve as invaluable complements to technical expertise.

Interdisciplinary collaboration

Modern life sciences research boldly traverses disciplinary boundaries. The quest to unravel the molecular complexities of diseases and engineer innovative biotechnological solutions presents formidable challenges that demand interdisciplinary collaboration for resolution. In this dynamic landscape, researchers possessing the prowess to communicate effortlessly across diverse domains and adeptly span these intellectual divides are in extraordinary demand.

The Role of Skill Development Programs

A multitude of organizations, ranging from esteemed academic institutions to industry pioneers, have risen to the occasion, answering the resounding call for skill development. In this ever-evolving landscape, skill development programs have emerged as nothing short of imperative, equipping the scientific community with the precise tools and techniques necessary to not just thrive but excel.

These skill development endeavors wield an influence that reverberates far beyond the boundaries of individual scientists and organizations. They constitute a driving force behind the overarching progress of science and research, igniting the flames of innovation, and elevating the international competitiveness of nations on the global stage.

Nurturing the next Generation

Encouraging young researchers to embark on their upskilling journey transcends mere individual growth; it stands as a profound investment in the future of scientific discovery. These emerging talents are the torchbearers of knowledge, the driving force behind the relentless march of innovation in the years that lie ahead.

Recognizing the paramount importance of skill development, the Council of Scientific & Industrial Research (CSIR) has embarked on a visionary path with the One Week One Lab program. This initiative serves as a powerful catalyst, igniting the minds of young innovators, students, startups, academia, and industry to come together in a collective pursuit of opportunities that promise to reshape the very fabric of our scientific future.

The Role of awards and recognition

In India, several awards and recognition programs have been established to honour and motivate young scientists who excel in their fields. These awards celebrate not only their contributions but also the skills and dedication that underpin their success. Awards like the Merck Young Scientist Award and the Future Insight Prize serve as beacons of inspiration for budding researchers, motivating them to reach new heights.

In the context of life science research in India, the development of skills is the cornerstone of scientific progress. It enables researchers to investigate uncharted territory and collaborate across disciplines. Not only do skill development programs and awards advance individual professions, but they also bolster the scientific community. As India continues to make advances in life science research, the importance of both technical and social skill development remains unwavering. This multifaceted approach ensures the nation remains at the forefront of scientific innovation, nurturing a future in which interdisciplinary collaboration and comprehensive skill development are the driving forces behind ground-breaking discoveries. ■

INTERVIEW

"We are also planning to invest ₹ 2000-2500 mn capex in current & next two financial Year."

Dr. Satish Wagh
Chairman & Managing Director
Supriya Lifescience

Dr. Satish Wagh talks about the overview and opportunities of the Pharma industry. He shares insights into capacity expansion plans, investment, and the company's future plans.

Brief us about the overview and opportunities do you see for the Pharma industry.

The pharma industry in India is expected to reach by US$ 65 billion by 2024 & US$ 130 billion by 2030 from our current label of US$ 50 billion (2022) with CAGR 12% to 14%. In 2019, it was US$ 20 billion , touch US$ 50 billion in 2022 with 30% + CAGR. Indian pharma industry is world's 3rd largest by volume and 14th largest in term of value. India is major exporter of pharmaceutical, over 200+ countries is served by Indian pharma exporters. Industry having 7 important segments such as CRAMS (Contract research and manufacturing services), API (Active pharmaceutical Ingredients), Formulations, Biologics, Biosimilars, Vaccines.

Pharma sector has numerous opportunities for growth and development. In current scenario , the Indian pharma industry is all set to witness healthy growth owing to digitalization, colossal demands & surge in domestic production. It is expected to grow by 3 times over the next 5-7 years.

Can you please tell us about the capacity expansion plans.

Our capacity expansion strategy is used in business as a pre emptied strategy to lock up a major share of the market and to discourage competitors and rivals with backward integration & technology upgradation. The CAPEX will help us to increase overall productivity, finally meet growing demand of existing molecules,

backward integration of existing molecule and capture new opportunities of CMO & CDMO. We are investing in new facilities, equipment's, technology, HR and upgradation of existing one to remain sustainable in business.

Brief us about your plans for global market? What percentage of revenue comes from exports.

Our plan is to increase our stakes in EUROPE, USA & JAPAN, which will help us in further value addition along with EBIDTA target 30+. About 80% of our revenue comes from exports and 20% comes from domestic market. We are exporting in 86 countries and focus over 1200+ customers. Our focus is increasing on regulatory market, which may go up to 85% over the next 3-4 years.

What are your investment plans.

We have made ₹ 1500 million Capex in last two financial year, which will enhanced our manufacturing capacity by 50-60%. We have also upgraded our warehouse, Admin block, ETP, QA,QC ,QC & R&D to meet out statutory and regulatory requirement. We are also planning to invest ₹ 2000-2500 mn capex in current & next two financial Year (2023-24-25-26) to enhance our existing manufacturing capacity by 100% along with forward integration .

Tell us about your financials. What are your views on margins.

We have made 17% Compound annual growth rate (CAGR) in sales in last 5 year and 59% CAGR in profits in same duration. Our target is to double EBIDTA (In terms of absolute value) in coming three financial year. Our plan is to maintain existing 28-32% EBIDTA margin on increase volume of business. Our target is to maintain 30%+ CAGR in PAT in the coming years. Our overall market share globally is 15-20% in Key molecule and 2-3 % in other molecules, which we are planning to increase by 20- 25%. ■

Energy Efficient Drying Equipment

M H Choudhary, Managing Director of Advanced Expertise Technology Pvt. Ltd. elaborates the concept of drying process, which is vital in any industry specially Pharma/ Chemical. Numerous equipment are available in the market for this application, ANFD and VTD stand tall among the rest where efficient drying with optimum cost is concerned.

Agitated Nutsche Filter Dryer (ANFD)

Agitated Nutsche Filter Dryer (ANFD) is a type of equipment used for separating solids from liquids and drying wet materials. The principle of ANFD involves mixing wet materials using an agitator, filtering the slurry through a filter medium to separate the solid particles from the liquid, and then drying the solid particles using the agitator and heat. The ANFD is a versatile equipment that can be used in a wide range of industries, including pharmaceuticals, chemicals, food, and biotechnology, which are available in Sizes: 50L to 12,000L. The construction of ANFD typically involves the following components such as Vessel, Agitator, Filter, Discharge System, Drying System, Vacuum System.

ANFD is a complex piece of equipment that requires careful design and construction to ensure efficient filtration, washing, and drying of materials.

Principle and Working of ANFD

Agitated Nutsche Filter Dryer (ANFD) is a multi-purpose equipment used for solid-liquid separation, washing, and drying of various chemicals, pharmaceuticals, and food products. The ANFD has a cylindrical vessel with a perforated plate at the bottom and a stirrer inside the vessel. The working of ANFD involves the following steps:

Loading: The slurry or wet cake is loaded into the vessel through the top manhole.

Filtration: The slurry is then agitated by the stirrer, which creates a vacuum below the filter media. The liquid is filtered through the filter media and collected in the vessel.

Washing: After filtration, the solid cake is washed with a suitable solvent or liquid to remove any impurities or residual product.

Drying: After washing, the stirrer is used to dry the solid cake by applying heat or vacuum. The solvent is evaporated, leaving behind a dry solid cake.

Discharging: Once the drying is complete, the dry cake is discharged from the vessel through the bottom discharge valve.

The ANFD offers several advantages over other types of filters, including high filtration efficiency, minimal product loss, reduced processing time, and a closed system, which eliminates the risk of product contamination. The equipment is also easy to clean and maintain, making it a popular choice for various industrial applications.

Uses of ANFD

Agitated Nutsche Filter Dryer (ANFD) is a type of equipment that is commonly used in the pharmaceutical, chemical, and food industries for various applications. Some of the uses of an Agitated Nutsche Filter Dryer:

Established Since 2004

Solid-Liquid Separation: ANFD is commonly used for separating solids from liquids. It can be used for separating solids from a variety of liquids such as suspensions, slurry, and solutions.

Filtration: ANFD can be used for the filtration of fine particles from the liquid. It is ideal for filtering particles that are difficult to filter with conventional methods.

Drying: ANFD is an effective drying equipment that is commonly used for drying of wet cakes or slurry. It can be used for drying heat-sensitive or temperature-sensitive materials.

Washing: ANFD can be used for washing of solids to remove impurities. It is ideal for washing of fine particles that are difficult to wash with conventional methods.

Crystallization: ANFD can be used for crystallization of solids from the liquid. It can be used for crystallization of heat-sensitive or temperature-sensitive materials.

Reactor: ANFD can be used as a reactor for various chemical reactions. It can be used for reactions that require high agitation and heating.

Advantages of ANFD

The Agitated Nutsche Filter Dryer (ANFD) has a combination of functions like, filtration, washing, and drying in a single unit. Some of the advantages of using an ANFD include:

Efficient and time-saving: ANFDs can process large volumes of material in a relatively short time. The combination of filtration, washing, and drying functions in a single unit eliminates the need for multiple pieces of equipment, reducing processing time and increasing productivity.

High product quality: ANFDs provide excellent separation and washing of solids, ensuring that the final product is of high quality with low residual moisture content. The ANFD design also minimizes the risk of product contamination.

Cost-effective: ANFDs are cost-effective in terms of equipment investment and operational costs. The use of a single unit for filtration, washing, and drying reduces capital expenditures and operating costs, such as labor, energy, and maintenance.

Safe operation: ANFDs are designed with safety in mind. The unit is completely sealed, minimizing the risk of exposure to hazardous or toxic materials. The use of an agitator ensures that the solids are well mixed, minimizing the risk of hotspots and ensuring uniform drying.

Easy to clean: ANFDs are designed for easy cleaning and maintenance. The unit can be disassembled quickly, and the interior can be easily accessed for cleaning and inspection. The ANFD design also minimizes the risk of product buildup, reducing the need for frequent cleaning.

ANFD is a highly efficient and versatile piece of equipment that can provide many benefits to a variety of industries, including pharmaceuticals, chemicals, and food processing.

Advanced Vacuum tray Dryer (VTD)

Vacuum Tray Dryer is one of the most popular vacuum drying equipment, which is economic, as compared with other vacuumized drying equipment. Just like the RCVD, VTD too is majorly used in Pharmaceutical (especially API) Drying operations. VTD is also used in other industries for Drying purpose such as Chemicals, Food, Cosmetics etc, which has a capacity of 3,6,12,24,48,96

The major components of VTD includes VTD Chamber, Heating Shelves, Inlet and Outlet Headers, Condenser, Receiver, Vacuum Pump, Water Heating system Or Low-Pressure Steam (for heating the VTD Hot Plates and Limpet, Trays, Nitrogen Purging system (optional)

Advantage of VTD:

Minimum Loss/ Wastage of Material: VTD works on the principle of static bed. Hence, the LOD (loss on dying) majorly is nothing but the mass of solvent or water evaporated. There are possibilities of minute and light powder particles getting lost due to vacuum, however, the loss is negligible.

Safe to Operate: Since, it is a Static Dryer, chances of operational hazards are less.

Space Saver: Many a times, the body of the VTD is taken off the operational area (viz. VTD Body is taken off the Clean Room) and only the Door is inside the operation area. This saves a lot of space and offers a great amount of operational flexibility to the operator and/or user.

Simplicity of Operation: Operating is very simple and straight forward. With minimal training, operators can use it easily.

Ease of Cleaning: Internal Hot Plates or Heating Shelves are completely removable, hence, can be cleaned once in a while. Otherwise, the entire interiors of the chamber are washable in place.

Provision of Solvent Recovery: Solvent recovery rate is very high, as compared with other or traditional dryers.

Energy Saver: Power or Electricity consumption is minimum.

Easy to Automate: Level of automation is mostly Non-Complex or Straightforward, as, it is a static dryer.

Economical: VTD is indeed economical, when compared with the other types of Vacuum Dryer, because it is simple cabinet dryer with static bed vacuum drying.

Possibility of integrating it with a Flexible or Rigid Isolator: Small size VTDs can be used for Containment Application, thus avoiding the product and vapor contacts with the operator.

Challenges that come along with VTD:

- Loading and Unloading of the Wet/ Dry mass respectively
- Shuffling/ Racking of Wet Mass between the Batches
- Handling Wastages
- Size and Capacity wise Limitation
- Human Exposure to Hazardous Vapors and Wet mass.

Factors to be taken into consideration while designing a VTD:

- Orientation of VTD, Available Floor Space, Availability of the Utilities and Floor Layout/ Elevation
- Level of Automation
- Statutory and Safety compliance
- Batch Size Calculations
- Product Specific Operational Challenges (based on the previous experience Or Studies
- Mechanical and Process Design, as well as, Sizing of the Equipment

How to select the right VTD model / Vendor:

- Flatness of the Heating Shelves
- Flatness of the Door Frame, Body Frame/ Uniformity of the engrooved Gasket Channel
- Type and Quality of Door-Gasket
- Welding Quality of the Heating Shelves
- Close to Zero or Minimum Leakage of Vacuum
- Other Engineering and Design Aspects like Heat Load calculations, Nozzle Sizing, Material Selection and Workmanship, all aspects need to be studied properly. ■

Author

M H Choudhary
Manager Director
Advanced Expertise Technology Pvt. Ltd.

INTERVIEW

"West's focus is to continuously enhance manufacturing capabilities to benefit the wider APAC region."

Alagu Subramaniam
Senior Director, Sales and Commercial Operations,
Asia Pacific, West Pharmaceutical Services, Inc.

Alagu Subramaniam spoke about the challenges and opportunities for the biologics industry globally & in India. He also talks about the current market size, growth and importance of containment & delivery systems.

What are the challenges and opportunities do you see for the biologics industry globally & in India?

Globally, the biotechnology and biopharma sectors are setting themselves on a sustained growth trajectory, with an expected compound annual growth rate of 10.3% from 2023 to 2030. This means that the popularity of biologic therapies will continue to rise, with more interest and investment, thereby opening more opportunities for the sector. This may be due to an improved understanding of the benefits provided by biologics treatments – targeted, efficient, and safe – for patients at home and in hospitals. Cross-border collaboration is also on the rise to help foster more innovation around the world.

In India, the biologics market is expected to grow at a CAGR of 22% by 2025 according to research – and this is in line with the global market growth as well. The development of the industry in India means that more investments and support of regulators can be tapped into. In 2016, the Indian government has launched the Biotechnology Industry Partnership Program to support small and mid-sized enterprises in the development of biosimilars while recently the National Biotechnology Development Plan was announced to support the

biologics and biotech sectors. This regulatory support is bound to help the industry grow in India.

On top of governmental support and investment, India also boasts a favorable environment for production with lower development costs and a huge talent pool. These factors will help India continue to rise and stay competitive in the global biologics industry, as it is an attractive destination for production, innovation, and clinical trials. West is witnessing the growth trajectory of India and and have invested in a commercial office, manufacturing facility in India, and also opened our first Digital Technology Centre over the last two decades.

Cross-border regulations is perhaps one of the main challenges to overcome for the global market. Each market has their own standard guidelines to adhere to, so industry players looking to expand manufacturing processes will have to take time to understand respective market needs and regulations. This may require resources, but from West's experience, this is a necessary investment for any industry player to grow. At West, we take special care to meet and work with regulators to ensure that we are aligned with necessary guidelines based on the market.

For India, the growing opportunity lies in biologics and biosimilars to boost the production value of India's supply lines. This will require time and proper investment from private and public sectors, with whom we are working with, and we hope to be able to help further innovation through our work in India.

What is the current market size and anticipated growth. Which regions will drive the growth of containment & delivery systems globally and how West Pharmaceutical plans to leverage the opportunities.

The current market size of containment and delivery systems is on the rise, with a predicted 11.87% compound annual growth rate from this year through to 2031. This is in line with West's own development through the last few years, where in 2022, we recorded a phenomenal growth in business and interest in our solution across markets such as India, Singapore, China, and Korea.

The biologics market in APAC is steadily on the rise. In particular, the Indian biologics market is one of the fastest growing in the region along with South Korea which has been receiving very strong support from regulatory boards. Singapore is strengthening its place as a leading hub of biomedical sciences in Asia. All of this has reinstated West's focus to continuously enhance manufacturing capabilities to benefit the wider APAC region, while maintaining high quality and safety standards. Recently, we also unveiled our updated manufacturing facility in Singapore to support our growth in APAC.

The Asia market is ripe with opportunities for growth and development and has one of the fastest drug discovery innovation speeds in the world. We welcome the support from our partners and regulators in each market and are poised to continue tapping into the potential of the overall APAC region. We are committed to supporting our talented workforce by offering exciting career and upskilling opportunities, that will contribute to the overall growth and enhancement of the healthcare industry.

Brief us about the rising importance of containment and delivery systems and latest trends in the space.

The medicines of today are evolving rapidly, with more complex innovations, utilising sensitive molecules that need to be stored and contained in a well-managed environment. Over the last decade, we have observed the rapid rise in trials, and according to data by Pharma Intelligence, APAC contributed close to half of the world's clinical trial activities in 2021 alone. The home-based healthcare, telehealth, and injectable therapies are growing – all of which will contribute to the demand of biologics, biosimilars, and trials. This steady development and growth of healthcare sector in the APAC region means that delivery and containment systems for drugs and therapies remains more crucial than ever. More patients, at homes or in hospitals, will require innovative packaging and delivery solutions, that can allow safe, efficient, and accessible administration of treatments and injectables. It is only with a safely developed containment and delivery system, aligned with regulatory guidelines, that we can achieve minimised risk and overall improvement to patient health.

This role will continue to evolve, spurring further innovation from manufacturers of these containment solutions. The company continues to be radical in our overall approach and look at cutting edge solutions according to market needs, along with collaboration with local stakeholders to minimize interventions and roadblocks. ■

"We are looking at expanding both team size and warehouse capability to better serve our customers in the future."

Journey Hong
General Manager, South Korea
West Pharmaceutical Services, Inc.

Journey Hong spoke about the company's growth plans and strategies for Korea & globally. He also spoke about the growth for South Korea.

What are the company's growth plans and strategies for Korea & globally.

The company is looking at expanding both team size and warehouse capability to better serve our customers in the future. Our team is operating with various functions including sales & marketing, technical customer services, warehouse, etc. to serve our customers in Korea.

We hope to better meet and serve our customers through physical interactions and training sessions. This will be particularly helpful to our customers, as more companies enter the biologics and biomanufacturing sector, they may also require more support in understanding the regulatory guidelines for containment services.

The company is planning to develop our people's capabilities and operations through new trainings and onboarding of the latest technological systems and will continue to tailor our solutions and enhance our understanding of customer demands in the Korean market.

What is the growth do you see for South Korea and how does the group plan to emulate the success in other international markets?

In South Korea, we have been progressing well on a high growth trajectory. We made the active choice to focus on delivering the right products by understanding our customers' needs, their value proposition and

building trust with them. Internal checks and operational training have always been a key priority to ensure that we are following the highest industry standards. Our internal processes are unique and adaptive to change and unexpected needs, such as acceleration in product timelines or global supply chain disruptions. Meanwhile, we have been investing in 13 sites of our global network to increase capacity and quality to support the evolving needs as well as mitigating the risks.

Using the most advanced cutting-edge technologies, on top of strong industry partnerships, helps us innovate and strengthen our offerings. For example, we most recently extended our complete containment solution, West Ready Pack containment solution, with Corning and now hold the global exclusive distribution rights for the Corning Valor RTU Vials.

Lastly, our growth in Korea and worldwide has also been aided by the generous support of regulatory parties whom we work closely with. The positive policy environment helped us establish a strong foundation to offer products that are required by the market.

Globally, West continues to be committed to a consistent enhancement of our capabilities with high quality and safety standards. Across all the markets we serve, we continue to support our talents with upskilling opportunities and training that will also help them grow. As an organisation, we work together as a team and with specific regulators to contribute to the growth of the markets our customers are in. ■

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