VOL 22 | ISSUE 11 | JUNE 2024 | MUMBAI | TOTAL PAGES 50 | PRICE ₹ 150

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PHARMA BIO WORLD
R.N.I. No.: MAHENG/2002/08502

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Annual Subscription: ₹ 1620/-, Foreign: USD 180

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PLACE OF PUBLICATION
JASUBHAI MEDIA PVT. LTD.
210, Taj Building, 3rd Floor, Dr. D. N. Road, Fort, Mumbai 400 001, Tel: +91-22-4037 3636

Printed and published by Mr Hemant K. Shetty
Address: 406-D, The Karachi Citizens Co-Op Hosg Soc Ltd., Juhu Varsova Link Road, Andheri West, Mumbai - 400053.

Printed at The Great Art Printers
25, Unique House, S A Brelvi Road, Fort, Mumbai 400 001.

Editor: Ms. Mittravinda Ranjan, 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

Published from Jasubhai Media Pvt .Ltd. 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

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US-focused Pharma companies to benefit from drug shortages: India Ratings

Mumbai, India: India Ratings and Research expects US-focused pharma companies to sustain their revenue improvement trend in FY25 on account of heightened drug shortages in the US market. This will not only provide potential for volume growth, but also limit price erosion to single digits over the next 12-18 months, leading to improved returns.

The US is facing an active shortage of 233 drugs across 22 therapeutic categories, led mainly by discontinuation of drug production, rising demand and delays in shipments. The agency believes Indian pharma companies with a reasonable track record, recent cost rationalisation and enhanced research & development capabilities can capture a higher market share in many of these therapeutic categories.

"The price erosion in the US generics market is expected to remain in single digits in the near future, primarily due to drug shortages. US-catering Indian generic players have seen a strong financial performance during FY24, due to lower raw material cost and stability in pricing. With improving complexity of products and recurring supply chain issues leading to uncertainty, we expect the pricing scenario in the US will remain supportive", according to Vivek Jain, Director, Corporate Ratings, India Ratings and Research.

Taking cognizance of the drug shortages, there has been an improvement in USFDA approvals and tentative approvals of the original ANDAs filed by pharma companies. The median timeline for approval has increased to 26 months which is a six-quarter high, from 21 months. With the reduced ANDA filing intensity, the pricing scenario will improve amid decreasing competition.

Indian Pharma industry projected to reach USD 130 billion by 2030

Hyderabad, India: The theme "Optimizing Pharmaceutical Quality and Compliance," convened with over 35 key industry leaders engaging in strategic discussions about the future of the pharmaceutical sector at the PharmaLytica expo.

As the Indian pharmaceutical industry is projected to grow from USD 65 billion in 2024 to USD 130 billion by 2030, with CAGR of over 10%, the expo highlights its potential trajectory. By 2047, the industry is expected to reach an impressive USD 450 billion, underscoring India's significant role in the global pharmaceutical landscape.

Experts delved into technology trends aimed at maximizing pharmaceutical productivity, explored analytical advancements transforming pharma labs, and discussed regulatory and quality frameworks essential for biosimilar development and covered strategies for drug repositioning, integrating quality in clinical development, innovations in pharma packaging and machinery, and advancements in analytical instrumentation.

Ravi Uday Bhaskar, Director General of Pharmaceuticals Export Promotion Council of India (Pharmexcil), said "We are expecting to reach more than USD 31 billion in the next financial year. 50% of our exports are going to highly regulated markets. In North America and Europe, it's almost 55%. In the US, we exported more than 8 billion with a 15% growth rate, and to the UK, we achieved a 21% growth rate."

Dr. Gaurav Pratap Singh, Senior Principal Scientific Officer, Indian Pharmacopoeia Commission said, "The significant growth in biosimilars approvals and manufacturing further enhances patient access to biopharmaceuticals. Innovation remains paramount, especially in emerging prophylactic and therapeutic products like medical devices, complex generics, monoclonal antibodies, and gene therapy."

Deepak Khurana, Vice President-Procurement & SCM, Suven Pharmaceuticals Limited said, India leads in generic drug manufacturing and exports, meeting global demand for affordable medications. The emphasis on biopharmaceuticals and biosimilars is increasing, driven by their rising demand. Regulatory reforms are set to boost innovation and quality. Indian pharmaceutical companies are ramping up R&D investments for novel drug discoveries."

Dr. Subhash Thuluva, Sr. Vice President & Head - Clinical Development, Biological E. Limited said "With Indian Pharmaceutical exports projected to grow by 10%, India remains a key global supplier, earning the title 'Pharmacy of the World' solidified, catering to 20% of the global demand for generics."

Biocon Limited signs deal for commercialization of Liraglutide

Siddharth Mittal, CEO and MD, Biocon Ltd

Bengaluru, Karnataka, India: Biocon Limited, an innovation-led global biopharmaceutical company, announced the signing of licensing and supply agreement with Handok, a specialty pharmaceutical company in South Korea, for the commercialization of its vertically integrated, complex drug product, Synthetic Liraglutide. Liraglutide is an injection in pre-filled pen, used in the treatment of chronic weight management as an adjunct to a reduced-calorie diet and increased physical activity.

Under the terms of this agreement, Biocon will undertake the development, manufacturing and supply of the drug product, and Handok will be responsible for obtaining regulatory approval and commercialization in the South Korean market.

Handok is amongst Korea's leading companies in the management of diabetes, offering a host of solutions from diagnosis to treatment and care. The Company's diabetic portfolio includes products such as Amaryl, Tenelia and the recently launched Barozen Fit, a real time glucose monitoring device.

Siddharth Mittal, Chief Executive Officer and Managing Director, Biocon Ltd, said "We are pleased to enter into this strategic partnership with Handok, which will enable patients in South Korea dealing with weight management to gain access to our GLP-1 peptide drug product, Synthetic Liraglutide. This also aligns with our commitment to expand our portfolio of innovative, affordable medicines to address the unmet needs of patients around the world."

YoungJin Kim, Chairman of Handok, commented, "Liraglutide is an important drug product for treating diabetes and obesity. Our collaboration with Biocon will enable Handok to expand its portfolio into the obesity sector, which will benefit patients and sharpen our competitive edge. We look forward to successfully launching and growing Liraglutide in the Korean market."

Lupin completes acquisition of brands from Sanofi

Dr. Fabrice Egros, President – Corporate Development, Lupin

Mumbai, India: Global pharma major Lupin Limited announced that its European hub entity, Lupin Atlantis Holdings SA, has completed the acquisition of two well-known brands, Aarane in Germany and Nalcrom in Canada and the Netherlands, along with the associated trademark rights, from Sanofi.

The transaction aligns with Lupin's strategy to grow its global presence in Specialty areas, where the company has a leading position, with high-quality products that are innovative or unique in the market. This acquisition will enhance Lupin's Respiratory business in Germany, by aiding in the expansion of the newly established franchise, following the introduction of Luforbec.

Nalcrom (sodium cromoglicate Oral) belongs to a group of medicines called anti-allergics. It is used to treat food allergies after adequate testing for sensitivity to specific allergens in conjunction with restricting the main allergens.

Aarane (sodium cromoglicate/reproterol hydrochloride pressurized inhalation) is a chromone complex indicated in symptomatic acute treatment of sudden asthma attacks (e.g., allergic forms or those triggered by exertion, stress or infections) and targeted prevention of exercise-induced asthma or in cases of foreseeable allergen contact.

Dr. Fabrice Egros, President – Corporate Development, Lupin said, "This acquisition will strengthen our global position in treating patients suffering from diverse respiratory diseases and conditions, and it adds accretive assets in gastro-intestinal care that broaden our portfolio of branded products."

Strides receives USFDA approval for Sucralfate Oral Suspension

Bangalore, India: Strides Pharma Science Limited announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for the generic version of Sucralfate Oral Suspension, 1gm/10 mL, from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Carafate 1gm/10mL of AbbVie. Sucralfate is used to treat stomach ulcers, gastroesophageal reflux disease (GERD), radiation proctitis, and stomach inflammation and to prevent stress ulcers.

Sucralfate Oral Suspension, 1gm/10 mL has a market size of ~USD 124mn as per IQVIA (March 2024). The Sucralfate Oral Suspension, 1gm/10 mL will be manufactured at the company's flagship facility in KRS Gardens in Bangalore, India.

Serum Institute of India ships first set of Malaria Vaccine to Africa

Natasha Poonawalla, Adar Poonawalla, Serum Institute of India & Hon. Eric Garcetti, US Ambassador to India

Pune, India: Serum Institute of India, the world's largest manufacturer of vaccines by number of doses, marks a significant milestone with the shipment of its first set of R21/Matrix-M malaria vaccine to Africa. The initial shipment will be sent to the Central African Republic (CAR), followed by other African countries such as South Sudan and Democratic Republic of Congo in the next coming days. In total, 1,63,800 doses of the R21/Matrix-M malaria vaccine have been specifically allocated for CAR region, out of which only 43,200 doses will be dispatched from Serum Institute of India's facility.

Developed in collaboration with the University of Oxford and Novavax's Matrix-M adjuvant, the R21//Matrix-M vaccine is the second malaria vaccine to be authorized for use in children in malaria-endemic regions.

The R21/Matrix-M malaria vaccine, developed through collaboration between the Jenner Institute at Oxford University and the Serum Institute of India leveraging by Novavax's saponin-based adjuvant technology, received support from the European and Developing Countries Clinical Trials Partnership (EDCTP), the Wellcome Trust, and the European Investment Bank (EIB). Till date, Serum Institute of India has manufactured 25 million doses with a capacity to scale up to 100 million doses annually.

"As two diverse democracies, the United States and India have flourishing private sectors that foster innovation, knowledge, and access to high-quality healthcare. The development of the R21/Matrix-M malaria vaccine represents a great step forward in our battle against this deadly parasite," said the Hon. Eric Garcetti, US Ambassador to India.

Dr. Umesh Shaligram, Executive Director, R&D, Serum Institute of India said, "The shipment of the R21/Matrix-M Malaria Vaccine to Africa marks a milestone in our collective fight against this life-threatening disease. This achievement is a testament to the power of collaboration and the efforts of our workforce at the Serum Institute of India, working in partnership with Novavax and the University of Oxford."

"The R21/Matrix-M vaccine is a vital new tool to help stop the devastating health and economic impact of malaria on nearly half of the world's population, including the tragic loss of 1,300 children every single day,"" said John C. Jacobs, President and Chief Executive Officer, Novavax.

Cipla receives final approval for generic version of Somatuline Depot Injection

Mumbai, India: Cipla Limited announced that it has received the final approval for its Abbreviated New Drug Application (ANDA) for Lanreotide Injection 120 mg/0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL from the United States Food and Drug Administration (USFDA).

Cipla's Lanreotide Injection is AP-rated therapeutic equivalent generic version of Somatuline Depot (lanreotide) Injection. Lanreotide Injection is supplied as 120 mg/0.5 mL, 90 mg/0.3 mL, 60 mg/0.2 mL single-dose, pre-filled, ready-toinject syringe. Cipla's Lanreotide injection is indicated for the treatment of patients with Acromegaly and Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs). According to IQVIA (IMS Health), Somatuline Depot (Lanreotide) had US sales of approximately $898M for the 12-month period ending March 2024.

Zydus Lifesciences announces completion of Enrolment for Phase II clinical trial of Usnoflast

Ahmedabad, India: Zydus, a leading discovery-based, global pharmaceutical company, announced that it has completed enrolment of its Phase II clinical study of NLRP3 inhibitor 'Usnoflast (ZYIL1)' in patients with Amyotrophic Lateral Sclerosis (ALS).

ALS patients experience neuroinflammation and rapid neurodegeneration leading to steady loss of the ability to move, speak, eat and eventually breathe. ALS results in loss of motor neurons in the brain and spinal cord which controls voluntary muscle movement. ALS affects approximately 31,000 people in the U.S.A and on an average 5,000 new patients are diagnosed every year with this disease in USA as per statistics from Centers for Disease Control and Prevention (CDC).

The Phase II clinical trial has recruited 24 ALS patients across 7 clinical trial sites in India and will study safety, tolerability, pharmacokinetics and pharmacodynamics of Usnoflast. The change from baseline in the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) score will be measured at week 4, week 8 and week 12, as the trial's primary endpoint is the placebo-controlled, randomised, double-blind Phase 2 clinical trial. The trial will also evaluate Key Secondary Endpoints including Slow Vital Capacity (SVC), a predictor of functional loss in ALS and neurofilament levels at week 4 and week 12.

Usnoflast (ZYIL1) is a novel, oral small molecule NLRP3 inhibitor. Studies have demonstrated that ZYIL1 is highly potent in human whole blood assay and can suppress inflammation caused by the NLRP3 inflammasome.

Aurobindo Pharma arm signs agreement with MSD Singapore

Hyderabad, India: Aurobindo Pharma Ltd' wholly-owned subsidiary, TheraNym Biologics, has signed a master service agreement for contract manufacturing of biologicals with Merck Sharpe & Dohme Singapore. The area of agreement includes for expansion of the biologics manufacturing facilities of TheraNym situated at Borapatla(V), Hathnoora Mandal, Medak District, Borapatla, TS and exploring the possibilities to enter into contract manufacturing operations ("CMO") for biologicals.

K. Nityananda Reddy, Vice Chairman & Managing Director, Aurobindo Pharma

TheraNym will build the manufacturing facility, manufacture the products and supply to MSD as per the arrangement. The company added that Theranym will invest around ₹.1,000 crores for establishing manufacturing facility with large scale bioreactors for any mammalian cell culture product and a vial filling isolator line for commercial drug product manufacturing upto 25-30 mn vials per annum.

Torrent Pharma enters into Patent licensing agreement with Takeda Pharmaceuticals

Ahmedabad, India: Torrent Pharmaceuticals Limited has entered into a non- patent licensing agreement with Takeda to commercialize Vonoprazan in India. Vonoprozan is a novel potassium-competitive acid blocker (P-CAB), used for the treatment of acid related disorders - Gastroesophageal Reflux Disease (GERD).

Torrent will market Vonoprazan under its own trademark, Kabvie. As per a 2019 study published by Indian Journal of Gastroenterology prevalence of GERD in Indian population is around 8.2%, with a higher prevalence of around 11.1% in urban population.

Commenting on the agreement, Aman Mehta – Director, Torrent Pharma said, "We are delighted to commercialize this novel treatment for Indian patients. I am confident that the launch of Kabvie will aid in reducing the disease burden of GERD and further strengthen our Gastrointestinal offerings, augmenting our position as a leading player within the Indian Pharmaceutical Market."

According to AWACS MAT April 2024 data, the Indian market for treatments used in GERD is valued at ₹ 8,064 crore, growing at 8% CAGR over the last 4 years. Currently treatments such as Pantoprazole (Proton Pump Inhibitors) are used to treat GERD. Availability of P-CABs such as Kabvie will make accessible new and effective treatments of GERD for the Indian population.

Orchid Pharma receives DCGI approval for antibiotic drug Combination of Cefepime and Enmetazobactam (NCE)

New Delhi, India: Orchid Pharma, based in Chennai, India, has received Drugs Controller General of India (DCGI) approval for the manufacturing and marketing of its invented New Chemical Entity Active Pharmaceutical Ingredient (API), Enmetazobactam. DCGI has also granted permission to manufacture and market Finished Dosage Form (FDF) of Cefepime and Enmetazobactam as a dry powder injectable. This formulation is indicated for the treatment of complicated Urinary Tract Infections (cUTI) including acute Pyelonephritis, HospitalAcquired Pneumonia (HAP) including Ventilator-associated pneumonia (VAP), and Bacteremia when it is associated or suspected to be associated with either complicated urinary tract infections or hospital-acquired pneumonia.

Manish Dhanuka, Managing Director, Orchid Pharma, said, "Enmetazobactam's approval in India is personally fulfilling as being an Indian company, we wanted to expand access to advanced and affordable treatment options for patients in India. Orchid Pharma is committed to innovation and is poised to provide an effective solution for patients suffering from severe infections, particularly in the face of rising antimicrobial resistance. We continue our dedicated efforts towards research and development to address unmet medical needs."

Caplin Steriles gets USFDA approval for Phenylephrine hydrochloride Ophthalmic Solution

Chennai, India: Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Phenylephrine hydrochloride Ophthalmic Solution USP 2.5% and 10% (eye drops), a generic therapeutic equivalent version of the Reference Listed Drug (RLD), from Alcon Research LLC.

Phenylephrine hydrochloride Ophthalmic Solution USP 2.5% and 10% is indicated to dilate the pupil of the eyes. According to IQVIATM (IMS Health), Phenylephrine hydrochloride Ophthalmic Solution USP 2.5% and 10% had US sales of approximately $32 million for the 12-month period ending Mar 2024.

Aurigene Pharmaceutical opens its biologics facility

Akhil Ravi, CEO, Aurigene

Hyderabad, India: Aurigene Pharmaceutical Services Limited, a Dr. Reddy's Laboratories Limited company, inaugurated its biologics facility spread across 70,000 sq.ft. in Genome Valley, a bio cluster, located in Hyderabad, India.

The facility is designed to serve customers with process & analytical development and small scale manufacturing of antibodies and other recombinant proteins for preclinical and early phase clinical requirements. The process and analytical development laboratories are now operational while the commissioning of manufacturing capacity will be completed later in 2024.

The new facility is complementary to the company's current discovery capabilities and infrastructure, which primarily focuses on recombinant proteins including mAbs, bi- and multi-specifics, immune-fusion molecules, antibody drug conjugates and other complex proteins.The opening of this latest facility is one of multiple strategic initiatives that Aurigene is implementing to support rapid growth in both the small molecule and biologics spaces, as illustrated by recent announcements related to AI/ML-led drug discovery in small molecules and a collaboration with Vipergen, a DNA-encoded library (DEL) technologies service provider.

Akhil Ravi, CEO, Aurigene, commented, "The journey started a year back when we decided to invest in creating the facility. It is great to see the facility operational and the addition of this capacity and capabilities shows our firm commitment to the continued expansion of our biologics business, building on 25 years of proven experience. The state-of-the-art facility will enable us to service our global customers efficiently and support in the development of innovative medicine."

Dr. Roger Lias, Global Commercial Head – Biologics, Aurigene, added, "Our new facility further strengthens Aurigene's capabilities and builds on our technical excellence, demonstrated global compliance and state-of-the-art facilities as companies from start-up biotechs to global multinationals continue to strengthen their supply chains and seek economically viable support for both their development portfolios and marketed products."

Akums Drugs introduces Capsules for GIT disorders

Sandeep Jain, Managing Director, Akums Drugs & Pharmaceuticals Ltd

Mumbai, India: Akums Drugs & Pharmaceuticals Ltd, India-focused CDMO serving the Indian domestic pharmaceutical industry, has announced the launch of Rabeprazole + Levosulpiride SR Capsules. Approved by the Drug Controller General of India (DCGI), this new formulation aims to enhance relief for patients suffering from gastrointestinal tract (GIT) disorders.

[GERD, or gastro-oesophageal reflux disease, is a debilitating condition characterised by the reflux of stomach contents into the oesophagus, leading to troublesome symptoms and potential complications. With GERD often dubbed as chronic acid reflux, its prolonged presence not only impacts the quality of life but also poses risks of serious health complications, including stomach and esophageal cancer.

[Rabeprazole sodium, a potent antisecretory compound, selectively inhibits gastric acid secretion by targeting the H+ and K+ ATPase at the surface of gastric parietal cells. It has demonstrated efficacy in treating gastric and duodenal ulcers, as well as GERD.

Arushi Jain, commented, "Our Rabeprazole + Levosulpiride SR Capsules aim to offer an effective remedy, ease symptoms, enhance gastrointestinal function, and booste patients' overall well-being. Levosulpiride offers rapid relief and better healing outcomes with fewer side effects, elevating the overall treatment experience."

Sandeep Jain, Managing Director, Akums Drugs & Pharmaceuticals Ltd., added, "The first step to curing any ailment is awareness. It's crucial to raise awareness about GERD to mitigate the risk of developing this condition. The introduction of Rabeprazole + Levosulpiride SR Capsules shows Akums' commitment to providing effective pharmaceutical solutions that cater to medical needs."

ACG Partners with EY-Parthenon to achieve net zero goals

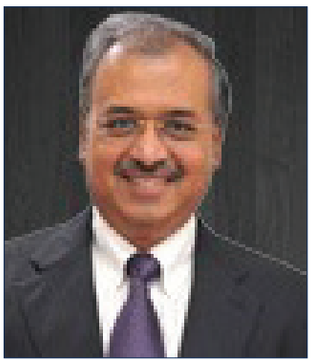
New Delhi,India: ACG, the world's largest integrated supplier and service provider to the pharmaceutical industry, has announced a strategic partnership with EY-Parthenon, one of the largest professional services networks in the world, aiming to enhance ACG's sustainability initiatives through a comprehensive Net Zero strategy and implementation roadmap aligned with the Science Based Targets initiative (SBTi).

Combining ACG's industry expertise with EY-Parthenon's sustainability consultancy, the partnership seeks to significantly reduce carbon emissions and promote sustainable practices across ACG's operations has already initiated its journey by conducting a comprehensive greenhouse gas emissions (GHG) emissions inventory and carbon footprint assessment for their most prominent products. ACG, in collaboration with EY-Parthenon, is developing a comprehensive Net Zero Roadmap.

Shivshankar S.R, CEO of ACG Packaging Materials, said, "Our alliance with EY Parthenon marks a pivotal advancement in our sustainability pursuit. Leveraging their esteemed expertise in industrial decarbonization, we are poised to expedite our Net Zero objectives, thereby effectuating a meaningful reduction in our carbon emissions."

Kapil Bansal, Partner and Leader of Industrial Decarbonization, EY-Parthenon India, added, "EY-Parthenon is proud to announce its collaboration with ACG as they advance towards achieving SBTi aligned Net Zero strategy and roadmap. With our extensive expertise in strategic decarbonization and CBAM impact mitigation, we are committed to guiding ACG in meeting the company's emission reduction goals, optimizing costs, minimizing risks, and driving meaningful transformation in the sector."

Sun Pharma Q4 net profit stood at ₹. 26,546 million


Dilip Shanghvi, CMD, Sun Pharma

Mumbai, India: Sun Pharmaceutical Industries Limited reported results for the fourth quarter and full year ending March 31st, 2024. The company's gross sales stood at ₹. 118,133 million, growth of 10.1%, while India formulation sales was at ₹. 37,078 million, up 10.2%. The company's net profit for Q4FY24 was ₹. 26,546 million as compared to ₹. 19,845 mn during Q4FY23. The company's US formulation sales was at USD 476 million, up 10.9%, while R&D investments at ₹. 9,000 million.

Dilip Shanghvi, Chairman and Managing Director, Sun Pharma said, "During FY24, two of our businesses surpassed USD 1 Billion in annual sales, namely Global Specialty and Emerging Markets. We shall continue to build our specialty portfolio and invest further to gain scale across our businesses."

For the full year FY24, sales of formulations in India were 148,893 million, up by 9.5% over the same period last year. India formulations sales were ₹. 37,078 mn for Q4FY24, a growth of 10.2% over Q4 last year and accounted for 31.4% of total consolidated sales for the quarter.

Formulation sales in the US for the full year FY24 were USD 1,854 million up 10.1% over the same period last year. US formulation sales were USD 476 million for Q4FY24, a growth of 10.9% over Q4 last year and accounted for 33.5% of total consolidated sales for the quarter.

Piramal Pharma Q4 net profit stood at ₹ 132 Crores


Nandini Piramal, Chairperson, Piramal Pharma

Mumbai, India: Piramal Pharma Limited announced its standalone and consolidated results for the fourth quarter (Q4) ended 31st March 2024. The company's revenue from operations grew by 18% YoY and 15% YoY in Q4FY24 and FY24 respectively, driven by healthy growth in our CDMO and ICH businesses, while EBITDA grew by 48% YoY and 61% YoY in Q4FY24 and FY24 respectively, primarily driven by revenue growth, operating leverage, cost optimization, and operational excellence initiatives. The company's net profit (before exceptional Items) more than doubled in Q4FY24 at ₹ 132 Crores compared to ₹ 50 Crores in Q4FY23.

Nandini Piramal, Chairperson, Piramal Pharma Limited said, "FY24 has been a strong year for the Company with all round improvement, mainly driven by our CDMO business that delivered a robust 19% YoY revenue growth. We saw significant increase in order inflows, especially for on-patent commercial manufacturing, amidst a difficult biotech funding environment."

Glenmark Pharma Q4 consolidated revenue stood at ₹. 30,630 mn


Glenn Saldanha, CMD, Glenmark Pharmaceuticals Ltd.

Mumbai, India: Glenmark Pharmaceuticals Limited, a research-led, global pharmaceutical company, announced its financial results for the fourth quarter ended March 31, 2024.

For the fourth quarter of FY 2023-24, Glenmark's consolidated revenue was at ₹. 30,630 mn as against ₹. 30,005 mn recording an increase of 2.1% YoY. The company's EBITDA was ₹. 5,043 mn in the quarter ended March 31, 2024, as

compared to ₹. 3,979 mn in the previous corresponding quarter, registering growth of 26.7%. EBITDA margin for the quarter was 16.5%.

"This past year has been a period of significant transition and transformation for Glenmark. We successfully divested a majority stake in Glenmark Life Sciences, concluding the year in a strong net cash positive position. Our branded markets continued to deliver robust growth, particularly in Europe and other key international markets. While we encountered some headwinds in our US business, we remain optimistic about ability to regain our growth trajectory in the coming year." said Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals Ltd.

Morepen Laboratories Q4 net profit stood at ₹ 28.74 crore

Sushil Suri, CMD, Morepen Laboratories

New Delhi, India: Morepen Laboratories Limited, announce its financial results for the fourth quarter of the fiscal 2023-24. The company's gross revenue stood at ₹. 427 crores, 16.5% increase from ₹. 367 crores in Q4'FY23, while EBITDA for Q4'FY24 surged by 182% to ₹ 52.62 crores from ₹. 18.68 crores in the same quarter last year. For the full fiscal year, EBITDA more than doubled, achieving ₹. 172.60 crores, up 101% from ₹. 85.67 crores in FY23.

The company's PAT for Q4'FY24 stood at ₹. 28.74 crores, showing a 249% growth compared to ₹. 8.24 crores in the same period last year. On an annual basis, PAT increased by 150% to ₹. 96.62 crores from ₹. 38.68 crores in FY23.

Sushil Suri, Chairman and Managing Director of Morepen Laboratories, commented on the results, stating, "We are excited with the robust performance across all segments. Our strategic investments in the medical devices and API businesses have yielded excellent results, and we are confident of sustaining this momentum. The future looks promising as we continue to increase capacities and expand our market reach."

Indoco Remedies Q4 revenue stood at ₹. 4,351 mn

Aditi Panandikar, MD, Indoco Remedies Ltd

Mumbai, India: During the fourth quarter of FY 2023-24, revenues of Indoco Remedies grew by 1.7 % at ₹. 4,351 mn, as against ₹ 4,280 mn, same quarter last year. EBIDTA to net sales for the quarter is 13.2 % at ₹. 574 mn, as compared to 15.0 % at ₹. 642 mn, same quarter last year. Profit After Tax to net sales is 8.6 % at ₹. 376 mn, compared to 5.9 % at ₹. 254 mn, same quarter last year.

For the year, revenues grew by 7.6 % at ₹. 17,619 mn, as against ₹. 16,381 mn, same period last year. EBIDTA to net sales for the period is 14.6 % at ₹. 2580 mn, compared to 17.4 % at ₹.2849 mn, same period last year. Profit After Tax to net sales is 6.6 % at ₹. 1166 mn, compared to 8.6 % at ₹. 1414 mn, same period last year.

Commenting on the results, Aditi Panandikar, Managing Director, Indoco Remedies Ltd. said, "Indoco is set to take a big leap based on the various strategic decisions taken during this year. We are optimistic to improve our performance in the coming quarters."

Innova Captab Q4 net profit rises 66%

Mumbai, India: Innova Captab Limited, an integrated pharmaceutical company in India has announced its financial results for the fourth quarter and full year ended March 31st, 2024. The company's revenue from operation stood at ₹ 262.63 crore in Q4 FY24 as against ₹ 240.95 Crore of previous year registering a growth of 9.0%.The Company's EBITDA stood at ₹ 43.76 crore in Q4 FY24 against ₹ 29.42 crore of previous year registering a growth of 48.7%. The company's net profit stood at ₹ 28.72 Crore in Q4 FY24 against ₹ 17.25 crore of previous year, registering a growth of 66.5%.

Commenting on the results, Vinay Lohariwala, Managing Director, - Innova Captab Limited said, "Our all business areas are getting good traction and are expected to grow at a healthy rate in the coming years. Over the last 3-4 years, we have grown at a healthy rate of ~ 20% CAGR. With our upcoming Jammu facility and recent

Sharon acquisition, we are positively looking forward to maintaining the same healthy growth rate over the next 3-4 years. As a company we continue to drive sustainable growth by exploring new opportunities and focusing on value-added products."

Lincoln Pharmaceuticals Q4 net profit rises 55%


Mahendra Patel, MD, Lincoln Pharmaceuticals

Ahmedabad, India: Lincoln Pharmaceuticals Limited, one of India's leading healthcare companies has reported financial performance for Q4 and FY 23-24 ended March 2024. With focused growth strategies and business expansion plans for value added products and expanding to newer markets, company is targeting revenue of ₹. 750 crore in FY26.

The company's net profit during FY24 reported a growth of 28.61 % Y-o-Y to ₹. 93.37 crore as against the net profit of ₹. 72.60 crore in FY23. The Company reported EBITDA of ₹. 134.33 crore in FY24, rise of 20.28% as compared to EBITDA of ₹. 111.68 crore in FY23. Total Income during FY24 was reported at ₹. 614.97 crore.

For Q4 ended FY24, company reported net profit of ₹. 18.88 crore as against net profit of ₹. 12.17 crore in the corresponding period last year, growth of 55.14%. Total Income for the Q4FY24 was reported at ₹. 149.51 crore, higher by 28.49% over previous fiscal's same period income of ₹. 116.36 crore. The company reported EBITDA of ₹. 25.40 crore in Q4 FY24, rise of 23.66% as compared to ₹.20.54 crore in the corresponding period last year.

Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited, said, " Looking ahead, Lincoln is poised to sustain and even accelerate its growth momentum. With plans for new product launches in both domestic and export markets, alongside strategic expansions into newer markets, the company aims to further solidify its market presence."

Wockhardt Q4 revenue stood at ₹ 750 Crore

Mumbai, India: Wockhardt Limited, the Pharmaceutical and Biotechnology major, reported its fourth quarter results for Financial Year 2023-24. The company's revenue for FY24 of ₹ 2,879 crore as compared to ₹ 2,693 crore in the previous year, while Revenue for the quarter being ₹ 750 crore compared to ₹ 710 crore in Q4FY23.

The company's EBITDA for FY24 at ₹ 251 crore as compared to ₹ 144 Crore in the previous year. Quarterly growth in EBITDA by 49% compared to the previous year, The company's EBITDA for Q4FY24 at ₹ 70 crore as compared to ₹ 47 crore in Q4FY23. The company's UK Business stood at ₹.268 crore in Q4FY24 compared to ₹.242 crore in Q4FY23 registering a growth of 11% and contributed about 36% of Global Revenue in the current quarter.

The company's India Business stood at ₹.181 crore in Q4FY24 compared to Rs.125 crore in the previous year registering a growth of 45%. India business stood at ₹. 641 crore compared to ₹.609 crore in FY23 registering a growth of 5% and contributing to 22% of the Global Revenue in FY24.

The company's Research and Development expenditure during the quarter was at ₹.33 crore (4.4% to sales) and including capital expenditure was at 11.2% to sales. Research and Development expenditure during the year ended was at ₹.132 crore (4.6% to sales) and including capital expenditure was at 9.8% to sales.

Suven to acquire controlling stake in Sapala Organics

Mumbai, India: Suven Pharmaceuticals Limited, one of India's largest integrated CDMO players, has entered into a definitive agreement for a strategic controlling investment in Sapala Organics Private Limited, subject to regulatory approvals and conditions.

Sapala is a Hyderabad based CDMO focused on Oligo drugs and nucleic acid building blocks including specialized/modified Amidites & Nucleosides, drug delivery compounds (including GalNAc), Pseudouridine, amongst others. Oligo & nucleic acid building blocks market is a USD 750M market and is expected to grow at a robust ~20% CAGR. Sapala is one of the very few players globally with experience in a comprehensive range of specialized building blocks. Sapala has a strong

Annaswamy Vaidheesh, Executive Chairman, Suven Pharmaceuticals Ltd

customer base including innovator Pharma, CDMOs & diagnostic companies, and is a key partner in their Oligo drug NCE programs.

On the acquisition, Annaswamy Vaidheesh, Executive Chairman, Suven said "We are delighted to partner with Sapala and believe it is a strong strategic fit. We see massive potential given it's a niche technology in the rapidly growing space. Nucleic acid based therapy targets diseases at a genetic level and has the potential to help patients immensely and cure previously incurable conditions. With this acquisition, we now have multiple differentiated technology platforms such as ADCs and Oligos amongst others. We will continue to invest both organically and inorganically to further build on these."

Suven to acquire 67.5% equity stake (i.e. 51% of the share capital of Sapala Organics Private Limited on a fully diluted basis) for a consideration of ₹. 229.5 crore subject to customary working capital and net debt adjustments. The company will acquire the remaining equity stake a few months after FY2026-27, as per the terms of the definitive agreements. Upon consummation, the company will own 100% of the share capital of Sapala on a fully diluted basis. The transaction is subject to customary closing conditions. Steadmount Capital Advisors and Banyan Advisory acted as advisors to Sapala.

Dr V Prasada Raju, Managing Director, Suven added "Sapala has built unique capabilities in the complex Oligo building blocks segment. The space is poised to grow multi-fold with many of our own customers looking to expand in this space. We are convinced that combining Sapala's R&D depth, team's 30+ years of experience and Dr Reddy's Japan experience with our customer access & manufacturing capabilities will help drive significant synergies across the entire platform."

Dr P Yella Reddy, founder of Sapala said "We have built Sapala as a unique CDMO player in the oligonucleotides value chain, largely thanks to the highly capable team that I have had the privilege of leading. Sapala has earned the trust of its customers over the last two decades by consistently taking up challenging projects, developing and scaling up highly complex technologies. A strategic partner like Suven, with its wider reach and resources will help to take Sapala to the next level while providing significant growth and development opportunities for Sapala's employees as well. We at Sapala are excited with the possibilities that this partnership brings. I also look forward to working with the larger team at Suven for their Japan market initiatives and hope to contribute to the platform's success in that market."

Emcure Pharmaceuticals gets SEBI nod for IPO

Mumbai, India: Emcure Pharmaceuticals has received market regulator Securities and Exchange Board of India ("SEBI") nod for IPO launch. The company had filed its Draft Red Herring Prospectus ("DRHP") with market regulator Securities and Exchange Board of India ("SEBI") in December 2023.The IPO comprises a fresh issuance of equity shares worth ₹. 800 crore and an Offer of Sale (OFS) of 1.36 crore equity shares by promoters and existing shareholders, according to the fresh draft red herring prospectus filed last week. The proceeds of the fresh issue will be used towards payment of debt and for general corporate purposes.

Emcure Pharmaceuticals is one of the leading Indian pharmaceutical companies engaged in developing, manufacturing and globally marketing a broad range of pharmaceutical products across several major therapeutic areas. The company is research and development ("R&D") driven company with a differentiated product portfolio that includes orals, injectables and biotherapeutics, which has enabled them to reach a range of target markets across over 70 countries, with a strong presence in India, Europe and Canada. Kotak Mahindra Capital Company, Jefferies India, Axis Capital, and JP Morgan India are the book-running lead managers to the issue. The equity shares are proposed to be listed on BSE and NSE.

Jubilant Pharmova announces completion of USFDA audit of contract manufacturing facility at Montreal, Canada

Noida, India: Jubilant Pharmova Limited announced that the United States Food and Drug Administration (USFDA) has concluded the audit of the Jubilant HollisterStier General Partnership ("JHSGP")'s contract manufacturing facility located in Montreal, Canada. The USFDA has issued 15 observations pursuant to

the completion of audit. JHSGP will submit an action plan on the observations. JHSGP is a subsidiary of Jubilant HollisterStier Inc., USA, a step down subsidiary of Jubilant Pharma Limited, Singapore, and a wholly owned subsidiary of the Company.

Jubilant Pharma Limited (JPL), a Company incorporated under the laws of Singapore and a wholly-owned subsidiary of Jubilant Pharmova Limited, is an integrated global pharmaceutical company engaged in manufacturing and supply of Radiopharmaceuticals with a network of 46 radio-pharmacies in the US, Allergy Immunotherapy, Contract Manufacturing of Sterile Injectables and Non-sterile products and Solid Dosage Formulations through multiple manufacturing facilities that cater to all the regulated market including USA, Europe and other geographies.

India emerges as a global Leader in Nutraceuticals

Mumbai, India: India is rapidly becoming the epicenter of the global nutraceutical market. Transitioning from a latent player a decade ago to a leading market for nutraceutical ingredients and finished products, India is now attracting significant attention from innovators and investors worldwide. This transformation was showcased at the Global Nutrify Today C Suite Sumflex 2024, where over 360 decision-makers from around the globe gathered to explore and discuss the burgeoning opportunities within the Indian market.

The summit commenced with a compelling keynote by Daniel Hopkins, Managing Partner of Kinos Capital USA, titled "All Roads Lead to India – Why US Private Equity Wants a Taste of India." This presentation set the stage for global nutraceutical leaders, followed by an international startup pitch session to investors. Some of the leaders were Yoni Glickman- Managing Partner- PeackBridge Ventures, Eric Caston- CEO- Fuji Chemicals, Milind Thatte- Managing Director- P&G-Health, Amal Kelshikar- Executive Director Torrent Pharmaceuticals, Sanjaya Mariwala- Executive Director- Omniactive Health Technologies, Dr Jean Porracchia- Chief R&D officer, Dr Ananad Swaroop- President – Cepham INC; USA, Russel Michelson- Global Regulatory Head- Reckit Benkiser, Len Monheit- CEO Trust transparency Center, Raja Ram Sankaran; Managing Partner- Heidrick & Struggles. A highlight of the event was the emphasis on India's Mission USD100 Billion, an ambitious initiative aimed at exponentially growing the country's nutraceutical sector. This mission underscores India's commitment to becoming a global powerhouse in the industry.

Sridhar Babu inaugurates Innovera Pharma's New Site in New Jersey

Hyderabad, India: In a significant stride towards helping Telangana companies and entrepreneurs scale globally, Minister Sridhar Babu inaugurated Innovera Pharma's latest site in New Jersey, USA, during his recent visit. he roots of this robust collaboration were established during a key meeting at the World Economic Forum (WEF) in Davos wherein Hon'ble Chief Minister Revanth Reddy and Hon Minister Sridhar Babu led a delegation earlier this year. These discussions paved the way for the company to invest in Telangana.Solidifying this partnership, within 30 days of announcement, a groundbreaking ceremony was held on February 22, 2024, in Suryapet, Telangana. This event marked the commencement of a significant project aimed at enhancing local manufacturing capabilities and infrastructure.

This state-of-the-art facility is expected to play a crucial role in expanding Innovera Pharma's research, development, and production capabilities. His presence at the inauguration highlights the importance of international collaboration and the Telangana government's commitment to supporting innovative companies in their global endeavors.

The partnership also exemplifies how regional governments can support enterprises in scaling their operations globally. By fostering such alliances, Telangana continues to position itself as a leader in the pharmaceutical and biotechnology sectors, attracting investments and enhancing its global footprint. This active partnership not only strengthens Innovera Pharma's global presence but also reinforces Telangana's status as a pivotal player in the global healthcare landscape. ■

"Over the next two-three years, we aim to establish a formidable presence in the injectable space"

Saransh Chaudhary
President,
Global Critical Care,
Venus Remedies Ltd, and CEO,
Venus Medicine Research Centre

Saransh Chaudhary talks about the overview of the Pharma industry and insights on the future trajectory of antibiotic R&D. He also spoke about the global market, product portfolio and priorities for the company's growth.

Brief us about the overview of the pharma industry?

Among the largest in the world, the Indian pharmaceutical industry is valued at approximately USD 50 billion, as of 2023. The third largest in the world in terms of volume and the 14th largest in terms of value, India's pharma sector is expected to grow at a CAGR of 11-12% to reach USD 130 billion by 2030 and USD 450 billion by 2047, according to a recent EY FICCI report. Accounting for 20% of the global exports in terms of volume, India is also the world's third largest producer of APIs, besides being the top global manufacturer and supplier of vaccines. Of late, the country has even emerged as a preferred outsourcing destination for contract research and manufacturing on account of lower costs and a skilled workforce. Driven by the high demand for Indian generics and biosimilars in international markets like the US and European Union and the country's renewed focus on R&D, the Indian pharma industry will continue to register impressive growth.

What are the challenges and landscape of antibiotics?

The biggest challenge with antibiotics is the rise of antimicrobial resistance (AMR), which renders many bacteria resistant to even the strongest antibiotics. This resistance is primarily due to the misuse and overuse of antibiotics, leading to longer hospital stays, increased healthcare costs and higher mortality rates. The lack of new antibiotics to combat drug-resistant bacteria is another significant challenge, as the high cost and long duration of R&D make antibiotic research unviable for many pharma companies.

The antibiotics market is currently experiencing a market failure, where innovations are not adequately rewarded. This has led to many companies exiting the space, unable to sustain themselves financially. Many firms that launched new antibiotics over the past decade have faced bankruptcy due to the lack of effective pull mechanisms. Unlike other therapies, the overuse of new antibiotics directly correlates with resistance development,

discouraging their use, except in rare circumstances. While essential for antibiotic stewardship, this undermines innovation and disincentivises companies.

Addressing this market failure is critical to reviving the field and attracting researchers. Novel mechanisms such as transferable exclusivity vouchers, subscription models and other sales-delinked incentive structures are being tested globally. India must adopt similar strategies domestically to combat its high burden of antibiotic resistance.

Please share your insights on the future trajectory of antibiotic R&D.

Given the immense time, effort and funds required to develop new antibiotics, coupled with a low success rate, the best approach is to develop innovative solutions through novel mechanisms of action and alternative strategies to extend the life of existing antibiotics. Researchers are focusing on breakthrough technologies and repurposing drugs using antibiotic resistance breakers (ARBs), also known as antibiotic adjuvants. ARBs are non-antibiotic components which, in combination with antibiotics, enhance antimicrobial activity and overcome resistance barriers. ARBs are faster and cheaper to develop than new molecules and have a higher probability of success, overcoming many commercial barriers.

Our approach to antibiotic R&D addresses market realities directly. Through our flagship Renal Guard program, we have reformulated certain critical care antibiotics to reduce their adverse impact on the kidneys, increasing the therapeutic window and allowing clinicians to administer the full therapeutic dose without nephrotoxicity concerns. Such solutions are urgently needed to bridge the gap between current clinical and market realities and the necessary reforms to create a sustainable market for novel antibiotics in the future.

What are the major priorities for the company's growth?

Our primary focus this fiscal year is on improving access to affordable medicines in India by strengthening our generics and institutional business nationwide. Over the next two-three years, we aim to establish a formidable presence in the injectable space and expand our on-ground presence to cover all districts in the country. We have already made significant strides in this space over the past three years by leveraging data and technology.

Globally, we plan to fortify our presence in key markets such as Europe, Commonwealth of Independent States (CIS), Latin America, Asia and Africa. We will achieve this through strategic partnerships, joint ventures and enhancing our distribution network. Additionally, we are focusing on obtaining regulatory approvals for our pipeline products in multiple countries to facilitate smoother market entry and expansion.

We are all geared up to make a committed investment in R&D, plant and machinery under the Production-Linked Incentive Scheme. To maintain and acquire global quality accreditations, we will constantly upgrade our facilities and carry out a structured revamp of our manufacturing operations by investing in automation and more advanced technologies, thereby optimising costs and ensuring higher production volumes.

What are your plans in terms of manufacturing infrastructure and product portfolio?

Over the past four years, we have significantly enhanced our manufacturing infrastructure. For instance, we upgraded our anticoagulant facility to a fully autonomous robotic setup, doubling our capacity. We are also developing proprietary machine learning models to assist with visual inspection, aiming for zero-defect manufacturing.

We are also expanding our product portfolio, focusing on parenteral injectables across a range of therapy areas like oncology, neurology and antibiotics, among others. With over 25 international GMP approvals and a presence in 80 countries, the company is rapidly emerging as a frontrunner in the pharmaceutical industry. Within our R&D portfolio, our flagship Renal Guard programme is also expected to reach clinical readiness this fiscal with regulatory filings expected to commence internationally in FY26.

In December 2023, we transformed our consumer healthcare division, RESET, marking its entry into the wellness arena and expanding its pain management portfolio. Today, RESET addresses wellness needs such as pain relief, mental wellness, sleep quality and detoxification, with plans to expand into other areas of wellness soon. We will continue to focus on the direct-to-consumer market, launching innovative solutions for discerning Indian consumers seeking high-quality products.

As an export-driven pharma company, what strategies is Venus Remedies adopting to enhance its international presence?

While focusing on expansion in new and existing markets, our blueprint for growth in exports entails sharpening our focus on tender participation. We will build on our customer base in existing overseas markets through aggressive campaigning and promotion to secure a larger market share, besides exploring uncharted territories through extensive market study and analysis.

As we continue to capitalise on our robust export base and execute our strategy of aggressively obtaining more marketing authorisations around the world, we have set our eyes on expanding our global footprint to over 100 countries by the end of the next financial year. Our emphasis on securing marketing approvals also reflects our commitment to addressing the rising demand for high-quality healthcare solutions. The last two years have seen a record number of marketing approvals for the company, which is already the market leader in India in terms of exports of injectable antibiotics and among the top three exporters of injectable oncology drugs.

Equipped with CTD dossiers for major regulated international markets, we will market a wider range of injectables for critical care segments like antibiotics, oncology and now anticoagulants through retail sales, institutional sales and marketing collaborations. We will continue to align our operations with international standards to secure global and national endorsements as part of our growth strategy. We will also maintain an aggressive dossier filing strategy to capitalise on our dominance in key therapeutic areas. Riding on our expertise in developing super-speciality products and technologically advanced injectables, we will keep on signing contract manufacturing agreements with leading multinationals, forming marketing alliances and setting up overseas marketing offices in strategic markets.

How funds will be utilised under PLI scheme?

The first disbursement of ₹ 7.5 crore that Venus Remedies has got under the PLI scheme covers 75% of the total incentive due to the company for the financial year 2022-23. This grant will be utilised to strengthen the company's manufacturing capabilities, foster product diversification and invest significantly in plant and machinery. We also recently received the second instalment of ₹ 2.50 crore under the PLI scheme, which covers the remaining 25% of the total incentive of ₹ 10 crore.

These funds enable us to undertake more projects, particularly in R&D, which would otherwise be challenging. The government's emphasis on R&D is a positive sign as it helps generate employment for talented scientists and encourages Indian pharma companies to engage in drug discovery. In the long run, this will empower the industry to compete with big pharma in both manufacturing and new drug development.

How will the launch of three key oncology drugs in Ukraine contribute to the advancement of healthcare?

We expanded the reach of our oncology drugs in the Asia CIS region with marketing authorisations from Ukraine for three cancer drugs, including paclitaxel, oxaliplatin and irinotecan, in March this year. These marketing approvals mark a significant milestone in our global expansion strategy. We are planning to introduce the entire range of our oncology products in Ukraine in due course, thereby contributing to the advancement of healthcare and making a positive impact on people's lives. Having a presence in the Ukrainian market for more than two decades, Venus Remedies has 57 product registrations in Ukraine. We are awaiting approval from Ukraine on another 10 applications for marketing authorisations. By strengthening our product portfolio in Ukraine, we aim to grow our share by 20 per cent in the next one year.

Brief us about the UNICEF GMP approval for the company's Baddi unit.

The GMP approval from UNICEF for our manufacturing unit located in Baddi, Himachal Pradesh is a milestone that underscores Venus Remedies' commitment to delivering top-quality pharmaceutical solutions worldwide and further validates our relentless pursuit of excellence in pharmaceutical manufacturing. It will help us make substantial contributions to UNICEF's global healthcare initiatives and positively influence communities worldwide by enabling us to supply essential medications to regions facing health challenges owing to lack of access to medicines.

Three months after this GMP approval, we have been awarded a tender by UNICEF for supplying ceftriaxone, a beta-lactam antibiotic. This tender serves as an opportunity for the company to extend its reach as well as serve the needy. Building on such prestigious orders, we will continue to strengthen our international presence.

Having a presence in over 190 countries, UNICEF is recognised globally for its efforts in providing humanitarian aid and developmental support to children in need. Its rigorous GMP approval process sets a benchmark for quality and safety in pharmaceutical production. UNICEF provides humanitarian and developmental assistance to child. ■

GUEST COLUMN

Balancing Innovation with Regulatory Requirements in a CRDMO Setting

Alok Mehrotra
Chief Quality Officer,
Syngene International

Contract Research Development and Manufacturing Organizations (CRDMOs) play a vital role in bridging the gap between scientific discovery and patient care. They act as trusted partners for pharmaceutical and biotech companies, offering a complete spectrum of services to navigate the complex process of developing new drugs, from the initial research phase to final production.

Alok Mehrotra talks about how Contract Research Development and Manufacturing Organizations (CRDMOs) play a critical role in maintaining compliance with Good Manufacturing Practice (GMP).

However, CRDMOs must carefully balance two important aspects: innovation to create new and improved therapies and strict adherence to regulatory guidelines to ensure the safety and effectiveness of the drugs. This balance is crucial. It allows CRDMOs to deliver life-changing medicines faster to patients in need, while prioritizing their well-being.

Evolution of CRDMOs

The CRO and CDMO industry is experiencing significant growth, with the global market for Contract Research Organizations (CROs) projected to reach USD 63.35 billion by 2028 (Source: Market Watch) and the CDMO (Contract Development and Manufacturing Organizations) market reaching USD 295.95 billion by 2033 (Source: BioSpace). Over the years, CRDMOs have undergone significant transformation. Initially, these organizations were primarily focused on providing supplementary research and manufacturing services to pharmaceutical companies. As the landscape of drug discovery was revolutionized by the advent of new therapeutic modalities, innovations such as CAR-T cell therapies, PROTAC degraders and highly targeted monoclonal antibodies emerged, demanding specialized expertise far beyond traditional small molecule drug development.

These innovative approaches necessitate a comprehensive understanding of advanced biological processes, complex manufacturing techniques and stringent quality control measures. CRDMOs have risen to this challenge, evolving their capabilities to include expertise in biologics, advanced analytics, and state-of-the-art manufacturing technologies. This evolution has positioned CRDMOs like Syngene as indispensable partners in the ecosystem, capable of bridging the gap between groundbreaking scientific discoveries and large-scale clinical application.

The regulatory landscape

Recognizing the critical role innovation plays in developing life-changing medicines, CRDMOs, as partners to pharma and biotech companies, must also adhere to strict regulatory requirements to ensure the safety and efficacy of new therapies. Regulatory bodies such as the FDA, EMA, and others have established comprehensive guidelines that govern every aspect of drug development and manufacturing. Compliance with these regulations is non-negotiable, as it ensures that therapies are safe for patients and effective in treating their intended conditions.

CRDMOs play a critical role in maintaining compliance not only with Good Manufacturing Practice (GMP) standards but also with Good Laboratory Practice (GLP) standards. They implement robust quality management systems, conduct thorough preclinical and clinical testing and ensure that manufacturing processes adhere to both GMP and GLP guidelines. Quality in the laboratory is essential to ensure data integrity and the reliability of experimental results, making adherence to GLP standards equally vital alongside GMP standards. This involves meticulous documentation, regular audits and continuous monitoring to identify and address any potential issues that could compromise the quality or safety of a therapy.

Moreover, the regulatory landscape is constantly evolving, with new guidelines and requirements emerging in response to advances in drug discovery and development. CRDMOs must stay abreast of these changes, adapting their processes and practices accordingly. This requires a proactive approach to regulatory affairs, with dedicated teams that monitor regulatory updates, engage with regulatory agencies, and ensure that their operations remain in compliance.

Striking the right balance

Drug development thrives on scientific exploration and bold ideas. However, a well-defined path with appropriate controls is essential to navigate the regulatory landscape and ensure future success. The key lies in truly understanding the rationale behind compliance, not just adhering to rigid rules. By implementing effective yet adaptable controls, CRDMOs can safeguard data integrity, patient safety, and fuel innovation without compromising regulatory requirements. This fosters an environment where quality is seen not as a standalone function but as a core value embedded within a company's culture. It's this cultural shift that propels CRDMOs to the forefront of responsible drug development.

The Indian opportunity

The global shift towards dual supply chains and the "China + 1" strategy has created a opportunity for India in the CRDMO space. Pharmaceutical and biotech

companies are increasingly seeking geographically diversified partners to mitigate risks and ensure supply chain resilience. India's robust scientific talent pool, competitive cost structure, and growing government support for the biopharmaceutical sector position it as a strong contender to capitalize on this opportunity. However, capitalizing on this opportunity hinges on India's ability to establish a reputation for consistent quality that matches global standards. By prioritizing robust quality management systems, regulatory compliance, and fostering a culture of quality within the organization, Indian CRDMOs can build trust with international partners and solidify their place in the global drug development landscape.

Enablers to ensure a high quality and compliance culture

▪ **Focus on quality culture:** Building a strong quality culture goes beyond simply having documented procedures in place. It requires fostering a company-wide commitment to quality and a shared understanding of the importance of regulatory compliance. This can be achieved by conducting routine Gemba walks, engaging with employees on the shop floor and demonstrating visible commitment to quality and regulatory standards. Implementing a well-structured reward and recognition process incentivizes compliance and responsible behavior, fostering a culture of accountability and excellence. CRDMOs can enhance compliance awareness and understanding among employees through structured training and capability programs that explain the science and logic behind regulatory requirements.

▪ **Utilization of digital tools and platforms:** CRDMOs like Syngene and others are increasingly leveraging digital tools and platforms to achieve efficient and compliant data management with comprehensive audit trails. Electronic Lab Notebooks (ELNs) and Electronic Batch Manufacturing Records (eBMRs) offer a prime example. These advanced systems minimize the chances of human errors and ensure adherence to data integrity principles. By embracing such technologies, CRDMOs can streamline data handling processes, enhance traceability, and demonstrably comply with regulatory standards.

▪ **Simplified operating procedures:** To facilitate better understanding and adherence to compliance protocols, CRDMOs can develop simple and easy-to-follow operating procedures. Incorporating visual aids such as pictures and flow charts can significantly enhance comprehension and compliance among personnel. Clear and intuitive procedures empower employees to perform tasks accurately and in accordance with regulatory guidelines.

▪ **Well-developed internal audit process:** A well-defined internal audit program is essential for proactively identifying and addressing potential issues. Regular internal audits evaluate adherence to regulatory requirements, identify areas for improvement, and propose corrective actions. This proactive approach allows CRDMOs to continuously strengthen their quality management systems. For example, at Syngene, "Anytime Audit Ready" is the standard. This rigorous internal program ensures the organization is prepared for not only client and regulatory audits but also self-inspections throughout the year.

▪ **Risk-based approach:** To optimize resource allocation and ensure patient safety, CRDMOs can adopt a risk-based approach. This prioritizes close scrutiny on processes and materials with the highest potential to impact drug quality. By streamlining procedures for less risky aspects, CRDMOs can achieve greater efficiency while maintaining unwavering focus on critical areas.

▪ **Continuous improvement:** The regulatory landscape is constantly evolving. CRDMOs must adopt a culture of continuous improvement, staying abreast of regulatory updates and proactively implementing best practices. This ensures that their compliance practices remain robust and adaptable in the face of change.

Conclusion

CRDMOs are crucial partners to the pharma and biotech companies, which is evident from the increased collaborations over the last years and the anticipated growth in the future. This, therefore, presents the sector with the opportunity to work in tandem with their ecosystem and invest in systems and processes that safeguards and maintains high quality, while driving innovative scientific breakthroughs. ■

"JB Pharma aims to grow its revenue by 12-14 per cent in FY25"

Nikhil Chopra
CEO & Whole Time Director, JB Pharma

Nikhil Chopra emphasizes about the opportunities and challenges for Indian pharma in India & globally. He also spoke about the CDMO business and priorities for the company's growth going ahead.

Brief us about the overview of the Pharma industry?

The Indian pharmaceutical industry is experiencing a dynamic transformation, driven by a relentless focus on quality and safety. This commitment is crucial for maintaining our position as a global leader.

Innovation plays a central role in this transformation. This ensures the highest standards of quality throughout the entire drug development and delivery process. Additionally by embracing cutting-edge technologies, we can significantly enhance patient safety, monitoring and pharmacovigilance practices.

The future holds immense promise for the Indian pharma industry. Emerging trends like personalized medicine, which tailors treatments to individual patient profiles, and the development of biosimilars, which make advanced therapies more accessible, present exciting opportunities. By tackling existing challenges and leveraging these trends, we can further solidify India's position as a global leader in quality, innovation, and patient safety.

This transformation positions the Indian pharmaceutical industry for a projected growth rate of around 15% over the next six years, reaching a value of USD130 billion, according to government reports.

What are the opportunities and challenges do you see for Indian pharma in India & globally?

The industry stands as a formidable force on the global stage, brimming with opportunities for further expansion. Domestically, India's burgeoning population and increasing incomes are driving a significant surge in demand for affordable healthcare, creating a vast market for Indian pharma companies to sell their generic drugs.

Internationally, India is already the largest manufacturer and exporter of generic drugs, and as patents for many branded drugs expire, Indian companies are well-positioned to provide more affordable alternatives. Additionally, the trend of foreign pharma companies increasingly outsourcing research and manufacturing to India, due to its cost-effective and skilled workforce, presents a substantial opportunity for Indian firms to broaden their service offerings in Contract Development and Manufacturing Services. Furthermore, the Indian government's push for investment in biotechnology and innovation, particularly in biosimilar drugs, could spark a new wave of advancements from Indian pharma companies.

While the industry enjoys a strong position, navigating its future growth requires addressing certain hurdles. Industry needs a more robust intellectual property (IP) framework. Stronger IP laws will incentivize innovation, crucial for developing new drugs. Geopolitical tensions and disruptions like the Red Sea crisis further complicate matters by disrupting global supply chains. Despite these obstacles, the Indian pharma industry remains remarkably resilient and adaptable. By addressing these challenges head-on, the industry can solidify its path as the 'Pharmacy of the world'

What are the major priorities for the company's growth going ahead? How many products are you looking to expand in therapeutics areas?

At JB Pharma, we're charting a course for sustained growth with a focus on two key pillars:

Therapeutic Area Expansion:

- We will maintain our leadership position in cardiology, specifically focusing on hypertension, heart failure, and lipid-lowering treatments. This segment will continue to be a cornerstone of our growth.
- We are actively expanding into adjacent therapeutic areas like diuretics etc. This expansion will be achieved through a combination of strategic acquisitions and organic product development.

Innovation and New Product Launches

- We are committed to a robust pipeline of new product introductions, aiming to launch 6-8 new products annually in the Indian market. These new offerings will significantly contribute to our revenue growth.
- Recent launches like Ranraft for acid reflux and Sporlac Eva, a women's health probiotic, exemplify our commitment to innovation and addressing unmet medical needs.

How do you see domestic business in terms of chronic portfolio? What growth do you see for Chronic business?

Our domestic business is witnessing exciting developments, particularly in the chronic segment. We are strategically prioritizing cardiology, heart failure, hypertension, and lipids within the chronic portfolio. This focus has yielded impressive results. All five of our major brands – Nicardia, Cilacar, Rantac, Metrogyl, and Cilacar-T – are now ranked within the top 150 brands nationally.

In the cardiology segment itself, a USD 3 billion market, JB Pharma has achieved significant growth. We have climbed from the 13th position to the 8th position within just three years. This rapid ascent makes us the fastest growing company in cardiology among the top 10 players in India, with our cardiology revenue exceeding ₹ 1,000 crore in the calendar year 2024, as per IQVIA.

Looking ahead, we are optimistic about the continued growth potential of our chronic portfolio. We will maintain our focus on strategic expansion, product development, and market leadership in this crucial segment to ensure JB Pharma remains a leading provider of chronic care solutions in India.

What are your plans for CDMO business? What growth do you see for CDMO business?

The CDMO business is a strategic engine for JB

Pharma's future. We are targeting growth, aiming to double our current USD 50 million revenue to USD 100 million within 3-5 years. This translates to a significant contribution to our international business, potentially reaching over 50% from its current 27%.

To achieve this, we are making strategic investments:

- **Doubling Lozenge Capacity:** We are expanding manufacturing from 1 billion to 2 billion dosages annually, anticipating a surge in demand for high-quality lozenges. Looking ahead, we also aim to diversify our lozenge portfolio into categories of sleep disorders, pain management, immunity-boosters and anti-inflammatory
- **Global Market Expansion:** We have expanded into four European countries and aim to cover the entire region by the second half of the next fiscal year. Additionally, we plan to commercialize lozenges in the Middle East and Southeast Asia later in the year. From the second half of this fiscal year through December 2026, JB will complete its entry into the Brazilian market. These strategic partnerships and targeted market expansion, coupled with increased capacity, solidify our position as a key player in the global CDMO landscape.

What growth do you see for ophthalmology business? Brief us about your new product launches?

Our recent acquisition of a Novartis ophthalmology portfolio presents exciting growth opportunities. We are confident in achieving double-digit growth in this segment, significantly outpacing the overall market growth rate.

The next few months would also see new products in ophthalmology around dry-eyes, antioxidants and in the biologics segment (through licensing deals). We have expanded the original team of 65 people who joined us through the acquisition to a robust 100 members. We plan to continue this strategic growth moving forward.

What were the major drivers for growth for Q4? What is your outlook on margins?

JB Pharma delivered a strong Q4 with a 22% rise in domestic revenue, driven by growth in chronic therapies. Our CDMO business also achieved a significant milestone, reaching ₹ 100 crore in revenue for the first time in any fourth quarter.

Our focus on chronic therapies, product mix optimization, and efficiency improvements will drive overall gross margins to 65% and EBITDA margins of 26-28% in the coming years. We are also seeing positive margin improvements in our South African business.

Looking ahead, we are well-positioned for continued growth with a strong domestic base, an expanding international presence, and a commitment to delivering strong margins for our shareholders.

What is your revenue growth for FY25?

JB Pharma is aiming to exceed target of 12-14% revenue growth for FY25. This growth will be fueled by a strategic focus on expanding our chronic medicine segment, with the goal of increasing its contribution to a dominant 60% of our overall domestic revenue.

We see this solidifying our position as a leader in the crucial chronic care market, while India remains a core focus for JB Pharma. Leveraging our existing strengths and strategic focus, we will continue driving robust domestic growth. ■

The Evolving Landscape of Pharmaceutical Packaging

The Indian pharmaceutical industry is experiencing significant growth and is projected to reach USD 130 billion by 2030, from USD 40 billion in 2021. This growth highlights India's critical role in the global pharmaceutical market, supplying approximately 60% of the worldwide demand for vaccines. Additionally, India supplies 40% of the generic drug demand in the United States and provides 25% of all medicines in the United Kingdom. **Rajesh Khosla, President and CEO, AGI Glaspac** spoke about the challenges, opportunities and future for Pharma Packaging.

The ability to consistently deliver high-quality products has positioned India as a key player in the pharmaceutical industry. India's substantial contributions to the global pharmaceutical market underscore the importance of maintaining high standards in production and packaging to meet stringent regulatory requirements in the USA, the UK, and other countries.

As the industry grows, the pharmaceutical packaging sector in India is undergoing significant transformation driven by globalization, technological advancement and regulatory changes. Innovative and compliant packaging solutions are essential for ensuring that Indian pharmaceutical products meet international quality and safety standards. This evolution in packaging is crucial for maintaining India's competitiveness and leadership in global markets.

Personalisation and connected packaging

Personalised medicine, a revolutionary approach where treatments are tailored to individual patients, based on their genetic makeup and health requirements, is reshaping the pharmaceutical landscape. Packaging is evolving to support this shift, enhancing the precision and effectiveness of medication delivery, thereby improving patient outcomes. Customised packaging solutions, including personalized dosage instructions, ensure that each patient receives the appropriate amount of medication tailored to their specific needs.

Simultaneously, connected packaging is also gaining prominence. This involves using smart technologies to boost patient adherence and track medications. Advanced features such as tracking capabilities help monitor the medication supply chain in real-time, making sure drugs reach patients without any issues. Smart packaging can even remind patients to take their

medication, and provide valuable data to healthcare providers. This integration of technology improves patient compliance and helps healthcare professionals manage treatment based on real-time information.

Smart packaging

The pharmaceutical manufacturing industry is experiencing remarkable advancement with the introduction of cutting-edge solutions such as blow fill seal (BFS) vials, anti-counterfeit measures, AI-powered inspection systems, and intelligent packaging, near-field communication (NFC) tags, and radio-frequency identification (RFID) labelling. Active packaging solutions extend the shelf life of medications by regulating the environment around the product even as intelligent packaging provides real-time updates on the condition of the product, such as temperature and humidity levels. NFC tags and RFID labelling improve traceability and security, making it simpler to track medications through the supply chain and safeguard against counterfeit. These advancements enhance the reliability and safety of pharmaceutical products and also boost patient compliance and treatment outcomes.

Sustainability and eco-friendly solutions

Market dynamics are increasingly influenced by the pharmaceutical industry's commitment to environmental sustainability, with companies striving to reduce emissions across the value chain. Firms are actively pursuing net-zero emission targets by minimizing greenhouse gas (GHG) emissions throughout their supply chain. The steps that they are taking include adopting greener manufacturing processes, optimizing logistics, and implementing eco-friendly packaging solutions to lower overall environmental impact.

Companies are turning to biodegradable and recyclable materials to replace traditional plastics. These materials, either derived from nature or engineered to break down more easily, help reduce the long-term waste from pharmaceutical products. Efforts to minimise packaging waste, through smarter design and sizing, are gaining traction too. For example, using compact, minimalist packaging not only cuts down on material but also reduces transportation emissions, thanks to smaller volumes and weights.

Child-resistant and anti-counterfeiting features

Ensuring the safety of pharmaceuticals, especially for vulnerable groups such as children, is top priority. Child-

resistant packaging is crucial to prevent accidental ingestion of medicines. Innovations in this area include designs that are user-friendly for adults but not for kids including featuring mechanism such as push-and-turn caps or blister packs, with seals that are hard to peel. These features comply with regulatory standards while keeping things convenient for users.

Anti-counterfeiting measures are equally important. Counterfeit drugs pose significant risks to patient safety and undermine trust in healthcare systems. To combat this, advanced technologies including tamper-evident seals and serialization are being integrated into packaging to ensure authenticity and traceability. Serialization, which gives each product unit a unique identifier, allows for thorough tracking throughout the supply chain, making counterfeiting more difficult. Additional features such as holographic seals and RFID tags add another layer of security.

Efficiency and cost optimisation

In a competitive market, pharmaceutical companies are on the lookout for ways to streamline packaging design and production to optimize costs while maintaining superior quality. One approach involves adopting lightweight packaging material for lower shipping expenses and easier handling. Despite the reduced weight, these materials must still offer robust protection for the products. Progress in polymer science has led to the development of strong, yet lightweight, materials boasting exceptional strength and barrier properties against moisture and oxygen ensuring product integrity through the supply chain.

Simplified manufacturing methods, including automation and advanced quality control systems, are playing a pivotal role in cost optimization. By simplifying and standardising packaging processes,

companies can achieve enhanced consistency and efficiency. This proactive approach increases yields and optimizes resource utilization, contributing to improved profitability and competitiveness within the pharmaceutical sector.

Challenges and opportunities

However, adopting new packaging technology is not without hurdles for the pharmaceutical industry. One of the main challenges is integrating these technologies into existing supply chains. The pharmaceutical supply chain is intricate and heavily regulated; so bringing in new packaging solutions needs careful planning and coordination to avoid disruptions. Switching to new materials or technology often means retraining staff, updating equipment, and possibly changing distribution setups; all of which can eat up resources.

Navigating regulatory hurdles poses a significant challenge in the adoption of innovative packaging solutions within the pharmaceutical industry. New materials and functionalities have to go through rigorous testing and approval to make sure they meet safety and efficacy standards. This evaluation can result in lengthy and costly delays in the rollout of new packaging innovations. And regulations can vary between regions and countries, necessitating companies to navigate different standards across the globe.

Cost is another consideration. Advanced packaging features can offer big benefits, but they often come with a substantial price tag. Pharmaceutical companies have to weigh these costs against potential gains, ensuring that investments in new packaging technology align with financial objectives. This entails assessing long-term benefits such as reduced counterfeiting risks, improved patient adherence, and enhanced brand reputation against upfront expenses.

Enhanced product security is a significant advantage. Anti-counterfeiting measures and better traceability help shield patients from counterfeit drugs and make sure they receive authentic medications. This protects patient health and boosts the reputation of pharmaceutical companies.

The future

The pharmaceutical packaging industry needs to innovate and collaborate. Team efforts that involve packaging manufacturers, pharmaceutical companies, and regulators are key to creating safe, sustainable, and efficient packaging solutions. By working together, these players can make sure pharmaceutical packaging meets current needs and anticipates future challenges.

For instance, collaboration between material scientists, packaging designers, and regulatory experts can lead to the development of new materials that are both eco-friendly and compliant with safety standards. Pharmaceutical companies can partner with technology firms to integrate smart technologies into their packaging, enhancing patient engagement. By fostering a collaborative environment, the pharmaceutical industry can continue to advance, ensuring that packaging solutions meet regulatory standards and provide significant benefits to patients and the environment.

Continued emphasis on research and development is imperative to stay ahead of emerging trends and challenges in the pharmaceutical packaging industry. Allocating funding and resources to explore cutting-edge solutions is crucial in driving innovation and revolutionizing pharmaceutical packaging.

Finally, it's important for industry leaders to engage in discussions and exchange insights regarding the future of pharmaceutical packaging. By fostering an environment of collaboration and sharing, the pharmaceutical sector can develop packaging solutions that prioritize safety, efficiency, and sustainability. This collective effort benefits patients and society by ensuring the integrity of medication and contributing to overall well-being. ■

Author

Rajesh Khosla,
President and CEO, AGI Glaspac

The potential & challenges of personalized medicines globally and in context with Indian market

The traditional approach of treating patients with a one-size-fits-all method is quickly losing its relevance in today's healthcare landscape. The future of healthcare is personalised medicine, a cutting-edge field that tailors treatments based on each patient's unique genetic composition and other health parameters. **Dr Debojyoti Dhar, Co-founder and Director, Leucine Rich Bio** talks about the benefits and challenges of personalized medicines globally and for the Indian market.

This change is being fueled by developments across a number of areas, with the gut microbiome emerging as a major factor with enormous potential in personalized medicine space, both internationally and in an Indian setting. Through the utilization of the gut microbiome's immense potential, medical practitioners can offer more precise and efficient treatments that are customized to meet the unique requirements of every patient.

There is no denying the fact that the human gut is home to trillions of bacteria and other microorganisms that make up a complex ecosystem. Together, these diverse organisms are referred to as the gut microbiome, and they are essential for proper digestion, immunological response, and general health. Recent research suggests that a healthy gut microbiome is associated with a lower risk of various chronic diseases, including diabetes, obesity, inflammatory bowel disease (IBD), and even certain cancers. In this context, the understanding of the human body, especially the gut microbiome, has become increasingly important in personalized medicine and healthcare.

Benefits of personalized medicine

Today, the advantages of personalized medicine cannot be underestimated. This is a revolutionary approach to healthcare—one that will enhance efficiency and improve outcomes through treatments tailored to individual genetic and microbiota makeups. Through precise disease diagnosis and treatment, the likelihood of therapeutic effectiveness is greatly raised, while the likelihood of side effects is greatly reduced. That represents a big win-win. So, let's delve into some significant benefits.

- **Better patient outcomes and satisfaction:** Better patient outcomes and satisfaction are two of personalized medicine's biggest advantages. Healthcare professionals can deliver more individualized and successful care by customizing a patient's course of treatment to fit their particular

needs. For instance, a patient with a specific genetic mutation can receive targeted therapy that is more likely to be effective and less likely to cause adverse reactions. This method can lead to improved health outcomes and overall satisfaction for the patient.

- **Better diagnosis and prognosis:** Advances in the gut microbiome and genomics space can enable better diagnosis and prognosis of diseases. This can lead to efficient disease management and improved quality of life of the patients

- **Reduced healthcare costs and more efficient care:** Personalized treatment may lower medical expenses while increasing effectiveness. Healthcare professionals can focus resources on the most effective treatments for each patient and avoid expensive and treatments by employing data-driven methods of therapy. Furthermore, by identifying those who are more likely to contract specific diseases, healthcare professionals can take preventive action and lessen the demand for costly and time-consuming therapies down the road.

- **Improved drug safety and effectiveness:** Personalized medicine also increases the efficacy and safety of medications. Given that each patient's response to medication is influenced by their genetics and other circumstances such as their gut microbiota, healthcare practitioners can identify the safest and most effective medications for each patient. This can increase the likelihood of successful treatment outcomes while decreasing the likelihood of negative consequences. Nevertheless, despite the promises it holds for revolutionizing healthcare, personalized medicine is not without challenges.

Here, let's get into some of the challenges and how to cope with them:

- **Cost and accessibility issues:** As can be expected with a revolutionary approach to healthcare, there are various challenges, but the main one is cost. Precision medicine, despite its immense benefit in diagnostics, treatments, and preventative measures, comes with hefty price tags. Due to their high cost, these drugs have become a financial burden for patients, which has an impact on accessibility and affordability.

- **Data management:** Today, where data has become more and more important, efficiently managing and organizing it can be very difficult. It includes clinical data, genetic data, and other private information. Thus, implementing strong data management systems and standards can assist in ensuring data security and accessibility, resulting in increased efficiency and decision-making processes. Additionally, staying up-to-date on the newest data management technology and trends will help handle these difficulties. Also, all these modern technologies provide huge data so understanding and making sense of the "big data" is a challenge.

- **Data interpretation:** The modern "omics" technologies provide data dump that needs proper co-ordination and interpretation. The challenge is to integrate all the new data points from the various technologies into a common understandable outcome to better deliver the endpoints to the patient or the healthcare professional.

- **Regulatory hurdles and standardization:** Although tailored medicine is still in its infancy and confronts numerous regulatory obstacles, it has emerged as a potential subject in the healthcare industry. The absence of standards and procedures for data administration, processing, and interpretation is a significant barrier. This can make ensuring the quality, accuracy, and dependability of diagnostics and therapies using personalized medicine challenging.

Thus, professionals in the field must stay informed and adaptable to changes in regulations and standards to effectively navigate these challenges. By staying ahead of the curve, healthcare providers can better implement personalized medicine practices and improve patient outcomes.

The future of precision medicine

The Precision Medicine Market size is expected to reach USD 104.40 billion, growing at a CAGR of 5.20% during the forecast period (2024–2029), as per Mordor Intelligence. The factors that are driving the growth of the sector are increasing online collaborative forums, increased efforts to characterize genes, microbiota and advancements in cancer biology.

In the coming future, new-age technology will probably be heavily integrated, allowing researchers and healthcare professionals to more correctly and efficiently analyse and interpret enormous volumes of clinical and genomic data. But as we move forward, new obstacles like moral dilemmas and legislative modifications can appear.

Concerns over data ownership and privacy, as well as the possibility of discrimination based on genetic information, may arise as precision medicine gains traction. Moreover, legislative adjustments might be required to guarantee that tests and therapies using tailored medicine are secure, efficient, and available to all patients. To guarantee the outcome of customized medicine protocols and technologies, standardisation of data administration, analysis, and interpretation will be required.

End of a one-size-fits-all approach!

Healthcare is expected to be significantly impacted by further developments in customized medicine and the legalization of customized drugs. Aside from making healthcare more effective and efficient, personalized medicine has the potential to significantly improve therapies for a large number of people. It can also have a preventive effect, addressing the risk of disease at its source and improving clinical outcomes for patients.

In addition, there are a lot of challenges at the moment as discussed above, however, customized medicine has the potential to completely alter the healthcare industry if the government gives it the right encouragement and support. Thus, with the increase in public awareness about various diseases and their effects on the human body, it is becoming clearer with each passing year that medicine and healthcare cannot follow the one-size-fits-all principle. ■

Author

Dr Debojyoti Dhar
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The Dawn of Targeted Therapies: Unveiling the High Costs of Cell and Gene Therapy

There is a famous saying in the world of science and biopharma: "We are not made of drugs; we are made of cells," and I think this era of Cell and Gene therapy, where the focus of therapies is shifting towards biologics and the utilization of cells for curing diseases, is turning a vision into reality. **Sakshi Walia, Business Excellence-Executive, Cell and Gene Therapy, Intas Pharmaceuticals** talks about the importance for Cell and gene therapy and Governments, pharmaceutical companies, and research institutions must work collaboratively to explore cost-reduction strategies.

For centuries, breakthroughs in medicine have held the power to astonish and inspire mankind. We have witnessed the dawn of antibiotics and the triumph of vaccination, and now, on the horizon, stands a new era of targeted therapies—cell and gene therapy. These revolutionary approaches are rewriting the rules of treatment, offering a level of precision and personalization once unimaginable.

Cell therapy, also known as cellular therapy, is a revolutionary approach that harnesses the potential of a patient's own cells to combat diseases. Autologous cell therapies like CAR-T is a cutting-edge medical field harnessing the power of a patient's own cells to combat disease. This innovative approach starts by extracting cells, often from blood or bone marrow. These cells are then nurtured and potentially modified in a lab setting. The modifications might involve equipping them with new abilities to target specific illnesses or enhancing their natural functions. Finally, the cells are reinfused into the patient's body. This personalized therapy offers several advantages. Since the cells come from the patient themselves, the risk of rejection by the immune system is significantly reduced. Additionally, autologous cell therapies hold immense promise for treating various conditions, from cancers like leukemia to chronic wounds and degenerative diseases. Six CAR-T cell therapies, including Kymriah for acute lymphoblastic leukemia and Yescarta for lymphoma, have been approved by the FDA.

Gene therapy aims to rectify mutations within the DNA that cause genetic disorders. These therapies can be achieved through various methods, the most common and prevalent of which is using modified viruses as vectors to deliver the therapeutic gene. This targeted approach minimizes side effects and offers a more potent weapon against the disease. Products like Luxturna, for a rare genetic eye disease, and Zolgensma, for spinal muscular atrophy, showcase the potential of this approach. India, a nation with a vast population and a growing burden of genetic disorders, presents a unique and promising market for Cell and Gene therapy. India has a significant population suffering from genetic disorders like thalassemia, sickle cell anemia, and cystic fibrosis. Gene therapy offers the potential for life-changing cures for these patients. With growing awareness among the population, the diagnosis of genetic disorders has significantly increased.

However, this market also faces significant challenges that need to be addressed to unlock its full potential. It is very well known that gene therapy is expensive globally, and India is no exception. The high cost of production and limited treatment options create a barrier to access for most patients. India needs more well-equipped laboratories and facilities for clinical-grade vector production and gene therapy research. This includes not just the equipment but also trained personnel to operate it effectively. One other important challenge to overcome is the lack of the lack of clarity in the regulatory framework surrounding the approval and market authorization of these therapies.

While India has guidelines for gene therapy development, some argue they might not be comprehensive enough for full market authorization. Clear and efficient regulatory pathways are crucial to expediting research and development while ensuring patient safety. The Indian population has a high degree of genetic variation. This means gene therapies developed elsewhere might need modifications to be effective in the Indian population, requiring additional research and development efforts.

There's a growing emphasis on research into streamlining manufacturing processes and developing alternative delivery methods to bring down the cost of gene therapy in India. Partnerships between academic institutes and pharmaceutical companies are fostering innovation and optimizing production processes

specifically for the Indian market. The number of gene therapy clinical trials underway in India is increasing, targeting various diseases and paving the way for potential future therapies

However, as with any ground-breaking innovation, challenges arise. Gene therapy, in particular, has captured headlines with its potential to cure previously untreatable genetic disorders. Yet, a significant hurdle stands in the way: the staggering cost of these therapies. Witnessing the astronomical price tags on gene therapies approved in the West, a natural question emerges: why are these medications so expensive.

My own experience within the industry has shed light on this complex issue. Unlike conventional drugs produced in bulk quantities, gene therapies often involve intricate manufacturing processes. The creation of a few milliliters of these life-saving medications can require specialized equipment and meticulous protocols, driving up production costs. Furthermore, gene therapy often represents a one-time shot at a cure. This unique characteristic presents a economic challenge. Unlike traditional medications requiring continuous prescriptions, gene therapies offer a potential cure with a single dose. This necessitates recouping the significant research and development investments within a shorter timeframe. Consequently, the market valuation of these therapies reflects both their innovative nature and their potential to deliver life-changing benefits.

Another factor contributing to the high cost is the limited number of players in the market. Cell and Gene therapy is a relatively young field, and the sheer complexity of developing and manufacturing these therapies restricts the number of companies actively involved. This lack of competition allows companies to set higher prices, further hindering widespread access to these potentially life-saving treatments. The high cost of gene therapy presents a significant ethical dilemma. While these therapies hold immense promise for patients with debilitating conditions, their current price tags restrict access to those with the most financial resources. This disparity raises critical questions about affordability and healthcare equity.

Moving forward, addressing this challenge requires a multifaceted approach. Governments, pharmaceutical companies, and research institutions must work collaboratively to explore cost-reduction strategies. Streamlining manufacturing processes, fostering greater competition within the field, and exploring alternative financing models are all crucial steps towards making gene therapy accessible to a wider population. Furthermore, fostering international collaboration is essential. Sharing knowledge and resources between developed and developing nations can accelerate research and development while optimizing production costs. By working together, we can ensure that this powerful technology doesn't become a privilege for the few but a beacon of hope for all.

The journey towards a future where gene therapy is readily available and affordable for all is an ongoing one. While the high costs present a formidable challenge, the potential rewards are immeasurable. With continued innovation, collaboration, and a commitment to equitable access, we can usher in a new era of healthcare, one where gene therapy fulfills its true potential—to transform lives and rewrite the narrative of countless diseases.

Many academic institutes in India have recognized this challenge and are actively partnering with pharmaceutical companies. These collaborations aim to optimize and revolutionize gene therapy production processes, specifically targeting cost reduction. This collaborative approach holds immense potential for bringing down the cost of gene therapy in India. Also, the Indian government recognizes the potential of gene therapy and is actively supporting research initiatives through grants and policy frameworks. These examples demonstrate India's proactive approach to tackling the affordability challenge. By fostering further collaboration between academia and industry, India can become a leader in developing costeffective and accessible gene therapy solutions.

Conclusion

The future of gene therapy is brimming with potential. By addressing affordability challenges through continued innovation, collaboration, and a commitment to equitable access, cell and gene therapy can become a transformative force in healthcare, offering hope and cures to a wider population, not just the privileged mass. ■

Author

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Importance of Cold Chain logistics in Pharma Industry

Pharmaceuticals are unique cargo; their efficacy and safety directly impact patient health. Any deviation from the specified temperature range during transportation can lead to catastrophic consequences, including compromised patient safety and product effectiveness. This makes pharmaceutical logistics a high-stakes endeavour where failure is not an option. **Niranjana Neelakantan, Co-Founder and COO, Tessol** discusses about the importance of Cold Chain logistics in Pharma industry and supply chain challenges in India.

Rapid advances in treatment options like stem cell therapy, biomarker testing, cellular therapies etc. involve movement of samples and medicines which are not just temperature sensitive, but also sensitive to shock, light, humidity, and other ambient conditions. In most of these cases, the treatment is only as effective as the cold chain that carries the samples/ medicines. These high value products also have very stringent compliance requirements which call for highly specialized transportation solutions. Shipment failures can result insignificant financial losses due to product wastage and potential liability claims. Such scenarios in medical treatment only highlight the importance of cold chain logistics and remote monitoring of pharmaceutical shipments. The success of the currently booming pharmaceutical e-commerce market will also to a great extent depend on right choice of cold chain solutions by e-commerce brands. With many large brands offering home delivery of medicines and home collection of blood samples,it has become extremely important to have reliable and viable packaging and transportation solutions.

The biggest challenge in supply chain in India is the viability given very low-price points, especially towards the last mile of the supply chain when package sizes become very small. Unfortunately in many cases it was considered cheaper to waste the product than to save it, given the high cost of maintaining the cold chain. Traditionally most pharmaceutical shipments, especially those which are smaller in size, was done using dry ice or gel packs. During the early days of the vaccination drive in India, many of us have read about how these solutions have backfired and large shipments gone waste. Dry ice also poses severe health hazards and has a huge impact on greenhouse emissions. Other challenges include increasing fuel prices leading to margin erosion which makes it unviable for many players to adopt effective cold chain solutions. One cannot also ignore the environmental impact of single use packaging solutions, used by many suppliers.

The good news is that with the latest advances in cold chain packaging technologies, things are changing for the better. With the introduction of passive packaging solutions, cost of cold chain packaging and transportation can be brought down tremendously, especially for the last mile, thereby opening up a whole range of affordable and reliable options for

pharmaceutical companies. Passive PCM based solutions allow pharma companies/logistics providers to offer end-to-end transportation of pharmaceutical packages from source to end customers without breaking the cold chain up in a highly temperature-controlled environment. Advancements in cold chain technology have resulted in multiple options that make cold chain for pharmaceuticals viable, reliable and sustainable thereby enabling easier adoption. These include:

Phase Change Chemical based temperature-controlled boxes with a much closer temperature maintenance range compared to traditional ice pack based solutions

Active and passive cooled pallet sized boxes that can be used for transport with a plug in / battery for long distance part load movement. They have flexibility on temperature setting as well. Through a hub and spoke model like what is used by courier companies, these boxes can be used to ship part loads at reasonable costs.

Traditionally used reefer solutions continue to be deployed for larger long distance larger loads, though replacement of reefer vehicles with Rechargeable Refrigerated Vehicles helps suppliers optimise costs.

Switching to more sustainable alternatives like fuel-free refrigeration/cooling systems will also become mandatory as regulatory compliances like the Green House Gas Protocol becomes applicable in India.

Temperature monitoring is also very crucial to ensure maintenance of product quality. Most times, the only data which is provided to the end user is the temperature details at which the consignment was shipped and it can get very hard to determine the temperatures maintained during transit. Real time temperature monitoring is therefore a much needed feature for cold chain transport. Latest developments in this technology include IoT based devices offers temperature and humidity data as well. The devices are small, have a 6 month to two year battery life, require no hub or sim recharge cost and provides an automatic set up with any smart phone. These systems are very simple to install and includes setting up the device on a mobile app, keeping the device on the container and fixing the QR code and thirdly, by monitoring the application. Such solutions ensures that the products are maintained at the precise temperature required for optimal pharmaceutical transportation. The wireless connectivity that they provide enables seamless data transmission, allowing for immediate access to critical temperature data throughout the entire journey. This connectivity is particularly valuable for maintaining pharmaceuticals within the required temperature range, even during the last-mile deliveries and diagnostics. samples pickup. These products also offer cloud-based alerts that keeps you informed and in control. It provides trip data and compliance assurance through real-time alerts at the device level. This feature is invaluable for maintaining pharmaceutical products within the required temperature range, ensuring they remain safe and effective.

Conclusion

By investing in robust cold storage and distribution solutions, pharmaceutical companies can prevent shipment failures, safeguard patient health, and avoid the devastating financial losses that can result from temperature excursions. In this high-stakes industry, there are several innovative solutions that are currently available, enabling pharmaceuticals to reach their destination in prime condition, ready to make a positive impact on patient health and well-being. ■

Author

Niranjana Neelakantan
Co-Founder and COO, Tessol

GUEST COLUMN

Essential Elements of Clinical Trial Manufacturing, Packaging & Labeling

Sujay S Salvi
Head CTSM, Siro Clinpharm Pvt Ltd

One of the key requirements for the success of any clinical trial is the efficient and rational Investigational Medicinal Product (IMP) strategy which optimally fits the trial design; however, as the clinical trial designs and dosage regimens are becoming complex by the day so are the challenges associated with IMP manufacturing, packaging, and labeling activities. **Sujay S Salvi** talks about the Packaging and Labeling of Investigational Medicinal Product (IMP) strategy.

Poor quality products may result from inaccurate IMP strategies as well as, manufacturing, packaging, and labeling errors, which can adversely affect the blinding, subject compliance, patient safety, result in product wastage and jeopardize the trial outcome.

In order to mitigate these challenges, careful planning and execution is imperative and to do so one must first comprehend the unique characteristics of an IMP compared to the marketed product. The IMP manufacturing, packaging, and labeling involves more complexities than the marketed product due to,

- IMP being exclusively manufactured, packaged, and labeled depending on the study design and country labeling requirements.
- IMPs are normally packed in an individual way for each subject included in the clinical trial.
- The lack of fixed routines and variety of clinical trial designs and consequent packaging designs.
- One packaged unit may have different products and strengths.
- Need for randomization, blinding of different dosage forms as per the trial requirements.

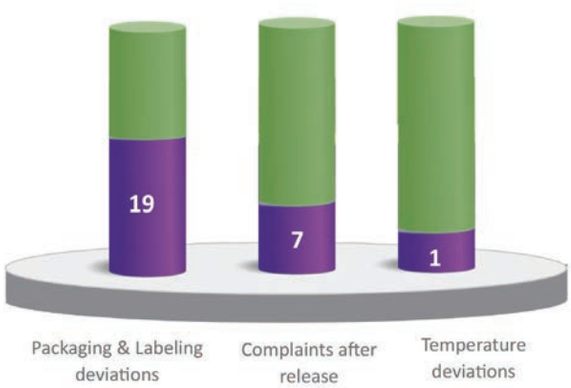
- Lack of full process validation or a marketed product used which have been repackaged or modified in some way.
- IMPs are still under testing hence many aspects are still under investigation including the use by date.
- Poor quality products may result from manufacturing / packaging errors, which can affect the blinding, subject compliance, safety, trial outcome and result in product wastage.
- Stability data may not be available for the significant changes made to IMP during packaging.
- Need for flexibility in supplies to counter emergency situations.

These challenges require personnel with thorough understanding of and training in the application of GMP to IMP as well as GCP to GMP.

Parameters to be considered while manufacturing, packaging, and labeling of IMP:

Manufacturing of IMP

- Selection of appropriate dosage form relevant to the future commercial representation.
- IMP should be produced in accordance with the principles and the detailed guidelines of GMP for Medicinal Products.
- Procedures need to be flexible to provide for changes as knowledge of process increases, and appropriate to the stage of development of the product.



- The application of GMP to the manufacture of IMP is intended to ensure that trial subjects are not placed at risk and results of clinical trials are unaffected by inadequate safety, quality or efficacy resulting from unsatisfactory manufacture.
- Intended to ensure that there is consistency between batches of the same IMP used in same or different clinical trials.
- Changes during the development of IMP are adequately documented and justified.
- If a product is modified, data should be available (e.g., stability, dissolution, bioavailability) to demonstrate that these changes do not significantly alter the original quality characteristics of the product.

Packaging and Labeling of IMP

Most critical aspect of the trial but is prone to errors and product wastage if not planned properly. As per the survey conducted by McKinsey & Co the product wastage levels were as high as 50%, so this area has a lot of scope for improvement, innovation, and opportunities for tremendous cost savings.

In addition, around 19% of packaged and labeled kits had deviations and 7% gave rise to complaints.

Packaging

- During packing of IMPs, it may be necessary to handle different products on the same packaging line at the same time hence the risk of product mix up must be minimized by using appropriate procedures, equipments and trained staff.
- Specifications and quality control checks should include measures to guard against unintentional

unblinding due to changes in appearance between different batches of packaging materials.

- The original expiry date of the comparator product may not be applicable where it has been prepacked in a different container that may not offer equivalent protection or be compatible with the product.
- A suitable use by date should be determined based on the nature of the product, characteristics of the container and the storage conditions.
- Such a date should be justified and must not be later than the original expiry date.
- There should be compatibility of expiry dating and clinical trial duration.
- Packaging must ensure that the IMP remains in good condition during transport and storage at intermediate destinations.
- Any opening or tampering of the outer packaging during transport should be readily noticeable.

Labeling

- Labeling should comply with the applicable local regulations.
- This operation should be performed at an appropriately authorized manufacturing site, however when justified can be performed at site by or under the supervision of pharmacist/ investigator or by the monitor who is appropriately trained.
- This operation should be performed as per GMP principles, SOPs and under contract, if applicable.
- Precautions against mislabeling such as label reconciliation, line clearance, in process control checks by appropriate trained staff should be intensified.
- The labelling operation should be checked by a second person.
- This additional labelling should be properly documented both in the trial documentation and in the batch records.

Blinding Operations

- Systems should be in place to ensure that the blind is achieved & maintained while allowing for identification of the blinded products where necessary including the batch numbers of the products before the blinding operation.
- Rapid identification of the product should also be possible in an emergency.

Randomization Code

- Procedures should describe the generation, security, distribution, handling and retention of any randomization code used for packaging IMPs and the code break mechanisms.
- Appropriate records should be kept.

IMP Packaging Prerogatives in a Clinical Trial

In clinical trials the subject compliance to treatment regimen is very critical as well as challenging. Poor compliance with the dosage schedule can jeopardize the data collected and pose serious risk to the trial outcome. Hence the packaging techniques should be finalized only after careful evaluation of the study design.

Subject compliance with the treatment regimen can be improved by developing an appropriate packaging strategy (e.g. Kitting) in terms of set parameters by working closely with the specialized IMP packaging service providers.

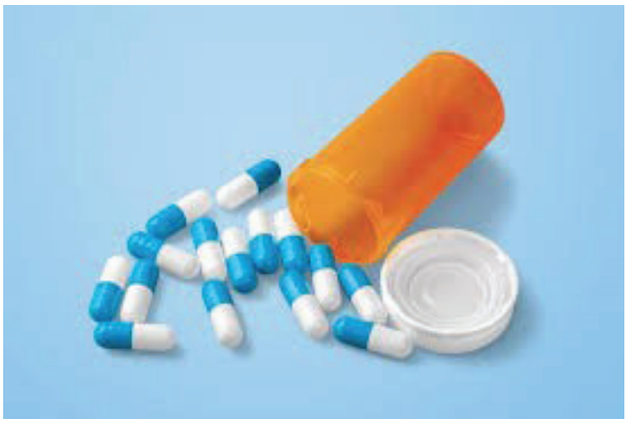
The packaging of an investigational product should be user friendly. It should be designed by keeping the subject in mind (patient-centric) especially in trials where subject is going to administer the drug without Investigator' supervision.

Most common primary packaging options in clinical trials are bottles and blisters. But a choice between bottles and blister cards should be made by scrutinizing their pros & cons against the study design and with due consideration to the stability of the product.

Descriptive labels, packaging units with diagrams, pictures, colors can help in better understanding.

Use of booklet labels in multinational trials can provide flexibility in supply, can handle emergencies, and avoid product wastage.

Let us ponder over the most popular packaging techniques used in clinical trials and their pros and cons,



Bottles Vs Blisters Philosophy

The biggest advantage for bottles is that the packaging in bottles is very cost effective and the turnaround time required is much less and the process is simple compared to blister packaging. Bottles can also be used for powders and liquids. Bottles are preferred when child resistant packaging is required. If the clinical trial has few strengths of IMP and comparator to be consumed by the subject, then packaging in bottles is a good option.

But when treatment regimen is complex with multiple products and strengths then the subject might find it difficult to remember and take the units from different bottles strictly as per the dosing schedule which will affect the compliance to the treatment.

In such scenario blister cards come handy.

Although the packaging in blisters is more time consuming and expensive, they have various advantages over bottles.

Blisters have more space for labelling. Sponsors can have pictorial depiction on blisters like sun / moon and weeks and days mentioned to remind the subject about dosage schedule.

Such visual aids give very little scope for errors and ensures better subject compliance.

Moreover, it helps in drug accountability as the investigator can calculate the balance unused drugs by just looking at the blister rather than emptying the bottle and counting every unit.

In addition, the blister package is inherently tamper evident as any break in the individual seal cannot be repaired or resealed, thus identifying a tampering of the package integrity.

This peculiar characteristic of blister package also provides better protection to its contents. A bottle needs to be opened every time for dose administration exposing the other units to external conditions or potential contamination due to any foreign particle.

In a clinical trial usually, packaging activities are performed at an early stage of the Clinical Trial lifecycle. Hence the selection of right packaging option becomes imperative in the successful conduct and result of the clinical trial. ■

India's Healthcare Renaissance: Bridging the Gap between Tech and Medicine

India, a nation renowned for its rich cultural heritage and rapid economic development, is experiencing a transformative phase in its healthcare sector. The confluence of advanced technology and innovative medical practices is revolutionizing the landscape of healthcare delivery, making it more accessible, efficient, and effective. **Siddharth Singhal, Co-founder & MD, Vibcare Healthcare** discusses the evolution and current challenges faced by India's healthcare system.

The Evolution of India's Healthcare System

India's healthcare system has historically been characterized by a dual structure. On one hand, there is a public sector that provides free or subsidized services to the masses. On the other hand, there is a growing private sector that caters to those who can afford better facilities. While the public sector has played a crucial role in addressing the healthcare needs of the underprivileged, it has often faced issues such as inadequate infrastructure, insufficient funding, and a shortage of skilled personnel. In contrast, the private sector, despite offering high-quality services, has remained inaccessible to a significant portion of the population due to high costs.

Current Challenges

The healthcare system in India faces multifaceted challenges, which include burden of communicable and non-communicable diseases, an uneven distribution of healthcare resources, and a significant gap in healthcare access between urban and rural areas. Moreover, the COVID-19 pandemic has exposed the vulnerabilities of the existing healthcare infrastructure, underscoring the need for a robust and resilient system.

The Technological Revolution in Healthcare

Digital Health Records

One of the most significant advancements in the integration of technology with healthcare is the adoption of digital health records. Electronic Health Records (EHRs) and Electronic Medical Records (EMRs) have revolutionized the way patient information is stored, accessed, and managed. These digital records ensure that patient data is accurate, up-to-date, and easily accessible to healthcare providers, thus improving the quality of care and reducing the risk of medical errors.

Artificial Intelligence and Machine Learning

Artificial Intelligence (AI) and Machine Learning (ML) are playing transformative roles in the healthcare sector. These technologies are being utilized to analyze vast amounts of medical data, enabling healthcare providers to predict disease outbreaks, personalize treatment plans, and improve patient outcomes. AI-powered diagnostic tools are also assisting doctors in detecting diseases at early stages, often with higher accuracy than traditional methods.

Robotics and Automation

Robotics and automation are redefining surgical procedures and patient care. Robotic-assisted surgeries allow for greater precision, minimal invasiveness, and faster recovery times. Automation in pharma manufacturing plants, like Vibcare Healthcare,

ensures high efficiency, consistency, and quality in the production of medicines. This not only reduces the cost of production but also ensures that the medications meet stringent quality standards.

Pioneering Innovation in Pharma Manufacturing

Commitment to Quality and Excellence

Vibcare Healthcare has established itself as a leader in the pharma manufacturing industry through its unwavering commitment to quality. The company employs state-of-the-art technology in its manufacturing processes, ensuring that every product meets international standards. The adoption of Good Manufacturing Practices (GMP) and rigorous quality control measures ensures that the medicines produced are safe, effective, and of the highest quality.

Advanced Manufacturing Techniques

Vibcare Healthcare utilizes advanced manufacturing techniques such as High-Performance Liquid Chromatography (HPLC), Mass Spectrometry, and Nuclear Magnetic Resonance (NMR) spectroscopy. These techniques enable precise analysis and quality control of pharmaceutical products. Additionally, the use of automated machinery and robotics in the production line enhances efficiency, reduces human error, and ensures consistent quality across batches.

Research and Development

Innovation is at the heart of Vibcare Healthcare's operations. The company's robust Research and Development (R&D) division focuses on developing new formulations, improving existing ones, and exploring novel drug delivery systems. By investing in cutting-edge research, Vibcare Healthcare ensures that it stays ahead of industry trends and meets the evolving needs of patients.

Enhancing Accessibility and Affordability

Affordable Medications

One of the primary goals of Vibcare Healthcare is to make high-quality medications accessible and affordable to all. The company achieves this by optimizing its manufacturing processes, reducing production costs, and passing on the savings to the consumers. By maintaining a balance between affordability and quality, Vibcare Healthcare ensures that its products are accessible to a broader population, including those in low-income segments.

Expanding Reach

To bridge the gap between urban and rural healthcare access, Vibcare Healthcare is expanding its distribution network to reach even the most remote areas of the country. The company collaborates with various stakeholders, including government bodies, non-governmental organizations (NGOs), and healthcare providers, to ensure that its medications are available where they are needed the most.

Embracing Technology for Better Health Outcomes

Health Information Systems

Health Information Systems (HIS) are integral to improving healthcare delivery. These systems enable the collection, storage, and analysis of health data, facilitating better decision-making and resource allocation. Vibcare Healthcare leverages HIS to track the distribution and usage of its products, monitor patient outcomes, and identify areas for improvement.

Mobile Health Applications

Mobile health (mHealth) applications are becoming increasingly popular in India, providing users with easy access to health information, medication reminders, and virtual consultations. Vibcare Healthcare is exploring partnerships with tech companies to develop and promote mHealth apps that can enhance patient engagement and adherence to treatment plans.

Wearable Devices

Wearable devices, such as fitness trackers and smartwatches, are gaining traction in the Indian market. These devices monitor vital signs, track physical activity, and provide valuable health insights to users. By integrating wearable technology with its healthcare solutions, the company aims to empower patients to take a proactive role in managing their health.

Training and Empowering Healthcare Professionals

Continuous Medical Education

Continuous Medical Education (CME) is crucial for healthcare professionals to stay updated with the latest advancements in medicine and technology. Vibcare Healthcare actively supports CME programs, providing training and resources to doctors, nurses, and pharmacists. By equipping healthcare professionals with up-to-date knowledge and skills, the company ensures that patients receive the best possible care.

Collaborative Research

Vibcare Healthcare collaborates with academic institutions, research organizations, and healthcare providers to conduct clinical trials and research studies. These collaborations foster a culture of innovation and enable the development of new treatments and therapies. By contributing to the scientific community, Vibcare Healthcare plays a pivotal role in advancing medical knowledge and improving patient outcomes.

Sustainability and Ethical Practices

Environmental Responsibility

As a responsible corporate entity, Vibcare Healthcare is committed to minimizing its environmental impact. The company adopts sustainable practices in its manufacturing processes, such as reducing waste, conserving energy, and using eco-friendly materials. Additionally, Vibcare Healthcare invests in green technologies and renewable energy sources to further its commitment to environmental sustainability.

Ethical Manufacturing

Ethical manufacturing is a cornerstone of Vibcare Healthcare's operations. The company adheres to the highest ethical standards, ensuring that its products are produced in a safe and responsible manner. This includes fair labor practices, safe working conditions, and compliance with all regulatory requirements.

Future Prospects and Vision

Expansion and Growth

Looking ahead, Vibcare Healthcare has plans for expansion and growth. The company aims to increase its production capacity, diversify its product portfolio, and enter new markets both domestically and internationally. By leveraging its strengths and capabilities, Vibcare Healthcare is poised to become a global leader in the pharmaceutical industry.

Innovation and Technology

Innovation and technology will continue to drive Vibcare Healthcare's growth. The company is committed to investing in new technologies, exploring novel drug delivery systems, and developing innovative healthcare solutions. By staying at the forefront of technological advancements, Vibcare Healthcare will ensure that it continues to meet the evolving needs of patients and healthcare providers.

Commitment to Patient Care

The company strives to improve the quality of life for patients by providing safe, effective, and affordable medications. By focusing on patient-centric solutions and maintaining high standards of quality, Vibcare Healthcare will continue to make a positive impact on the healthcare sector in India and beyond.

Conclusion

India's healthcare renaissance, driven by the integration of technology and medicine, is ushering in a new era of healthcare delivery. Vibcare Healthcare, with its commitment to innovation, quality, and accessibility, plays a pivotal role in this transformation. By embracing advanced manufacturing techniques, leveraging technology for better health outcomes, and upholding ethical practices, Vibcare Healthcare is bridging the gap between technology and medicine, ensuring that quality healthcare is within reach for all. ■

Author

Siddharth Singhal
Co-founder & MD, Vibcare Healthcare

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Honeywell introduces Batch Historian to digitalize manufacturing operations

Mumbai, India: Honeywell introduced Honeywell Batch Historian, a software digitalization solution designed to provide manufacturers with contextualized data history for reporting and analytics, leading to more efficient and cost-effective operations. The digitalization of manufacturing operations supports Honeywell's alignment of its portfolio to the automation megatrend.

Manufacturers often encounter complications analyzing data with a lack of batch visualization, which makes it difficult to expand data usage to advanced applications. With Honeywell Batch Historian, manufacturers can now directly capture data with context from batch engines without complex configuration. The new solution leverages simple drag-and-drop tile configuration, eliminating the need for advanced programming skillsets or detailed historian database knowledge to develop reports.

"Honeywell's full suite of digital manufacturing technologies will help manufacturers improve product quality, regulatory compliance and overall efficiency in order to drive business outcomes," said Shawn Opatka, Vice President and General Manager of Life Sciences at Honeywell Process Solutions. "Our approach is modular and flexible, helping companies begin their digitalization journey by adopting new technologies as they need them."

Honeywell Batch Historian supports several industries including specialty chemicals, life sciences, food & beverage, pulp & paper, and mining, materials, and metals (MMM). By leveraging the software, manufacturers can enhance process efficiency and simplify troubleshooting, ultimately improving operational outcomes. The solution's configuration for batch reporting simplifies the reporting and data analysis process, making it easier for operators to comply with strict industry reporting regulations.

By enabling manufacturers to efficiently capture, analyze, and utilize manufacturing data, Honeywell Batch Historian empowers users to make informed decisions, optimize processes, and drive continuous facility improvement. The software is a standalone application that can be delivered as a module on the Manufacturing Excellence Platform (MXP), or made available as a standard part of every Experion Batch system.

Schneider Electric launches EcoStruxure for Life Science Segment

Mumbai, India: Schneider Electric, the global leader in the digital transformation of energy management and NextGen automation, has launched EcoStruxure for Life Sciences Segment. This cutting-edge software technology aims to accelerate the efficiency and decarbonization of the pharmaceutical sector by facilitating the transition to Pharma 4.0.

By harnessing digital technologies, EcoStruxure for Life Sciences promises to reduce up to 70% of carbon emissions by leveraging universal automation to develop smart facilities, manufacturing, supply chains, and sustainability. The IoT-enabled solution is designed to drive water conservation, implement process electrification, foster sustainability by design, utilize green electricity, reduce Scope 1, 2, & 3 emissions, and promote circularity.

The pharmaceutical industry faces mounting pressure to adopt sustainable practices and minimize its environmental footprint. EcoStruxure for Life Sciences aims to enable pharmaceutical production and biotech facilities to become future-ready by integrating sustainability, resilience, and agility into their operations, accelerating the transition to Pharma 4.0.

Speaking at the launch, Arvind Kakru, Vice President – Industrial Automation, Schneider Electric India said, "Schneider Electric's EcoStruxure for Life Sciences presents an excellent opportunity for the pharmaceutical sector to collaborate in achieving the country's climate goals by embracing Pharma 4.0. Our pioneering solutions will empower our customers and partners to embrace sustainability. The launch of our EcoStruxure solutions underscores our dedication to engaging with key stakeholders in the pharma industry and guiding them towards the future of Pharma in India." ■

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R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month. Poster Registration No: MCS/207/2023-25
Posted at Patrika Channel Sorting Office, Mumbai 400001. On 27th every month. Total Pages 50

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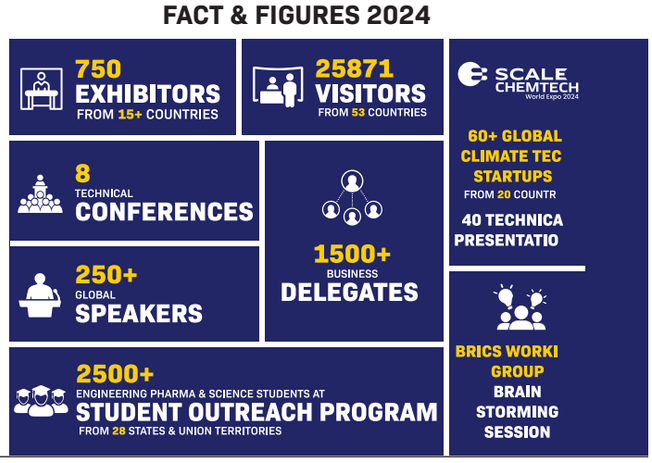

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