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Department of Pharmaceuticals organises workshop on the Promotion of Research and Innovation in PRIP Scheme

Amit Agrawal, Secretary, Department of Pharmaceuticals, Abhay Karandikar, Secretary, DST, S. Krishnan, Secretary, MeitY; Dr N. Kalaiselvi, Secretary, DSIR, Dr Rajiv Bahl, Secretary, DHR

New Delhi, India: The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India, organised a workshop on the Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) Scheme. The workshop was inaugurated in the presence of the Secretaries of five stakeholder Ministries and Departments of the Government of India, namely, Amit Agrawal, Secretary, Department of Pharmaceuticals; Professor. Abhay Karandikar, Secretary, Department of Science and Technology (DST); S. Krishnan, Secretary, Ministry of Electronics and Information Technology (MeitY); Dr N. Kalaiselvi, Secretary, Department of Scientific and Industrial Research (DSIR) and Director General (DG), Council of Scientific and Industrial Research (CSIR); and Dr Rajiv Bahl, Secretary, Department of Health Research (DHR) and DG, Indian Council for Medical Research (ICMR).

The workshop served as a platform for identifying key action points and approaches to further the shared commitment to promote research and development in the pharmaceuticals and medical technologies sector.

Amit Agrawal, Secretary, Department of Pharmaceuticals highlighted the rapid expansion in the sector, underscoring the importance of research and innovation in driving making and innovating in India for India and the world. In this regard, he highlighted that the global share of personalised and precision technology platforms (such as antibody-drug conjugates, bi-specific antibodies, and cell and gene therapy) among the top-100 drugs by value is growing rapidly, from 5% in 2020 to 9% in 2025 and projected to grow to 20% by 2030. He also highlighted the 10 times increase in the number of Indian healthcare and life sciences startups over the last four years, from over 900 in 2020 to more than 10,000 in 2024.

Amit Agrawal said that the groundwork and the pipeline for projects for the PRIP scheme has been laid through this growing innovation ecosystem of Indian startups and industry, supported by a wide array of initiatives of the scientific Ministries/ Departments.

Professor Abhay Karandikar, Secretary, DST underscored the importance of cutting-edge scientific research in driving advancements in pharmaceuticals and MedTech, reinforcing India's healthcare ecosystem and highlighted the supports available through the extensive incubator and accelerator network of DST.

S. Krishnan, Secretary, MeitY emphasised the transformative potential of digital health, artificial intelligence (AI) and data-driven technologies in drug discovery and medical device development.

Dr Rajiv Bahl, Secretary, DHR and DG, ICMR highlighted the critical role of clinical research, indigenous drug development and regulatory advancements in accelerating pharmaceutical innovation. Dr N. Kalaiselvi, Secretary, DSIR and DG, CSIR underscored the need to foster a culture of scientific collaboration between research institutions and industry to ensure the seamless translation of research into commercially viable applications.

Union Health Ministry takes action in response to concerns on export of unapproved drug combination

New Delhi, India: The Ministry of Health and Family Welfare has taken immediate and decisive action following some news reports highlighting concerns regarding the export of unapproved combination drugs containing Tapentadol and Carisoprodol by Indian Pharmaceutical Manufacturer M/s Aveo Pharmaceuticals, Mumbai to certain countries in West Africa.

To ensure regulatory compliance across the pharmaceutical sector, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcase notices, depending on the severity of non-compliance. This initiative has provided valuable insights into the ground reality of manufacturing

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practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

During end Jan'25, CDSCO in collaboration with State Regulators had done focused audit of firms manufacturing and exporting NDPS drugs. Based on analysis of observations from the audit, important decisions were taken to strengthen regulatory oversight on export of NDPS drugs from India.

Regarding the specific issue at hand, both Tapentadol and Carisoprodol are individually approved by CDSCO in India. Tapentadol is approved in 50, 75, and 100 mg tablet forms, as well as 100, 150, and 200 mg extended-release tablets. However, the combination of Tapentadol and Carisoprodol is not approved in India. Neither of these drugs is included in the NDPS (Narcotic Drugs and Psychotropic Substances) list in India.

The Ministry of Health and Family Welfare, along with the CDSCO, remains committed to ensuring the safety and well-being of citizens in India and abroad. The steps taken in response to this issue reflect the Government's zero-tolerance policy towards illegal or unethical export of unapproved and potentially harmful drugs.

Dr. Reddy's issues nationwide recall of Levetiracetam in 0.75% Sodium Chloride Injection in U.S

Hyderabad India: Dr. Reddy's Laboratories Ltd is recalling one Batch/Lot No: A1540076 of Levetiracetam in 0.75% Sodium Chloride Injection, 1,000 mg/100 mL (10 mg/mL) single-dose infusion bags to the consumer level, in the United States. The product is being recalled because the infusion bag is incorrectly labeled as Levetiracetam in 0.82% Sodium Chloride Injection 500 mg/100 mL single-dose bag, while the aluminum overwrap packaging correctly identifies the product as Levetiracetam in 0.75% Sodium Chloride Injection 1,000 mg/100 mL.

Levetiracetam in 0.75% Sodium Chloride Injection, 1,000 mg/100 mL (10 mg/mL) and Levetiracetam in 0.82% Sodium Chloride Injection, 500 mg/100 mL (5mg/mL) are both indicated for adjunct therapy in adults (≥16 years of age) with the following seizure types when oral administration is temporarily not feasible.

Sun Pharma to acquire Checkpoint Therapeutics

Mumbai, India and Waltham, Mass: Sun Pharmaceutical Industries Limited and Checkpoint Therapeutics, Inc announced that they have entered into an agreement by which the company will acquire Checkpoint, an immunotherapy and targeted oncology company.

Checkpoint is a Nasdaq-listed commercial-stage company focused on developing novel treatments for patients with solid tumor cancers. Checkpoint has received approval from the U.S. Food & Drug Administration (FDA) for UNLOXCYT (cosibelimab-ipdl) for the treatment of adults with metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC who are not candidates for curative surgery or curative radiation.

Dilip Shanghvi, Chairman & Managing Director of Sun Pharma, said, "Combining UNLOXCYT, an FDA-approved anti-PD-L1 treatment for advanced cutaneous squamous cell carcinoma, with Sun Pharma's global presence means patients with cSCC may soon have access to an important, new treatment option. The acquisition further bolsters our innovative portfolio in onco-derm therapy."

"I am proud of the dedication and passion of our team at Checkpoint that allowed us to achieve the first and only FDA-approved anti-PD-L1 treatment for patients with advanced cSCC, and we are excited to enter this transaction with Sun Pharma as the next step to bringing UNLOXCYT to cSCC patients in need of a differentiated immunotherapy treatment option," said James Oliviero, President and Chief Executive Officer of Checkpoint.

Upon completion of the transaction, Sun Pharma will acquire all outstanding shares of Checkpoint and Checkpoint stockholders will receive, for each share of common stock they hold, an upfront cash payment of $4.10, without interest, and a non-transferable contingent value right (CVR) entitling the stockholder to receive up to an additional $0.70 in cash, without interest, if cosibelimab is approved prior to certain deadlines in the European Union pursuant to the centralized approval procedure or in Germany, France, Italy, Spain or the United Kingdom, subject to the terms and conditions in the contingent value rights agreement.

The upfront cash payment of USD 4.10 per share of common stock represents a premium of approximately 66.0% to Checkpoint's closing share price on March 7, 2025, the last trading day prior to today's announcement.

Biocon Biologics announces Positive Results from Phase 3 Study of Yesintek

Elena Wolff-Holz, M.D., Global Head Clinical Development, Biocon Biologics

BENGALURU, Karnataka, India: Biocon Biologics has announced the successful results of a pivotal Phase 3 study comparing our biosimilar YESINTEK (bUstekinumab) with the reference product Stelara (Ustekinumab) in adult patients with moderate to severe chronic plaque psoriasis (PsO). The data are being presented at the 2025 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Florida.

The study demonstrated equivalent efficacy, safety, immunogenicity, and pharmacokinetics between YESINTEK and the reference product Stelara (Ustekinumab), marking a significant milestone for Biocon Biologics in advancing the accessibility of biosimilar therapies for patients worldwide.

Elena Wolff-Holz, M.D., Global Head Clinical Development, Biocon Biologics said, "The positive results from this Phase 3 study reaffirm the quality and therapeutic equivalence of YESINTEK compared to reference product Ustekinumab. This milestone underscores our commitment to providing cost-effective, high-quality biosimilars to patients with chronic conditions like psoriasis, expanding access to critical treatments globally."

The primary efficacy endpoint, percentage change from baseline in Psoriasis Area and Severity Index (PASI) score at Week 12, demonstrated that YESINTEK was equivalent to reference Stelara (Ustekinumab), with both treatments showing similar improvement in PASI scores. The mean difference between the two groups was 0.68%, falling within the predefined equivalence margins for both the U.S. Food and Drug Administration (U.S. FDA) and European Medicines Agency (EMA).

Uwe Gudat, M.D., Chief Medical Officer, Biocon Biologics said, "The results from this study show convincingly once more that in-vitro analytical comparability translates well into in-vivo clinical performance. The study reinforces the confidence we can have in the biosimilar regulatory pathways and the principles they are built on. Specifically, for YESINTEK the study shows that it offers an effective, safe, and comparable alternative to reference Ustekinumab in the treatment of moderate to severe chronic plaque psoriasis and by extension the other indications for which Ustekinumab is indicated."

Glenmark Therapeutics Inc., USA launches Polyethylene Glycol 3350, Powder for Solution, 17 grams/capful (OTC)

Mahwah, New Jersey: Glenmark Therapeutics Inc., USA announced the launch1 of Polyethylene Glycol 3350, Powder for Solution, 17 grams/capful (OTC); compare to the active ingredient in MiraLAX®2 Powder for Solution, 17 grams of Bayer HealthCare LLC.

According to Nielsen syndicated data for the latest 52 weeks' period ending February 22, 2025, the MiraLAX Powder for Solution, 17 grams (OTC) market3 achieved annual sales of approximately USD 555.7 million*.

Commenting on the launch, Marc Kikuchi, President & Business Head, North America said, "We are excited to announce the launch of Polyethylene Glycol 3350, Powder for Solution, 17 grams/capful, addressing the growing demand for a new supplier in this category. This addition highlights our commitment to meeting market needs and providing high-quality over-the-counter solutions for our customers."

Lupin launches Rivaroxaban tablets USP, 2.5mg in US

Mumbai, India: Global pharma major Lupin Limited announced that it has launched Rivaroxaban Tablets USP, 2.5 mg, following the final approval of its Abbreviated New Drug Application from the U.S. FDA.

Rivaroxaban Tablets USP, 2.5 mg, is bioequivalent to Xarelto Tablets, 2.5 mg of Janssen Pharmaceuticals, Inc., and indicated to reduce the risk of major cardiovascular events in patients with coronary artery disease (CAD); to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD.

Rivaroxaban Tablets USP, 2.5 mg had estimated annual sales of USD 446 million in the U.S, according to IQVIA MAT January 2025).

Lupin Limited is a global pharmaceutical leader headquartered in Mumbai, India, with products distributed in over 100 markets. Lupin specializes in pharmaceutical products, including branded and generic formulations, complex generics, biotechnology products, and active pharmaceutical ingredients.

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UPCOMING ISSUE - APRIL 2025

PHARMACEUTICAL PACKAGING

The global **Pharmaceutical Packaging** valued at USD 143 Billion in 2020 and is expected to reach USD 500 billion in 2028 growing at a CAGR of 15%, according to Vantage Market Research.

Packaging plays an important role in Pharma industry. Pharmaceutical packaging is an important element of drug delivery, ensuring the safety, and efficacy of pharmaceutical products.

The **April edition** of **'Pharma Bio World'** will bring insights into the latest trends in **"Pharmaceutical packaging".**

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Zydus receives final approval from USFDA for Ketoconazole Shampoo, 2%

Ahmedabad, India: Zydus Lifesciences Limited has received final approval from the United States Food and Drug Administration (USFDA) to manufacture Ketoconazole Shampoo, 2% (USRLD: Nizoral® Shampoo, 2%).Ketoconazole shampoo is an antifungal medication used to treat dandruff, fungal infections, and other skin conditions.

Ketoconazole shampoo will be produced at the Group's topical manufacturing site at Changodar, Ahmedabad. Ketoconazole shampoo had annual sales of USD 68.89 mn in the United States (IQVIA MAT January 2025).The group now has 418 approvals and has so far filed 483* ANDAs since the commencement of the filing process in FY 2003-04.

Venus Remedies secures first International Market Authorization for Sugammadex from Philippines

Saransh Chaudhary, President, Global Critical Care, Venus Remedies

Mumbai, India: Venus Remedies Limited, a leading Indian manufacturer of injectable drugs, has received its first ever global marketing authorization for Sugammadex from the Philippines. This approval marks a major step in the company's expansion into complex generics, reinforcing its commitment to high-value, technology-intensive formulations and expanding its foothold in the ASEAN market.

Sugammadex is a selective relaxant-binding agent (SRBA) used for the rapid reversal of neuromuscular blockade induced by rocuronium and vecuronium—two commonly used muscle relaxants in anesthesia. Unlike traditional agents, Sugammadex directly encapsulates and inactivates these drugs, offering a faster, safer, and more predictable recovery from anesthesia, reducing the risk of post-operative respiratory complications.

Saransh Chaudhary, President, Global Critical Care, Venus Remedies, and CEO, Venus Medicine Research Centre shared, "There is a growing demand for advanced surgical care and high-growth therapeutic segments in the Philippines which makes this approval particularly relevant. Venus Remedies holds marketing authorizations for several crucial drugs in the Philippines. Sugammadex represents our entry into high-barrier-to-entry complex generics, and we are committed to ensuring equitable access to such advanced medicines globally".

Overall, the pharmaceutical market in the ASEAN region is projected to grow at a CAGR of 4.83% from 2025 to 2029. With its state-of-the-art manufacturing facilities, Venus Remedies is poised to capture a significant share in the Philippines and the wider ASEAN region.

"As a company committed to affordable access to cutting-edge edicines, our expansion into complex injectables and critical care drugs aligns with our long-term vision. The approval of Sugammadex is part of a broader strategy to penetrate both regulated and emerging markets, reinforcing our position in the high-growth ASEAN region", said Aditi Chaudhary, President, International Business, Venus Remedies.

Cadila Pharmaceuticals unveils Advanced Pharmaceutical Warehouse to enhance efficiency and market Reach

Ahmedabad, India: Cadila Pharmaceuticals proudly announces the expansion of its state-of-the-art pharmaceutical warehouse, a strategic move aimed at bolstering efficiency, streamlining logistics, and supporting the company's growing market presence.

Spanning approximately 30,000 sq. ft., the newly expanded warehouse is designed to optimize storage and distribution. With a storage capacity of 3,888 pallets in the main warehouse and 75 pallets in a temperature-controlled cold room, it ensures safe storage for sensitive products such as vaccines and insulin.

The facility is equipped with advanced Warehouse Management Systems (WMS), a fixed racking system, Very Narrow Aisle (VNA) equipment, and reach trucks, reinforcing Cadila Pharmaceuticals' commitment to technological excellence.

Morepen Laboratories launches Empamore, a game-changing treatment for Type 2 Diabetes Mellitus

New Delhi, India: Morepen Laboratories Limited announced the launch of Empamore, a game-changing treatment for Type 2 Diabetes Mellitus (T2DM), Heart Failure with Reduced Ejection Fraction (HFrEF), and Chronic Kidney Disease (CKD). With India being the diabetes capital of the world and over 101 million people

suffering from the disease, Empamore is poised to make a significant impact by offering high-quality treatment at an affordable price point, empowering millions of Indians to take control of their health.

Morepen manufactures Empagliflozin (API) in its USFDA-approved facilities and already has European DMF. The launch of Empamore reflects Morepen's 40 years of pharmaceutical excellence, providing a cost-effective alternative to leading brands while ensuring affordability without compromising quality. The product range includes Empagliflozin (Empamore 10mg/25mg) and Empagliflozin 12.5mg with Metformin 500/1000mg (Empamore M 500/1000mg).

Empagliflozin is a globally recognized SGLT2 inhibitor, widely used for diabetes management. With pre-diabetes cases in India rising to nearly 136 million and the diabetes market expected to grow at a CAGR of 10.9%, Morepen's launch of Empamore comes at a crucial time to provide an affordable and effective solution.

Ashutosh Sharma, V.P. - Sales & Marketing, Morepen Laboratories, said"At Morepen, we are dedicated to democratizing healthcare by making world-class treatments accessible to all. With Empamore, we are providing a trusted, high-quality diabetes treatment at nearly 90% lower cost than existing brands, helping millions manage their condition effectively without financial strain. This aligns with our commitment to empower people to take charge of their health."

India's pharma and healthcare sectors eye 30-40% productivity gains with GenAI adoption: EY report

Mumbai, India: Generative AI (GenAI) is poised to transform India's healthcare and pharmaceutical industries, unlocking unprecedented efficiency and innovation, according to a report by EY titled, 'How much productivity can GenAI unlock in India? The AIdea of India: 2025.'

The EY study reveals a growing momentum in GenAI adoption, with 66% of healthcare organizations and 50% of pharmaceutical companies already initiating proof-of-concept projects. In pharma, 25% of companies have taken it a step further, with GenAI applications now running in production. These advancements are reshaping traditional healthcare models, streamlining operations, and enhancing patient care.

As healthcare providers modernize their systems, GenAI is being deployed to address some of the sector's most pressing challenges, from improving diagnostic precision and advancing telemedicine to extending access to quality care in rural areas. 56% of healthcare organizations identified operations as a key priority for GenAI implementation, while 44% highlighted clinical services, finance, and operations.

These investments are already delivering measurable impact—44% of healthcare companies reported increased revenue and customer satisfaction, while 75% of pharmaceutical firms saw cost reductions and increased customer satisfaction.

Kaivaan Movdawalla, National Healthcare Leader, EY-Parthenon India, said, "GenAI is reshaping India's healthcare landscape by driving efficiency, enhancing patient outcomes, and improving financial sustainability. With 66% of healthcare firms already piloting GenAI, we are seeing significant traction in areas like medical documentation, diagnostics, and revenue cycle management. As adoption scales, GenAI will play a crucial role in expanding healthcare access, especially in underserved regions, and optimizing operational efficiencies."

Adding to it, Suresh Subramanian, National Lifesciences Leader, EY-Parthenon India said, "The pharma industry is rapidly embracing GenAI, with 50% of firms already investing in or exploring AI-driven solutions. From R&D acceleration and manufacturing optimization to supply chain resilience and commercial insights, GenAI is revolutionizing operations. In fact, an EY-led GenAI transformation program for a global pharmaceutical company demonstrated a potential 14% incremental growth in EBITDA, underscoring the tangible financial impact of AI adoption in the sector. As the industry scales its AI efforts, a structured approach—combining investment in infrastructure, responsible AI practices, and workforce upskilling—will be key to unlocking GenAI's full potential."

Mankind Pharma launches affordable Empagliflozin in India

New Delhi, India: Mankind Pharma offers a range of products under Empagliflozin tablets which include EMPAGLYDE, EMPAGREAT and DYNADUO. EMPAGLYDE tablets are available in strengths ranging from 10 mg to 25 mg. EMPAGREAT tablets are also available in strengths ranging from 10 mg to 25. DYNADUO are available in strengths ranging from 10 mg to 25 mg.

Rajeev Juneja, Vice Chairman and Managing Director, Mankind Pharma stated, "With this launch, Mankind


Rajeev Juneja, Vice Chairman and MD, Mankind Pharma

Pharma has once again broken cost barriers by offering a product that combines international quality with affordability. By introducing Empagliflozin at INR 5.49 per tablet for the 10 mg variant and INR 9.90 per tablet for the 25 mg variant, we are ensuring that cost is no longer a barrier to access. Aligned with our vision towards building a healthier Bharat, we remain committed in making high-quality medicines affordable and accessible to every patient in need. Our decision to deploy two separate teams to promote these offerings under distinct names ensures deeper market penetration and a broader reach in this highly competitive segment. Additionally, our extensive distribution network will ensure that this price innovation benefits patients in both urban and rural areas."

Alembic Pharma completes USFDA inspection at Bioequivalence Facility at Vadodara

Mumbai, India: Alembic Pharmaceuticals Limited announced that the United States Food and Drug Administration (USFDA) has conducted an inspection at our Bioequivalence Facility located at Vadodara from 3rd March, 2025 to 7th March, 2025. This was a scheduled inspection. The USFDA issued a Form 483 with one procedural observation.

The Company will provide comprehensive response to USFDA for the observations within the stipulated period. The Company is committed to maintain the highest quality standards and compliance at all times.

The company has also received Establishment Inspection Report (EIR) today with classification as "Voluntary Action Indicated (VAI)"for the inspection carried out by US Food and Drug Administration (USFDA) at our Solid Oral Formulation Facility (F-4) at Jarod, Vadodara. The inspection was conducted from 14th November, 2024 to 22nd November, 2024.

Granules India enters peptide segment and CDMO business by acquiring Senn Chemicals AG

Hyderabad, India: Granules India Limited announced the signing of the acquisition agreement regarding Senn Chemicals AG, a Swiss-based CDMO specializing in peptides. Senn develops and manufactures, Peptides and Peptides based applications for its global customers, providing contract research, development, and manufacturing services. The closing of the acquisition is subject to certain conditions.

The closing is expected to occur in the first half of 2025. The acquisition brings Senn's expertise in Liquid-Phase Peptide Synthesis (LPPS) and Solid-Phase Peptide Synthesis (SPPS), along with a strong CDMO business and established customer relationship, including innovators and brand owners across Pharma, Cosmetics, Amino Acid Derivatives (AAD) & theragnostic segments. Senn's manufacturing facility is certified under ISO 9001:2015 and is regularly inspected and approved for cGMP production by Swissmedic.

Under the Mutual Recognition Agreement (MRA) between Swissmedic and the U.S. Food and Drug Administration (FDA), cGMP inspections conducted by Swissmedic are recognized by the FDA. This acquisition enables Granules' acquiring capabilities into high-growth peptidebased therapeutics. The acquisition aligns with Granules' vision to enter the rapidly expanding peptide-based anti-diabetic and anti-obesity market, including GLP-1 receptor agonists and other next-generation therapeutics. Granules and Senn have been developing two GLP-1 based APIs, and both the projects are progressing well, and more peptide-based APIs are planned to be added in the portfolio, to be developed using Senn's R&D capabilities.

The acquisition marks Granules foray into CDMO segments, leveraging Senn's existing CDMO business and customer relationships, on back of its R&D and manufacturing platform. With this transaction, Granules will leverage Senn's European presence and innovation-driven peptide platform to accelerate its CDMO expansion and meet the fast-growing demand for Amino Acid Derivative (AAD), peptide fragments, and peptide-based therapeutics. Senn presence in Europe, provides access to a skilled R&D talent pool and regulated market clients, further strengthening Granules' global footprint.

Orchid Pharma's Alathur API facility successfully completes USFDA inspection


Manish Dhanuka, MD, Orchid Pharma

New Delhi, India: Orchid Pharma Ltd., a vertically integrated pharmaceutical company spanning the entire pharmaceutical value chain from discovery to delivery, announced the successful completion of a surprise U.S. Food and Drug Administration (USFDA) inspection at its Active Pharmaceutical Ingredient (API) manufacturing facility in Alathur, Tamil Nadu. The inspection, which commenced on 10 February 2025 and concluded on 18 February 2025, resulted in seven minor observations, none of which pertain to the data integrity of the facility.

This successful inspection maintains Orchid Pharma's distinguished position as India's only USFDA-approved facility for Sterile Cephalosporins. It reaffirms Orchid Pharma's compliance with USFDA regulatory standards, reinforcing the company's commitment to quality and excellence in pharmaceutical manufacturing.

The Alathur facility specializes in the production of Cephalosporin antibiotics, a critical class of life-saving drugs. Orchid Pharma remains committed to maintaining the highest standards in pharmaceutical manufacturing to ensure continuous supply to the U.S. and global markets. Additionally, the Alathur API facility has also secured the renewal of its EU Good Manufacturing Practice (GMP) certificate following a successful inspection. This further validates the facility's compliance with European regulatory requirements and its capability to serve global markets. Speaking on the achievement, Manish Dhanuka, Managing Director, Orchid Pharma, said:

Eris Lifesciences appoints Murari Ranganathan to spearhead Cardiometabolic Business


Murari Ranganathan, President, Eris Lifesciences

Mumbai, India: Eris Lifesciences Limited, a leading Indian branded formulations manufacturing company has appointed Murari Ranganathan as President, Cardiometabolic Business. He will be based out of the company's Mumbai office and take charge of the company's Anti-Diabetes and Cardiology businesses.

Prior to joining Eris, Ranganathan was Commercial Director, Women's Health, Metabolics, and International Business at Abbott India Limited. He joined Abbott in 2010 as Head Sales, Medical Nutrition and played a variety of roles in his 15-year stint with the Company. Prior to Abbott, he has worked with organisations like Baxter, Novo Nordisk, and Torrent Pharma. He has a bachelor's in physics and mathematics from Bangalore University and has completed his Postgraduate Diploma in Marketing from St. Joseph College of Business Administration, Bangalore.

Welcoming Ranganathan, Amit Bakshi, Chairman and Managing Director, Eris Lifesciences said, "We are delighted to have Murari join our team. His extensive experience and domain expertise will be highly valuable in strengthening our position in our flagship Cardiometabolic franchise. I welcome him to Eris and wish him success."

On his new appointment, Ranganathan, Eris Lifesciences said, "I'm excited to join Eris Lifesciences in its growth journey. Eris is the youngest among the Top-20 companies in the Indian Pharmaceutical Market with a dynamic and entrepreneurial culture. I look forward to working together with the team and set new benchmarks in disease management and patient care.

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Indoco's Clinical Research Organisation, AnaCipher completes USFDA inspection


Aditi Kare Panandikar, Managing Director, Indoco Remedies

Mumbai, India: Indoco Remedies Limited announced that its Clinical Research Organisation, AnaCipher, located at Hyderabad, has completed its 5-day comprehensive USFDA inspection. The on-site inspection was conducted from 3rd March, 2025 to 7th March, 2025, by investigators from Bioresearch Monitoring Program ("BIMO") and Office of Study Integrity & Surveillance ("OSIS") of USFDA.

The inspection covered both clinical & bioanalytical phases of three Bioavailability and Bioequivalence (BA/BE) studies submitted by clients, to the US Food and Drug Administration (FDA). The facility received one Form 483 at the end of the inspection, which will be responded within the timeframe.

"This is an exciting step in our journey of excellence and a validation of our adherence to applicable regulations and maintaining the highest standards in delivering quality services to our clients." stated Aditi Kare Panandikar, Managing Director, Indoco Remedies Limited.

Alkem Laboratories launches generic empagliflozin and its combinations in India


Dr. Vikas Gupta, CEO, Alkem Laboratories

Mumbai, India: Alkem Laboratories Ltd announced the launch of generic empagliflozin and its combinations in India under the brand name "Empanorm" at prices that are approximately 80% lower than the innovator products.

Empagliflozin is an SGLT-2 (Sodium-Glucose Co-Transporter-2) inhibitor indicted for use in the treatment of type-2 diabetes mellitus, chronic kidney disease (CKD) and chronic heart failure (HF). Alkem's generic empagliflozin and its combinations are bioequivalent to innovator products.

With a patient-centric approach, Alkem has introduced anti-counterfeit security band on the pack of Empanorm, as well as comprehensive patient education information, including basic details on diabetes management in Hindi and English with infographics, and QR codes that provide prescribing information and additional patient education information on diabetes, heart failure, and chronic kidney disease in 11 languages. Keeping patient-convenience in mind, Alkem is offering the medicine in a considerably smaller tablet size than the innovator products.

Alkem's generic empagliflozin is available under the brand name "Empanorm" and its combinations namely: empagliflozin and linagliptin is available under the name "Empanorm L"; empagliflozin and sitagliptin is available under the name "Empanorm Duo" and "Alsita E"; and empagliflozin and metformin is available under the name "Empanorm M".

Commenting on the launch, Dr. Vikas Gupta, Chief Executive Officer, Alkem, said, "As we expand and strengthen our chronic portfolio, the introduction of generic empagliflozin in India is an important milestone. This globally-accepted molecule has transformed diabetes care with its additional benefits in managing chronic kidney disease and cardiovascular health. Leveraging Alkem's strong distribution network, we aim to make this therapy widely available, enhancing treatment accessibility and improving health outcomes for patients across the country."

Syngene acquires its first manufacturing facility in US


Peter Bains, CEO Designate, Syngene International

Bangalore, India: Syngene International Limited , a global contract research, development, and manufacturing organization (CRDMO), announced the acquisition of its first biologics site in the USA – fitted with multiple monoclonal antibody (mAbs) manufacturing lines.

The state-of-the-art biologics facility, acquired by Syngene USA Inc., a wholly owned subsidiary of Syngene, from Emergent Manufacturing Operations

Baltimore, LLC (a subsidiary of Emergent BioSolutions Inc.), will expand Syngene's growing global biologics footprint to better serve its customers across both human and animal health market segments.

The new site will increase Syngene's total single-use bioreactor capacity to 50,000L for large molecule discovery, development, and manufacturing services. Additionally, it will provide Syngene's customers with continuity of supply from its four development and manufacturing facilities located in India and North America, offering services ranging from cell line development, process optimization and both clinical and commercial supply.

Syngene's investment in its first facility in the United States marks a strategic commitment to the US market, with significant benefits for the local economy and the broader life sciences industry. The facility is expected to create jobs, stimulate local economic activity, and strengthen domestic biologics manufacturing capabilities, while also contributing to pharmaceutical innovation and supply chain resilience.

Peter Bains, CEO Designate, Syngene International Ltd., said, "With one of the largest biologics R&D teams and commercial scale manufacturing capabilities in both India and the USA, we now offer a compelling and flexible solution for global pharma and biotech customers. This investment will enable Syngene to cater to growing client requirements in an expanding market. It will also provide clients, access to collective service capability of multiple geographic sites, scientists and experience."

Alex Del Priore, Senior Vice President – Development & Manufacturing Services, Syngene International Ltd., said, "This facility is a significant milestone for Syngene and comes in response to growing client demand in the United States, the fastest-growing biologics market. It strengthens our offering for animal health clients looking for USDA approval for their products."

"The investment will be synergistic with expected additional process development work that will be executed in India while manufacturing can be done in the US. As we ramp up utilization, we expect asset turnover to grow to 1x in less than 5 years, with EBIT margins expected to be in line with the Company average from FY30 and positively contribute to bottom line. The acquisition will not materially impact the current financial guidance given for fiscal year 2024 - 2025. In the short term, we expect minor dilution of operating margins as a result of costs to be incurred in this facility," added Deepak Jain, CFO, Syngene International Ltd.

Pharmaceutical growth hampered by Distribution Gaps: Vector Consulting report

Mumbai, India: A recent report by Vector Consulting Group exposes a critical issue in India's pharmaceutical distribution: even the leading pharma companies have significant gaps in brand availability at chemists.

The study, which surveyed over 900 chemists and 68 stockists across 18 cities, reveals that the coverage of pharmaceutical company brands at chemists is only 60% to 85%, despite these companies maintaining high inventory levels — averaging 15 weeks in the supply chain and 7 weeks with distributors. This shortfall leads to the unavailability of prescribed brands at chemists in 10% to 60% of cases, varying by region.

"Companies are relying on the assumption that having large quantities of stock and working with the bigger stockists in the country ensures availability, but the reality is far different," says Chandrachur Datta, Partner, Vector Consulting Group. The price they pay is product obsolescence, expirations, and an annual inventory write-off averaging 4% to 10%.

The report reveals that chemists, whether sourcing medicines from wholesale markets or distribution-focused stockists, typically work with a limited number of stockists. These stockists usually concentrate on specific therapeutic areas from each company rather than carrying the full product range of a company across therapeutic areas.

Datta noted, "India's pharmaceutical market is growing rapidly, yet the backbone of its distribution remains fragmented. Companies are losing significant revenue and market opportunities because their brands are not consistently available where and when they are needed."

"This is not just a business challenge; it's a missed opportunity to enhance healthcare in the country," added Datta. "Pharma companies need to rethink their approach by adopting smarter, more agile, consumption-based restocking systems to ensure better stock availability and prescription fulfilment. By unlocking the untapped potential of their distribution networks, they can resolve these issues and drive sustainable growth."

CitiusTech launches CitiusTech HealthSPARX, A Real-World Data Platform for Life Sciences Organizations

Princeton, New Jersey: CitiusTech, a leading provider of healthcare technology, services & solutions, announced the launch of a highly scalable and integrated Real-World Data (RWD) platform designed for efficient data management and accelerated insights. The platform provides out-of-the-box support in ingesting datasets from industry's leading real-world data vendors, and offers a flexible, customizable data pipeline to onboard newer datasets.

CitiusTech HealthSPARX streamlines real-world-data management and empowers companies with cutting-edge analytics to drive impactful insights across clinical, research, medical, and commercial operations. Built to support transformative analytics, including SaMD development, the platform accelerates data-driven innovation for life sciences and healthcare organizations.

"CitiusTech HealthSPARX was purpose-built to address the growing need for faster, AI-driven analytics in life sciences," said Joseph Paxton – Senior Vice President & Market Head, Life Sciences, CitiusTech. "By simplifying the ingestion, preparation, and analysis of diverse datasets, the platform eliminates traditional bottlenecks in big data management. This empowers organizations to innovate faster and deliver tangible outcomes in an increasingly complex healthcare landscape."

Priya Devapriya, Ph.D., Head of Data Fluency at UCB said, "CitiusTech HealthSPARX has transformed how we manage and analyze healthcare data. By enabling the seamless integration of syndicated claims data along with advanced patient feature generation, the platform has empowered us to leverage predictive analytics and uncover valuable insights that support our mission. These insights have also enhanced our commercial decision-making, driving meaningful outcomes across therapeutic areas."

OneSource Specialty Pharma strengthens its Board by appointing three new Independent Directors

Bangalore, India: OneSource Specialty Pharma Limited announced the appointment of three new non-executive independent directors to its Board — Dr. Claudio Albrecht, Ms. Debarati Sen and Mr. Vijay Karwal—effective February 27, 2025. The directors bring decades of leadership experience and expertise in Pharma, Business Strategy, Transformation, Merger & Acquisition (M&A) among others. These appointments align with the group's philosophy of having a strong and independent board with exceptional industry experts, ensuring strategic guidance and effective governance.

With the appointment of these non-executive directors, the OneSource Board now comprises Chairperson: Arun Kumar – Founder & Non-Executive Director

The Independent Directors include Dr. Claudio Albrecht – Non-Executive Independent Director; Ms. Debarati Sen – Non-Executive Independent Director; Dr. Rashmi H Barbhaiya and Non-Executive Independent Director include Vijay Karwal – Non-Executive Independent Director; Non-Independent Directors; Bharat D Shah – Non-Executive, Non-Independent Director and Neeraj Sharma – CEO & Managing Director.

Commenting on the development Neeraj Sharma CEO OneSource said "I am delighted to welcome Debarati Sen, Dr. Claudio Albrecht, and Vijay Karwal, to our Board. Their expertise, strategic leadership, and global market insights will support us as we embark on the next chapter of our growth journey. Each of them will bring a new perspective that aligns perfectly with our aspiration to position OneSource as a global leader in the CDMO sector. I am confident that their contributions will not only help us achieve greater heights in corporate governance but also help us build a world class business. I would also like to thank Ms. Rajashri Ojha, Bhushan Bopardikar, Dr. Gopakumar Nair, Mahadevan N for their valuable contribution to OneSource as they step down from the board. Each of them has played a pivotal role in our journey since inception right upto our listing."

HaystackAnalytics secures patent for cutting-edge secure genomic analysis technology

Mumbai, India: In a country like India, with a rapidly advancing healthcare landscape and a growing focus on equitable access to enhance disease diagnosis and personalized treatment, HaystackAnalytics, a pioneer in genomics-based diagnostic solutions, has secured a patent for its groundbreaking invention, "Systems and Methods for Secure Genomic Analysis Using a Specialized Edge Computing Device." This patent marks a significant advance, enabling real-time genomic analysis at the point of use, reducing reliance on complex infrastructure and specialized personnel. It empowers laboratories and hospital labs with real time reporting capabilities with accurate, simplified and timely insights for enhanced patient diagnosis and treatment.

HaystackAnalytics holds exclusive rights to this patent for the next 20 years and is committed to integrating it into all its solutions while making it widely accessible. As genomic sequencing becomes more widespread, the lack of standardized analysis tools has been a major bottleneck. This patent allows real-time sequencing data analysis, minimizing dependence on bioinformatics experts and complex infrastructure.

Dr Anirvan Chatterjee, CEO & Co-founder, HaystackAnalytics said, "India is making big strides in biotech and genomics, and our patented technology is a game-changer. It enables faster, more accessible genomic analysis, improving rare disease diagnosis, AI-driven healthcare, and public health preparedness. Our long-term vision is to create a seamless ecosystem where genomic insights can be leveraged effectively to improve patient outcomes and contribute to the global fight against infectious diseases and antimicrobial resistance."

By collaborating with its network of 250+diagnostic labs, 100+ hospitals, and potential public and private healthcare partners, the IIT-B-based company aims to establish this technology as a cornerstone of precision medicine on a global scale.

CORONA Remedies introduces affordable solution of Empagliflozin

Nirav Mehta, CEO & Managing Director, CORONA Remedies

Mumbai, India: CORONA Remedies Limited, has launched generic version of Empagliflozin introduced under the brand name "Empabite & it extensions" a SGLT-2 inhibitor, for Type 2 diabetes. With a commitment to affordability and accessibility, CORONA Remedies will offer the medication at a significantly reduced price, making it more accessible to patients.

Empagliflozin works by blocking the sodium-glucose co-transporter 2 (SGLT2) in the kidneys. This increases the amount of glucose that is excreted in the urine, which lowers blood glucose levels. Beyond Glucose lowering property, Empagliflozin can delay Chronic Kidney Disease (CKD) and Heart failure progression in patients with or without Diabetes[1].

Commenting on the launch, Nirav Mehta, CEO & Managing Director of CORONA Remedies, stated, "At CORONA Remedies, our vision has always been 'One world, one quality.' We are committed to making essential medicines, affordable without compromising on global standards. We believe, the launch of our Empagliflozin, will empower many Indian patients, with access to advanced diabetes care at a reduced cost. This reinforces our dedication to public health and our mission to provide quality treatment at an affordable price."

Allchem Lifescience files DRHP with SEBI

Mumbai, India: Allchem Lifescience Limited, an Indian manufacturer of active pharmaceutical ingredients (API) intermediates and speciality chemicals, has filed its Draft Red Herring Prospectus ("DRHP") with market regulator Securities and Exchange Board of India ("SEBI").

The IPO comprises of a fresh issue of equity shares of face value of ₹10 each aggregating up to ₹ 190 Crores and an offer for sale of up to 7,155,000 equity shares of face value of ₹ 10 each. The offer for sale comprises of up to 3,577,500 equity shares of face value of ₹ 10 each by Kantilal Ramanlal Patel and up to 3,577,500 equity shares of face value of ₹ 10 each by Manisha Bipin Patel

(Promoter Selling Shareholder).

The company's manufacturing facility is in Manjusar, Vadodara, Gujarat. As on December 31, 2024, the Manufacturing Facility had a total equipment capacity of 1,133.50 KL.

The company has demonstrated consistent growth in the financial performance across parameters. The revenue from operations has grown at a CAGR of 12.75% between FY22 and FY24. The revenue from operations during the 6 month period ended September 30, 2024, and during FY24, FY23 and FY22, was ₹ 784.48 million, ₹ 1,374.21 million, ₹ 1,057.19 million and ₹ 1,081.01 million Further, the profit after tax (PAT) has grown at a CAGR of 28.65% from March 31, 2022 to March 31, 2024. The profit after tax for 6 month period ended September 30, 2024, and for FY24, FY23 and FY22, was ₹ 108.91 million, ₹ 234.09 million, ₹ 179.89 million and ₹ 141.39 million, respectively.

Emkay Global Financial Services Limited is the sole Book Running Lead Managers to the issue.

Merck Q4 Net sales up 3.8%

Darmstadt, Germany: Merck, a leading science and technology company, returned to profitable growth in 2024 and delivered on its guidance for the year. A strong performance of Healthcare, a rebound in Life Science and profitable growth in Electronics contributed to this. During the year, Merck also strategically sharpened its portfolio's focus on future growth areas. After a strong fourth quarter 2024, the company is looking toward 2025 with confidence and expects continued profitable growth. The company's fourth quarter sales was up 3.8% organically year-on-year.

"Merck is back on a growth path with all three businesses. The challenges of recent years have been taken as an opportunity to strengthen our supply chains and invest in Europe, the United States and Asia. In 2025, we will continue to deliver profitable growth across our company. With our innovation-driven portfolio, we are ideally positioned to benefit from global macro trends such as complex biologics, novel modalities, and semiconductors for the AI era," said Belén Garijo, Chair of the Executive Board and CEO of Merck.

For the full year, Merck delivered net sales of € 21.2 billion, an organic increase of 2.0%. Strong sales across all Healthcare franchises and in the Semiconductor Materials business played a key role in this. Life Science resumed growth during the second half of the year.

Merck's Life Science business sector staged a turnaround in the second half of 2024. In particular, the first half of the year was overshadowed by inventory destocking by customers and tough year-over-year comparables in the wake of Covid-19. This caused full-year sales to decline to € 8.9 billion (organically: −3.3%) and EBITDA pre to € 2.6 billion (organically: −6.3%). In the fourth quarter of 2024, sales grew organically by 1.9%, while EBITDA pre rose organically by 16.0%.

Marksans Pharma Q3 revenue up 16%

Mark Saldanha, MD, Marksans Pharma

Mumbai, India: Marksans Pharma Ltd. reported the financial results for the quarter and nine months ended December 31, 2024.

Mark Saldanha, Managing Director of the Company said "We are delighted to announce an all-time high quarterly PAT, driven by robust growth of 16.3% YoY in Q3 revenue. Revenue growth was led by the US region, which witnessed 37% YoY growth, followed by UK, which improved during the quarter. Improved product mix and softer raw material prices compared to the previous year led to gross margin expansion of 279bps YoY. We witnessed some headwinds in terms of EBITDA margin due to our investments in the acquired facility and increased freight costs during the quarter. Looking ahead, we anticipate growth to continue in the coming quarters augmented by planned new launches and further ramp up of the TEVA facility."

The company's Operating revenue stood at ₹ 681.8 crore, up by 16.3% YoY driven growth across key markets, led by US region, while Gross profit stood at ₹ 383.5 crore., up by 22.4% YoY, with a gross margin expansion of 279 bps YoY to 56.2%. The company's US & North America Formulation business grew 34.9% YoY to ₹ 908.0 crore. in 9MFY25, on account of incremental revenue from new product launches and increase in the market share.

Price Reduction in essential medicine results in annual savings of approximately ₹ 3788 crore for patients

New Delhi, India: Union Minister of State for Chemicals and Fertilizers, Anupriya Patel in Rajya Sabha in written reply stated that Ministry of Health and Family Welfare notifies the National List of Essential Medicines (NLEM), which is incorporated as Schedule-I to the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals (DoP) fixes ceiling prices of these scheduled medicines in accordance with the provisions of DPCO, 2013. All manufacturers and marketers of scheduled medicines are required to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. Further, NPPA fixes the retail price of new drugs, as defined in DPCO, 2013.

For applicant manufacturers and their marketers, who too are required to sell the new drug within the price notified by NPPA. In respect of non-scheduled formulations, manufacturers are required to not increase the Maximum Retail Price of the drugs launched by them by more than 10% during the preceding 12 months. As on 12.3.2025, ceiling prices of 928 scheduled formulations and retail prices of over 3,200 new drugs stood fixed by NPPA. The average price reduction due to fixation or refixation of prices under NLEM, 2022 was about 17%, resulting in estimated annual savings of approximately ₹3,788 crore to patients.

Besides price regulation, Government has also enabled access to affordable essential medicines through Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), under which quality medicines are offered through Jan Aushadhi Kendras (JAKs) at rates that are typically 50% to 80% lower than the prices of branded medicines available in the market. In addition, under the Affordable Medicines and Reliable Implants for Treatment (AMRIT) initiative of the Department of Health and Family Welfare, medicines for the treatment of cancer, cardiovascular and other diseases, implants, surgical disposables and other consumables etc. are provided at significant discounts of up to 50% of market rates through AMRIT Pharmacy stores set up in some hospitals/institutions.

To ensure availability of essential drugs and reduce out-of-pocket expenditure of patients visiting public health facilities, Government has rolled out the Free Drugs Service Initiative under the National Health Mission under which financial support is provided to State and Union Territory Governments for 106 drugs at the Sub-Health Centre level, 172 drugs at the Primary Health Centre level, 300 drugs at the Community Health Centre level, 318 drugs at the Sub-District Health level and 381 drugs at the District Hospitals.

Currently, 2,047 medicines and 300 surgicals, medical consumables and devices are under the PMBJP scheme product basket, covering all major therapeutic groups, such as cardiovascular, anti-cancers, anti-diabetic, anti-infectives, anti-allergic and gastro-intestinal medicines and nutraceuticals etc. The Department of Pharmaceuticals has set the target to increase the product basket to 2,100 medicines and 310 surgicals, medical consumables and devices by 31.3.2025.

The prices of both scheduled and non-scheduled drugs are monitored by NPPA. Monitoring activities are based on references from State/UT Price Monitoring Resource Units (PMRUs), State Drugs Controllers (SDCs), market samples, market-based databases and complaints received through the Pharma Jan Samadhan (PJS) portal, Centralised Public Grievance Redress and Monitoring System (CPGRAMS) and other reliable sources. Instances of overcharging are dealt with by NPPA under relevant provisions of DPCO, 2013. ■

Laurus Labs to invest ₹833 crore in KRKA Pharma

New Delhi, India: Laurus Labs Ltd announced that the Board of Directors of the Company have approved for investment of an amount of ₹ 833,000,000/- in KRKA Pharma Private Limited ("KRKA"), a joint venture of the Company.

Further, KRKA d.d., Novo mesto, Slovenia (co-venturer) shall also invest an amount of ₹ 867,000,000/- in KRKA. Thereby, maintaining the existing shareholding ratio of 51:49 between KRKA d.d., Novo mesto and Laurus Labs Limited.

The purpose of this investment is to acquire land and to meet initial cost of setting up of a manufacturing facility for production of finished products for the new markets, including the Indian market. This investment aligns with the company's strategic growth plans and long-term business objectives.

As a research-driven pharmaceutical manufacturing organization, Laurus Labs has been developing and assisting its client organizations to succeed in innovative medicines that globally enhance the health outcomes for patients. The company has global leadership position in APIs, including anti-retroviral, Oncology, Cardiovascular, and Gastro therapeutics. Our position was strengthened by our backward-integration and strong regulatory compliance across all operations. It has emerged as one of the most trusted CMO and Contract Development and Manufacturing Organization (CDMO) service provider to Global Innovators from drug development phase to commercial manufacturing.

Motilal Oswal Alternates invests in Megafine Pharma

Mumbai, India: MO Alternate Investment Advisors Private Limited has agreed to invest upto ₹ 460 crores for a majority stake in Mega Fine Pharma Private Limited. The Sanghvi Family, one of the founding-promoter groups, has also participated in this transaction, increasing their stake in the Company.

Megafine is a Mumbai based export focused API company with two USFDA approved manufacturing facilities in Nashik and Vapi. The company specializes in the manufacture and sale of a diverse range of high-value, low-volume niche Active Pharmaceutical Ingredients (APIs) for chronic therapies.

Established in 1995, Megafine is backward integrated to manufacture its own intermediates while also offering contract manufacturing services for APIs and Intermediates to third-party customers. The Company has long-standing relations with leading global pharmaceutical companies and has achieved global market leadership in some of its key APIs.

Shailesh Sanghvi, Founder, Promoter and now Managing Director of Megafine stated, "Our focus remains on delivering high-quality products as an independent API supplier in specialized and niche segments. With our manufacturing facilities approved by all major global regulatory authorities, we are committed to excellence. We look forward to partnering with the MO Alts' team as we embark on the next stage of growth. Their practical approach and deep expertise in life sciences will be instrumental in transforming Megafine into a long-lasting institution, as they have successfully demonstrated in several growth stage franchises."

Rohit Mantri, Managing Director and Co-Head of Private Equity at MO Alts commented, "India's API industry is witnessing a double-digit growth, driven by increased outsourcing, lower costs and de-risking of global supply chains from China. This is our first sole control investment as MO Alts and we would focus on further strengthening R&D and manufacturing capabilities and creating a platform for further inorganic opportunities. We also thank Jhaveri and Gandhi families who have been instrumental in building Megafine franchise for over three decades and are very excited to partner with Shailesh and Megafine management team to build a large and differentiated API Company." ■

Advancement of monoclonal antibody (mAb) biosimilars: perspective highlights and future prospects

Biosimilars are biological medicinal products that contain a version of the active substance found in an already authorized original biological medicinal product, known as the innovator or reference medicinal product. Initially, the first approved biosimilar medicines were peptides and small proteins. In the last decade, biosimilar versions of innovator monoclonal antibody (mAb) drugs have started ruling the market of biopharmaceuticals as patents on these more complex proteins are expiring and many are soon to expire.

In India (CDSCO) the first mAb biosimilar was approved in the year 2007 which was Reditux (rituximab) and Remsima (infliximab) was approved by EMA in 2013 as the first biosimilar in the regulated market. Post that mAb biosimilars have witnessed rapid growth and transformative trends in recent years. The mAb biosimilars market is projected to grow significantly, with estimates reaching approximately $240 billion by 2032, driven by increasing demand for cost-effective alternatives to branded biologics.

Dr. Sanjeev Gupta, Dr. Shuvankar Ballav and Ms. Rinky Madan present an overview of the recent developments and the future trends of mAb biosimilars along with some focus on the market.

Treatment landscape:

Over the years the focus of mAb biosimilars has expanded to oncology, autoimmune diseases and inflammatory disorders to provide effective and more accessible therapeutic options for patients. mAb biosimilars are presently preferred by clinicians and physicians since these provide accelerated access to affordable drugs compared to expensive innovators. For instance, biosimilars of infliximab and adalimumab are used to treat conditions like rheumatoid arthritis, Crohn's disease, and psoriasis.

Oncology indications of mAbs include non-Hodgkin's lymphomas, chronic lymphocytic leukemia, prostate and breast cancer etc. Multiple mAb biosimilars are being developed to cover dual therapeutic areas for example denosumab for osteoporosis and bone cancer indications, rituximab for rheumatoid arthritis and oncology indications. As the patent expiry of the many mAb innovator molecules is approaching, a bright future awaits for developing mAb biosimilars.

Recent Regulatory Developments

Below are few details on the regulatory advancements, revised guidelines and approvals which show the forecast of a golden era for mAb biosimilars:

Table 01: Approved biosimilars with varying expression/host systems compared to the innovator

Brand name	Expression system of biosimilars	Agency and year of approval
Remicade (Infliximab) - Innovator in Sp2/0 cells		
Flixabi	CHO cells	EMA (2016)
Ixifi		US FDA (2017)
Zessly		EMA (2018)
Avsola		US FDA (2019)
Stelara (Ustekinumab) – Innovator in Sp2/0 cells		
Wezlana	CHO cells	US FDA (2023)
Wezenla		EMA (2024)
Steqeyma		EMA (2024) & US FDA (2024)
Pyzchiva		EMA (2024) & US FDA (2024)
Otulfi		EMA (2024) & US FDA (2024)
Fymskina		EMA (2024)
Eksunbi		EMA (2024)
Soliris (Eculizumab) – Innovator in NS0 cells		
Bekemv	CHO cells	EMA (2023) & US FDA (2024)
Epysqli		EMA (2023) & US FDA (2024)
Tysabri (Natalizumab) – Innovator in NS0 cells		
Tyruko	CHO cells	US FDA (2023) & EMA (2023)

Note: Table includes information found in the public domain by EMA & USFDA available at https://www.ema.europa.eu/en/medicines & https://purplebooksearch.fda.gov/.

Approvals with varying host system: The selection of high-producing mammalian cell lines is a critical step in process development for the production of therapeutic antibodies. However, the use of the same host system as the reference product is no more a mandate for the development of mAb biosimilar. Scientific justification of the minor quality differences and comparable safety and efficacy studies has gained approvals from EMA and the US FDA (Table 01).

CHO cells are considered to be the gold standard for the production of mAbs due to faster growth in suspension culture, tolerance to varying culture conditions, suitable post-translational modifications and applicability for a wide variety of potential products. These approvals have created a much smoother path for the development of mAbs and their commercial manufacturing.

Guideline reforms and waiver for non-clinical and Phase-III clinical trial (CT) studies: A prominent boost has come for biosimilars with the waiver of non-clinical studies and case-by-case basis waiver of Phase-III CT. The majority of biosimilars including mAbs do not elicit pharmacological activities in non-relevant species like small animals. Hence, are not predictive of possible toxicity. MHRA (UK) [1] and Health Canada [2] clearly state that the non-clinical evaluation using animal models is not necessary and requested any more. US FDA and EMA encourage early discussion on analytical similarity data and these days have given a waiver for the conduct of in vivo non-clinical studies for various biosimilar products.

The thought behind this is when analytical similarity is well established by structural and functional studies, and where extensive in vitro biological studies are indicative of similarity, in vivo toxicity studies may not be necessary as these are not relevant for showing comparability between similar biologics candidates and its reference biologic. Many countries of RoW, LATAM and MENA markets are also in the favor of waiving the animal studies.

Waiver for Phase–III CT (confirmatory efficacy trial) has been a big milestone achievement for the development of mAb biosimilars as well as for all the

biosimilars. MHRA-UK has clearly stated for biosimilars in most cases a confirmatory efficacy trial may not be necessary if sound scientific rationale supports this approach [1]. EMA and the US FDA have started giving approvals (case-by-case basis) based on the Phase–I CT data and available PD biomarker studies. This waiver has resulted in drastic cost reduction and much faster completion of the development which is favoring global patient access of the mAb biosimilars. If a biosimilar drug is approved in EMA or US FDA then country specific phase – III trials may not be necessary for RoW, LATAM and MENA markets.

EMA and FDA's take on interchangeability: Breakthrough has come for mAb biosimilars as well as all the biosimilar products with streamlined interchangeability status by EMA and FDA. Interchangeability refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect, in this case, reference product and biosimilar.

In April 2023, EMA issued a statement saying that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product or one biosimilar can be replaced with another biosimilar of the same reference product. Interchange should only take place after careful consideration of the approved therapeutic indications.

In 2024, the US FDA proposed removing switching study requirements for biosimilars seeking interchangeability status, expediting approvals. This regulatory shift significantly enhances competition and patient access and also supports industries developing interchangeable. For example, despite more than 10 biosimilars including one interchangeable (Cyltezo) being approved for Adalimumab, there has been another BLA and approval of Simalandi as interchangeable in 2024; Jubbonti and Wysot have been approved as Denosumab biosimilars of Prolia and Xgeva in March 2024.

Technological Advancements

Cutting-edge analytical techniques are enabling precise characterization of mAbs, reducing the need for extensive clinical trials. The past decade has seen significant advancements in the 'state of the art' technology for both physicochemical and functional characterization. Advanced techniques such as sequence coverage and post-translational modification (PTM) quantification by LC-MS, mixed lymphocyte reaction (MLR) assay etc. have been developed as 'orthogonal methods' which also support address the minor quality differences (eg. level of impurities, receptor binding which are not part of the MOA) which are observed due the change in the host systems as well as variations in the process conditions. Most recent advancements are the multi-attribute method (MAM) and emerging intact multi-attribute method (iMAM), utilizing LC-MS methods [3, 4] as powerful analytical tools that enable the monitoring of critical quality attributes (CQAs) of mAb biosimilars in compliant settings. Extensive analytical similarity exercise is the present-day expectation of the regulatory agencies for mAb biosimilar applications since them being large and complex molecules where any minor difference can have impact on the potency and efficacy.

Process Intensification: In the last decade we have seen though great progress has been made in mAb process development, the manufacturing cost remains much higher for mAbs than small molecules. To reach more patients, reduce supply shortages and compete with biosimilars, reducing mAb manufacturing costs (e.g. by increasing cell culture titer, while maintaining desired quality) remained a major challenge which had to be addressed. The fed-batch process intensification strategies have come as a solution to the manufacturing of mAbs using CHO and other host cells.

The goal of cell culture process intensification is to increase volumetric productivity by increasing viable cell density (VCD), cell-specific productivity or production bioreactor utilization in manufacturing without compromising product quality and safety. In process intensification, a higher initial seeding cell density can be achieved by implementing N-1 perfusion seed culture in fed-batch production bioreactors, which can achieve a much higher final VCD than conventional batch N-1 seed culture. Two major advantages of this approach (i.e. fed-batch production with N-1 perfusion) over perfusion

production culture are: (a) less perfusion medium is required, decreasing the overall raw material cost, and (b) the implementation of only small changes at the N-1 seed step are required in the existing fed-batch manufacturing facilities. These intensification strategies are showing very promising outcomes in the production processes, which will ultimately benefit the bottom line and reinforce the market position.

Challenges and path forward

Despite massive development and growth, approved mAb biosimilars are facing legal battles since patent disputes remain a hurdle, as seen in recent litigation by Amgen against Samsung Bioepis over biosimilars of Prolia and Xgeva. Innovators are posing a strong eye on the mAb biosimilar approvals for patent infringement to hold the market. The challenge lies in physician and patient awareness, as education campaigns are critical and much needed to overcome scepticism and increase mAb biosimilar uptake.

Another, challenge lays in the requirement of the CT with the country licensed reference products particularly for EMA and US FDA where an additional arm is expected to apply to the respective agencies. This additional CT arm with the expensive reference products (particularly US-licensed products being more expensive) adds on to the overall cost for the development of the mAb biosimilars as well as others. A harmonization in such cases is expected with the support of the analytical similarity as a 'bridging study' between two reference products since in most of the cases the reference product is manufactured by the same company in the same plant and supplied to both the markets. However, remarkable growth prospects are showing in the acceptance of a EMA or US-approved dossier without any additional CT study in many countries from the RoW market.

Partnerships and collaborations between pharma giants are accelerating the development of the mAbs. For instance, Celltrion and Johnson & Johnson partnered to launch a biosimilar for Stelara by 2025. For manufacturing, continuous improvements in cell line development and bioprocessing are reducing production costs and improving scalability. The biosimilars of mAbs have led to price reductions, with discounts of up to 30%-50% compared to originator biologics. This affordability is driving adoption, especially in low- and middle-income countries.

In a nutshell, the mAb biosimilar market is set for unprecedented growth, fueled by regulatory reforms, technological advancements and increasing market competition. These developments promise to make life-saving treatments more accessible and affordable globally. ■

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The Evolving Landscape of Diagnostic Innovations

Diagnostics has always been the first step in saving lives. Whether it's detecting infections, monitoring chronic diseases, or guiding treatment decisions, the ability to diagnose quickly and accurately can mean the difference between life and death particularly in critical conditions like sepsis, cancer, and antimicrobial resistance (AMR). The diagnostic industry has undergone significant transformative evolution over the past decade owing to rapid technological advancements and now shaping the way diseases are being detected, monitored, treated and making tests faster, more accurate, and accessible to a wider population.

From traditional laboratory-based methods to AI-driven diagnostics and point-of-care (PoC) testing, innovations in this space are bridging the gap between early disease detection and effective treatment ensuring that more lives are saved through timely intervention. However, as the burden of infectious diseases, AMR, and chronic illnesses continues to rise, the demand for better diagnostic solutions has never been greater.

As the burden of infectious diseases, antimicrobial resistance (AMR), and chronic illnesses continue to rise, the demand for better diagnostic solutions has never been greater.

Dr. Preeti Nigam Joshi, Founder Director and CEO FastSense Innovations Pvt. Ltd explores the key trends, breakthroughs, challenges, and prospects in diagnostic innovations, shedding light on how they are transforming healthcare and bringing us closer to a world where early detection becomes the norm rather than the exception.

From Waiting Days to Instant Answers

Not too long ago, getting test results even for routine tests, often meant waiting for days, if not weeks of anxious waiting. Blood samples were collected, sent to centralized labs, and processed using bulky equipment. While this system was effective, this system had limitations—delays in diagnosis could cost lives, especially in cases like sepsis, antimicrobial resistance (AMR), or rapidly spreading infections where early intervention is needed. Even today, culture tests take more than 24-72 h and 5 days in some cases.

Today, innovation is rewriting these rules. Point-of-care (PoC) diagnostics allow doctors to get real-time answers right at the patient's bedside. Whether it's a rapid test for infections, a portable device for chronic disease monitoring, or AI-driven analysis that detects patterns invisible to the human eye, the new era of diagnostics prioritizes speed, accuracy, and accessibility.

The impact of faster diagnostics is particularly evident in critical care settings. For instance, in infection management, every hour of delay in initiating the right treatment increases mortality risk. Similarly, in cancer care, early detection can significantly improve survival rates, but drug-resistant infections pose a severe challenge to patients undergoing chemotherapy. Rapid diagnostics that detect infections and AMR early can prevent complications and save lives.

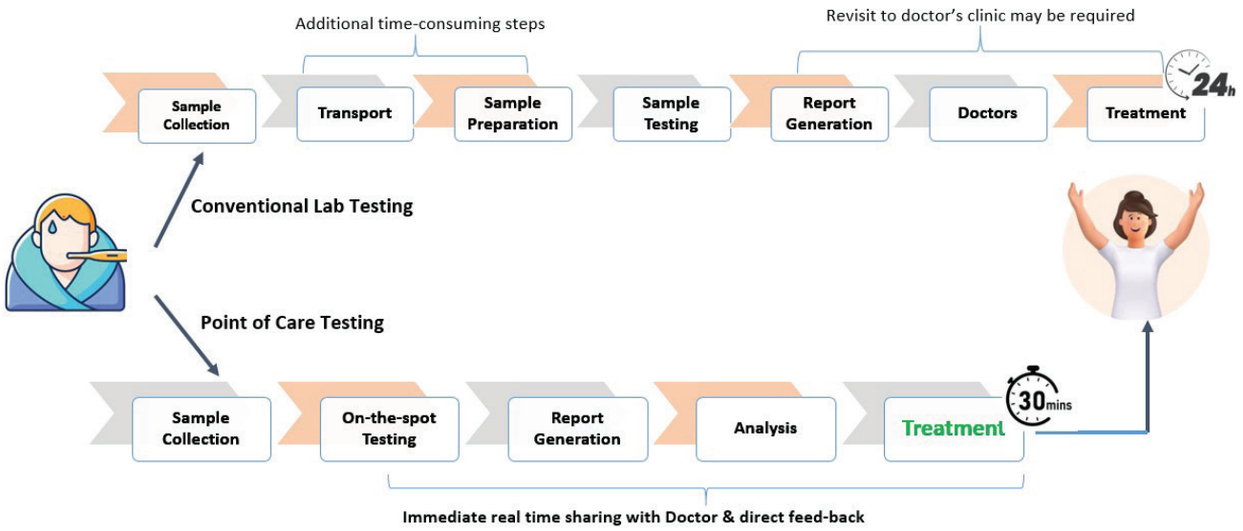

Figure-1: Reducing Diagnostic Delays: A Comparative Workflow of Conventional Lab vs. Point-of-Care Testing

What's Driving the Change? The Bigger Picture

In January 2025, Pune witnessed a significant outbreak of Guillain-Barré Syndrome (GBS), a rare neurological disorder where the body's immune system attacks the peripheral nerves. Few lives were lost and many are still dealing with the after-effects post hospital discharge. Health authorities quickly traced the outbreak to Campylobacter jejuni, a bacterium often linked to contaminated food and water and keep the situation under-control. Although measures are being taken to prevent such situations in future, this outbreak highlighted how rapid diagnostic advancements are transforming public health responses. Unlike traditional methods that could take weeks, modern molecular diagnostics, particularly PCR-based tests, helped quickly detect Campylobacter jejuni, enabling authorities to act swiftly. This early detection was crucial in controlling the outbreak before it escalated further.

The Pune GBS outbreak serves as a reminder of why continuous innovation in diagnostics is essential. Faster, more accurate testing not only helps identify the cause of disease outbreaks but also ensures timely public health interventions, preventing widespread impact. As diagnostic technology evolves, the ability to predict, detect, and contain such health crises improves aligning it with global health goals for better disease surveillance and prevention.

The COVID-19 pandemic completely transformed the way we approach diagnostics. Before 2020, routine lab testing was the norm, and Point-of-Care (PoC) diagnostics were mostly limited to specific diseases like glucose monitoring or pregnancy tests. Post-COVID, we are witnessing an accelerated shift towards rapid, decentralized, and technology-driven diagnostic solutions.

Here's what's driving this change:

Shift Towards Decentralized & PoC Diagnostics

The pandemic highlighted the inefficiencies of centralized lab testing, especially when mass-scale testing was needed. PoC devices are being developed for a wider range of diseases (e.g., infectious diseases, AMR, STIs like chlamydia etc.) that results in faster diagnosis, reduced hospital burden, and early disease containment. Although a long way to fully transform the healthcare landscape but progress so far is good. Fig. 1 is demonstrating how PoC diagnostics is shaping the future of healthcare.

Technological Innovations:

AI, IoT & 3D Printing

Accelerated research in AI-powered diagnostics, smart biosensors, and 3D-printed medical devices.

Smart algorithms can now analyze test results, predict disease progression, and even identify patterns that help in early detection. AI-driven diagnostics are particularly effective in detecting cancers, infectious diseases, and even rare genetic disorders.

For instance, AI-powered imaging tools can detect tumors at an early stage with remarkable accuracy, helping oncologists make informed decisions about treatment. AI-assisted PoC tools improve accuracy & speed, while 3D printing enables on-demand, low-cost diagnostic production (useful for outbreaks like GBS in Pune). It improves personalized diagnostics, reduces dependency on global supply chains, and sustainability. 3D printing and open-source diagnostic platforms are lowering production costs, ensuring affordable testing solutions in low-resource settings. As governments and global health organizations invest in decentralized healthcare, PoC devices will continue to play a transformative role in ensuring equitable access to early detection and better patient outcomes worldwide; well aligned with WHO sustainability goals of universal health coverage (SDG 3) and reducing inequalities (SDG 10).

Advances in Molecular Diagnostics Tools

Polymerase Chain Reaction (PCR) and Loop-Mediated Isothermal Amplification (LAMP) are game-changers in diagnostic science. These molecular methods allow for rapid and highly sensitive detection of pathogens, even from tiny biological samples. Unlike traditional culture methods that can take days, PCR and LAMP deliver results in under an hour, enabling faster treatment decisions. During the COVID-19 pandemic, PCR became the gold standard for detecting the virus,demonstrating its value in infectious disease management. Now, similar molecular approaches are being adopted for detecting tuberculosis, and sexually transmitted infections (STIs) with unprecedented speed and accuracy.

Wearable & Home-Based Diagnostics: Diagnostics are no longer confined to hospitals and labs. The rise of wearable health devices and home-based diagnostic tools has empowered individuals to monitor their own health. Devices like continuous glucose monitors for diabetes management, smartwatches with ECG capabilities, and at-home pregnancy or ovulation tests are reshaping how people engage with their health.

The Push for Personalized Medicine: Diagnostics are essential in the era of personalized medicine, where treatments are customized based on a patient's genetic makeup, disease profile, and lifestyle. Companion diagnostics help doctors figure out which treatments will work best for each patient, reducing guesswork and improving outcomes. For cancer patients, genetic testing can identify the most effective chemotherapy drugs, cutting down on side effects and improving survival rates. In infectious diseases, molecular diagnostics can pinpoint the exact bacterial strain causing an infection, helping doctors choose the right antibiotic and fight antimicrobial resistance (AMR).

Global Investment & Policy Shifts: The world of diagnostics is changing faster than ever, driven by major global investments and shifts in healthcare policies. The COVID-19 pandemic exposed critical gaps in disease detection and response, leading governments, health organizations, and private investors to prioritize faster, more accessible diagnostic solutions. Today, we see a strong push toward decentralization, affordability, and innovation, ensuring that even remote and underserved areas have access to life-saving tests.

One of the biggest changes is the rise in funding for next-generation diagnostics. Government funding organizations are investing heavily in point-of-care (PoC) technologies, AI-driven diagnostics, and antimicrobial resistance (AMR) surveillance. At the same time, venture capital and private investors are pouring resources into startups working on smart, portable testing devices that can deliver results in minutes rather than days. This shift is not just about convenience—it's about saving lives through early detection.

Alongside these investments, policy changes are making it easier for innovative diagnostic tools to reach the market. Regulatory bodies are trying to streamline approval processes for emergency-use tests and AI-integrated diagnostic platforms. Governments are also encouraging self-testing and home-based diagnostics, recognizing that people need faster, more accessible healthcare solutions. Another critical development is the adoption of 3D printing and open-source platforms, which reduce production costs and make diagnostics more affordable in lower-income regions.

Beyond Innovation: The Challenges Ahead

Despite the progress, there are hurdles to overcome. The road ahead in diagnostics evaluation presents several significant challenges. Major challenges faced by diagnostics innovations are:

Cost Barriers: Many advanced diagnostic technologies remain expensive, restricting access, particularly in low-resource settings.

Regulatory Challenges: The lengthy and complicated regulatory approval processes often delay the launch of life-saving diagnostic innovations. To speed things up, more effort is needed, and raising awareness is crucial. Regulatory bodies must focus on educating stakeholders about the regulatory framework. An out of box approach is needed to fill the gaps w.r.t. regulatory pathways for new era diagnostics tool and conventional techniques.

Limited Access in Low-Resource Settings: High costs and lack of infrastructure prevent widespread adoption of state-of-the-art diagnostic tools in underfunded healthcare environments.

Rise of Antimicrobial Resistance (AMR): The increasing prevalence of AMR necessitates not just rapid detection but also the development of smart, decision-support tools to guide appropriate treatment choices.

Need for Smart Diagnostic Tools: The focus is shifting from just rapid diagnostics to tools that can help clinicians make informed, context-specific treatment decisions, particularly in critical situations.

Integration into Healthcare Systems: While new diagnostic tools are being developed rapidly, integrating and their adaption into existing healthcare infrastructures still remains a huge challenge. Training healthcare workers, ensuring interoperability with electronic health records, and addressing logistical constraints are essential for seamless implementation.

A Future Where Diagnostics Save More Lives

The diagnostic industry is no longer just about testing; it's about transforming healthcare. The shift toward faster, more personalized, and AI-powered solutions is already making a tangible difference in patient care. The question is no longer whether we can innovate but how quickly can we make these technologies available to everyone who needs them.

Investments in research, policy support, and global collaboration are crucial to ensuring that diagnostic breakthroughs translate into real-world impact. Initiatives promoting decentralized testing, AI-driven disease surveillance, and affordable PoC devices will play a key role in bridging gaps in healthcare access in coming years.

After all, a diagnosis is not just a test result—it's a turning point in a patient's life. The faster and more accurately we diagnose, the better we can treat, save, and heal. With continuous advancements in diagnostic science, we are moving closer to a future where early detection becomes the standard, not a privilege.

Because the first step in saving lives starts with knowing what we're fighting!! ■

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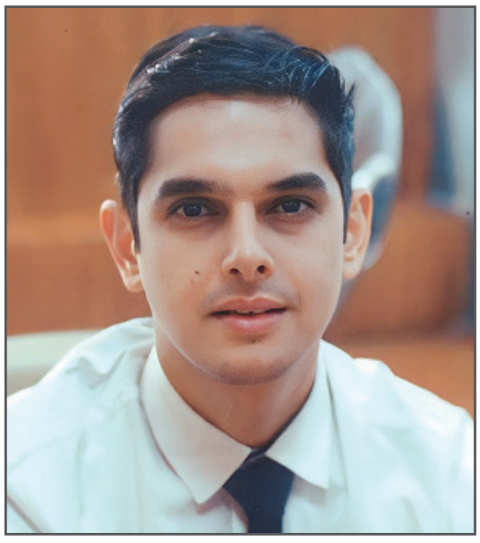
GUEST COLUMN

Why Biologics are Important

Biologics are large, complex molecules derived from living organisms such as microbial or mammalian cells. They are unlike traditional small molecule drugs, which are chemically synthesized with simple structures.

Ishaan Bhardwaj, Senior Vice President, Anthem Biosciences emphasizes how biologics plays a role in global health and been essential in developing diagnostic tests. He also spoke about the emergence of biosimilars as a promising development in making biologic therapies more accessible and affordable.



Ishaan Bhardwaj
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Biologics also include vaccines, stem cell therapies, gene therapies, tissues, whole blood, blood components, and cell therapies to name a few. One could fill a volume of encyclopedias with the underlying science, efficacy, regulatory and commercials of each of these vast therapeutic categories.

The impact biologics have had on the healthcare industry is obvious. By 2022 over a 100 antibody based therapeutics had been approved by the US Food and Drug Administration. In 2023 the top three pharmaceutical drugs by revenue were all biologics (Buntz, 2024). At number one Merck's Keytruda (pembrolizumab) which has indications in various cancers with USD 25 billion in sales. Despite sales decreasing significantly due to multiple biosimilars now available, AbbVie's Humira (adalimumab) for autoimmune disorders, still continues at number two with USD 14.4 billion. Easily the most famous weight-loss and diabetes pharmaceutical is at number three; Novo Nordisk's peptide semi-synthetic Ozempic (semaglutide) with USD 13.9 billion.

Biologics also played a crucial role in the 2019 COVID pandemic, particularly in the development of the Messenger RNA (mRNA) vaccines developed by Pfizer-BioNTech and Moderna. These vaccines use mRNA to instruct cells to produce a protein that triggers an immune response, providing protection against the virus.

The speed with which these vaccines were developed, tested, and distributed was unprecedented. This no doubt saved potentially millions of lives while removing the myth that biologics don't have the potential to respond rapidly to emerging global health threats. In addition, biologics have been essential in developing diagnostic tests. For instance, antibodies are used in many rapid diagnostic tests to detect the presence of viral antigens in patient samples, enabling quick and widespread testing, which was critical in controlling the spread of COVID-19.

The treatment of infectious diseases, both viral and bacterial, is another area where biologics have shown some potential. Monoclonal antibodies (MAbs) have been used to target viruses and prevent them from entering cells and target bacteria by tagging them allowing immune system to deal with them. These treatments can be particularly valuable for patients who have comorbidities and are at high risk of severe disease or those who cannot receive vaccines. In 2022, six mAbs targeting infectious diseases had been granted approval by the USFDA. The indications included the treatment of Ebola virus, prevention of respiratory syncytial virus (RSV) infection, prevention and treatment of anthrax infection caused by the bacterium Bacillus anthracis and infection and prevention of recurrence of the gram positive Clostridioides difficile bacteria.

Biologics have paved the way to more specific and effective therapies such as immunotherapy in cancer, which harnesses a patients' own immune system to fight cancer. Such treatments include monoclonal antibodies, checkpoint inhibitors, cytokines, vaccines, and adoptive cell transfer, most prominently in the form of hematopoietic stem cell transplants (HSCTs) and chimeric antigen receptor (CAR) T-cell therapies. This has attributed to the advancement of precision and personalized medicine (PPM), in which therapy selection is tailored to an individual.

However, manufacturing biologics is inherently more complex than traditional small-molecule drugs. The production of biologics begins with the expression of the protein of interest in cell-based systems such as Chinese Hamster Ovary (CHO), Escherichia coli, Pichia pastoris amongst others. This protein subsequently requires recovery and purification through multiple complex filtration and chromatography techniques. Each step in the process is intricate, from the careful selection and genetic manipulation of cells, which are then cultured under highly controlled conditions, to the isolation of the biologic from the cell culture while maintaining its structural integrity and function. Any slight deviation can affect the yield and quality of the biologic.

Biologics are held to stringent quality control measures to ensure their safety and efficacy. The manufacturing process must be highly consistent, as even minor variations can lead to significant differences in the final product. These measures include comprehensive analytical characterization methods to assess the product's structure, potency, purity, and biological activity, rigorous in-process controls and final product testing to ensure batch-to-batch consistency and use of aseptic techniques and sterile environments.

In addition, biologics and the living cells that produce them are particularly sensitive to environment and enzymatic action and therefore, require complex and thorough bioassays for batch release and stability assessments. Their sensitivity necessitates special handling, storage, and distribution processes to maintain their stability and efficacy. There is a greater chance that the biologics trigger an immune response when administered.

On the regulatory front, biologics are subject to rigorous regulatory scrutiny before they can be approved for use. In the U.S., a Biologics License Application (BLA) must be submitted to the U.S. Food and Drug Administration to gain approval for a biologic. This application includes extensive data from preclinical studies, clinical trials, and manufacturing processes to demonstrate the product's safety, efficacy, and quality. The BLA review process is more detailed and time-consuming than the New Drug Application (NDA) process for small molecules.

In the EU, companies submit an MAA to the European Medicines Agency (EMA), which undergoes a similar evaluation process. The EMA's Committee for Medicinal Products for Human Use (CHMP) assesses the application, and if approved, the biologic receives a marketing authorization valid across all EU member states. After approval, biologics are subject to ongoing monitoring to ensure long-term safety and effectiveness. Regulatory agencies require companies to report adverse events and may mandate additional studies to gather further data on the biologic's performance in the real world.

The complexity of manufacturing biologics significantly contributes to their high cost. The processes require sophisticated facilities, skilled personnel, and expensive raw materials, all of which drive up production costs. Additionally, the stringent regulatory requirements for quality control further increase expenses. These high costs present a potential barrier to patient access. While biologics can offer life-saving treatments, their price often makes them unaffordable for many patients and healthcare systems, particularly in low- and middle-income countries. The challenge lies in finding ways to reduce costs without compromising the quality or safety of these products, which is a key focus of ongoing research and innovation in the field.

The emergence of biosimilars is a promising development in making biologic therapies more accessible and affordable. Biosimilars are biologic products that are highly similar to already approved reference biologics, with no clinically meaningful differences in terms of safety, purity, or potency. They offer a cost-effective alternative to expensive biologics and have the potential to increase patient access to biologic therapies. However, it comes with regulatory and market hurdles that must be carefully navigated. Biosimilars must undergo comparative analytical studies, preclinical studies, and clinical trials to demonstrate their similarity to the reference product. In addition, for the FDA to designate a biosimilar as "interchangeable" with its reference product, meaning that it can be substituted for the reference biologic without the intervention of the prescribing healthcare provider, additional evidence is required, particularly data showing that switching between the biologic and the biosimilar does not lead to adverse outcomes. The complexity of manufacturing biosimilars means they are not as inexpensive as generic small-molecule drugs. Additionally, there may be market resistance from physicians and patients who are cautious about switching from a tried-and-true biologic to a biosimilar, despite regulatory assurances of similarity.

Advancements in genetic engineering and cell culture techniques, such as recombinant DNA (rDNA) technology, perfusion culture techniques, single-use bioreactors, de novo protein design, gene editing and CRISPR, gene amplification and stable cell lines, have revolutionized the production of biologics, leading to more efficient, scalable, and precise manufacturing processes. They have shortened development timelines, reduced costs, expanded the therapeutic possibilities and enabled more effective and personalized treatments.

Biologics are typically difficult to scale up from laboratory pre-clinical batches to large-scale commercial batches while maintaining product purity and batch-to-batch equivalence. This particular pain point can be eased with the help of Contract Development and Manufacturing Organizations (CDMOs) which have the capacity and technical know-how required to scale up. This includes bioreactors, purification systems, and filling and finishing lines that can produce biologics in the quantities required for clinical trials and commercial distribution. CDMOs ensure that the scale-up from lab to manufacturing scale is smooth and that the product retains its quality throughout the process.

CDMOs are specialized service providers in the biopharmaceutical industry that offer comprehensive support throughout the drug development and manufacturing lifecycle. These organizations provide pharmaceutical and biotechnology companies with the expertise, resources, and infrastructure needed to develop, manufacture, and bring biologic drugs to market. CDMOs play a critical role in enabling companies, especially those without in-house capabilities, to focus on core activities such as drug discovery and commercialization while outsourcing the complex and resource-intensive processes associated with biologics development and production.

In summary, biologics are playing an increasingly vital role in global health, offering new tools and strategies to combat pandemics, advance personalized medicine, and mitigate other pressing health challenges. However, realizing their full potential requires addressing challenges related to cost, accessibility, and infrastructure, particularly in resource-limited settings. ■

Article Courtesy: Anthem Biosciences - Published earlier in PBW September 2024

India's Pharma Logistic Boom: Key Trends Shaping the Future and Driving Supply Chain Growth

The pharmaceutical sector in India was once a force to reckon with, driven by robust manufacturing and exports, accounting for over 20% of the global pharmaceutical supply chain. However, the challenges in multiple areas resulted in gaps in cold chain logistics and slow technology adoption. Prakash Singh, COO Jeena Criticare Logistics emphasizes about Key trends shaping the Future and driving supply chain growth.

For instance, maintaining consistent temperatures for biologics across India's diverse climate was a significant hurdle. Similarly, while some explored track and trace systems, widespread adoption of technologies like RFID (Radio Frequency Identification - to track and monitor the movement of goods throughout the supply chain) and real-time monitoring were limited. The sector was evolving, with an increasing focus on cold chain capabilities and a growing awareness of advanced technologies, though implementation was in its early stages. This period laid the foundation for India's global healthcare role while highlighting areas for improvement, such as greater investment in cold chain infrastructure and wider technology adoption.

The year 2020 was unprecedented, disrupting global supply chains worldwide. The pharmaceutical sector faced significant logistical roadblocks due to strained production of essential medicines, hindered by factors like lockdowns and travel restrictions during the COVID-19 pandemic. Disruptions in sourcing key ingredients, particularly from China, further impacted both pharmaceutical production and logistics. Labor shortages and production hurdles, despite essential status, made meeting rising demands difficult. This period accelerated the adoption of advanced technologies, advanced temperature-controlled logistics, and strategic expansion of cold chain infrastructure, among others, which became essential for supply chains.

Despite significant challenges, the pharmaceutical logistics industry has experienced a remarkable boom, fuelled by increased tech adoption for better visibility and efficiency, expanded cold chain and warehousing to ensure product integrity, and greater automation for faster turnaround times. These advancements are being driven by both industry investment and government support. Government initiatives, such as the Production Linked Incentive (PLI) scheme and Medical Device Parks, have created dedicated manufacturing hubs, further streamlining logistics. The Strengthening of Pharmaceutical Industry (SPI) scheme has supported MSMEs and pharma clusters, improving productivity, quality, and sustainability. Furthermore, the National Logistics Policy and PM Gati Shakti National Master Plan have strengthened infrastructure, simplified regulations, and promoted multimodal connectivity, further supporting the logistics ecosystem.

India has not only sustained its position but has firmly established itself as the "Pharmacy of the World" by providing critical pharmaceutical support to more than 100 countries. One game-changing humanitarian initiative by the name "Vaccine Mantri" was launched by the government of India, which saw the country exporting millions of doses of vaccines to developing countries across the world. Additionally, India remains a leading supplier of generic medicines, vaccines, biologics, Active Pharmaceutical Ingredients (APIs), over-the-counter (OTC) drugs and specialized treatments like biosimilars and oncology drugs to many countries in North America, Europe, Africa and Asia.

Global conflicts like the war in Ukraine and instability in regions such as Afghanistan and Sri Lanka disrupted trade and cross-border pharmaceutical shipments, which heightened security delays in temperature-sensitive transport. However, the sector is adapting with alternative routes, increased collaboration, and advanced cold chain tracking technologies. These efforts, alongside supply chain diversification, aim to improve medication access despite global instability.

Future outlook:

Reflecting on 2024, the pharmaceutical and logistics sector saw significant growth, driven by technological advancements and the increasing demand for specialized solutions. Cold chain logistics remained essential for transporting temperature-sensitive medications, particularly biologics. Despite the ongoing challenges, both the pharmaceutical and logistics

sectors demonstrated resilience and are on a strong trajectory of growth.

Some of the trends that would shape the future of the supply chain growth :

- Advanced temperature-controlled logistics as a foremost need: In pharmaceutical logistics, maintaining product integrity requires precise cold chain management, real-time tracking, and strict compliance with global regulations. Expertise in handling temperature-sensitive biologics, vaccines, and personalized medicines is essential. The use of the Internet of Things (IoT) and Artificial intelligence (AI) enables real-time visibility and proactive risk management, ensuring safe and efficient delivery.

- Digital transformation for real-time visibility and control: The logistics industry is rapidly integrating cutting-edge technologies. The Internet of Things (IoT) enables real-time shipment tracking, while robotics and automation streamline warehouse operations and inventory management. Simultaneously, Artificial intelligence (AI) driven insights enhance decision-making, creating smarter and more efficient pharmaceutical supply chains.

- Sustainability: a non-negotiable imperative: Developing a resilient and sustainable cold chain infrastructure is essential for mitigating risks and ensuring equitable healthcare access. Key investments include strong logistics networks, solar-powered cold storage, and real-time monitoring to protect pharmaceuticals during crises and pandemics. Sustainability efforts go beyond compliance, focusing on fuel-efficient transport, eco-friendly packaging, and carbon-neutral supply chains, along with energy-efficient cold storage, which are essential to curb environmental impact.

- Strategic expansion of cold chain infrastructure with a focus on resilience: The rising demand for pharmaceuticals and temperature-sensitive products is driving the rapid expansion of cold chain logistics. Building a strong and diverse cold chain network requires investments in strategically located cold storage facilities and temperature-controlled packaging solutions.

- Last-mile delivery and enhanced patient access as key priorities: One of the most effective ways to improve pharmaceutical logistics is by establishing decentralized warehousing systems. Initiatives like the Bharatmala Pariyojana program can enhance road connectivity, enabling better distribution hubs for essential medicines. Technologies such as GPS tracking, route optimization, and real-time monitoring can streamline supply chains, while digital platforms can strengthen coordination between manufacturers and rural distributors.

- Public-private partnerships (PPP) to strengthen pharmaceutical logistics: Integrating policies like Public-Private Partnerships is crucial for enhancing pharmaceutical logistics, especially in underserved areas. Collaboration between government and private sectors can pool resources and expertise to overcome infrastructure limitations. For example, leveraging PPPs could significantly improve the distribution of affordable generic medicines under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), ensuring wider access to essential medications in rural India.

India's pharmaceutical logistics sector is truly at a pivotal juncture. With a growing focus on universal healthcare, the industry must adapt to ensure efficient and affordable medicine delivery, both domestically and globally. Cold chain logistics for temperature-sensitive products is becoming increasingly vital. Through decentralized warehousing, cutting-edge technology, strategic public-private partnerships, and workforce development, India is poised to lead the global pharmaceutical logistics sector in the coming days.

India's unique socio-economic landscape, coupled with evolving regulatory frameworks and a growing emphasis on sustainability, presents an unparalleled opportunity to revolutionize its healthcare logistics and existing infrastructure. Similarly, strengthening cold chain infrastructure, enhancing last-mile connectivity, and integrating AI-driven supply chain solutions will ensure seamless access to life-saving medicines, even in the most remote regions-leaving no community behind. ■

Author

Prakash Singh
COO
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Promoting Patient Centricity Through Full-Spectrum Life Sciences Infrastructure

"The secret of the care of the patient is in caring for the patient," wrote American physician Francis Peabody. His words highlight the essence of patient-centricity, an approach that places patient needs at the core of drug development, clinical research, and healthcare delivery. While this model has driven advancements in life sciences, its full potential can only be realized through infrastructure that accelerates discovery, trials, and commercialization. Purpose-built research spaces, trial-ready environments, and integrated ecosystems ensure that innovations transition from laboratories to real-world applications efficiently. **Milind Ravi, CEO, Rx Propellant** emphasizes how Sustainability is critical factor influencing life sciences infrastructure. He added that National Policy on Research & Development and Innovation in the Pharma-MedTech Sector and the BioE3 Policy reinforce the need for full-scale infrastructure supporting the growth of life sciences.

Scaling Innovation with Research and Trials

India's pharmaceutical sector continues to expand, ranking third globally in production volume and contributing significantly to vaccine and generic drug supply. As chronic diseases rise and personalized medicine gains momentum, the demand for research-driven drug development has swelled. The ability to create rapid cures for healthcare depends on the availability of advanced research and development environments that facilitate early-stage discoveries and trial facilities that validate new therapies efficiently. Without a well-structured ecosystem that fosters seamless collaboration between scientists, clinicians, and manufacturers, treatments face delays in reaching patients.

India's pharmaceutical market is valued at USD 50 billion in FY 2023-24, with exports contributing USD 26.5 billion, underscoring the country's role as a key supplier of life-saving treatments. This growth also requires infrastructure that enhances scientific progress, streamlines regulatory processes, and enables large-scale production to meet global demand.

Digital health platforms and large-scale public health missions, such as e-Sanjeevani and Ayushman Bharat Digital Mission, rely on a consistent flow of new therapies. This is only achievable when research spaces and trial-ready infrastructure operate in sync to accelerate drug approvals and manufacturing. India has

already demonstrated its leadership in this space with major breakthroughs, such as its first indigenous CAR-T cell therapy and advancements in biosimilars that have improved access to biologics on a global scale.

Gaps in Life Sciences Infrastructure

Despite India's strengths in pharmaceutical production, gaps in infrastructure limit the ability to scale complex biologics, cell and gene therapies, and precision medicine. Many existing facilities were built for traditional drug manufacturing and lacked the adaptability for cutting-edge treatments. Regulatory bottlenecks further complicate progress, with evolving compliance requirements slowing the establishment of specialized research and trial-ready environments. Sustainability is another critical factor influencing life sciences infrastructure.

Research and production facilities that do not incorporate energy-efficient systems and waste management strategies face rising operational costs and regulatory pressures. Sustainable biomanufacturing practices are becoming essential for companies looking to maintain R&D efficiency while meeting environmental standards.

Integrating Research, Trials, and Manufacturing

A strategically designed life sciences ecosystem facilitates drug discovery, clinical validation, and large-scale manufacturing in a seamless cycle. Integrating research environments that support advancements, trial-ready spaces that enable rapid validation, and production hubs designed for scalable therapies create a framework that aligns with industry and patient needs. With the contract development and manufacturing organization (CDMO) market projected to reach USD 14 billion by 2028, the necessity for this integrated infrastructure is greater than ever.

The location of these facilities also plays a significant role in optimizing efficiency and collaboration. Life sciences hubs near academic institutions, hospitals, and clinical trial centers foster interdisciplinary partnerships that align drug development with evolving healthcare needs. The proximity to talent pools and regulatory bodies further ensures that therapies can move from discovery to market without unnecessary obstacles. Policies such as the National Policy on Research & Development and Innovation in the Pharma-MedTech Sector and the BioE3 Policy also reinforce the need for full-scale infrastructure supporting the growth of life sciences.

Conclusion

Progress in healthcare takes a comprehensive life sciences ecosystem encompassing research spaces, integrated trial facilities, and scalable manufacturing hubs to accelerate innovation. Companies investing in optimized R&D environments to meet growing patient needs and ensuring innovative treatments are accessible will ride the next wave of life sciences boom. ■

Author

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Compressed Air Treatment

Compressed air treatment is an indispensable requirement of the pharma industry to ensure the production of highly competitive and quality products. The industry is involved in a lot of pneumatic processes that rely heavily on compressed air. As a result, it becomes a prerequisite to continuously supply pressurized air devoid of any form of contaminants that can sabotage the entire manufacturing process of drugs.

Deepesh Upadhyay, Assistant Vice President, Delair India Pvt. Ltd emphasizes about how Compressed air treatment is important for pharmaceutical industry and its applications.

The pharma industry is thriving at a phenomenal pace, majorly driven by rising healthcare demand with people prioritizing overall health. At the same time, increasing lifestyle diseases, a surge of chronic conditions, an ageing population, and many other factors are further driving the growth and expansion of the industry. Giving desired impetus to the sector, the Indian pharma industry has been exhibiting significant feats, gaining the moniker of 'pharmacy of the world.' Projecting an upswing trajectory in recent years, the country is the third largest producer of pharma products by volume across the globe.

To facilitate such massive manufacturing, the country demonstrates an extensive network of 3,000 drug companies along with a robust 10,000 custom manufacturing units. Looking at the bolstering prospects of the sector, the Indian pharma industry is poised to reach a USD 120 billion market by 2030 as per the India Briefing report. Where the country vies to become a leading pharma hub across the world, it underscores the need to manufacture medicines of the highest quality more than ever to sustain and solidify its position as 'pharmacy of the world.'

Working towards achieving the goal, it becomes essential to produce world-class pharma products that meet global excellence. As part of the plan, the Central Drugs Standard Control Organization (CDSCO) recently announced a zero-tolerance policy for substandard drugs. To ensure compliance with the same, even the government has tightened its hold on Good Manufacturing Practices under Schedule M guidelines to not compromise on the quality of products.

Striving to infuse quality in Indian pharma products that conform to global benchmarks, the scheme also outlines equipment requirements used for manufacturing pharma products. This mandates the deployment of compressed air treatment across the pharma industry to extract impurities and provide quality compressed air for diverse manufacturing processes.

Considering that contaminated compressed air accounts for low-grade medicines, it can defeat the entire purpose of medication by causing treatment failure. The substandard quality drugs can also lead to adverse reactions and resist drug development in the process, risking the life of patients. Responsible for inadequate safety and efficacy, they can increase the cases of morbidity and mortality in the person.

Delving deep into the importance of quality compressed air, it finds application in a wide range of operations throughout the processing, manufacturing, and packaging of pharma products. It is essential for driving intricate operations involving pneumatic processes such as the manufacturing of tablets and

capsules, giving the right flavour, colour and texture to the tablet. The list of advantages also includes protection of products from any sort of contamination and goes a long way in ensuring the right balance of ingredients as well. Altogether, compressed air is required at every step of the pharma process, forming a necessary framework of the industry.

Moving ahead, the automatic packaging machinery employs compressed air for sealing, Capsule Filing Machine, Powder Filing Machine, Blister Pack Machine. Along with this, the Tablet Press Machine, Drying Container also make use of pressurized air and find application in vacuum cleaning of the systems as well. Understanding the crucial role of compressed air, in case the air is untreated, there are high chances of the presence of moisture in it, which is destructive in nature. It comes with the ability to jeopardize the production efficiency and quality of end products.

Moisture is a major threat to the pharma industry, where it has a damaging effect on the products. It causes tablet disintegration, lumping and caking of powdered materials, decomposition of formulations, and uneven tablet coating. In addition to this, it is also responsible for the agglomeration of chemical products and resists tablet compression. All the factors cumulatively account for the shorter shelf life of medicines, severely impacting their efficacy.

Further compounding the issue, the pharmaceutical products are highly hygroscopic in nature, which shows great affinity for water. Even in the slightest presence of humidity, they undergo physical, enzymatic, microbiological, and biochemical degradation. Adding to the challenges, moisture also alters the colour coating of the tablet and goes a long way in giving rise to blisters, culminating in the breakage of tablets.

Additionally, during the tablet compression stage, powdered materials are required to be maintained in their dry state to mould them into tablets or capsules under high pressure. However, humidity in compressed air hinders the binding process and even leads to the decomposition of drugs while reducing their medicinal value at the same time. Likewise, at the time of tablet coating, failing to cool and dry the tablet at the desired rate and in the absence of quality compressed air results in rough and translucent coating that gives a very unsatisfactory appearance.

Moisture provides a conducive environment for the growth of microorganisms, initiating the germination of mould, mildew, fungi, etc. Accounting for increased microbial activities in organic material, there is decay of material leading to substandard medicine. Here, it is important to note that the moisture menace is not just limited to the manufacturing stage but comes with the potential to contaminate the pharma products even at the packaging phase. Hence, it is essential to deliver quality compressed air at every stage of the product cycle.

The repercussion of moisture transcends to pneumatic tools and machines as well, which are involved in the production of pharma products. Initiating corrosion in pipelines, cylinders, and other components, moisture is responsible for the malfunctioning of the equipment. Contributing to the sluggish and inconsistent functioning of pneumatic valves and cylinders, it is responsible for increased downtime of the machines. The problem further gets complicated during cold weather when moisture freezes in the pipelines and valves. Incurring huge financial loss to the company in the form of unplanned maintenance costs, it can hugely impact the productivity and timelines of manufacturing.

Therefore, understanding that untreated compressed air is loaded with harmful contaminants, it is mandatory for the industry to perform compressed air treatment. It comes in handy for providing quality compressed air by conducting the removal of impurities entailing water/

moisture, dust particles, oil, and solid contaminants. Here, employing compressed air dryers comes with the proficiency to eliminate even the slightest trace of moisture from the pressurized air.

The dryers make use of desiccant-based drying technology for achieving the best atmospheric dew point temperature of (-40°C) to (-70°C) max. Being well-equipped with desiccant bed, it depends on the pressure swing principle/purge air for adsorbing and desorbing the water vapor to regenerate the desiccant bed. Furthermore, the dryers are advanced enough to optimize resource utilization as well for curtailing energy consumption of pneumatic systems. At the same time, the innovative systems incorporated into the dryers bode well for ensuring accurate management of energy-saving drying cycles.

In addition to this, the Dew Point Based Dependence Systems (DPDS) are adept at driving purge optimization with the purpose of prolonging regeneration cycle time aimed at minimizing purge losses, which contributes to huge energy savings. The integration of automatic condensate management and differential pressure gauges facilitates advanced filtration for removing dust, oil aerosols, and vapours for providing highly pure and reliable compressed air.

Therefore, gauging the importance of compressed air in the pharma industry, compressed air treatment is vital for protecting the integrity of the pharma products. Hence, the installation of compressed air dryers across the industry is crucial for driving the manufacturing of safe, effective, and high-quality drugs that comply with international standards as well. ■

Author

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New Frontiers of Growth in the Life Sciences Industry

The life sciences industry is on the cusp of change. While this change does give rise to some challenges, it throws open doors for new opportunities and possibilities. In order to capitalize on these opportunities, an organization must be on a dual mission of 'renew - new' – one that simultaneously focuses on renewing existing systems and processes for greater efficiency and adopting new advancements in technologies to gain value. In this paper, we discuss these opportunities and the way forward for the life sciences industry.

Recent scientific and technological advances coupled with an aging population, expansion in the emerging markets, and an exponential increase in mainstream adoption of digital technologies have set the ball rolling for the life sciences industry, providing it with a renewed platform to revive its fortunes.

With an explosion of digital data availability – electronic health records, social, genomics, clinical, insurance, and more digitally engaged consumers, the stage is set to derive benefits from an integrated drug development and manufacturing environment. Such an environment not only provides the best care for patients but also generates significant revenue growth. Furthermore, there is significant focus on personalized healthcare from both the Life Sciences industry and policy maker perspective. A case in point is President Barack Obama's precision medicine initiative. Personalized healthcare, however, would require a complete shift in how the industry evaluates the market (focus on an individual instead of a population), analyzes higher volumes of data, and puts in place newer processes and methods to complete their studies. The spate of recent investments in the immuno-oncology therapies is pointing towards a significant growth in the coming decade.

Technology is playing a massive role in enabling the industry to achieve these objectives, be it analytics in personalized medicine, cloud computing in collaboration, or wearable devices in remote and self-health monitoring. As the world becomes increasingly connected, information and communication technologies will fundamentally reshape both the consumption and delivery of services in life sciences. The industry must prepare for the future by embracing next-generation technologies and systems throughout the life sciences value chain.

We believe life sciences companies must adopt a more proactive strategy, one that allows them to maximize value from prior investments by renewing existing solutions and processes and generate new value by embracing new technologies, systems, and best practices.

Opportunities for 'renew' in Life Sciences

The Life Sciences industry is undergoing a major transformation. A large part of this is fueled by the integration of digital that has driven a powerful re-imagination of the Life Sciences industry landscape.

This transition has opened up new opportunities for development, but also comes with its own challenges.

- Innovate through cloud: Cloud's greatest impact is in facilitating innovation through increasing accessibility of both internal and external data. While initially the reasons for cloud adoption were centered on reducing the cost and the time for infrastructure provisioning, it is now providing many more strategic benefits such as enhancing collaboration and providing much greater computing power across the entire value chain from R&D, sales & marketing to enabling functions such as HR and finance.

In pharmaceutical research where large volumes of data (notably next- generation DNA sequencing systems and genomic tools) needs to be mined and the cost of obtaining this sequence is rapidly decreasing, data has further increased the number of both, instruments being used and labs using them. Through cloud's agility of provisioning and pricing (pay-per- use), setting up massive infrastructure resources for data crunching, analysis, or simulation is no longer an impediment.

Similar cases are happening in clinical research. A large pharma company is setting up a cloud-based solution to integrate clinical data across all its global trials and provide it to its global operations team for analysis. These big data solutions that receive clinical data instantly from all the current trails will reduce the time taken to analyze and predict the path of the trials, while decreasing the operating expenses substantially. On a broader application, the scope of collaboration is expanding to include R&D processes outsourcing, exemplified in virtual laboratories where thousands of researchers from contract research organizations can seek and provide help. Overall, by opening the doors of collaboration, exploding analytical power, and making information more accessible and manageable, the cloud is encouraging new practices such as open innovation in life sciences.

The industry must leverage these to the fullest.

- Smarter and transparent supply chains: Due to globalization and the ever increasing size of organizations, the need to integrate supply chains and gain visibility into them has become critical. Wide diversity of the product mix (biologics versus small molecule) will further compound the need for supply chains that can handle this mix. Furthermore, regulatory policies on transparency are evolving and several states in the U.S. have passed product pedigree laws, and many others are contemplating such legislations. In summary, supply chains will need to transport an increasingly diverse range of products in a challenging environment with resources that are much more geographically scattered while simultaneously optimizing costs.

As technology erases the distinctions between the virtual and the physical, it sets up the opportunity to create intelligent, analytics-driven, next-generation supply chains that provide real-time, end-to-end visibility and control. A smart supply chain, integrated across all business processes and systems, can also leverage real-time data and analytics to enable more accurate forecasting, shorter response times, optimized supply chain processes, and faster decisions.

To enable transparency, pharma organizations are not only implementing global track and trace solutions but are also experimenting with cloud-based, leaner supply chain management solutions. While more prevalent in the CPG Industry, discussions in the pharma community on these lean solutions that can provide visibility on their products after they leave their warehouses have taken place. These solutions are being used in the developing nations that have a more complex network of distributors and wholesalers. Such solutions will promote growth by preventing stock-outs and allowing further optimization of inventory and support recalls.

- Renew through automation and modernization: Most large pharmaceutical organizations are born out of numerous mergers and acquisitions and have inherited portfolios of IT applications in various stages of modernization. In our experience, a substantial part of the legacy portfolio is either outdated or manual, creating high cost burden

of managing them while ensuring they meet the complex and evolving regulatory compliance standards. While legacy systems are integral to the continued operational maintenance, they hinder the adoption of newer digital solutions.

Best-in-class companies are standardizing business processes, measuring manufacturing, focusing on visibility, and using the right tools. They are using automation to manage the processes and drive increased business value. Automation is being welcomed in the industry as an alternative to manual steps, especially across processes that have repetitive steps. Automation not only reduces the time taken to execute a task but also frees up time for valuable resources to focus on productive tasks. In manufacturing, Process Analytical Technologies (PAT) are being integrated across the assembly line to automatically capture unit operations data and integrate it with the plant quality equipment. This automation allows instant feedback on the batch quality based on the analysis of data while preventing waste and reducing costs. In R&D, numerous research labs are going paperless by integrating their critical solutions such as ELNs and LIMS with their high throughput chromatographs.

This has not only reduced the time taken, but also minimized errors and allowed scientists to collaborate more effectively leveraging digital data. Additionally, in core IT services, a novel use of automation is in enabling testing of large and complex enterprise solutions. Panaya, which was recently acquired by Infosys, uses artificial intelligence to provide impact assessment and execute automated testing of their enterprise solutions. As a result, it can achieve 75-80% reduction in time and resource consumption. This is now being utilized across a number of large organizations with substantial time and resource savings. Automation is also being effectively utilized in executing the many repetitive tasks in application support services resulting in greater than 35% efficiency savings for organizations.

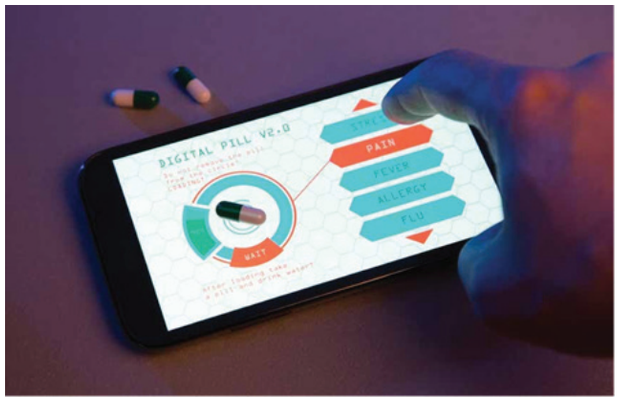
We envision that the automation of IT processes will soon become a key component of the life sciences operations and new-generation leaders will mandate these efficiency savings within their lean organizations.

New opportunities for life sciences

Populations are aging. Chronic illnesses are increasing. New disease strains are emerging at an alarming rate. Add to this mix, the soaring number of patients in a greater spread of geographies. Top it with global regulatory mandates. Then, factor in the variable dosage needs. Think about the shelf life of pharmaceutical drugs and medications. And, we are looking at skyrocketing global healthcare costs. At the same time, there is pressure to develop innovative drugs to save more lives.

Here are the opportunities that await the life sciences industry:

- Connected patients and partners: In today's socially connected world, pharmaceutical companies have a clear opportunity to play a greater role in delivering a better experience for patients and their providers. Patients are becoming demanding about how they want their care. This has precipitated a major transformation in business and technology and has led organizations to adopt a patient-centric model. Earlier attempts at creating these solutions were exclusively focused on adherence to the medication. However, an emphasis on continuity of care provides an opportunity for pharma companies to play a bigger role. Digital solutions are facilitating patient education,



behavioral change, and better communication with clinicians. There is also a wide variety of solutions that facilitate this connect including web portals, body sensors, and apps. These help the patient self-monitor and get needed support, between visits to the physician.

These solutions now provide health advice anytime, anywhere, by developing patient-centric smart tools and devices. These devices also detect and track data regularly and accurately and relay the same to physicians.

Mobility is another key feature of these solutions, making it easier for the patient to communicate. A hospital network in Boston empowers patients to use their home devices to track and report data to their doctors. Patient and physician- centric portals, where comprehensive information about treatments and drugs is actively shared, are also on the rise.

In the future, pharma companies will design holistic Medical-health (M-health), platforms that connect the patients and physicians across the globe, drive patient and physician engagement, and activation – all with the objective of improved care experience for patients, better clinical outcomes, and lower total cost of care. In the new collaborative, omni-access data world, this will be a key factor in attracting and retaining patients, partners and clients. To keep pace with a rapidly changing technology landscape, organization, would need to develop a deeper integration, collaboration, and synchronization of activities across all channels.

- Adoption of IoT and wearables across the value chain: Ubiquitous presence of smartphones and substantial investments in Internet-of-things (IoT) are providing an exciting opportunity to reduce the gap between the patients and the pharmaceutical industry. While still in its nascent stage, higher adoption of IoT has already started to facilitate at-home diagnostic testing, self-management of chronic diseases, and remote patient-health care provider interaction in the healthcare industry.

For life sciences companies, the adoption of IoT can improve medication adherence and reduce time by capturing critical clinical indicators directly and sending them to the EDC system, produce better outcomes based on analytic insights such as in clinical trials where patient data through wearables has been found to be useful for tracking recovery from cardiac surgery, judiciously replace physical interaction with digital intervention, and lower the cost of treatment. Doctors are turning to wireless devices such as Fitbits to understand the factors that help the recovery of patients. A report published in the Annals of Thoracic Surgery says, "Wireless monitoring of mobility after major surgery was easy and practical. This opens the door for changing recovery models and improving outcomes in surgical practice."

Early market movers already see the use of pill-shaped micro-cameras that traverse the human digestive tract, sensors in pills that track concordance, hip replacements that detect falls and send messages to care providers, and thousands of health-monitoring applications that send messages and data from the home to the hospital or patient to the HCP to improve early diagnosis and treatment solution.

One critical innovation in this area is the advancement by Proteus Digital Health. It has created an FDA-approved small pill that consists of a pinhead- sized sensor embedded in the pill and a battery-powered patch that monitors various health indicators such as sleep, activity, respiration, and heart rate. The recent announcement by Novartis of partnering with Google on developing contact lenses that will monitor blood sugar levels and even correct impaired vision will further transform eye care and exemplify another frontier in adoption of IoT.

The adoption of IoT is yet to pan out in the life sciences industry. The industry must work cohesively to overcome the barriers to wearable

technology adoption – concerns of security and privacy, data sharing and protection, regulatory compliance, among others – to take life sciences to the next level. In our view, companies that are proactive in using IoT will be the leaders of the future.

- Effective big data utilization to generate insights: From next-generation sequencing data and patient information to supply chain monitoring, pharmaceutical firms have been managing massive amounts of data for years. In recent years, rapid digitization has made access to larger volumes of data (EMR, clinical, genomics, wearables), an everyday reality. The need to design solutions that will systematically analyze and generate real-time insights from these mountains of data more effectively is critical for success. To develop and deliver the next generation of successful therapies, the industry must simultaneously minimize the cost of processing / managing data while maximizing its value. This is complicated by the need to continue integrating new data types and sources from around the globe and to glean insights from unstructured data, while complying with multiple complex regulations governing drug safety, supply chain security, patient privacy, and other sensitive information.

  Since early 2000, research units within biopharmaceutical organizations have been actively harnessing the powers of big data by leveraging the advancements in next-generation sequencing. This includes a variety of studies including whole-genome sequencing, targeted re-sequencing, discovery of transcription factor binding sites, and noncoding RNA expression profiling, among others. Organizations are now able to leverage the vast library of available molecular and clinical data, utilize predictive modeling techniques, and identify new potential candidate molecules with a high probability of being successfully developed into drugs while ensuring efficacy and safety.

  Clinical development now is also benefiting from big data solutions. We have already mentioned earlier how a large pharmaceutical company is creating a cloud-based aggregated clinical data solution that will house results from all of its global trials.

  Faster access to and analysis of this data will reduce the time-to-market and enable rapid decision-making capability. We envision that a further integration of clinical operations data with safety data will allow near real- time monitoring of trials and provide the ability to rapidly identify safety or operational signals demanding action to avert adverse events and unnecessary delays.

  We believe that the need to uncover valuable relationships within the existing data is the key to boosting innovation and driving new value. With computing power and storage becoming cheaper, as well as increase in cloud adoption, the life sciences industry stands to benefit tremendously from big data solutions.

Conclusion

There are several reasons for the conservatism of the life sciences industry. But given the current dynamism in the sector, occasioned by regulatory, market, and technological forces, life sciences companies can no longer hold back. We believe this is a time of great opportunity, albeit with some challenges, for this industry. As the industry looks to grow while managing existing investments, it must adopt a dual strategic approach towards technology- renew existing systems and processes for greater efficiency while adopting completely new technologies and practices for value creation ■

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Senores Pharmaceuticals acquires 14 ANDAs from Dr. Reddy's Laboratories

Swapnil Shah, Managing Director, Senores Pharmaceuticals

Atlanta, USA / Ahmedabad, India: Senores Pharmaceuticals Limited ("SPL"), through its wholly-owned subsidiary Senores Pharmaceuticals, Inc., USA ("SPI"), has signed agreements to acquire a basket of 14 Abbreviated New Drug Applications ('ANDAs') from Dr. Reddy's Laboratories and its applicable affiliates , along with its subsidiaries hereafter "DRL").

The basket acquired, comprises of 13 ANDAs, which are approved by the USFDA and 1 ANDA, which is pending approval from the USFDA. The addressable opportunity of the acquired ANDAs in the USA is approx. USD 421 Million (MAT December 2024),as per IQVIA and ~ approximately USD 1.13 Billion (MAT September 2024) as per the specialty data aggregator Symphony.

The acquisition will be funded through the Initial Public Offer ("IPO") proceeds raised by SPL. This is in line with the Objects of the IPO stated in the Red Herring Prospectus.

Commenting on the acquisition, Swapnil Shah, Managing Director, Senores Pharmaceuticals Limited said: "We are glad to announce the acquisition of a basket of products from Dr Reddy's. It spans across various therapeutic areas with growing consumption. The portfolio consists of controlled substances and general category of products. These products can be distributed through multiple/diverse channels, with large requirements in government, retail and specialty clinics. This Portfolio of products significantly increases our products offering in the US, and also it has a significant value in other Regulated and Semi-Regulated markets of the world."

Senores Pharmaceuticals Limited ('Senores') is a global, research-driven pharmaceutical company engaged in developing and manufacturing a wide range of pharmaceutical products predominantly for the US, Canada, and other regulated and emerging markets across various therapeutic areas and dosage forms. The companies' current portfolio includes 27 ANDA and 21 CMO/CDMO commercial products that are permitted for distribution in the USA. Senores is also engaged in the development and manufacturing of complex generics certified by global food and drugs authorities and delivers generic drugs for emerging markets catering to more than 40 countries.

The company has currently approval from regulatory bodies of more than 10 countries for its manufacturing facility in Chhatral for emerging markets with over 260 product registrations and 530 product applications. Senores also manufactures critical care injectables and Active Pharmaceutical Ingredients (API). ■

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Venue: Bombay Exhibition Center, Goregaon (East), Mumbai, India

Concurrent Events

EPC 2026 | Specialty ChemiCAL | Refining & Petro Chemicals 2026 | Bio Pharma | Industry Automation & Control 2026 | PVF | WaterEX WORLD EXPO 2026 | Surface Engineering Coating & Corrosion WORLD EXPO 2026 | Chlor-Alkali World Expo & Conferences 2026

Scope for ChemTECH World Expo 2026

- Plant Machinery & Industrial Consumables
- Engineering Consultants
- OEMs for Chemicals & Pharmaceutical Processing Equipment
- Metals & Metallurgy
- Bioprocessing Equipment
- Construction Services Providers
- Plant Maintenance Services Providers
- Logistics & Supply Chain Solutions Providers
- Instrumentation & Process Control
- Industry Automation (Process & Factory)
- Systems Integration & ERP Solutions Providers
- Water & Waste Water Treatment Consultants
- Environment Solutions Providers
- Waste Management Consultants
- Financial Institutions
- Fire & Safety Solutions Providers
- Material Handling Solutions
- Certification Bodies
- Welding Solutions
- Quality Health & Environment Solutions
- Analytical & Laboratory
- Packaging Materials, Machinery & Systems
- Business Consultants

Scope for Specialty Chemicals World Expo 2026

- Agrochemicals Intermediates
- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
- Enzymes
- Colorants, Dyes & Pigments
- Cosmetics & Personal Care Ingredients
- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
- Flavours & Fragrances
- Contract Manufacturers

Scope for Biopharma World Expo 2026

- Materials Processing
- Pharma Machinery
- Pharma Ingredients
- Plant Engineering, Process Plants & Equipment
- Laboratory & Analytical Solutions
- Process Measurement & Inspection
- Sterilization & Clean Room Solutions
- Biopharma R&D And Manufacturing
- IT Solutions
- Water & Waste Treatment Solutions

FACT & FIGURES 2024

- **750** EXHIBITORS FROM 15+ COUNTRIES
- **25871** VISITORS FROM 53 COUNTRIES
- **8** TECHNICAL CONFERENCES
- **250+** GLOBAL SPEAKERS
- **1500+** BUSINESS DELEGATES
- **2500+** ENGINEERING PHARMA & SCIENCE STUDENTS AT STUDENT OUTREACH PROGRAM FROM 28 STATES & UNION TERRITORIES
- SCALE@CHEMTECH World Expo 2024: 60+ GLOBAL CLIMATE TECH STARTUPS FROM 20 COUNTRIES; 40 TECHNICAL PRESENTATIONS
- BRICS WORKING GROUP BRAIN STORMING SESSION

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International Exhibition & Conferences

3-6 February 2026

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HIGHLIGHTS OF BIO-PHARMA WORLD EXPO 2024

Bio Pharma World Expo 2024

NAVIGATING THE PATH TO LEADERSHIP IN BIOPHARMA EXCELLENCE

(L to R) Guest of Honour Dr Krishna Ella , Executive Chairman, Bharat Biotech International Ltd, Prof (Dr) Samir Kulkarni , Head, Department of Biological Sciences & Biotechnology, Coordinator, DBT – ICT Centre, Dr Rajesh Gokhale, Secretary , DBT, Ministry of Science & Technology, Govt. of India & Chief Guest, Mr Suresh Prabhu Former Union Minister, Govt. of India & Chief Patron & Brand Ambassador, ChemTECH World Expo 2024

Biotech is one of the fastest-growing industries in the world right now, especially in India. The Indian bioeconomy registered a remarkable 28% growth in 2022. The past three years have been enormously successful, especially considering the challenges posed by the COVID-19 pandemic. The Indian bioeconomy is forecasted to reach USD 300 billion by 2030, a significant increase from its current valuation of USD 140 billion, which constitutes 4% of the total GDP of our country's growth. The BioPharma industry contributes approximately 43% to the economy and extends beyond pills; it encompasses aspects of healthcare, wellbeing, and cognitive enhancement. To capitalize on green growth and the bio economy, we are establishing Bio enablers in the form of Bio manufacturing hubs through Public-Private Partnerships.

Dr Rajesh Gokhale
Secretary, DBT, Ministry of Science & Technology, Govt. of India

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