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Sun Pharma announces Top-Line results from Phase 2 Clinical trials for Moderate to Severe Psoriasis

Mumbai India: Sun Pharmaceutical Industries Limited announced top-line results from the Phase 2 clinical trial evaluating the safety and efficacy of SCD-044 (a novel, orally bioavailable sphingosine-1- phosphate (S1P) receptor 1 agonist) for moderate to severe psoriasis. The study did not meet its primary endpoint of 75% improvement in PASI (Psoriasis Area and Severity Index) score (≥PASI75) at Week 16. The Phase 2 randomized, double-blind, placebo-controlled study of SCD-044 included 263 people living with moderate to severe plaque psoriasis.

Sun Pharma is also discontinuing studies of SCD-044 for atopic dermatitis after top-line results from a Phase 2 clinical trial did not meet the primary objective of 75% improvement in EASI (Eczema Area and Severity Index) score (≥EASI75) at Week 16. The Phase 2 atopic dermatitis study of SCD-044 included 250 people and compared three different dosages of SCD-044 with placebo.

"While we are disappointed with the top-line results of the clinical trials, we would like to thank all the psoriasis and atopic dermatitis patients, the healthcare professionals and administrators who participated in these pivotal clinical trials," said Marek Honczarenko, MD, PhD, Senior Vice President and Head of Global Specialty Development at Sun Pharma.

There were no major safety or tolerability concerns with SCD-044 in either the plaque psoriasis or atopic dermatitis studies. Sun Pharma is discontinuing clinical trials of the asset and has no further plans for development of SCD-044. Sun Pharma and its partner, Sun Pharma Advanced Research Company Ltd., will evaluate the appropriate next steps for SCD-044.

Zydus enters global biologics CDMO business

Ahmedabad, India: Zydus Lifesciences announces its entry into the global biologics contract development and manufacturing organization (CDMO) sector through the planned acquisition of Agenus Inc.'s state-of-the-art biologics manufacturing facilities in California, US. This acquisition positions Zydus at the forefront of the fast-growing global biologics CDMO market, establishing a robust presence in the world's leading biotech innovation hub.

Dr. Sharvil Patel, Managing Director, Zydus Lifesciences

With this strategic move, Zydus gains immediate access to advanced biologics development and manufacturing capabilities, further enabling partnerships with innovative biotechnology companies and enhancing its global footprint in high-growth markets. The facilities come with a strong professional team and offer Zydus the ability to serve as a one-stop solution provider from pre-clinical development to large-scale commercial manufacturing. As part of the transaction, Zydus will also become the exclusive contract manufacturer for Agenus' clinical and commercial supply of two advanced immuno-oncology products, Botensilimab and Balstilimab.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Zydus Lifesciences Ltd. said, "The acquisition will give Zydus a strategic foothold in the U.S. for biologics manufacturing in the global hub for biotech innovation, California. It will enhance our ability to partner with innovation-centric entities, advancing new products and prioritizing patient-centric solutions. This move strengthens our long-term biologics vision and positions us to better serve the evolving needs of the global biopharmaceutical industry."

In a parallel development, Zydus Lifesciences has entered into a definitive agreement with Agenus Inc. to secure exclusive commercial rights for India and Sri Lanka for their investigational immuno-oncology therapies—Botensilimab (BOT) and Balstilimab (BAL). These next-generation therapies are designed to address high-unmet needs across multiple cancer types and have demonstrated significant clinical activity in advanced trials involving over 1,200 patients.

On licensing agreement Dr. Sharvil Patel said, 'Our licensing partnership with Agenus aligns with Zydus' overarching biologics vision and our aim to advance novel solutions for high-unmet need areas (Managing Director of Zydus Lifesciences. 'Agenus' robust pipeline and research in immuno-oncology along with Zydus' reach as the largest Indian oncology player, is a significant step forward in our collective fight against cancer. We are confident that this collaboration will bring transformative therapies to patients who need them most, in India and Sri Lanka markets.'

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Biocon Limited gets approval for diabetes drug Liraglutide in India


Siddharth Mittal, CEO & MD, Biocon Ltd

Bengaluru, Karnataka, India: Biocon Limited , an innovation-led global biopharmaceutical company, announced that it has received approval in India for its Liraglutide drug substance, and its wholly owned subsidiary, Biocon Pharma Limited, has received approval for its Liraglutide drug product (6 mg/ml solution for injection in pre-filled pen and cartridge), from the Drugs Controller General of India, CDSCO (Central Drugs Standard Control Organisation).

The approval is for the generic version of Victoza, indicated for the treatment of insufficiently controlled Type 2 Diabetes Mellitus in adults, adolescents and children aged 10 years and above, as an adjunct to diet and exercise. The approval was received from the CDSCO under the recently formulated 101 route that enables recognition of approvals granted by established and referenced serious regulatory authorities.

Siddharth Mittal, Chief Executive Officer and Managing Director, Biocon Ltd, said: "The approval of our first vertically integrated GLP-1 in India, Liraglutide, is another significant step forward in expanding access of this product to patients suffering from diabetes. India has one of the highest number of people with diabetes globally, with estimates exceeding 77 million cases, and expected to rise further. The approval enables us to address a critical need by making this drug available, and aligns with Biocon's mission to provide affordable,lifesaving medications to those who need it the most. We are now gearing up to launch the product expeditiously through our commercialization partners in India"

Glenmark Pharmaceuticals to launch DCGI-approved BRUKINSA in India

Mumbai, India: Glenmark Pharmaceuticals Ltd a research-led, global pharmaceutical company, has announced the upcoming launch of zanubrutinib in India following approval by the Drugs Controller General of India (DCGI).

Zanubrutinib will be marketed in India under the brand name BRUKINSA®, an innovative therapy developed by BeiGene (now BeOne Medicines), a global oncology leader committed to delivering advanced treatments for cancer patients worldwide. BRUKINSA is the first and only Bruton's tyrosine kinase (BTK) inhibitor approved in India for the treatment of five distinct B-cell malignancies: chronic lymphocytic leukemia/ small lymphocytic lymphoma (CLL/SLL), Waldenström macroglobulinemia (WM), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), and follicular lymphoma (FL).1

Globally, BRUKINSA is approved in more than 70 countries, supported by compelling clinical evidence from pivotal trials including ALPINE, ASPEN, and SEQUOIA.2 This extensive clinical program underscores BRUKINSA's proven efficacy, strong safety profile, and broad therapeutic value.

"We look forward to bringing BRUKINSA to India in the coming months as part of our ongoing partnership with BeiGene (now BeOne Medicines)," said Mr.Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd. "This launch marks a significant milestone in our innovative oncology portfolio, offering patients in India with access to a globally trusted therapy with proven efficacy and safety. It underscores Glenmark's ongoing commitment to providing effective and advanced treatments for patients with haematological malignancies."

Adam Roach, Senior Vice President and Head of Japan and Asia Pacific region for BeiGene (to be renamed BeOne Medicines) commented, "The introduction of BRUKINSA in India marks an important step in our ongoing mission to expand patient access to innovative oncology treatments across the Asia Pacific region. We are proud to support Glenmark in bringing this therapy to patients in India, furthering our shared commitment to improve healthcare outcomes globally."

announces first day launch of Ticagrelor film-coated tablets


Aditi Kare Panandikar, MD, Indoco Remedies Ltd.

Mumbai, India: Indoco announced that its subsidiary company, Indoco Remedies UK Limited, officially launched Ticagrelor film-coated tablets 90mg in the United Kingdom on June 2, 2025. This significant addition to Indoco's portfolio will be marketed and distributed by Clarity Pharma, across the United Kingdom. Ticagrelor film-coated tablets are indicated to reduce the chances of heart attack, stroke, myocardial infarction (MI) or diseases related to the heart or blood vessels.

"This development underscores our commitment to bringing high quality, life-saving treatments to patients in the UK," said Aditi Kare Panandikar, Managing Director, Indoco Remedies Ltd.

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The Company's turnover is USD 180 million with a human capital of over 6000 employees, including over 400 skilled scientists and field staff who are the strength of the organization.

India Pharmaceutical Market reports 7.2% yoy revenue growth in May 2025

Mumbai, India: India Ratings and Research (Ind-Ra) opines the continued revenue growth (7.2% yoy) in India's pharmaceutical market (IPM) during May 2025 was driven by new product launches and price hikes taken by companies.

Strong volume growth was observed in key chronic therapies such as cardiac (11.7%) and anti-Infectives (7.6%). "IPM might grow to the tune of 7%-8% yoy during FY26, with sustained growth momentum in chronic therapies, led by price increases and product launches", says Nishith Sanghvi, Director, Corporate Ratings, Ind-Ra.

Chronic therapies such as cardiac and anti-infectives showed robust volume growth in the month of May 2025. The moving annual total (MAT) of therapies such as cardiac, gastro-intestinal, anti-diabetic and derma witnessed higher volume growth than IPM. Stable value growth was observed across therapies for the MAT May 2025. Acute therapies such as gastro-intestinal, vitamins, pain/analgesics witnessed sales growth of 9.5%, 7.1% and 8.1% yoy, respectively. Chronic therapies such as cardiac, anti-infectives, anti-diabetic and CNS grew at 10.4% yoy, 6.5% yoy and 7.8% yoy, respectively.

During the MAT May 2025, Torrent Pharma, Sun Pharma, and Intas outperformed the market at 12.5% yoy, 11.9% yoy, and 10.1% yoy, respectively. This was led by the improving performance of chronic therapies.

Venus Remedies Secures Ukrainian GMP Renewal


Saransh Chaudhary, President, Global Critical Care, Venus Remedies

Mumbai, India: Venus Remedies Limited, a leading global pharmaceutical company, has successfully renewed its Good Manufacturing Practices (GMP) certification from Ukraine's State Service on Medicines and Drugs Control (SMDC). The certification applies to the company's Unit-II manufacturing facility located in Baddi, Himachal Pradesh, covering its cephalosporin, non-cephalosporin (carbapenem), and oncology parenteral production lines, including liquid and lyophilized injections.

"Renewal of the Ukrainian GMP certification underlines our unwavering commitment to maintaining world-class manufacturing standards. This milestone not only reinforces our foothold in the Ukrainian market but also facilitates deeper penetration into PIC/S markets, significantly enhancing our international growth prospects," said Saransh Chaudhary, President, Global Critical Care, Venus Remedies, and CEO, Venus Medicine Research Centre.

Ukraine, being a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S)—a consortium comprising 56 countries spanning Europe, Asia, Oceania, and the Americas—further amplifies the global acceptance and strategic importance of this certification. Venus Remedies already has a robust presence in 32 PIC/S countries, including South Africa, Thailand, Malaysia, Saudi Arabia, and Australia, with plans for continued expansion.

The Ukrainian pharmaceutical market, projected to grow at a CAGR of 3.9% and reach US$822.26 million by 2029, is driven largely by increased demand for generics and oncology treatments. Venus Remedies, with over two decades of experience in Ukraine and 44 product registrations to date, views this certification as pivotal for sustained growth and expanded access within the broader Asia Commonwealth of Independent States (CIS) region.

Aditi K. Chaudhary, President, International Business, Venus Remedies Ltd, emphasized, "Ukraine continues to be a key strategic market for us. This renewed GMP certification enhances our credibility with regulators and partners across the region, enabling us to deepen our market presence, expand product portfolios, and provide high-quality medicines to a wider patient base."

Alvotech and Dr. Reddy's enter into Collaboration

HYDERABAD, India: Alvotech, a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, and Dr. Reddy's Laboratories Ltd., announced that the companies have entered into a collaboration and license agreement to codevelop, manufacture and commercialize a biosimilar candidate to Keytruda® (pembrolizumab) for global markets. Keytruda® (pembrolizumab) is indicated for the treatment of numerous cancer types.

In 2024, worldwide sales of Keytruda were US$29.5 billion. The collaboration combines Dr. Reddy's and Alvotech's proven capabilities in biosimilars, thereby, speeding up the development process and extending the global reach for this biosimilar candidate.

Under the terms of the agreement, the parties will be jointly responsible for developing and manufacturing the biosimilar candidate and sharing costs and responsibilities. Subject to certain exceptions, each party will have the right to commercialize the product globally.

"We are very pleased to enter into this collaboration for pembrolizumab with Dr. Reddy's. This agreement demonstrates Alvotech's ability to leverage its dedicated R&D and manufacturing platform for biosimilars, accelerating the expansion of our pipeline by pursuing growing global markets. It further enables us to increase the availability of cost-effective, critical biologic medications to patients world-wide," said Róbert Wessman, chairman and CEO of Alvotech.

"We are happy to collaborate with Alvotech for the pembrolizumab biosimilar. This demonstrates our ability to develop and manufacture high quality and affordable treatment options for patients worldwide. Additionally, oncology has been a top focus therapy area for us and this collaboration will further enhance our capabilities in oncology, as pembrolizumab currently represents one of the most critical therapies in immuno-oncology," said Erez Israeli, CEO of Dr. Reddy's.

Cadila Pharma launches Biscado, beta-blocker therapy

Ahmedabad, India: Cadila Pharmaceuticals Limited, one of India's most respected and innovation-driven pharmaceutical companies, has announced the launch of Biscado (Bisoprolol), marking its foray into the dynamic and fast-growing field of beta-blocker therapy, a vital component in the treatment of cardiovascular diseases.

Bisoprolol is a highly cardioselective beta-1 adrenergic blocker used to manage high blood pressure, angina (chest pain), and chronic heart failure. By reducing heart rate and blood pressure, it eases the strain on the heart and has been shown to significantly improve survival and reduce hospitalisations in heart failure patients.

The relevance of Biscado in India is particularly significant. Indians are predisposed to higher sympathetic activity and elevated resting heart rates, which are well-recognised predictors of poor cardiovascular outcomes. Studies have shown that an increase of just 10 beats per minute in resting heart rate is associated with a 20% increase in the risk of cardiovascular death.

"India is at the epicentre of a cardiovascular epidemic, and elevated heart rate is a major modifiable risk factor. With the launch of Biscado, Cadila Pharmaceuticals brings a powerful, clinically proven solution to physicians and patients right when it is needed most," said a senior spokesperson at Cadila Pharmaceuticals Limited.

The launch of Biscado reflects Cadila Pharmaceuticals' commitment to meeting unmet medical needs and expanding its presence in the cardiovascular segment.

Biscado is supported by extensive clinical research, including the landmark CIBIS-II (Cardiac Insufficiency Bisoprolol Study), which demonstrated a 34% reduction in all-cause mortality, a 44% reduction in sudden cardiac death, and a 36% reduction in hospitalisation due to worsening heart failure.

Other studies have reinforced Bisoprolol's superiority with a 20% lower risk of mortality compared to Metoprolol Succinate and better mortality outcomes than Carvedilol in chronic heart failure patients. A TIBBS study showed that in stable angina, Biscado users had lower rates of death, myocardial infarction, and hospitalisation, versus patients treated with calcium channel blockers.

Lupin receives Tentative approval from U.S. FDA for Oxcarbazepine ER Tablets

Mumbai, India: Global pharma major Lupin Limited announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Oxcarbazepine Extended-Release (ER) Tablets, 150 mg, 300 mg, and 600 mg. This product would be manufactured at Lupin's Nagpur facility in India.

Oxcarbazepine ER Tablets, 150 mg, 300 mg, and 600 mg are bioequivalent to Oxtellar XR® ER Tablets, 150 mg, 300 mg, and 600 mg, of Supernus Pharmaceuticals, Inc., and are indicated for the treatment of partialonset seizures in patients 6 years of age and older.

Oxcarbazepine ER Tablets (RLD Oxtellar XR®) had estimated annual sales of USD 206 million in the U.S. (IQVIA MAT April 2025).

Servier India introduces 'Ivosidenib' (Tibsovo), in India

Mumbai, India: Servier India, a subsidiary of the leading French pharmaceutical Servier Group, announced the launch of Ivosidenib (Tibsovo®), an oral targeted therapy approved in the management of cancer patients with Acute Myeloid Leukemia (AML) and Cholangiocarcinoma, with an isocitrate dehydrogenase-1 (IDH1) mutation. Servier India received the approval on 14th May 2025, from Central Drugs Standard Control Organisation (CDSCO) for the import, sale, and distribution of the medication.

Acute myeloid leukemia is a challenging hematological malignancy. Studies indicate that only about 30–40% of AML patients in India receive adequate treatment, with high mortality rates due to rapid disease progression and infections. Cholangiocarcinomas (CCA) are rare tumours originating from bile duct. Due to their asymptomatic nature they are usually diagnosed when the disease is advanced.

The announcement marks a significant advancement in management of the mentioned rare and difficult-to-treat cancers in India, addressing a critical unmet medical need.

Speaking on the occasion, Aurélien Breton, Managing Director, Servier India, said, "Our focus is to advance oncology care by bringing innovative, precision medicines to patients who need them the most. By prioritizing access and working to make treatment options affordable to patients, we are dedicated to bridging critical gaps in cancer care across the country. This launch is a significant step forward in our mission to support healthcare providers with targeted treatment options and ultimately improve survival outcomes and quality of life for patients throughout India."

osteolabs GmbH and labor team announce sales Partnership for Switzerland and Liechtenstein

KIEL, Germany: German biotech company specializing in innovative diagnostic solutions for calcium-related metabolic disorders, and labor team, one of the leading medical laboratories in Switzerland, announce a new strategic partnership.

Under the agreement, labor team w ag will distribute osteolabs' flagship product, the OsteoTest, throughout Switzerland and Liechtenstein. OsteoTest is an advanced IVD diagnostic test for early risk assessment and therapeutic monitoring in patients with osteoporosis, based on osteolabs' proprietary CIM (Calcium Isotope Marker) technology. Recent studies have demonstrated a strong correlation between CIM and various metabolic diseases that affect musculoskeletal health (Source). Moreover, CIM technology enables early and highly sensitive monitoring of transient changes in Bone Calcium Balance (BCaB)—a critical parameter of bone health—that cannot be reliably assessed using current standard methods (Source).

"We are excited to partner with labor team wag, one of the leading medical laboratories in Switzerland and Liechtenstein, to make our CIM technology available to clinicians and patients in these regions," said Dr. Michael Lutz. "This partnership helps us bring our advanced calcium isotope technology to a broader market."

Priv.-Doz. Dr. Thomas Brinkmann, COO at labor team and Prof. Dr. Guido Funke, CMO at labor team added: "We are proud to integrate osteolabs' pioneering OsteoTest into our diagnostic service offering. This test equips physicians with a powerful tool for early risk assessment and therapeutic monitoring of osteoporotic patients. According to the SVGO, over 500,000 patients in Switzerland are affected by osteoporosis."

MC2 Therapeutics appoints Trine Ahlgreen as New CEO

COPENHAGEN, Denmark: MC2 Therapeutics, a commercial-stage pharmaceutical company focused on topical therapies in inflammatory skin conditions, today announced the appointment of Trine Ahlgreen as Chief Executive Officer, marking a new chapter in the company's journey to unlock the full global potential of its commercial asset, Wynzora® Cream, and to maximize the commercial potential of its formulation and drug delivery system, PAD Technology.

With an extensive background spanning commercial leadership of global, regional and local pharmaceutical product launches, leadership of several successful cross-functional teams and business development across Europe, the US and Japan, Trine brings a breadth of experience to MC2 Therapeutics. With solid commercial foundation from large pharma and with a strong track record of strategic leadership and execution, Trine played key roles in several high-impact product launches at Novo Nordisk, including the launches of Ozempic®, Rybelsus® and the global cardiovascular indication launch for GLP-1. Most recently, at Swiss biotech Micreos Pharmaceuticals AG, Trine built the commercial and business development infrastructure focused on dermatology, forging valuable strategic partnerships across both pharma and OTC.

"MC2 Therapeutics has developed world-class innovation in topical therapies with a unique commitment to patient adherence and uncompromised efficacy", said Trine Ahlgreen. "I'm honored to lead the next phase of the company's growth, focused on realizing the full global commercial potential of Wynzora® Cream for plaque psoriasis, while exploring new opportunities through our proprietary PAD Technology formulation platform with selected partners".

Wacker Biotech and Expression Manufacturing announce strategic partnership

Munich/San Diego: In response to the growing demand for high-quality, scalable lentiviral vectors crucial in advancing innovative gene therapies, Wacker Biotech US Inc., a wholly owned subsidiary of Wacker Chemie AG specializing in plasmid DNA (pDNA) production, and Expression Manufacturing, a leader in viral vector technology, have entered into a strategic collaboration. Its goal is to advance the development and manufacturing of lentiviral-based gene and cell therapies.

The partnership combines the complementary strengths of both companies to provide biopharma and biotech clients with an end-to-end, optimized solution for viral vector development and production.

Wacker Biotech brings its proven PLASMITEC platform, which utilizes a proprietary E. coli strain to enable efficient production in as little as four months of high-quality (>90% supercoiled) pDNA, including transfer plasmids containing the gene of interest, as well as packaging and envelope plasmids. Operating out of its state-of-the-art pDNA center of excellence in San Diego, California and supported by sister sites in Europe, Wacker Biotech is a trusted partner for multiple drug delivery modalities.

Expression Manufacturing contributes its proprietary LentET platform, which features advanced lentiviral plasmid backbone technology and viral vector manufacturing capabilities. Expression's technology is designed to enhance the safety, efficacy, and precision of gene therapy, offering features such as ultra-low homology backbones to reduce recombination risks and increase safety, and optimized coding sequences for 293T cells, a widely used cell line for viral vector production, resulting in higher potency. Expression operates a state-of-the-art viral vector manufacturing facility in Ohio, equipped with cleanrooms, production suites, and process development rooms to support the next generation of cell and gene therapies.

DEBRA Research and Dermaliq enter into a Strategic Collaboration

MUNICH, Germany: DEBRA Research GmbH, a global non-profit organization dedicated to advancing research and drug development for those affected by Epidermolysis Bullosa (EB), and Dermaliq Therapeutics, Inc., a clinical-stage dermatology innovator company developing next-generation topical therapies, today announced a strategic, non-exclusive collaboration to advance cutaneous drug delivery into the skin for EB. Initially, the partners will focus on improving wound-healing and anti-itch therapies, plus developing prophylactic therapies for people suffering from EB. As part of the agreement, DEBRA Research has also made a strategic investment in Dermaliq.

EB is a group of rare and painful genetic skin disorders characterized by extremely fragile skin, leading to blisters and wounds from even minor friction or trauma. EB significantly affects the daily lives of people living with the condition and is associated with substantial morbidity and mortality over time due to chronic wounds, infections, and complications involving internal organs. It is caused by mutations in one or more genes that encode proteins responsible for maintaining the structural integrity of the skin. While there is currently no cure, novel treatments are being developed to manage symptoms, reduce pain, and improve quality of life.

Dermaliq is set to transform therapeutic strategies for skin and wound management in EB. Leveraging its proprietary hyliQ® technology, the company enables targeted delivery of active compounds into the skin without mechanical interference to fragile or wounded tissue. Applied touchless, hyliQ® is designed specifically for conditions like EB, where the skin is exceptionally delicate and prone to blistering or damage from even minimal friction. This innovative approach offers critical therapeutic benefits for patients by delivering effective treatments while preserving the integrity of compromised skin.

"This partnership aligns closely with our mission to accelerate the development of effective, high-impact therapies for people living with EB," said Dr Christoph Coch MD, Managing Director at DEBRA Research.

Gland Pharma receives approval for Angiotensin II Acetate Injection

Hyderabad, India: Gland Pharma Limited (Gland or Company), a generic injectable & ophthalmic- focused pharmaceutical company, has received approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application for Angiotensin II Acetate Injection 2.5 mg/mL.

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), GIAPREZA ® of La Jolla Pharma LLC.This Product is indicated for increasing the blood pressure in adults with septic or other distributive shock. Gland Pharma is the exclusive First-to-File and is eligible for 180 days of generic drug exclusivity.

According to IQVIA, the product had US sales of approximately USD 58 million for the twelve months ending March 2025.

Gland Pharma was established in 1978 in Hyderabad and has grown over the years from a contract manufacturer of small-volume liquid parenteral products to become one of the largest injectable-focused companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India, and other markets. It operates primarily under a business-to-business (B2B) model and has an excellent track record in developing, manufacturing, and marketing sterile injectables. It has a wide range of injectables, including vials, ampoules, pre-filled syringes, lyophilized vials, dry powders, infusions, oncology, and ophthalmic solutions. It also enjoys the distinction of having pioneered Heparin technology in India.

DBT-BIRAC supported innovation "FIBROPLUG" marks a significant step towards indigenously developed technology

New Delhi, India: FIBROPLUG, a breakthrough innovation for Haemorrhage Control has been used by Indian defence forces, various coveted units across the borders and in emergency response scenarios. More than 3000 units lifted by defence establishment in the last 5 days and more orders received, Fibroheal is operating at a war level to support the nation.

Jitendra Kumar, Managing Director, BIRAC, emphasised - "FIBROPLUG demonstrates the catalytic effect of targeted support and collaboration on India's innovation ecosystem. Through our SBIRI and PCP schemes, BIRAC is proud to have enabled the translation of cutting-edge research into an affordable, world-class healthcare solution addressing the critical need for rapid haemorrhage control. The success of FIBROPLUG highlights the strength of industry-academia partnerships and reaffirms our commitment to nurturing indigenous innovations that enhance India's healthcare capabilities and self-reliance."

FIBROPLUG is India's first patented silk-chitosan composite hemostatic sponge, a homegrown innovation enabled by DBT-BIRAC's SBIRI and PCP schemes. The technology was jointly developed by Fibroheal Woundcare Pvt Ltd, an innovative Indian medtech startup founded by Vivek Mishra and Bharat Tandon and the Indian Institute of Science, Bengaluru. FIBROPLUG marks a significant leap forward in rapid hemorrhage control for accidental, surgical, and field injuries. Its affordability, field readiness, and life-saving potential make it an ideal frontline tool during large-scale humanitarian and defence operations.

The journey of FIBROPLUG began in 2018, inspired by the urgent need for an indigenous solution after witnessing our defence and emergency responders rely on costly imported products. Participation in the DRDO-CRPF Grand Challenge and direct engagement with frontline personnel revealed the critical gaps in trauma care and motivated the team to develop a superior, affordable alternative in partnership with the Indian Institute of Science, Bangalore. With the support of DBT-BIRAC's funding, equity, and access to advanced research infrastructure, the innovators transformed cutting-edge biomaterial research into a clinically validated, life-saving product. FIBROPLUG launched during the Mega-international event Global Bio-India held in December 2023, was introduced in the market early 2024 with a clear focus on addressing the challenges faced in war-like conflict zones and critical care situations. FIBROPLUG is currently manufactured at a capacity of 5,000 units per month, with the potential to scale up as support and infrastructure grow.

Alembic Pharmaceuticals announces USFDA Final approval for Bosutinib Tablets, 100 mg and 500 mg

Mumbai, India: Alembic Pharmaceuticals Limited (Alembic) announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Bosutinib Tablets, 100 mg and 500 mg. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Bosulif Tablets, 100 mg and 500 mg, of PF Prism C.V. (PF Prism).

Bosutinib tablets are indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy. Refer label for a detailed indication. Bosutinib Tablets, 100 mg and 500 mg have an estimated market size of US$ 291 million for twelve months ending March 2025 according to IQVIA. Alembic has a cumulative total of 223 ANDA approvals (200 final approvals and 23 tentative approvals) from USFDA.

SeQuent-Viyash Merger Receives Stock Exchange Approvals

Benguluru, India: Sequent Scientific (SeQuent), a leading player in the global animal health industry, has announced that it has secured approvals from both the National Stock Exchange (NSE) and the Bombay Stock Exchange (BSE) for its proposed merger with Hyderabad-based Viyash Life Sciences (Viyash). The company has now filed for clearance with the National Company Law Tribunal (NCLT), marking a crucial milestone in the merger process.

The merger will bring together two strong business verticals—Global Animal Health and a world class API business unlocking access to over 150 countries. The combined entity will benefit from a five-fold increase

in R&D talent and a nine-fold expansion in USFDA-approved manufacturing capacity, creating a robust and scalable operating backbone.

US-based private equity firm Carlyle holds a 53% stake in SeQuent and is the majority shareholder in privately held Viyash. SeQuent operates in the niche segment of Animal Health and markets its products in 90+ countries. It has built local footprints in Europe, Latin America and emerging markets including India , while Viyash has built a strong presence in API and R&D space with strong business relations with leading companies around the globe.

Commenting on the development, Rajaram Narayanan, Managing Director of SeQuent Scientific, said: "We are pleased that our proposed merger with Viyash Life Sciences is progressing as planned. This merger will accelerate a compelling new journey for SeQuent as a leading player in animal health, and Viyash with its world-class R&D capabilities and USFDA-approved facilities. FY 2024–25 marks a pivotal year for us, with strong business results as we accelerate our growth and lay the foundation for the next phase of growth. With Viyash joining us, we are poised to become a significantly stronger business—2X in scale, capability, and opportunity."

Marksans Pharma arm receives Marketing Authorization for Oxybutynin hydrochloride

Mumbai, India: Marksans Pharma Limited announceD that its wholly owned subsidiary Relonchem Limited has received Marketing Authorization for the product Metformin Hydrochloride 500mg/ 5 ml Oral Solution from UK Medicines & Healthcare Products Regulatory Agency.

Marksans Pharma Limited headquartered at Mumbai, India is engaged in Research, Manufacturing & Marketing of generic pharmaceutical formulation in

the global markets. The company's manufacturing facilities located in India, USA and UK are approved by several leading regulatory agencies including USFDA, UKMHRA and Australian TGA. The company's robust product portfolio spreads over major therapeutic segments of CVS, CNS, Anti-diabetic, Pain Management, Gastroenterological and Anti[1]allergies. The company is marketing these products globally.

Gland Pharma receives approval for Angiotensin II Acetate Injection

Hyderabad, India: Gland Pharma Limited (Gland or Company), a generic injectable & ophthalmic- focused pharmaceutical company, has received approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application for Angiotensin II Acetate Injection 2.5 mg/mL.

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), GIAPREZA ® of La Jolla Pharma LLC.This Product is indicated for increasing the blood pressure in adults with septic or other distributive shock. Gland Pharma is the exclusive First-to-File and is eligible for 180 days of generic drug exclusivity.

According to IQVIA, the product had US sales of approximately USD 58 million for the twelve months ending March 2025.

Gland Pharma was established in 1978 in Hyderabad and has grown over the years from a contract manufacturer of small-volume liquid parenteral products to become one of the largest injectable-focused companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India, and other markets. It operates primarily under a business-to-business (B2B) model and has an excellent track record in developing, manufacturing, and marketing sterile injectables. It has a wide range of injectables, including vials, ampoules, pre-filled syringes, lyophilized vials, dry powders, infusions, oncology, and ophthalmic solutions. It also enjoys the distinction of having pioneered Heparin technology in India. ■

th 13Advent to acquire a significant minority stake in Felix Pharmaceuticals

Mumbai, India: Advent, a leading global private equity investor, today announced that funds managed by Advent have signed a definitive agreement to invest USD $175 million via primary and secondary for a significant minority stake in Dublin headquartered Felix Pharmaceuticals Pvt Ltd ("Felix"), a leading global Gx animal pharma player. Felix Pharma is one of the fastest growing developers and manufacturer of off-patent medicines for companion animals.

Felix develops, manufactures and supplies to distributors and other branded Gx players for private labelling, particularly in the US. With a portfolio of 14 approved products from USFDA and many more under review and development, Felix has the widest portfolio of products in the industry. The Company is differentiated by its development capabilities around incremental innovation in dosage and delivery, its breadth of portfolio, advance stage pipeline, and most importantly its cost-efficient manufacturing.

Shweta Jalan, Managing Partner at Advent, said, "Healthcare has been a long-standing focus for us, and we see strong parallels between India's success in human Gx and the emerging opportunity in animal health. Felix is well positioned to lead this space with its strong leadership, broad portfolio, and robust R&D and commercial capabilities. Its rapid growth and high customer satisfaction make it a differentiated platform, and we are excited to support Neeraj and the Felix team in scaling it into a global franchise."

Pankaj Patwari, Managing Director at Advent, said, "Felix has an opportunity to shape the companion animal health generics market. The industry is nascent, with less than 10% share held by generic players, providing a long-term growth opportunity. There are lot of learnings we can bring from our other pharma experiences and we are excited to partner with a like-minded founder, Neeraj, to work towards building the #1 generic animal health company globally."

Felix, founded in 2015 by Neeraj Agrawal, a McKinsey alum, Sir Jonathan Symonds, Chair of GSK and with 30 years of experience in global pharmaceuticals, and Dr Shumeet Banerji, ex-CEO of Booz-Allen, has pursued strategic growth through a disciplined approach. While the company achieved its first US FDA approval in 2020, marking a pivotal step in its expansion, it has quickly scaled to a 14 commercialised product portfolio and has several others in advanced stages of pipeline. It has a USFDA approved oral solid facility dedicated for animal health products and an injectable facility that is expected to be ready by Q3 2025.

Neeraj Agrawal, Co-Founder of Felix Pharma, said, "This marks an important milestone in Felix's journey. As we scale in a fast-evolving market, we were looking for a partner who brings not just capital, but also deep operating expertise and the right mindset and networks to help us grow faster and stronger. Advent's strong track record in healthcare and pharma, and their close involvement in building strong businesses, gives us great confidence. We are excited to have them on-board as we take Felix to its next phase of growth."

Jon Symonds, Co-Founder of Felix Pharma, said, "When Neeraj, Shumeet and I began Felix a decade ago our intention was to build a globally competitive business dedicated to companion animals. We are well on the path of doing this and bringing in Advent as a partner at this stage will enable us to accelerate our growth path and to bring high quality differentiated products to pet owners around the world."

OneSource and Xbrane Biopharma announces strategic Biosimilars Manufacturing Partnership

Bangalore, India: OneSource Specialty Pharma Limited, multi-modality specialty pharma pure-play CDMO, and Xbrane Biopharma AB, a Sweden-headquartered biotechnology company, announced a strategic partnership focused on the commercial manufacturing of Xbrane's biosimilar portfolio.

Xbrane has a portfolio of biosimilar candidates targeting EUR 23 billion in estimated annual peak sales of the respective reference products. The lead candidate Ximluci (a ranibizumab biosimilar) is granted market authorization approval in Europe (launched in 2023) and is now under the approval process for the US launch.

As part of the agreement, Xbrane will tech transfer its commercial product (Tech Transfer) to OneSource's state-of-the-art integrated Drug Substance and Drug Product (DS/DP) facility in Bangalore, India.

The collaboration aims to strengthen Xbrane's global supply chain, while enabling OneSource to accelerate regulatory approvals, including from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), for its biologics drugs substance facility. As part of the collaboration, OneSource has also participated in Xbrane's latest funding round, reinforcing the long-term strategic alignment between the two companies.

Neeraj Sharma, Managing Director & CEO of OneSource Specialty Pharma, said: "The partnership with Xbrane reflects our shared ambition to drive broader access to cutting-edge biologics worldwide. Xbrane's proven success in biosimilar development, combined with OneSource's fully integrated biologics platform, creates a strong platform for global impact. We are pleased to support the scale-up of high-quality biosimilars and advance our vision of being a trusted partner to the world's leading biotech companies."

Martin Åmark, CEO of Xbrane Biopharma, added: "Our partnership with OneSource gives us access to top-tier, cost-competitive manufacturing and expertise for our biosimilars. This is essential for our global competitiveness and our commitment to providing affordable medicines to patients and payers."

SCHOTT Pharma invests in sterile cartridge production in Hungary

Hungary, Lukácsháza: SCHOTT Pharma, a pioneer in drug containment and delivery solutions, is investing more than 100 million euros in its existing site in Lukácsháza, Hungary, to expand its capacity for sterile ready-to-use (RTU) cartridges. Following the opening of a new facility for prefillable glass syringes at the site in 2024, the company has now broken ground for another facility that will add further manufacturing capacity for high-value solutions (HVS).

The move aligns with the company's expansion strategy to increase its share of these high-margin products. "To meet growing demand, we are expanding our capabilities and presence in the diabetes and obesity fields. That is why we are investing more than 100 million euros in our plant in Hungary," said Andreas Reisse, CEO of SCHOTT Pharma.

Building on its strong existing foundation and capabilities, the high-tech RTU cartridge manufacturing facility will be equipped with state-of-the-art machinery. In addition, an advanced washing line and a new steam sterilization process for cartridges will reduce environmental impact. Manufacturing will be fully integrated and automated with minimal manual intervention, providing the highest quality sterile products to the market. Following St. Gallen, Switzerland, Lukácsháza will be the second SCHOTT Pharma site to manufacture sterile cartridges.

SCHOTT Pharma's Lukácsháza site already plays an important role in supplying the global industry with drug containment solutions and delivery systems. In June 2024, the company opened a new state-of-the-art facility at the site for high-quality prefillable glass syringes, which are widely used to store GLP-1 therapies, critical vaccines, and biologics. Since then, with 120 new employees on board, production has started, and further production capacity has been added.

With RTU cartridges, the company is now looking to add additional manufacturing capacity for high-value solutions to the site, which has sufficient space to support the company's growth strategy. "We would like to express our sincerest gratitude to the Ministry of Foreign Affairs and Trade for its support of these two expansion projects. Lukácsháza is not only an important location for ensuring supply security to customers in the region but also makes an important contribution to SCHOTT Pharma's global growth strategy," says Eva Szabó, Site Manager Lukácsháza. ■

INTERVIEW

Mankind Pharma's ESG Vision: From Compliance to Commitment on Climate, Safety, and Sustainability

Suresh Raju Penmetsa
Chief Risk Officer and SVP
Corporate EHS&S, Mankind Pharma

Charting a bold course in environmental stewardship, safety, and sustainability, driven by its top leadership and a clear ESG strategy, **Suresh Raju Penmetsa, Chief Risk Officer and SVP – Corporate EHS&S**, outlines the company's proactive efforts in carbon footprint reduction, Zero Liquid Discharge (ZLD) implementation, advanced waste management, and safety automation.

With ambitious goals like achieving carbon neutrality by 2030 and ranking among India's top 3 sustainable companies by 2028, Mankind Pharma is embedding ESG deeply into its corporate DNA—transforming regulatory compliance into strategic advantage.

What are the top emerging risks you see for the pharmaceutical industry, especially in the post-COVID era?

Here are the top emerging risks for the pharmaceutical industry in a post-pandemic world:

- **Climate Change and Sustainability**

The pharmaceutical industry, much like the chemical industry, also consumes fossil fuels for industrial applications. With a growing emphasis on Environmental, Social, and Governance (ESG) principles and sustainability, there's a strong push for companies to transition to renewable energy sources.

For example, at Mankind Pharma, all standalone units (except in Sikkim due to geographical constraints) have already shifted from fossil fuels to renewable alternatives. This includes sourcing electricity from hydropower and using renewable fuels such as agro-based briquettes for steam generation in boilers. This proactive approach has significantly reduced the company's carbon footprint. Across the broader pharma industry, major players are actively exploring this transition and utilizing carbon credits to offset emissions.

Mankind Pharma, being a responsible organization, is actively pursuing various options to shift to cleaner fuels like PNG (Piped Natural Gas) from HSD (High

Speed Diesel), as and when the PNG is made available by the government, for its DG Sets operation to further reduce its carbon foot print.

▪ Environmental, Health, and Safety (EHS) Risks

EHS concerns are multifaceted and require careful management.

Environmental Issues: These primarily involve air pollution, wastewater management, and waste management. Waste can be further categorized into hazardous, plastic, and other types.

Health and Safety: While formulation products generally pose lower safety risks, the Active Pharmaceutical Ingredient (API) also called as bulk drug manufacturing processes carry much higher risks. Key factors to consider for hazardous products include storage conditions, proper usage, and the safety of chemical reactions during production. A concerning trend is the increase in accidents due to inadequate storage, inadequate process safety precautions/ fire prevention and protection systems and poor maintenance of the same.

▪ Cybersecurity

In today's interconnected world, cybersecurity has emerged as a critical risk for pharmaceutical organizations. The industry handles sensitive data and relies heavily on digital systems, making it a prime target for cyber threats.

▪ Business Continuity

Ensuring business continuity is another significant risk area. This involves having robust plans in place to mitigate disruptions and continue operations in the face of unforeseen events. As a risk officer, the focus extends beyond operational risks to encompass financial, administrative, and reputational risks to ensure holistic business resilience.

These emerging risks highlight the need for the pharmaceutical industry to adapt to a changing global landscape, prioritizing sustainable practices, applicable regulatory compliances, robust safety measures, and resilient business models.

What are Mankind Pharma's key initiatives in the areas of environmental sustainability and health & safety compliance?

The company is actively committed to environmental stewardship through various initiatives aimed at reducing its ecological footprint, transitioning to renewable energy, and implementing robust waste management strategies.

▪ Renewable Energy and Carbon Footprint Reduction

To combat climate change, Mankind Pharma has significantly shifted away from fossil fuels. The company recently commissioned a 5 MW solar power plant in Jaisalmer, which will provide energy for two of its major Active Pharmaceutical Ingredient (API) facilities. Furthermore, Mankind Pharma utilizes agro-based briquettes for steam generation in its boilers, a renewable fuel source that further reduces reliance on conventional fossil fuels. All 3 manufacturing plants in Himachal Pradesh and manufacturing plant at Sikkim procures 89% and 100% green power respectively, meeting Mankind's aggressive ESG Goals of Carbon Neutral by FY 2030.

▪ Water Conservation and Zero Liquid Discharge (ZLD)

Mankind Pharma has implemented Zero Liquid Discharge (ZLD) systems across all its API industries, with the exception of its Vizag facility (API Unit II) located in Jawaharlal Nehru Pharma City. Due to government and pollution control board mandates, the Vizag facility adheres to a centralized CETP model. All industries within the Pharma City send their high and low Total Dissolved Solids (TDS) streams to a common effluent treatment plant and multiple effect evaporator respectively, where a third party manages it.

▪ Comprehensive Waste Management

Mankind Pharma has established a multi-pronged approach to waste management, focusing on reducing landfill burden and promoting resource recovery:

▪ Hazardous Waste Management: All hazardous waste generated from manufacturing plants is 100% directed to authorized Treatment, Storage, and Disposal Facilities (TSDFs). Going beyond this, Mankind Pharma has set an ambitious ESG goal to send 70% of its hazardous waste for co-processing by 2027 to avoid burden on Environment by land filling of the waste, with a remarkable 55% already achieved in FY 2025.

▪ Ash Management: Ash generated from the burning of agro-based briquettes at one of its Rajasthan API units (API unit I) is sent to authorised brick manufacturers, where it's combined with other raw materials to produce bricks. Additionally, ash from formulation Unit

I is sent to cement industries for utilization, a significant improvement from previous practices of landfilling.

- **Plastic Waste Management:** As part of its Extended Producer Responsibility (EPR) under the Central Pollution Control Board (CPCB) mandate, Mankind Pharma ensures 100% recycling of both pre-consumer and post-consumer plastic waste. Pre-consumer waste, which includes rejected materials during manufacturing, is sent to authorized recyclers to be converted into granules. For post-consumer waste, an equivalent quantity of plastic waste to the product introduced into the Indian market is collected and sent for recycling. Mankind Pharma is registered with the CPCB and ensures that 100% of this waste goes to recyclers.

Looking ahead, Mankind Pharma plans to integrate a portion of these recycled granules into plastic manufacturing procured from third party for product packaging. While currently using rigid plastic drums with two internal liners to prevent contamination and ensure product integrity of its various other products, the company is actively exploring and piloting compostable plastics for product packaging, as demonstrated by a recent successful pilot study.

These comprehensive efforts highlight Mankind Pharma's strong commitment to environmental sustainability across its operations, from energy sourcing to waste disposal and product packaging.

What challenges do you face in aligning with global ESG frameworks such as GRI, TCFD, or SASB?

We're relatively new to formal ESG reporting, only about two years in. Right now, our primary focus is on the Business Responsibility and Sustainability Reporting (BRSR), which is a mandatory public disclosure here in India. While we haven't officially published under the Global Reporting Initiative (GRI) Standards yet, we've definitely started laying the groundwork. We're aiming to make our GRI-aligned reports public either this year or next. It's a significant step for us in terms of transparency.

Looking further ahead, we're planning to integrate the Task Force on Climate-related Financial Disclosures (TCFD) and Sustainability Accounting Standards Board (SASB) frameworks. We're taking a very methodical approach, building towards these in next couple of years, and tying them closely with our science-based targets.

Of course, this journey isn't without its challenges. The biggest one for us is data collection and granularity. Moving from our current BRSR requirements to the much more detailed demands of GRI, TCFD, and SASB means we need to significantly enhance our data systems and processes.

Then there's the aspect of resources and expertise. Implementing these complex frameworks requires dedicated teams and specialized knowledge. We're actively working on utilizing that internal capacity, both through training our existing team and bringing in external experts when needed.

Ultimately, it's about integrating ESG into our core business strategy. It's more than just reporting; it's about embedding sustainability deeply into how we operate and make decisions. Our phased approach reflects this commitment. We're also constantly monitoring the evolving regulatory landscape to ensure we stay compliant and up-to-date with global best practices.

Do you see upcoming Indian or international regulations reshaping the risk landscape for pharma companies?

Pharma marketing in India is governed by regulations such as the UCPMP (Uniform Code of Pharmaceutical Marketing Practices) and stringent quality standards enforced by authorities like the FDA and CDSCO etc. Mankind Pharma has implemented a robust risk management framework and a strong quality management system to effectively mitigate risks and ensure consistent adherence to regulatory and quality standards.

Moreover, one major area that's top of mind for us right now is Anti-Microbial Resistance (AMR). This has been a significant focus in European countries, and we're seeing it increasingly become a critical challenge for the Indian pharmaceutical sector as well. Essentially, anti-infective drugs manufactured in India will need to adhere to very strict AMR standards regarding their discharge, even though no such regulations are enforced in India as of now.

At Mankind Pharma, we've taken a proactive stance on this. Last year itself, we began analyzing our wastewater streams of one of our factories specifically for AMR residues to identify any concentrations. We understand the gravity of this issue. Our strategy to address this threat is two-fold:

- **Stringent Manufacturing Controls and Operational Excellence:** We're implementing even more stringent controls during the

manufacturing stage. This isn't just about routine production; it ties into our concept of operational excellence, where we're constantly striving to maximize product yield. For example, if our yield was typically 95%, we're pushing to increase it to 97% or even higher. The logic here is simple: if we produce more products from the same raw materials, the amount of waste generated, including AMR residues, is drastically reduced. Historically, along with other residues, AMR residues would also end up as hazardous waste, often sent for co-processing/ incineration. By increasing our yield by even a small percentage, say from 95% to 9798% or more, we're directly reducing the 5% waste to less than 2%, meaning less of these substances is collected and disposed of as Hazardous Waste.

- **Proactive Monitoring and Compliance:** We're not waiting for mandates. Last year, we had our wastewater tested by an NABL-accredited lab at one of our manufacturing plants. The good news is that we found our residue levels were well below the currently drafted Indian Regulations. However, we're fully aware that for the pharmaceutical industry, especially with antibiotics, the limits are incredibly stringent—we're talking about maintaining levels in micrograms in wastewater. This is a significant challenge.

  In my view, given these extremely strict draft standards, particularly where anti-infective drugs are manufactured, I strongly believe that Zero Liquid Discharge (ZLD) should be made mandatory for such industries where treated wastewater is allowed to discharge outside the factory premises from such industries or particular operations. It's the most effective way to ensure that these critical residues do not enter the environment, safeguarding public health and mitigating the risks associated with AMR. This proactive approach is crucial for the industry's future.

What role do technology and data analytics play in risk assessment and EHS&S monitoring at Mankind Pharma?

We're always looking for ways to enhance safety and efficiency, and for us, that increasingly means exploring IoT, particularly within Health and Safety. We're actively engaging with suppliers, and a company like Tata Communications is definitely on our radar. Mankind Pharma has already established internal data analytics like Tableau, predictive maintenance tools, CIO Portal, operational equipment efficiency, contractor management and online regulatory compliance tools.

- **IoT and Safety in Bulk Drug Manufacturing**

I truly believe IoT is going to play a transformative role in reducing risks, especially in our bulk drug manufacturing facilities. Where we have hazardous reactions, we've already taken significant steps towards total automation. This means human intervention in these high-risk areas has been minimized by about 99%. The beauty of this new technology and automation is that, in the event of any safety risks, our workers are virtually unaffected.

Think about a "run-away" reaction, which can be a highly hazardous scenario. With our current setup, if such a safety event were to occur, the material automatically diverts into a dedicated dump tank. From there, it can be safely recycled, disposed of, or even reprocessed, depending on nature of the material. This kind of technology is a game-changer for us.

Mankind is actively looking into options to identify the unsafe acts or conditions committed by the workers or contractors through IOT for taking preventive actions to avoid its recurrence.

Mankind at its one of the manufacturing plants has built a fully automated ware house operation to minimise the safety risks and increase efficiency of the product storage and despatch.

In one of the API manufacturing facilities, fully automated foam flooding system is under execution. This ensures timely activation of protection systems to minimise loss to facility and worker.

- **Automation and Safety in Formulations**

Technology is also making a major impact in our formulation's plants, even though the safety risks there are comparatively lower than in API manufacturing. For instance, with our sophisticated, high-speed machines, we're implementing interlocks everywhere. This completely avoids or at least significantly minimizes human intervention at critical points. Instead of manually transferring materials from one machine to another, the entire process is becoming fully automated.

To minimize the health impact on the workers, quite a few products replaced solvents with water that shows Mankind commitment on workers wellbeing. Wherever

gas emissions are expected both within and outside the operations, the particular area is provided with gas sensors with evacuation signals that ensures timely evacuation of workers from the affected areas.

▪ Towards Continuous Manufacturing

This push for automation and reduced human intervention is also driving our interest in continuous manufacturing. We're looking at it very seriously as a way to enhance both safety and efficiency. Just last year, in 2024, our production team visited Germany, Belgium and Italy specifically to explore where continuous manufacturing could be implemented within our operations. These technologies are currently under evaluation, and if it proves feasible for us, we are absolutely committed to moving forward with it. It's about leveraging the best available technology to create a safer and more efficient manufacturing environment across the board.

How do you measure the success and impact of your EHS&S programs? Highlight some of the key initiatives by Mankind Pharma.

When we talk about our operational excellence initiatives, I can confidently say they're truly paying off, and a huge part of that success comes down to the unwavering commitment from our top management, especially concerning Environment and Safety. This commitment influences everything we do, from technology transfers to adopting Green Chemistry principles.

Let me give you a few concrete examples. For many of our formulated products, solvents are a key raw material. We've made a very deliberate decision to eliminate the use of solvents with water in some of products, which shows our commitment towards Sustainability of products.

Another significant area where we've seen immense dividends is in our nitration reactions, which is completely automated to minimise human intervention during highly hazardous operations. Another example is of hydrogenation operations. These are inherently highly hazardous, as they involve the use of hydrogen gas to create products in subsequent unit operations. We've completely automated this area as well, drastically reducing the need for human intervention. We're also in the process of automating other hazardous areas, such as bromination. Our goal is to continually move towards less hazardous operations by leveraging technological improvements.

This isn't just about efficiency; it's fundamentally about protecting our people and the environment. This strategic focus on operational excellence, backed by strong leadership commitment, is helping us achieve a safer, more sustainable, and ultimately more efficient manufacturing footprint.

How is Mankind Pharma preparing for increasing ESG-related disclosures and investor expectations?

The increasing investor expectations around ESG are definitely a significant development, and it's something we at Mankind Pharma are actively preparing for. It's a relatively new focus in the Indian context, even things like Anti-Microbial Resistance (AMR) are now a part of the discussion.

One area that's getting a lot of attention, and where we've been very proactive, is Occupational Exposure Levels (OEL). We meticulously categorize these based on real-time values into what we call Occupational Exposure Banding (OEBs).

To give you an idea, very low OELs, which are in micrograms, generally fall into bandwidths of4 & 5. However, if we identify OELs in bandwidths 4 and 5, it means there's potential for harm to our workers unless robust engineering controls are in place. Engineering controls are an absolute must for us; they're our primary line of defense.

We also layer in administrative controls and, of course, provide appropriate Personal Protective Equipment (PPEs) like breathing air supply or alike to ensure worker safety. This proactive approach to OELs and OEBs is something investors are increasingly looking at. Beyond worker safety, investors are also keenly focused on how industries manage their waste, particularly regarding Zero Liquid Discharge (ZLD) and incineration. There's a growing preference for solutions that don't just consume energy, but actually generate energy from waste.

We've been very successful in this area. At two of our factory units, in Sikkim and Rajasthan, 100% of our hazardous waste is now sent for co-processing. This is a significant achievement. We're now in the process of extending this initiative to our other facilities, including our formulation factories. By sending our hazardous

waste to cement industries for co-processing – where it can be used as an alternative fuel source – we've been able to achieve an average of 55% of our total hazardous waste going for this energy-generating disposal method.

These initiatives – from our stringent OEL management to our advanced hazardous waste co-processing at authorized third party sites– demonstrate our commitment to addressing evolving ESG expectations and ensuring we're operating responsibly and sustainably.

How do you see the convergence of ESG and risk shaping corporate strategy in the next decade?

The key factor, in my opinion, will be a robust governance mechanism that is not just in place, but actively reviewed and prioritized by top management across industries. At Mankind Pharma, for example, sustainability is directly reviewed by our Board, integrated right alongside our overall business risk management framework. This ensures that ESG isn't seen as a separate initiative, but as an intrinsic part of our core business strategy and risk profile.

Furthermore, our governance mechanism extends beyond just our manufacturing plants. We're meticulously assessing and mitigating ESG and EHS risks across our warehouses, CNF (Carrying and Forwarding) facilities, and our own subsidiaries. The same ESG risk assessment is extended further to our critical suppliers as well. We're looking at the specific risk levels in these diverse areas and developing strategies to reduce them. For instance, we mandate quarterly mock drills at all our CNF facilities apart from all manufacturing sites to ensure preparedness and minimize safety risks.

Our other major focus areas on ESG is on responsible sourcing of raw materials by critically evaluating the supply chain management and reducing the Scope-3 emissions from the logistics point of view, apart from other areas.

▪ Ambitious Sustainability Targets

Looking ahead, we have some very ambitious targets that underscore how ESG is shaping our strategy:

▪ **Top 3 in Sustainability by 2028:** We're relatively new to formal sustainability reporting, just two years in, but we aspire to be among the top 3 companies in India as far as sustainability performance is concerned by 2028. This isn't just a vision; it's driving our current investments and strategic choices.

▪ **100% Carbon Neutral by 2030:** This is a firm commitment. We are working towards achieving 100% carbon neutrality across our standalone operations by the year 2030.

▪ **Plastic Neutrality Achieved in 2025:** I'm proud to say we've already achieved plastic neutrality in 2025. This means that for every piece of plastic we put into the market, both pre- and post-consumer, we ensure an equivalent amount is collected and sent for recycling.

▪ **Aggressive Water Reduction Targets:** While the majority of our factories currently rely on groundwater, we've set an aggressive target to reduce our water consumption by 50% based on intensity (per metric ton of APIs/ per million number of tablets). We've already made significant progress here; in the last 1.5 years alone, we've managed to reduce our water consumption intensity by 31%.

These targets are not just aspirational; they are deeply integrated into our operational planning and capital allocation. The convergence of ESG and risk means that failing to address environmental and social factors is increasingly seen as a direct business risk.

Conversely, strong ESG performance opens up new opportunities, enhances resilience, and strengthens our social license to operate. We believe that by proactively managing these aspects and setting such bold goals, Mankind Pharma will be well-positioned for sustainable growth and value creation in the next decade. ■

INTERVIEW

"We remain committed to invest in next-generation capabilities."

Alex Del Priore
Senior Vice President- Manufacturing,
Syngene International Ltd

Alex Del Priore, Senior Vice President- Manufacturing, Syngene International Ltd emphasizes about the acquisition of US facility and how it will benefit India's growth in biologics and biosimilars sector. He also spoke about the company's future plans and how expanded capacity will support clinical and commercial manufacturing.

Syngene has a strong presence in India. How does the acquisition of this US facility strengthen its global capabilities and complement its existing operations?

The acquisition of the US biologics manufacturing facility is a strategic addition to our global network. With two biologics facilities in India and now a site in North America, we are expanding our ability to support clients across different geographies.

This expansion provides clients with the flexibility to choose between India- and US-based manufacturing, based on regulatory requirements and market needs. The US site will provide clinical and commercial-scale biologics manufacturing, with a strong focus on monoclonal antibodies (mAbs). What makes this facility particularly exciting is that it extends our ability to serve both human and animal health clients. We can support projects at various stages – from early development to full-scale production – making this site a truly flexible addition to our global manufacturing network.

With the growing demand for biologics, how will Syngene's expanded capacity support the industry's needs, particularly in clinical and commercial manufacturing?

Bringing biologics manufacturing onshore helps to de-risk supply chains and provide greater reliability for clients. For animal health in particular, US-based production is often a regulatory requirement, making this facility an invaluable asset. By expanding manufacturing capacity in the US, we are contributing to a more resilient supply chain and offering clients greater flexibility in how they structure their production strategies.

The US facility adds approximately 16,000L of single-use bioreactor capacity to our network, contributing to a total capacity of 50,000L across our biologics operations. The site houses 2 × 4,000L and 4 × 2,000L bioreactors, along with pilot-scale 50L and 75L systems.

With a presence in both India and the US, how does Syngene plan to offer flexibility to clients in terms of development and manufacturing? Do you foresee US-based clients leveraging the Baltimore site for early-stage production and shifting large-scale manufacturing to India?

In today's environment, flexibility isn't optional—it's essential. Our presence in India and the US enables clients to design development and manufacturing strategies tailored to their clinical plans, regulatory pathways, and commercial ambitions. The US acquisition expands our ability to offer flexible development and manufacturing solutions tailored to client needs. The facility provides a US-based manufacturing option, which is a regulatory requirement for approximately 50% of animal health products approved in the United States. This also opens up the possibility to engage with innovators who mandate US-based production.

Our expanded network of four sites allows clients to access development and manufacturing services in both India and the US. While specific patterns of use are client-dependent, we are positioned to support a range of needs through modular and location-flexible offerings.

How does Syngene plan to balance operations to optimize costs, efficiency, and regulatory compliance? Do you anticipate shifts in client preferences based on geography?

Balancing global operations requires a deep understanding of regulatory frameworks, market expectations, and cost structures. Our decision to establish operations in US was driven by proximity to leading pharmaceutical hubs, a strong talent ecosystem, and the opportunity to integrate into the North American regulatory landscape.

At the same time, our facilities in India continue to offer exceptional value in terms of scale, speed, and scientific expertise. We are investing in aligning quality systems across sites, ensuring consistent standards irrespective of geography. This dual-presence model enables us to offer clients a globally compliant, regionally responsive solution—wherever they choose to engage with us.

What specific upgrades or modifications will Syngene undertake to align the US facility with its existing MAb production standards? Beyond monoclonal antibodies, what other therapeutic modalities are planned for development at Syngene's US site?

The Baltimore facility is undergoing a comprehensive revalidation to ensure it meets the same standards we apply across our global biologics network. This includes qualifying equipment, enhancing process controls, and strengthening quality assurance systems. The site previously received a "No Action Indicated" classification from the US FDA, providing a strong foundation on which to build. Drawing on our experience in converting facilities—such as Unit 3 in India—we are confident in our ability to scale the site efficiently and effectively. As of now, the focus remains on monoclonal antibodies.

How does this acquisition benefit India's growth in biologics and biosimilars sector? What are Syngene's future expansion plans for biologics manufacturing in India?

The US facility supports our global growth strategy and complements our two biologics sites in India. Together, these facilities provide integrated support from early development through to commercial manufacturing. The addition of a US site enables us to expand our service offerings without displacing operations in India, thereby contributing to the continued growth of our capabilities across both geographies.

Looking ahead, we believe India will continue to play a critical role in our global biologics strategy. The country offers deep scientific talent, competitive manufacturing economics, and a rapidly evolving regulatory landscape that supports innovation. As demand for large molecule therapies grows globally, we are focused on scaling our biologics infrastructure in a way that ensures capacity, quality, and speed for our clients. We remain committed to investing in next-generation capabilities, expanding capacity in line with client needs, and maintaining global compliance benchmarks that position India as a key partner in global biopharmaceutical supply chains. ■

Building a Sustainable Pharma Future

In the evolving healthcare landscape, India's pharmaceutical industry stands tall as a beacon of innovation, affordability, and scale. Rightly referred to as the "pharmacy of the world," the sector contributes more than 20% of the global supply of generic medicines, and 60% of vaccines, to over 150 countries. The COVID-19 pandemic reinforced India's leadership, as pharma companies ensured uninterrupted access to essential medicines. However, this defining moment also prompted scrutiny of the industry's environmental impact, from excessive water use to waste discharge and emissions.

Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA), emphasizes that India's pharmaceutical industry is increasingly embracing sustainability as a core operational principle, with a strong focus on ESG performance.

India's pharmaceutical production has grown rapidly, expanding at roughly 8% annually over the past decade, more than twice the global average.

As the world confronts the environmental costs of this rapid growth, India's pharma sector faces an opportunity to broaden its leadership beyond quality, cost, and access. The new frontier of global leadership lies in environmental sustainability.

It is no longer sufficient to focus solely on healing people; we share a fundamental responsibility to heal and protect the planet as well. The question posed by Jonas Salk, the developer of the first successful polio vaccine, remains as urgent as ever: "Are we being good ancestors?" With this, Salk challenged us not only to cure diseases but to consider the impact of our actions on future generations.

The Strategic Shift Toward Sustainability

This perspective by Salk now finds tangible expression in the industry's strategic shift towards environmental sustainability, which has emerged as a critical business imperative—no longer merely a regulatory checkbox but a core tenet of corporate responsibility, strategic positioning, and long-term competitiveness. Sustainability is rapidly evolving into the currency of trust in an increasingly conscientious global healthcare market. Across international markets, Environmental, Social, and Governance (ESG) criteria are becoming essential determinants of investment decisions, partnerships, and corporate reputation.

Indian pharmaceutical companies are proactively embracing this shift, aligning their operations with India's net-zero goals for 2070, the United Nations Sustainable Development Goals (UNSDGs), and the Business Responsibility and Sustainability Reporting (BRSR) mandates issued by SEBI. Testament to this progress, the Dow Jones Sustainability Index now ranks seven Indian pharmaceutical companies among the world's top eleven, affirming their growing global stature in sustainability performance.

While these achievements signify meaningful progress and reflect the sector's readiness to evolve with the times, much more remains to be done. India's leadership in the global pharmaceutical industry must now be defined by its capacity to innovate sustainably, adopt greener production practices, and build resilient supply chains that minimize environmental impact throughout the entire value chain.

From Molecule to Market: Aligning the Value Chain with Sustainability

Sustainability in pharmaceuticals demands a holistic approach. It is not the responsibility of any single department or phase but a continuous mandate

spanning the entire value chain. From research and development to manufacturing, logistics, and equitable distribution, each stage offers unique opportunities to drive sustainability.

a. Greening R&D: Starting with Innovation

The journey of every molecule begins in the laboratory. Indian pharmaceutical companies are increasingly embracing green chemistry principles, striving for less hazardous and more resource-efficient formulations. Cleaner synthesis processes for Active Pharmaceutical Ingredients (APIs) and eco-friendly excipients are gaining momentum. However, challenges remain in underfunded R&D ecosystems, regulatory frameworks that inadequately incentivize sustainable investments, and technical hurdles requiring novel synthetic pathways, solvents, and reaction conditions. These substantial obstacles can be overcome through government-backed incentives, public-private partnerships, and innovation clusters focused on green pharmaceutical technologies. Collaborative platforms and increased investment in research infrastructure will be essential to catalyse systemic change and accelerate progress toward sustainability.

b. Cleaner Manufacturing: Scaling Responsibly

Post-R&D, the focus shifts to cleaner manufacturing, where the Indian pharma sector has made notable strides. Initiatives such as the Production Linked Incentive (PLI) scheme and the development of dedicated pharma clusters encourage the adoption of global best practices. Several companies have integrated Zero Liquid Discharge (ZLD) systems, automated pollution control technologies, and renewable energy solutions into their operations. Yet, significant challenges persist - effluent discharge from bulk drug production, emissions from aging facilities, and inconsistent waste management practices continue to impact environmental outcomes. Industry-wide adoption of cleaner technologies, supported by robust regulatory frameworks and voluntary self-regulation, will be critical to reducing the sector's environmental footprint.

c. Greener Supply Chains: Logistics for a Low-Carbon Future

India's pharmaceutical supply chain, encompassing manufacturing hubs, cold storage, transportation, and last-mile delivery, is among the most complex worldwide. While operational efficiency and scale have improved, environmental concerns have mounted due to energy-intensive cold chains, excessive plastic packaging, and emissions from long-distance transport. Building a sustainable supply chain is not only an environmental imperative but also enhances resilience against disruptions and improves cost-effectiveness. Key enablers for this transformation include decentralized manufacturing hubs, adoption of electric or hybrid transport fleets, biodegradable packaging solutions, and digital tools for optimized route logistics.

d. Equitable Access: The Social Sustainability Dimension

At the heart of India's pharmaceutical leadership lies its unwavering commitment to affordability and access. Programs spearheaded by the National Pharmaceutical Pricing Authority (NPPA) and the Standing Committee on Affordable Medicines and Health Products (SCAMHP) have brought essential medicines within the reach of millions. Environmental sustainability must never come at the cost of social equity. The transition toward greener processes and materials should not compromise drug affordability or accessibility. Innovation must be inclusive, ensuring sustainable healthcare remains synonymous with equitable healthcare.

e: Driving Change: Pharma Industry Embracing Sustainable Practices

India's pharmaceutical industry is increasingly embracing sustainability as a core operational principle, with a strong focus on ESG performance. Companies are implementing forward-looking strategies to reduce carbon emissions, boost energy efficiency, and adopt responsible water and waste management practices.

One of the most impactful transformations has been the widespread adoption of Zero Liquid Discharge (ZLD) systems. These advanced technologies treat, recycle, and reuse wastewater within manufacturing facilities, significantly minimizing ecological footprints. The treated water is repurposed for non-potable applications such as cooling towers and cleaning operations, thereby improving overall resource efficiency.

In pursuit of clean energy, pharmaceutical firms are turning to renewable sources like solar power. Rooftop solar installations, biomass utilization, and renewable energy procurement have become common initiatives

contributing to long-term decarbonization goals. Energy efficiency efforts extend beyond power generation—LED lighting, motion sensors, and smart timers are being installed to optimize electricity use. Additionally, Heating, Ventilation, and Air Conditioning (HVAC) systems are being upgraded with variable-speed blowers, programmable thermostats, and automated controls to maintain indoor air quality while reducing energy consumption. The adoption of smart metering further enhances operational efficiency by enabling precise energy monitoring and management.

Moreover, companies are investing in employee training and awareness programs to foster responsible behavior and effective greenhouse gas (GHG) management. Aligning with global transparency standards, many Indian pharmaceutical companies publish dedicated ESG or Sustainability Reports that detail key achievements, ongoing initiatives, and future targets. This commitment to openness reinforces accountability and strengthens the industry-wide pledge toward a greener future.

Bridging Gaps: Navigating the Challenges

The path to sustainability is not without obstacles. Legacy infrastructure, capital constraints, and fragmented regulatory compliance remain significant roadblocks. Moreover, while leading firms have made substantial progress, smaller companies often lack the resources to follow suit.

Overcoming these challenges requires a multi-dimensional strategy. This includes strategically mainstreaming ESG principles by embedding sustainability into core business models with clearly defined metrics, targets, and accountability mechanisms. Innovation must focus on circularity—redesigning product life cycles to prioritize reusability, recyclability, and minimal environmental impact. Additionally, building collaborative ecosystems that involve government, academia, startups, and multinational corporations is critical to scaling sustainable innovations across the entire value chain.

A particularly complex challenge is addressing 'Scope 3' emissions - indirect greenhouse gas (GHG) emissions occurring throughout a company's value chain. Industry leaders are adopting an integrated "dual mission" approach that simultaneously optimizes costs and reduces Scope 3 emissions. To achieve this, pharmaceutical companies can focus on three key **levers:** decarbonizing the raw material value chain, improving process and energy efficiency, and promoting recycling and circularity.

Decarbonizing the raw material value chain requires a detailed analysis of both the cost and carbon footprint of products and components, enabling more informed procurement decisions and adoption of lower-impact alternatives. Enhancing process and energy efficiency through measures such as transitioning to renewable energy sources and implementing robust energy management systems can reduce emissions by 30–40% while cutting energy costs by up to 20%. Embracing recycling and circularity by redesigning packaging to reduce material use, eliminating single-use plastics, and simplifying packaging processes can also substantially lower the industry's overall environmental impact

A Future-Ready Vision for Indian Pharma

India has already redefined global healthcare leadership through its scale, efficiency, and commitment to access. Now, it stands poised to redefine leadership once more by setting new benchmarks in environmental sustainability. Pharma companies must prioritize adopting green technologies in legacy and new facilities, invest in bio-based APIs and green chemistry platforms, conserve energy and water across all operations, and ensure transparent ESG reporting with meaningful stakeholder engagement.

India's pharmaceutical sector is at a crossroads of immense opportunity and responsibility. The decisions made today will shape not only the future of healthcare but also the future of the planet. Environmental sustainability is no longer optional—it is essential to secure health for both people and the planet. The Indian pharmaceutical industry has the scale, capability, and vision to lead this transformation boldly, holistically, and irreversibly. ■

Author

Sudarshan Jain
Secretary General,
Indian Pharmaceutical Alliance (IPA)

The State of Counterfeiting in High-Risk Sectors in India: Pharmaceuticals, Chemicals, and Agrochemicals

Counterfeiting in India has undergone a dangerous transformation—from being a source of cheap, imitation products to becoming a major threat across critical sectors such as pharmaceuticals, agriculture, and chemicals. Mr. Manoj Kochar, President of the Authentication Solution Providers' Association (ASPA), unpacks how counterfeit goods now endanger public health, food security, and industrial integrity. Drawing on key insights from the ASPA CRISIL Report 2022, he explores how smarter counterfeit networks exploit regulatory gaps and fragmented supply chains, and outlines the urgent need for a coordinated, technology-driven response to safeguard consumers and legitimate businesses alike.

Manoj Kochar
President, Authentication Solution Providers' Association (ASPA)

Once limited to knock-off accessories and budget goods, counterfeiting in India has evolved into a sophisticated threat impacting high-value and high-risk sectors. From life-saving pharmaceuticals to critical agrochemicals and industrial chemicals, counterfeit products now pose serious risks to public health, food security, and economic integrity. As counterfeiters grow smarter and exploit regulatory loopholes, fake products are penetrating both urban centers and rural supply chains. Addressing this growing crisis demands a unified response, one that blends innovation, policy reform, public awareness, and technology-driven authentication solutions.

Pharmaceuticals: Strengthening Supply Chain Security

India's pharmaceutical industry, globally recognized for affordable medicines, faces mounting challenges from counterfeit infiltration, especially in tier II and III cities where limited organized retail, low authentication awareness, and dependence on unregulated online

sources increase risk. The ASPA CRISIL Report 2022 notes that 32 percent of consumers in Hyderabad, 29 percent in Indore, and 25 percent in Chennai have encountered counterfeit drugs.

Counterfeiters use advanced printing and design tools to replicate packaging and QR codes with high accuracy. Fake drugs often enter the system through informal routes, bypassing regulatory checks and directly risking public health. The rise of e-commerce and grey-market channels has further worsened the spread. Regulators struggle to monitor unregulated online sales, particularly those taking place through informal digital marketplaces and social media platforms. The challenge has grown more complex as the landscape of distribution has become increasingly fragmented.

These challenges underscore the urgent need for enhanced authentication and supply chain monitoring mechanisms to safeguard public health.

Agrochemicals: Threats to Yields and Food Security

Agriculture is the backbone of the Indian economy and agrochemicals play a critical role in ensuring food security and sustaining rural livelihoods. However, counterfeiting, particularly in pesticides, has emerged as a serious concern. The ASPA CRISIL Report 2022 highlights that insecticides account for 56 percent of pesticide use, herbicides 23 percent, fungicides 20 percent, and other categories around 1 percent. It estimates that counterfeit agrochemical products make up 30 to 40 percent of the market. Pesticides remain the most counterfeited category, primarily due to their scale of usage. The use of fake agrochemicals can lead to a reduction in crop yields by three to four percent, directly impacting farmer incomes.

Many of these counterfeit products contain banned or incorrect formulations that not only fail to protect crops but also lead to pest resistance, soil degradation, and long-term environmental damage. The ASPA CRISIL Report further points out the key states most affected by this problem, including Uttar Pradesh, Jharkhand, Madhya Pradesh, Andhra Pradesh, Telangana, Haryana, Maharashtra, West Bengal, Karnataka, Tamil Nadu, and Bihar. Limited availability of authentic products, economic pressures, and low awareness drive farmers to purchase cheaper alternatives, many of which are counterfeit.

Addressing these risks requires improved product verification methods and awareness initiatives to ensure farmers access authentic, effective agrochemicals.

Chemicals: Industrial Risks

The Indian chemical industry is essential to sectors like pharmaceuticals, food processing, manufacturing, and textiles. Its vast and often fragmented supply chain makes it vulnerable to the infiltration of counterfeit raw materials, solvents, and specialty chemicals. The risks associated with counterfeit chemicals are often less visible but can have deeply damaging consequences.

One counterfeit intermediate can compromise an entire pharmaceutical batch or food-grade product. In industrial settings, such materials can corrode equipment, disrupt manufacturing processes, or even cause safety hazards. Weak regulatory enforcement, particularly at the transit and storage levels, has worsened the problem. The challenge is amplified because many chemical products are visually indistinguishable and lack overt security features, allowing counterfeiters to exploit these blind spots effectively.

The chemical supply chain often involves multiple tiers across domestic and international borders. This complexity introduces vulnerabilities at several stages, including bulk imports, warehousing, and regional redistribution. These entry points are particularly difficult to monitor, giving counterfeit materials an opening to reach legitimate networks.

To tackle this, closer collaboration between manufacturers, regulatory authorities, and enforcement agencies is vital. Standardized traceability mechanisms and real-time data sharing across networks can play a significant role in minimizing these risks. Border control, especially at customs and logistics touchpoints, must also be strengthened to prevent illicit materials from entering domestic circulation. These factors highlight the critical need for strengthened traceability and cross-sector cooperation to mitigate counterfeit risks in chemical supply chains.

The Role of Advanced Technology and Standardization

The adoption of advanced authentication technologies across high-risk sectors is transforming India's response to counterfeiting. A layered security approach combining physical features with digital tools is proving to be the most effective. Technologies such as tamper-

evident packaging, holographic security labels, QR codes, NFC tags, and microtext printing offer visible signs of authenticity that consumers and distributors can use to verify products.

These visible elements are being increasingly combined with advanced digital authentication systems. Serialization allows manufacturers to assign unique identification codes to individual product units, enabling full traceability throughout the supply chain. When integrated with blockchain, this traceability becomes immutable and transparent, giving regulators and companies the ability to monitor product movement from production to the point of sale. Blockchain's distributed ledger systems, especially when supported by artificial intelligence, can detect anomalies, flag counterfeit activity, and support efficient recall mechanisms.

AI-enabled systems enhance this further by identifying suspicious distribution patterns or inconsistencies in real-time, providing actionable insights and increasing the speed and accuracy of investigations. QR codes printed on product labels offer an accessible tool for consumers, especially in rural areas, to instantly verify product authenticity using a smartphone. As public awareness improves and technology becomes more user-friendly, these tools are becoming central to anti-counterfeiting strategies.

International standards such as ISO 22383 help unify these efforts by offering a structured framework for deploying and auditing product authentication solutions. Aligning with such standards ensures that solutions are scalable, effective, and compatible with global best practices.

Collaborative Efforts Against Counterfeiting

A central pillar in the fight against counterfeiting is meaningful cross-sector collaboration. This challenge is too vast and complex to be managed by individual manufacturers or regulatory bodies alone. Addressing it effectively requires a shared commitment and coordinated action across the entire ecosystem. Industry leaders, government agencies, enforcement authorities, technology providers, and consumers all have a role to play in creating a resilient and transparent supply chain.

The scale and sophistication of modern counterfeiting networks demand unified strategies that cut across sectors and geographies. Without collective vigilance, even the most advanced security technologies can fall short. That is why building long-term partnerships, encouraging knowledge-sharing, and aligning policy frameworks have become essential steps in safeguarding product authenticity and public safety.

ASPA collaborates extensively with key stakeholders across different industries, to combat counterfeiting and promote secure supply chains. Through technical workshops, policy dialogues, and educational campaigns, ASPA supports pharmaceutical companies in adopting advanced authentication technologies and aligning with evolving regulatory frameworks. A flagship initiative led by ASPA, the Traceability and Authentication Forum (TAF) 2025, which convened industry leaders, government officials, and technology providers to address threats, policy developments, and technology-driven countermeasures. The forum continues to serve as a key platform for aligning global best practices, scalable authentication frameworks, and strategies to safeguard patients and supply chain integrity.

Towards an Integrated Strategy

India's high-risk sectors face an urgent need to adopt an integrated strategy. Fragmented actions and reactive measures are no longer sufficient in a landscape where counterfeiters are well-funded, tech-savvy, and exploit every available loophole. A forward-looking approach must focus on long-term investment in technology, public education, and harmonized regulation.

What is encouraging is the growing alignment among stakeholders. As authentication tools mature and awareness grows, businesses are increasingly recognizing that trust and transparency are not just regulatory necessities but strategic advantages. Those who lead in building secure systems will not only mitigate counterfeiting but also earn consumer loyalty, enhance their market reputation, and gain a competitive edge. ■

Regulatory Reforms & Collaborative Models: Catalysing Indian CROs Growth in Global Clinical Trials

India's clinical research industry is undergoing a significant transformation, propelled by progressive regulatory changes and the adoption of collaborative business strategies. In recent years, regulatory enhancements have improved the efficiency and transparency of clinical trial processes, while increased mergers, acquisitions, and international alliances have broadened the range of services offered by Indian Contract Research Organizations (CROs). These developments have positioned India as a leading destination for global clinical trials, underpinned by operational excellence, cost competitiveness, and a robust regulatory environment. The sector's growth is characterized by a synergy of affordability, regulatory responsiveness, and innovation, establishing Indian CROs as essential partners in global drug development initiatives.

Dr. Mahesh Bhalgat, Group CEO and MD of Veeda Lifesciences emphasizes about India's CROs growth in global clinical trials. He also spoke that Indian CROs are increasingly adopting collaborative business models, forging partnerships with global CROs.

Regulatory Reforms: Building Trust and Efficiency

India's regulatory landscape for clinical research has undergone significant transformation in recent years, creating a highly favourable environment for Contract Research Organizations (CROs):

- **Implementation of NDCT 2019 Rules:** The New Drugs and Clinical Trials (NDCT) Rules, 2019, introduced a transparent and predictable regulatory regime. This has led to expedited approval timelines—30 days for drugs manufactured in India and 90 days for those developed outside the country—making India a more attractive destination for global sponsors.
- **Digitization of Processes:** The digitization of the clinical trial application process has streamlined submissions and improved transparency, reducing administrative bottlenecks and increasing efficiency for both sponsors and CROs.
- **Enhanced Participant Protection:** The regulatory framework now mandates improved compensation for trial participants in the event of death or permanent disability, increasing trust and participation in clinical research.
- **Selective Waivers for Local Trials:** In certain cases, the requirement for local clinical trials has been waived, accelerating the introduction of

Regulatory Reforms & Achievements	Impact on Indian CROs
NDCT 2019 Rules & Fast-Track Approvals	Reduced timelines, increased global interest
Digitization of Application Processes	Greater efficiency, transparency
Improved Compensation for Participants	Enhanced trust, higher recruitment rates
Selective Waivers for Local Trials	Faster market access for new drugs
International Harmonization (ICH-GCP)	Increased credibility, global sponsor appeal
Cost Incentives (Tax/Fees Exemption)	Lower operational costs, competitive pricing
Support for BA/BE, Biosimilars, Generics	Growth in specialized and generic drug trials

innovative therapies, and facilitating international collaboration.

- **Alignment with International Standards:** Indian authorities have taken steps to harmonize approval processes with global benchmarks, including adherence to ICH-GCP (International Council for Harmonisation - Good Clinical Practice) guidelines. This alignment has boosted confidence among multinational sponsors and positioned India as a credible player in the global clinical research arena.

- **Cost Advantages and Incentives:** Regulatory reforms have delivered substantial cost advantages for Indian CROs. The exemption of service taxes and clinical trial fees, combined with a large, skilled workforce available at competitive wage levels, has significantly reduced the overall cost of conducting trials in India compared to Western countries. The introduction of fixed payouts for adverse events has minimized litigation risks, making India a safer and more predictable environment for sponsors and CROs alike.

- **Support for Biosimilars and Generics:** The regulatory framework actively supports the development of biosimilars and generic drugs. The mandatory implementation of Bioavailability/ Bioequivalence (BA/BE) studies for all approved drugs in India is expected to further strengthen the domestic generics market and enhance the capabilities of Indian CROs in this segment.

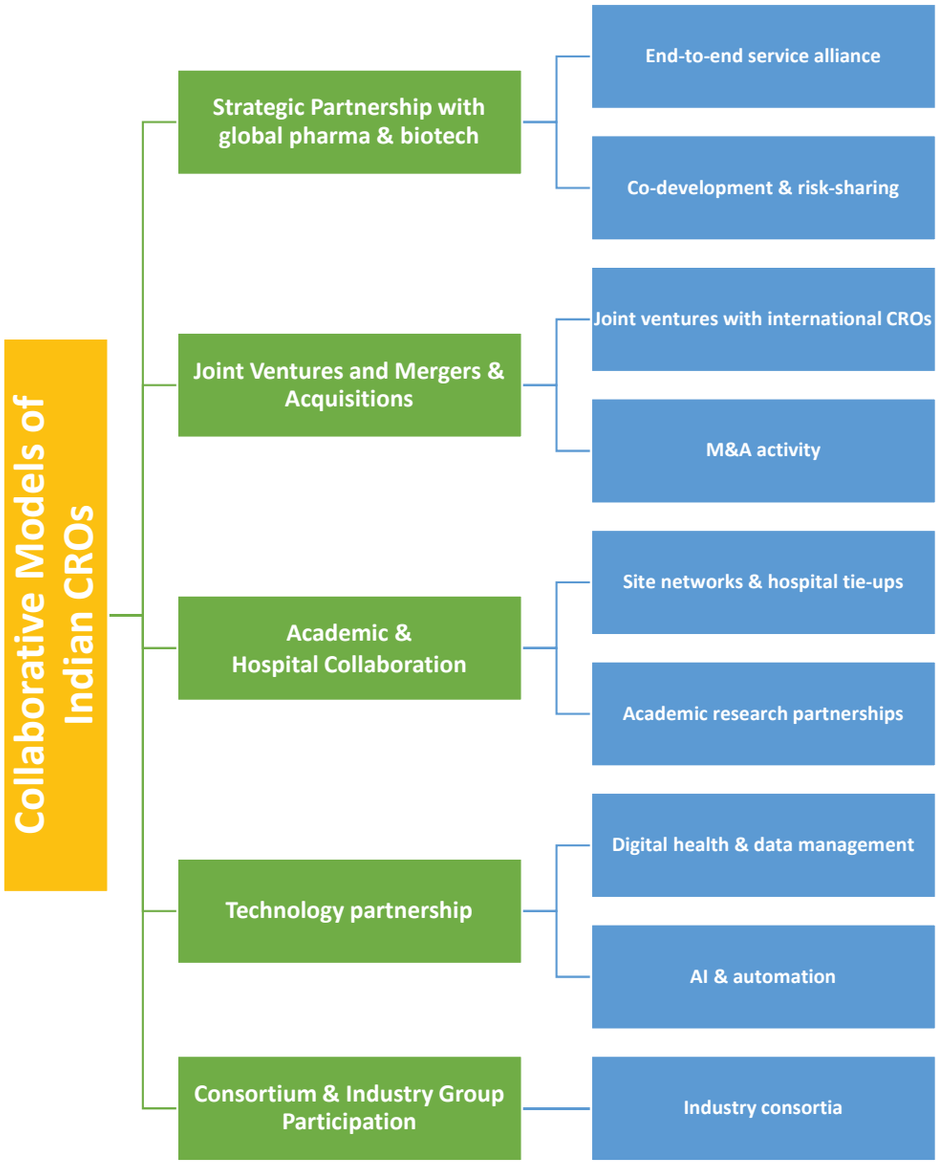
- **Opportunities in Preclinical and Specialized Services:** Indian CROs are increasingly focusing on expanding their service offerings to include preclinical development, toxicology, and specialized services such as bio-analytical testing, pharmacovigilance, and data management. This diversification is supported by regulatory clarity and a growing demand for comprehensive research services.

India's revamped regulatory framework has played a pivotal role in establishing the country as a leading global hub for clinical research. The combination of expedited approvals, international harmonization, cost advantages, and a supportive environment for innovation has not only attracted global sponsors but also empowered Indian CROs to compete effectively on the world stage.

Collaborative Models: Expanding Capabilities and Reach

To address the increasingly complex requirements of global clinical research, Indian Contract Research Organizations (CROs) are actively embracing collaborative and partnership-driven models. This strategic shift is a major driver for the sector's growth and international competitiveness.

- **Access advanced methodologies and global patient populations:** By forming alliances with leading international CROs, pharmaceutical companies, and academic institutions, Indian CROs are able to tap into advanced research



methodologies and technologies. These collaborations facilitate the adoption of best practices in trial design, regulatory compliance, and patient safety.

- **Share expertise and resources to manage multi-country trials:** Strategic partnerships enable Indian CROs to pool expertise and resources, which is essential for managing large-scale, multi-country clinical trials. By sharing operational know-how and logistical capabilities, these collaborations help Indian firms efficiently navigate varying regulatory environments and cultural contexts.

- **Leverage digital platforms for data management and remote monitoring:** The adoption of digital technologies—such as cloud-based data management systems, electronic data capture (EDC), and remote monitoring tools—is accelerating through partnerships with technology providers. These platforms not only streamline data collection and analysis but also support decentralized and virtual trial models, which have become especially important post-pandemic.

- **Integrated Service Offerings: End-to-End Collaboration:** - One of the most significant shifts in the Indian CRO industry has been the move towards integrated, end-to-end service models. Indian CROs now offer a comprehensive suite of services covering the entire drug development value chain—from discovery and preclinical studies to late-phase clinical trials (Phases I-IV), bioavailability/bioequivalence (BA/BE) studies, pharmacovigilance, biostatistics, and central laboratory services. This full-spectrum capability allows global sponsors to streamline their outsourcing needs, reduce vendor management complexity, and accelerate project timelines. Furthermore, the swift adoption of digital technologies—such as electronic data capture

(EDC) and remote monitoring—has significantly improved data quality, transparency, and reduced both costs and timelines.

- **Strategic Partnerships and Global Alliances:** Indian CROs have actively pursued strategic partnerships and alliances with multinational pharmaceutical companies, biotech firms, and academic institutions. These collaborations have enabled knowledge sharing, technology transfer, and access to global best practices. Indian CROs have participated in over 1,000 global clinical trials annually, underscoring their growing role in international projects. Furthermore, mergers and acquisitions have strengthened the capabilities of Indian CROs, allowing them to expand their geographic reach and service portfolios.

The move towards collaborative models is enabling Indian CROs to deliver world-class clinical research services, expand their global footprint, and drive innovation in drug development. These partnerships are not only enhancing operational capabilities but also positioning Indian CROs as integral players in the global clinical research ecosystem. Such collaborations are not only expanding the service offerings of Indian CROs but also enhancing their credibility and competitiveness on the world stage.

Conclusion:

A New era for Indian CROs The Indian CRO industry stands at a pivotal juncture, propelled by a powerful combination of regulatory modernization and strategic collaborations. Recent regulatory reforms—such as the implementation of the NDCT 2019 rules, digitization of approval processes, and alignment with international standards—have dramatically improved the operational landscape for Indian CROs, fostering transparency, efficiency, and global credibility. At the same time, Indian CROs are increasingly adopting collaborative business models, forging partnerships with global CROs, pharmaceutical companies, academic research centers, and technology innovators. These alliances are enabling Indian organizations to access advanced scientific methodologies, manage complex multi-country trials, and leverage cutting-edge digital platforms for data management and remote monitoring. ■

Author

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Turning the Tide: How Indian Pharma Is Redefining USFDA Compliance

The United States Food and Drug Administration (USFDA) continues to play a critical role in ensuring the safety, efficacy, and quality of pharmaceutical products in the U.S. market. In recent years, Indian pharmaceutical companies have come under increased regulatory scrutiny, reflecting the sector's expanding global footprint and operational complexity.

Post-pandemic, USFDA inspection activity has picked up significantly. In calendar year 2024 (CY24), the USFDA conducted over 256 inspections at Indian pharmaceutical facilities, with inspection frequency expected to rise further in CY25. Encouragingly, the share of inspections resulting in Official Action Indicated (OAI) observations has remained low at around 7%, a marked improvement from the 15–20% OAI rates recorded between CY13 and CY17. This sustained reduction highlights Indian pharma's improved focus on cGMP compliance and quality standards.

D. Naveen Kumar and Pulkit Agarwal, CareEdge Ratings remains confident in the continued growth trajectory of the Indian pharmaceutical sector, supported by ongoing investments in R&D, regulatory adherence, and quality enhancement. The sector remains well-positioned to manage evolving regulatory expectations, strengthening India's position as a key player in the global pharmaceutical supply chain.

Inspections/ audit by USFDA:

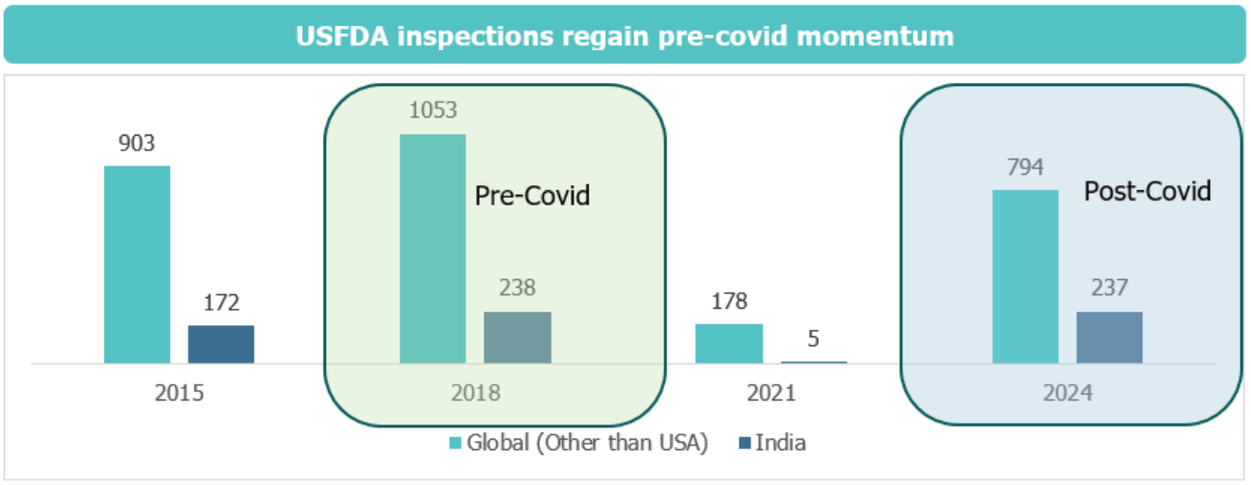
The chart depicts the trend of number of inspections carried out by the USFDA on the international facilities and Indian facilities over the past 10 years

The USFDA has significantly increased its global inspection activities, nearly reaching pre-Covid levels. While inspections outside the U.S. had sharply declined during the pandemic, they have now recovered substantially. In 2018, the USFDA conducted 1,053 inspections globally (excluding the U.S.), including 238 in India. However, pandemic-related restrictions saw this fall to just 178 globally and only 5 in India by 2021.

With the easing of travel restrictions and renewed regulatory focus, 2024 has seen a strong rebound. The USFDA carried out 794 inspections globally (excluding the U.S.), including 237 in India—almost matching pre-pandemic volumes.

The USFDA is also prioritizing inspections of facilities linked to high-priority drugs, complex generics, and injectables. This renewed focus bodes well for Indian pharma, enhancing regulatory visibility and potentially expediting product approvals. However, it also raises compliance expectations, reinforcing the need for stringent quality systems. The current trends align with the global emphasis on strengthening pharmaceutical supply chains and ensuring product safety in regulated markets.

USFDA action against India: Declining share of OAI observations indicates high compliance ratio



Source: USFDA; Compiled by CareEdge Ratings
Note: The inspection data represents the audit by USFDA for drugs and biologics manufacturing facilities.

The frequency of OAI statuses issued by the USFDA on approved pharmaceutical facilities in India has seen a downward trend over time. This suggests a decline in regulatory and/or administrative actions suggested by the USFDA, resulting in accelerated pace of product filing and approvals.

Quality of Inspections: Improvement in Compliance

The classification of observations indicates a consistent reduction in the proportion of Official Action Indicated (OAI) outcomes for Indian sites. From a high of 44% OAI in 2021, the share declined to 7% in 2024, signifying improved preparedness and compliance by Indian facilities during regulatory audits. Favorable trends are also visible in the global context, with the USA and other key geographies like China and Canada maintaining or improving their inspection compliance metrics.

Indian Pharma Well-Positioned to Capitalize on Emerging Opportunities

With the resurgence of USFDA inspections, there is a strategic focus on facilities linked to priority review products, injectables, complex generics, and critical supply chain elements. This approach aligns with global efforts to address drug shortages and enhance supply chain resilience post-pandemic. For India—currently supplying nearly 40% of generic drugs to the U.S.—this presents a dual scenario: opportunities to strengthen its global position, alongside the challenge of navigating heightened regulatory scrutiny.

In response to evolving regulatory expectations, particularly around data integrity, aseptic processing, and complex injectable manufacturing, Indian pharmaceutical companies are stepping up investments in compliance upgrades, automation, and digital quality systems. Additionally, the increased

Number of inspections carried out by USFDA

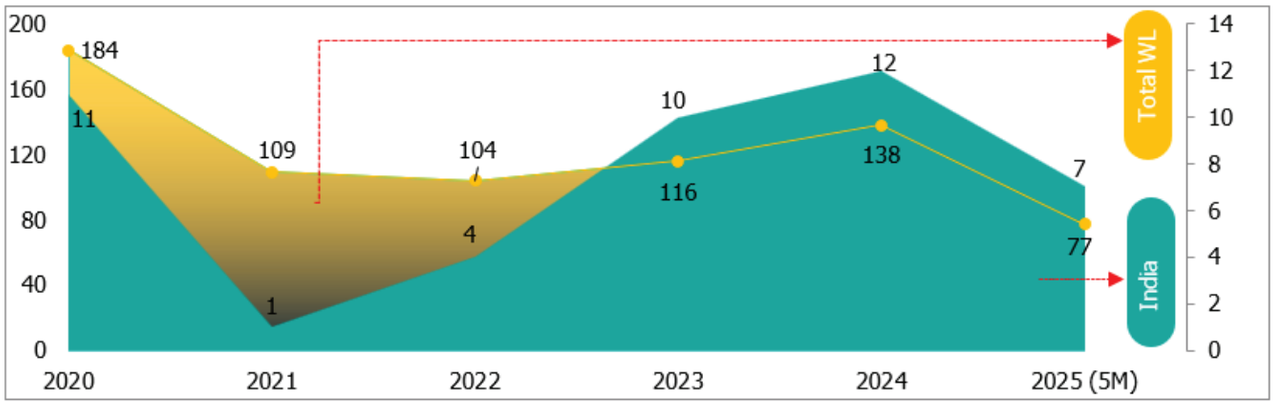
	2018	2019	2020	2021	2022	2023	2024
USA	3503	3330	1269	2157	3555	2625	963
India	286	346	103	20	108	220	256
China	123	127	4	17	5	58	142
Canada	52	87	21	5	42	63	57
Germany	72	74	43	34	58	39	27
Italy	81	73	7	18	58	36	25

Source: USFDA; Compiled by CareEdge Ratings

Classification of observations made by USFDA								
Country		**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**
USA	VAI+NAI	97%	96%	97%	93%	96%	97%	91%
	OAI	3%	4%	3%	7%	4%	3%	9%
India	VAI+NAI	92%	91%	91%	56%	86%	90%	93%
	OAI	8%	9%	9%	44%	14%	10%	7%
China	VAI+NAI	89%	84%	100%	82%	60%	90%	93%
	OAI	11%	16%	0%	18%	40%	10%	7%
Canada	VAI+NAI	90%	98%	86%	80%	88%	97%	93%
	OAI	10%	2%	14%	20%	12%	3%	7%
Germany	VAI+NAI	100%	99%	100%	100%	98%	100%	100%
	OAI	0%	1%	0%	0%	2%	0%	0%
Italy	VAI+NAI	99%	99%	100%	100%	100%	100%	88%
	OAI	1%	1%	0%	0%	0%	0%	12%

VAI:Voluntary Action Indicated NAI:No Action Indicated OAI:Official Action Indicated

Number of Warning letters (WL) issued by USFDA to India



Source: USFDA; Compiled by CareEdge Ratings

attention on contract manufacturing organizations (CMOs) by the USFDA has direct implications for Indian firms engaged in third-party and outsourcing models.

Overall, the positive trend in inspection outcomes and a decline in warning letters reflect the growing regulatory maturity of the Indian pharmaceutical sector. However, sustaining this progress will require continued investment in compliance and proactive alignment with evolving regulatory standards.

Nature of USFDA Observations for Indian Pharma Companies:

Based on the observations provided by USFDA in its warning letters to Indian pharma companies during CY2022 to 5M2025, CareEdge Ratings has categorized them into following various categories

An analysis of observations made by USFDA in its Warning Letters (WLs) issued to Indian pharmaceutical companies between 2022 and May 2025 reveals that quality lapses and documentation deficiencies remain key areas of concern. Of the 33 WLs issued during this period, the primary reasons were Failure to Maintain Quality and Purity (24%), Lack of Data Documentation Discipline (21%), and Poor Hygiene (21%). While data integrity concerns, once a major issue, accounted for only 6%, compliance lapses (15%) and inadequate deviation investigations (9%) were also notable contributors.

Classification of Observations	2022	2023	2024	5M2025	Total	% Share
Data Manipulation/Data integrity	-	-	-	2	2	6%
Lack of data documentation discipline	1	1	4	1	7	21%
Failure to Maintain Quality and Purity	1	4	2	1	8	24%
Inadequate investigation of critical deviations or a failure	0	2	1	-	3	9%
Lack of procedural awareness	0	1	-	-	1	3%
Lack of hygiene	1	1	4	1	7	21%
Compliance	1	1	1	2	5	15%
Grand Total	4	10	12	7	33	100%

Source: USFDA and compiled by CareEdge Ratings

A significant trend is that most recent WLs have been issued to small and mid-sized companies, many of which face resource constraints in meeting evolving cGMP standards. Challenges around documentation, quality assurance, and procedural discipline continue to expose gaps in compliance.

With the USFDA intensifying its focus on data integrity, risk-based quality management, and environmental monitoring—particularly for sterile facilities and complex generics—larger Indian pharma players have largely strengthened compliance. However, smaller firms will need to increase investments in systems, automation, and workforce training to mitigate regulatory risks.

The shifting regulatory environment highlights that compliance is no longer just a regulatory requirement but a strategic imperative for sustaining growth in global markets.

Conclusion

The resurgence of USFDA inspections to near pre-pandemic levels, coupled with a decline in adverse regulatory actions against Indian pharmaceutical facilities, highlights the sector's increasing regulatory maturity. India's role as a major supplier of generics to the U.S. has been further strengthened by consistent advancements in compliance systems, quality assurance, and operational discipline.

With the USFDA sharpening its focus on high-value segments such as complex generics, injectables, and critical supply chain components, Indian pharmaceutical companies are well-positioned to leverage emerging global opportunities. However, sustained investments in technology, talent, and proactive regulatory engagement will be critical. Going forward, regulatory compliance will not just be an obligation—but a strategic pillar for growth, competitiveness, and long-term sustainability in global markets. ■

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Streamlining Compliance within Indian R&D Labs

The evolving compliance landscape presents a constant challenge for Indian research labs. Aligning with international standards such as the U.S. Food and Drug Administration (USFDA) Code of Federal Regulations Part 11 can boost research credibility and enhance export readiness. To help meet regulatory challenges, labs are switching to Electronic Lab Notebooks and Lab Information Management solutions, looking to unlock efficiency, productivity and opportunity.

Chris Stumpf, Director, Drug Discovery Informatics Solutions, Revvity Signals emphasize that Indian labs aiming to supply drug products to regulated markets are increasingly implementing compliant digital infrastructure.

For Indian research laboratories in regulated industries such as pharmaceuticals, biotechnology and chemicals, the compliance landscape is undergoing a major shift, driven by updated regulatory frameworks.

For example, the New Drugs and Clinical Trials (NDCT) Rules 2019 aims to streamline clinical trial approvals and align India's practices more closely with international standards. The introduction of NDCT has been fueled by the elevation in India's standing as a global research collaborator. The data shows that there were more than 200 global clinical trials during 2023 involving Indian research organizations.

As Indian laboratories continue to integrate more closely with the global research sector and gain greater market share, regulators are ramping up their scrutiny. Oversight is growing from both domestic agencies such as Bureau of Indian Standards (BIS) and Central Drugs Standard Control Organization (CDSCO), and from international authorities such as the European Medicines Agency (EMA) and US Food and Drug Administration (FDA).

To align with global standards such as GLP, GMP and data integrity guidelines, research organizations are asked to prove that they possess robust and secure electronic record keeping systems, in line with the FDA's Code of Federal Regulations (CFR) Part 11. The regulation sets out the criteria for creating, modifying, maintaining, archiving and retrieving of electronic data, to ensure that it is credible, traceable and export-ready.

Pitfalls and Problems on the compliance journey

Traditional research environments often grapple with enduring compliance challenges arising from outdated data management practices. Many labs rely on manual data recording with fragmented information residing across departments, often in varying formats and isolated in specialized systems. Similarly, paper-based and hybrid records are prone to missing entries and unauthorized data changes. In both cases, retrieving, validating and using data can be a taxing, slow and frustrating task.

The inconsistencies in data integrity coupled with lack of traceability mean that many research labs fail to comply with regulatory audits. Inevitably this causes delays in product development and increases the time to market. To help drive adoption of GLP and GMP guidelines, the trend is towards centralized, standardized data management. Lab Information Management Systems (LIMS) and Electronic Lab Notebooks (ELNs) are now

almost baseline requirements for modern research, and establishing the foundations of compliance readiness through automation and real-time data, combined with enterprise-level security controls and data verification.

Alignment with global standards

Essentially, CFR Part 11 sets out the use of electronic records and signatures in select industries, particularly for those regulated by the U.S. Food and Drug Administration. The aim is to establish standards for authenticity and data integrity, which provide the equivalent of a paper trail in the electronic domain. While the FDA is a U.S. organization, in effect the CFR Part 11 rules establish the global standards.

Adopting a modern ELN will help to streamline documentation and processes, and the key to the selection is being able to fulfill the core criteria of CFR Part 11. The main requirements include access controls, audit trails, system validation, electronic signatures, system security, record protection and documentation for all systems involved in processing the electronic data.

For Indian companies seeking global reach, meeting CFR Part 11 standards is an entry qualification that must be achieved, and the only practical way is to ensure that the selected LIMS and ELN solutions offer suitable compliance-ready technical controls.

Indian labs aiming to supply drug products to regulated markets are increasingly implementing compliant digital infrastructure to meet expectations and this is only expected to grow. Available data indicates India is projected to have the highest annual compound growth rate (CAGR) in ELN adoption globally between 2025 and 2030, reflecting its rapid digital transformation.

With these adoption rates, Indian R&D pharmaceutical, biotechnology and chemical sectors are benefiting from a transformative business impact. With enhanced operational processes, the sector is better equipped to gain global market share. Over time, incorporating digital platforms will demonstrate to potential customers that Indian R&D labs have very strong relationships with global regulatory bodies, creating increased opportunities for collaboration and innovation.

Reaching out to new markets

As India works to enhance its position as a global R&D and manufacturing hub, alignment with international regulations such as 21 CFR Part 11 is clearly a strategic necessity for credibility, market access and innovation.

While adopting LIMS and ELN solutions do not instantly deliver regulatory compliance, they offer the essential digital capabilities that enable the critical workflows, processes and standards. Investing in compliance-ready capable electronic solutions and platforms with a strong global track record of success is the first step towards creating a streamlined organization that can comply with complex global regulations while simultaneously leading to the next phase of innovation and growth. ■

Author

Chris Stumpf
Director, Drug Discovery Informatics Solutions, Revvity Signals

Smarter Water: Reinventing Clean Utility Operations with Remote Monitoring

In pharmaceutical manufacturing, water is rarely the headline act. Yet at some of India's leading pharmaceutical organizations, water system management is becoming a key pillar of digital transformation – with predictive intelligence, operational agility, and environmental stewardship.

Shoeb Kurawadwala, Founder & Managing Director, CN Water emphasizes that select set of pharmaceutical organizations are fundamentally transforming how they monitor, maintain, and optimize their purified water systems using the company's remote monitoring platform. They are turning reactive clean utility management into a r**eal-time, intelligent system** that now helps drive uptime, compliance, and sustainability across its operations.

Remote Monitoring Solution with CN Water

One global pharmaceutical manufacturer, operating multiple production lines through isolated SCADA environments, found itself at an inflection point. Their water systems, though robust, were fragmented and increasingly difficult to manage amid rising regulatory scrutiny, data demands, and operational complexity. They needed was the ability to respond early, using predictive maintenance and seamless data visibility — something that traditional SCADA systems alone could not deliver.

The company worked closely with CN Water to design and implement a centralized, SCADA-driven architecture that brought multiple water systems under a unified digital layer. It leveraged CN Water's expertise to deliver a robust, cloud-enabled remote monitoring solution. It combined IoT, cloud platforms, and service orchestration to modernize one of the most foundational yet overlooked systems in the plant — purified water.

Real-time Visibility Drives Proactive Plant Management

The new system redefines how teams interact with water operations on the ground. Before the upgrade, operations teams grappled with common industry issues – sudden equipment failures, fragmented data, and delayed root cause analysis. The shift to a centralized, intelligent remote monitoring platform dramatically changed this dynamic. Operations teams can now receive daily digital reports which included alarms, system status anomalies, and key trends. This helps accelerate time-to-resolutions, reduce unscheduled downtime, and enable proactive site interventions. They also received monthly reports for preventive maintenance – enabling field engineers to spend less time in data collection and more time in addressing root causes.

Scalable, Sustainable, Intelligence-Driven Solutions

This shift has already delivered significant results. Within months of deployment, numerous distinct system-level insights were uncovered. From loop starvation events to EDI valve malfunctions, the system surfaced previously hidden inefficiencies and enabled early intervention.

An integrated CN Account system played a central role in this transformation. The water operations team can now connect directly to pre-configured workflows for service dispatch, spare part requests, maintenance schedules, and documentation updates. The approach not only strengthened daily operations but also helped drive smarter decisions— that helped raise water quality and reduce energy use. In addition, the integration with CN Account improved the operations team's audit readiness, by maintaining a consistent, traceable log of KPIs, deviations, and maintenance actions.

These outcomes show that sustainability is not a separate objective—it's a natural result of smarter, connected systems. With the right digital tools and strategic partnerships, clean utility infrastructure can shift from a background function to a powerful engine of efficiency, compliance, and sustainability. ■

Author

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Founder & Managing Director
CN Water

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Regular features will include 'Interviews' with the industry leaders, 'Industry News' from across the globe, **'Technical Articles & Case Studies'** by subject matter experts.

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Industry AUTOMATION & Control 2026
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WaterEX WORLD EXPO 2026
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Student Outreach Program 2026 Develop Future Leaders

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- 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 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

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

FACT & FIGURES 2024

- 750 EXHIBITORS FROM 15+ COUNTRIES
- 25871 VISITORS FROM 53 COUNTRIES
- SCALE@ CHEMTECH World Expo 2024: 60+ GLOBAL CLIMATE TECH STARTUPS FROM 20 COUNTRIES; 40 TECHNICAL PRESENTATIONS
- 8 TECHNICAL CONFERENCES
- 1500+ BUSINESS DELEGATES
- 250+ GLOBAL SPEAKERS
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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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