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Donald Trump to introduce major tariff on pharmaceutical imports

Mumbai, India: President Donald Trump stated that the U.S. is planning to introduce a "major" tariff on pharmaceutical imports. Trump also announced a 90-day pause on nearly all tariffs.

Earlier, Trump administration had exempted pharmaceuticals from the new reciprocal tariffs rule.

"Some goods will not be subject to the Reciprocal Tariff. These include: (1) articles subject to 50 USC 1702(b) and pharmaceuticals," the White House said in a factsheet.

India is the largest provider of generic drugs globally and is known for its affordable vaccines and generic medications, according to India Brand Equity Foundation. Indian pharmaceutical sector supplies over 50% of global demand for various vaccines, 40% of generic demand in the US.

India and the U.S. share a strong and growing bilateral trade relationship, with a shared vision to double trade to USD 500 billion under the Mission 500 initiative, according to Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA)

Jain stated that Pharmaceuticals remain a cornerstone of this partnership, as India plays a vital role in global and U.S. healthcare by ensuring a steady supply of affordable medicines. Pharmaceuticals have been exempted from tariffs. The decision underscores the critical role of cost-effective, life-saving generic medicines in public health, economic stability, and national security.

The Indian pharmaceutical industry is committed to advancing the shared priorities of both nations: strengthening medicine supply chain resilience and reinforcing national security by ensuring access to affordable medicines for all.

Bhavin Mukund Mehta, Vice-Chairman of Pharmexcil and Whole-Time Director of Kilitch Drugs Ltd stated, "As India evaluates the impact of reduced tariffs, we recognize the pharmaceutical sector as the clear winner. With India importing $800 million worth of pharmaceutical products from the U.S. and exporting $8.7 billion, the strong trade ties between the two countries create a powerful win-win scenario. This shift drives significant cost savings on life-saving medicines and also positions Indian exporters to gain a competitive edge over their Asian counterparts, further strengthening India's leadership in the global pharmaceutical market."

Dr. Jitendra Singh and Bill Gates discuss Biotech Collaboration

Union Minister Dr. Jitendra Singh (L) and Microsoft Co-Founder, Bill Gates

New Delhi, India: In a significant step towards strengthening technology driven collaboration, Microsoft co-founder and philanthropist Bill Gates, currently on India visit, called on Union Minister Dr. Jitendra Singh and held detailed discussions to expand private sector and StartUp participation in India's innovation push and biomanufacturing surge.

The meeting, assisted by delegations from both sides, covered advancement in gene therapy, vaccine innovation, biotechnology manufacturing, and India's evolving startup ecosystem.

Dr. Jitendra Singh emphasized that under Prime Minister Narendra Modi, India has witnessed a surge in biotech innovations, supported by policies like Bio E3—biotechnology for economy, employment, and environment. He highlighted the growing role of private players and startups in driving India's bio-revolution, with structured mechanisms like the Biotechnology Industry Research Assistance Council (BIRAC) fostering collaborations.

Bill Gates praised India's biotech advancements, acknowledging its leadership in vaccine development, including partnerships that led to the HPV and COVID-19 vaccines. He also expressed interest in supporting India's efforts in tackling diseases like tuberculosis and malaria, stating that India's research ecosystem presents immense opportunities for global health breakthroughs.

A key topic of discussion was India's biotechnology startup boom, with over 10,000 startups now operating in the sector. Dr. Jitendra Singh pointed out that 70% of these are focused on medical and health biotech, with the rest contributing to agriculture, environment,

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and industrial biotechnology. He underlined the government's commitment to scaling up these innovations, with increased funding and policy measures aimed at enabling faster commercialization.

CSIR-IIIM & HAPICO Industries sign MoU for Collaborative Biopesticide Development

Director CSIR-IIIM, Dr Zabeer Ahmed and MD HAPICO Industries

New Delhi, India: In a significant step toward fostering industry-academia collaboration, the CSIR - Indian Institute of Integrative Medicine (CSIR-IIIM), Jammu, signed a Memorandum of Understanding (MoU) with M/S HAPICO Industries Private Limited on 20 March 2025 to jointly develop novel biopesticides.

The MoU was formally signed by Dr Zabeer Ahmed, Director, CSIR-IIIM, and Mr. Shabeer Ahmed, Managing Director, HAPICO Industries, in the presence of Dr Asha Chaubey, Senior Principal Scientist & Head, FMB Division; Dr Saurabh Saran, Principal Scientist, FMB; and Dr Love Sharma, Scientist, RMBD&IST.

This strategic partnership aims to address the detrimental impact of chemical pesticides on human health and the environment. The collaboration seeks to harness their potential for developing innovative and sustainable biopesticide solutions.

Speaking on the occasion, Dr Zabeer Ahmed reaffirmed the commitment of CSIR-IIIM to the translational and sustainable approach in biopesticide development and providing industrial interface to the technologies emanating from the collaboration, ensuring direct benefits for farmers across the country.

CSIR-IIIM, with its advanced fermentation and microbial technology infrastructure, has been actively engaged in research pursuits and development of agricultural solutions, including plant growth-promoting products, Active Pharmaceutical Ingredients (APIs), enzymes and biocontrol formulations.

Shabeer Ahmed, Managing Director, HAPICO Industries, highlighted the collaboration as a strategic initiative to expand the company's product portfolio and contribute to sectoral growth.

The agreement signing ceremony was jointly organized by the RMBD&IST and FMB Divisions, under the overall supervision of Er Abdul Rahim, Head, RMBD&IST Division, and under the patronage of the Director, CSIR-IIIM, Jammu.

Department of Pharmaceuticals hosts Industry Dialogue on Promotion of Research and Innovation in Pharma-MedTech Sector

Amit Agrawal, Secretary, Department of Pharmaceuticals

New Delhi, India: The Department of Pharmaceuticals, Government of India, hosted an Industry Dialogue on the scheme for Promotion of Research and Innovation in the Pharma-MedTech Sector (PRIP) at Bangalore on 25th March 2025. The event served as a significant platform for representatives from industry, startups, and research institutes, including representatives from the Indian Council for Medical Research (ICMR), Council of Scientific and Industrial Research (CSIR), and innovation hubs like C-CAMP (Centre for Cellular and Molecular Platforms), to engage in discussions aimed at fostering collaboration, and leveraging government initiatives to accelerate research and development (R&D) in the pharmaceutical and MedTech sectors.

The session provided detailed insights into the PRIP Scheme, along with other government initiatives promoting and enabling research innovation in the sector. Notable initiatives such as ICMR's Patent Mitra, MedTech Mitra, and Indian Clinical Trial and Education Network (INTENT) programme were discussed, with an emphasis on support for patent filing, facilitating the innovation journey, clinical trials, and commercialization of R&D outcomes. The CSIR's Innovation Complex and C-CAMP's incubation facilities were also highlighted as key enablers for translational research and industry collaboration.

Amit Agrawal, Secretary of the Department of Pharmaceuticals, underscored India's comparative advantage in enhancing the resilience of global supply chains, a goal further supported by the PRIP Scheme. He advocated progression from "Make in India" also Innovate in India and Make for the World aiming to position the country as a global leader in innovation and manufacturing for the world.

Cipla signs multi-regional licensing deal with Formosa Pharmaceuticals

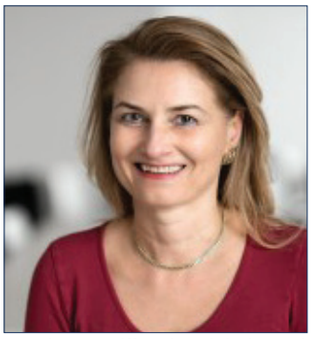
INDIA/TAIPEI: Cipla Limited announced an exclusive licensing agreement with Taiwan-based Formosa Pharmaceuticals (6838.TW) for the commercialization of clobetasol propionate ophthalmic suspension, 0.05% (APP13007). Under this agreement, Cipla has exclusive rights to market the innovative treatment for post-operative inflammation and pain following ocular surgery across 11 countries such as India, South Africa, Nepal, Sri Lanka, Bangladesh, Malaysia, Myanmar, Kenya, Nigeria, Argentina, and Colombia.

APP13007 is a novel, patent protected and USFDA approved ophthalmic product. It offers a convenient twice-daily dosing regimen for 14 days without tapering, providing rapid and sustained relief from inflammation and pain. This new steroid represents a significant advancement in the ophthalmic market, extending notable patient benefits.

Achin Gupta, Global Chief Operating Officer, Cipla said, "The partnership with Formosa Pharmaceuticals marks a significant milestone for Cipla, as it is our first multi-regional licensing agreement in ophthalmology. It reinforces our commitment to bringing cutting-edge treatments to patients worldwide. With exclusive rights to market APP13007 across 11 countries, we are excited to expand access to this innovative therapy and strengthen our ophthalmology portfolio. We look forward to leveraging Cipla's strong commercial presence to make a meaningful impact in post-operative eye care."

"Formosa Pharma welcomes this partnership with Cipla, a well-renowned and respected global pharmaceutical brand. We appreciate their recognition and desire to add APP13007 to their rich portfolio of innovative medicines and look forward to working together to provide our novel therapy to ocular surgery patients to their audience." said Erick Co, President and CEO of Formosa Pharmaceuticals.

Biocon Biologics announces Positive Results from Phase 3 Study of Yesintek Biosimilar to Ustekinumab for Chronic Plaque Psoriasis



Dr. Elena Wolff-Holz, Global Head Clinical Development

BENGALURU, Karnataka, India: Biocon Biologics Ltd. (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd. announced the successful results of a pivotal Phase 3, randomized, double-blind, parallel group, multicenter study comparing Yesintek (Biocon Biologics' biosimilar to Ustekinumab, called YESINTEK) with reference product Stelara (Ustekinumab) in adult patients with moderate to severe chronic plaque psoriasis (PsO). The data are being presented at the 2025 American Academy of Dermatology (AAD) Annual Meeting in Orlando, Florida.

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

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

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

Lupin acquires Renascience in UK

Fabrice Egros, President Corporate Development, Lupin

Berkshire, UK: Lupin Healthcare (UK) Limited, the wholly owned subsidiary of global pharma major Lupin Limited announced today the acquisition of Renascience Pharma Limited (Renascience), a UK-based pharmaceutical company and sole supplier of 4 specialty products targeting unmet medical needs in the UK.

With this acquisition, Lupin Healthcare (UK) Limited gains full ownership of Renascience which, going forward, will trade as its subsidiary. The portfolio includes branded injectable cephalosporines for infectious diseases, a topical treatment for ear pain and a branded quinazoline-like diuretic for cardiovascular and renal indications.

Commenting on the acquisition, Fabrice Egros, President Corporate Development, Lupin said, "In recent years Lupin has established a highly successful branded business in the UK delivering significant value to patients and the NHS (National Health Service). This strategic move allows Lupin to further enhance our branded medicine portfolio, catering to unmet medical needs and furthering our mission to provide accessible and sustainable healthcare solutions."

Co-founder & Director of Renascience, Eric Che commented, "Renascience was founded with the goal to improve patient access to speciality, critical medicines and we are extremely proud of what we have been able to revive to date for the benefit of patients. As we looked forward to the future, it was deeply important that Renascience has the best opportunity to build on what has been accomplished and expand its reach to improve outcomes for as many patients as possible, and we are pleased to have found that opportunity with Lupin.

Glenmark receives ANDA approval for Olopatadine Hydrochloride Ophthalmic Solution

Mahwah, New Jersey: Glenmark Pharmaceuticals Inc., USA has received final approval by the United States Food & Drug Administration (U.S. FDA) for Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (OTC), determined by the FDA to be bioequivalent to Pataday Once Daily Relief Ophthalmic Solution, 0.2% (OTC), of Alcon Laboratories, Inc.

Olopatadine Hydrochloride Ophthalmic Solution USP, 0.2% (OTC), will be distributed in the U.S. by Glenmark Therapeutics Inc., USA.

According to Nielsen syndicated data for the latest 52 weeks' period ending February 22, 2025, the Pataday Once Daily Relief Ophthalmic Solution, 0.2% (OTC) market3 achieved annual sales of approximately $50.7 million*.

Commenting on the launch, Marc Kikuchi, President & Business Head, North America said, "We are pleased to continue to expand our OTC ophthalmic portfolio. The addition of OlopatadineHydrochloride Ophthalmic Solution USP, 0.2% highlights our commitment to meeting market needs and providing quality over-the-counter solutions for our customers."

Bharat Biotech launches Cell and Gene Therapy, Viral Production Facility at Genome Valley

Dr. Krishna Ella, Executive Chairman, Bharat Biotech

Hyderabad, India: Bharat Biotech International Limited (BBIL), a pioneer in affordable indigenous vaccine development and manufacturing, announced its foray into Cell & Gene Therapy (CGT) & Viral Vector Production at Genome Valley - expanding its expertise from vaccine innovation to leading-edge regenerative and personalised therapies that promise hope for millions. This ushers in a new era of gene and cell therapies to tackle scientific challenges—such as targeted gene expression, immune system modulation, and long-term cell survival— The work will span from boosting immune responses against cancer

to ensuring that therapeutic proteins are safely accepted in patients with genetic diseases like hemophilia.

The 50,000-square-foot dedicated state-of-the-art CGT facility represents the next milestone in BBIL's longstanding mission to deliver targeted, life-saving treatments that address unmet clinical needs globally by concentrating on critical conditions such as hematological malignancies and inherited blood disorders.

Dr. Krishna Ella, Executive Chairman, Bharat Biotech said, "Bharat Biotech, with its extensive experience and proven excellence in viral vaccine manufacturing is uniquely positioned to master these complexities and produce human-grade vectors at the scale and consistency needed for clinical trials, thus advancing the global fight against rare and complex diseases."

Dr. Raches Ella, Chief Development Officer, Bharat Biotech, spearheading this CGT initiative, said, "Bharat aims to democratize gene therapies, traditionally considered prohibitively expensive and available primarily in developed nations or premium institutions. Our established expertise in producing viral vectors are essential for cell and gene therapy applications - the crucial material for anti-cancer and genetic disorders and robust clinical development abilities for QC release."

Sun Pharma introduces a novel class of drug, Fexuclue (Fexuprazan) in India

Mumbai, India: Sun Pharmaceutical Industries Limited announced that it has launched Fexuprazan tablets 40 mg in India under the brand name "FEXUCLUE®". FEXUCLUE®, a novel potassiumcompetitive acid blocker (PCAB), is approved as a new treatment for adults with Erosive Esophagitis of all grades.

Sun Pharma has obtained rights from Daewoong Pharmaceutical Co Ltd, Korea, a biopharmaceutical company, to manufacture and commercialise FEXUCLUE®(Fexuprazan) in India. As per agreement terms, Daewoong will be entitled to upfront and milestone payments, including royalties.

Kirti Ganorkar, CEO – India Business, Sun Pharma, said, "Erosive Esophagitis is a serious condition that greatly affects patients' quality of life. Despite available treatments, there remains a significant unmet need in its management. FEXUCLUE® is a best-in-class treatment option with the potential to bridge this gap. At Sun Pharma, we are committed to introducing innovative medicines that enhance patients' quality of life."

Fexuprazan was evaluated in a double-blind, double-dummy, comparative Phase 3 study in adult Indian population. The primary efficacy measure was healing of Erosive Esophagitis which was confirmed endoscopically. The study met its primary endpoint. Over 95% of the patients achieved

Erosive Esophagitis healing by 8 weeks. Fexuprazan was found to be well tolerated in Indian patients.

Home Minister Amit Shah applauds Arjun Deshpande for revolutionizing affordable healthcare in India

New Delhi, India: 22-year-old Arjun Deshpande, the founder and CEO of Generic Aadhaar, was appreciated by Shri Amit Shah, Hon'ble Home Minister of India, for his contributions towards making medicines affordable and accessible to 143 crore Indian citizens. The recognition marks a significant milestone in Arjun's journey to revolutionize the pharmaceutical industry and ensure that quality healthcare reaches every Indian at significantly reduced costs.

This appreciation by Shri Amit Shah, Hon'ble Home Minister, is a testament to Arjun's dedication and a significant step forward in realizing, especially those suffering from chronic ailments like diabetes and cancer.

Arjun Deshpande, Founder and CEO of Generic Aadhaar, said, "It is an honor to be recognized by Hon'ble Home Minister Shri Amit Shah Ji for our work in revolutionizing healthcare. Meeting him and receiving his encouragement further strengthens my commitment to making medicines affordable for every Indian. Amit Shah Ji also aligns with my mentor Shri Ratan Tata Ji's vision that every Indian should have access to affordable medicines. This is not just an appreciation for me, but a boost for all young entrepreneurs of India to contribute towards realizing Prime Minister Narendra Modi Ji's vision of a USD 5 trillion economy. This recognition fuels my passion to ensure that no Indian is deprived of essential medicines."

Arjun's mission with Generic Aadhaar has not only transformed the way medicines are distributed and priced in India but has also created opportunities for thousands of small entrepreneurs, making healthcare more accessible across urban and rural areas alike.

This appreciation by Shri Amit Shah, Hon'ble Home Minister, is a testament to Arjun's dedication and a significant step forward in realizing the dream of an affordable and self-reliant healthcare system in India.

Cadila Pharmaceuticals launches Cadilose for constipation and hepatic encephalopathy

Ahmedabad, India: Cadila Pharmaceuticals, a pioneer in healthcare innovation, has launched Cadilose, an advanced Lactulose formulation designed to effectively manage constipation and hepatic encephalopathy (HE). The latest addition to its gastrointestinal portfolio reaffirms the company's commitment to advancing patient care and improving quality of life through pharmaceutical innovation.

Cadilose is a disaccharide-based osmotic laxative, synthesised from galactose and fructose, which increases water retention in the intestines and promotes smooth bowel movements. It also functions as a prebiotic, encouraging the growth of beneficial gut bacteria.

Lactulose is US FDA-approved and has long been recognised as a treatment for chronic constipation and hepatic encephalopathy, a severe complication of liver disease, including cirrhosis. By lowering colonic pH and reducing ammonia absorption, Cadilose helps prevent cognitive impairment associated with HE and supports overall gastrointestinal health.

Developed with patient comfort in mind, Cadilose offers a range of benefits to enhance compliance, including a pleasant lemon flavour for improved palatability, strain-free evacuation, a non-habit-forming formula, and a sugar-free composition suitable for individuals with dietary restrictions. These features make it an ideal choice for long-term management of digestive health.

Cadilose reaches the large intestine in its unchanged form, where it is broken down by colonic bacteria into short-chain fatty acids. This process leads to a reduction in colonic pH, thereby minimising ammonia absorption. The increased osmotic pressure stimulates peristalsis, promoting water retention and aiding the effective clearance of hardened stools.

Cadilose reflects Cadila Pharmaceuticals' commitment to delivering innovative and accessible healthcare solutions. By addressing critical patient needs in gastrointestinal and hepatic health, the company continues to pursue its mission of improving lives worldwide.

SPARC announces submission of IND Application for SBO-154 to USFDA

Mumbai, India: Sun Pharma Advanced Research Company Ltd announced submission of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA).

The IND application supports the next phase of development of SBO-154 which has completed the required IND-enabling preclinical studies with favorable results. A global phase 1 dose-escalation and expansion study has been planned to evaluate SBO-154 in treatment of solid tumors.

"SBO-154, our first ADC is ready to advance in phase 1 with this IND submission, and this is an important milestone for SPARC as we hope to improve lives of cancer patients globally." said Anil Raghavan, CEO of SPARC.

AdjuTec Pharma and Venus Remedies initiate Research Collaboration to evaluate APC-148 against AMR

Mumbai,India: AdjuTec Pharma AS, a privately held company developing antibiotic resistance breakers, today announces that it has entered into a research collaboration agreement with Venus Remedies Limited (India). Venus Remedies Limited will perform a pre-clinical evaluation of AdjuTec Pharma´s APC-148 platform technology.

AdjuTec Pharma has developed novel inhibitor technologies that selectively destroy antibiotic resistance mechanisms in multidrug-resistant bacteria, thereby restoring the effectiveness of commercially available antibiotics. APC-148 is the lead program, that is presently in phase 1 clinical trials. As a frontrunner in antimicrobial resistance (AMR) research, Venus Remedies Limited will leverage its advanced R&D capabilities to assess APC-148's potential in restoring the effectiveness of antibiotics against multidrug-resistant bacterial strains.

As part of this engagement, Venus Remedies Limited will test APC-148 in combination with various antibiotics against its extensive library of clinical isolates collected through the GASAR study. The study forms part of Venus Remedies' broader commitment to combating AMR and contributing to the UN's 'One Health' objective.

AdjuTec Pharma and Venus Remedies Limited share a joint mission to address the global health threat against AMR. AMR directly causes 1.3 million global

deaths annually and is projected to cause 39 million accumulated global deaths by 2050. If left unchecked, AMR could surpass cancer as the leading cause of mortality.

AdjuTec Pharma AS, CEO, Jethro Holter said: "We are delighted to collaborate with Venus Remedies, a renowned Indian Company, with a share purpose and commitment to develop more effective antibiotics to combat the escalating global AMR crisis."

Saransh Chaudhary, President, Global Critical Care, Venus Remedies, and CEO, Venus Medicine Research Centre said: "We are pleased to collaborate with AdjuTec Pharma on the preclinical evaluation of APC-148. Our collaboration reflects a shared commitment to addressing the global AMR challenge through rigorous, innovation-driven research."

Morepen secures Loratadine approval for export to China

New Delhi, India: Morepen Laboratories Limited, a global leader in Active Pharmaceutical Ingredient (API) manufacturing, has received approval from the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China for its Loratadine (anti-allergy API).


Kushal Suri, Director – Sales & Marketing, Morepen Laboratories

Morepen commands an over 80% market share in the US generics market for Loratadine, making it the undisputed leader in its category. The company has been exporting to the US market for over 25 years, its API exports alone are valued at Rs.650 crores. This approval further solidifies Morepen's position as the dominant global manufacturer of Loratadine, a widely prescribed second-generation antihistamine and anti-allergy drug used to treat allergic symptoms such as hay fever and chronic urticaria. With this development, Morepen is poised to capture a significant share of the Chinese market while reinforcing its standing in the global pharmaceutical landscape.

"The approval by China's NMPA is a testament to Morepen's unwavering commitment to quality, regulatory excellence, and global market expansion," said Kushal Suri, Director – Sales & Marketing, Morepen Laboratories.

Morepen is the number one APIs exporter out of India for six leading products, including Loratadine, Montelukast, Desloratadine, Atorvastatin, Rosuvastatin, and Fexofenadine. The company exports to 82 countries and has a manufacturing capacity of 144 metric tons API annually.

With world-class manufacturing facilities at Masulkhana and Baddi, both USFDA-approved, Morepen continues to expand its footprint across regulated and emerging markets, including the US, Europe, Japan, China, and Russia.

Granules India announces closing of acquisition of Senn Chemicals

Mumbai, India: Granules India Limited announced the successful closing of the acquisition of Senn Chemicals AG, a Swiss- based Contract Development and Manufacturing Organization (CDMO) specializing in peptide development and manufacturing. This marks a strategic milestone in Granules' transformation into a science- and innovation-led organization and extends its capabilities into the fast- growing peptide therapeutics segment.

The acquisition follows the signing of a definitive share purchase agreement in February 2025, under which Granules, through its wholly owned Indian subsidiary, Granules Peptides Private Limited, acquired 100% of the equity of Senn Chemicals from the founding Senn family. Founded over 60 years ago, Senn Chemicals has built a strong reputation as a specialist in Liquid-Phase Peptide Synthesis (LPPS) and Solid-Phase Peptide Synthesis (SPPS), serving innovators and brand owners across pharmaceutical, cosmetic, amino acid derivative (AAD), and theragnostic markets.

The Senn Chemicals brand and its operations in Dielsdorf, Switzerland, will operate under Granules' ownership, with a commitment to maintaining the company's scientific excellence and customer focus.

Dr. Krishna Prasad Chigurupati, Chairman & Managing Director, Granules India, said, "The acquisition of Senn Chemicals AG marks a pivotal step in Granules' strategic evolution into a science- and innovation-led organization. By entering the rapidly growing peptide therapeutics segment and building on Senn's specialized CDMO capabilities, we are well- positioned to deliver high-quality, next-generation treatments. Senn's specialized expertise in peptide development and its strong customer relationships complement Granules' manufacturing strength and global reach. Together, we aim to drive meaningful impact in the complex therapeutics space."

Emcure's European subsidiary Tillomed acquires strategic pharma portfolio from Manx

Pune, India: Tillomed Laboratories Limited, a subsidiary of Emcure Pharmaceuticals Ltd. and a leading European pharma company, has entered into an Asset Purchase Agreement (APA) with UK based Manx Healthcare Limited and its subsidiaries Manx Pharma Ltd and Manx Generics Limited (collectively Manx).

Under the APA, Tillomed will acquire Manx's product portfolio inclusive of relevant Dossiers, Marketing Authorisations, Intellectual Property (collectively Intellectual Properties) and the relevant stocks for around £ 19.7 mn (including £ 4.7mn for inventory) of which £ 6.2 mn will be upfront and rest as milestone payments over the next 18 months. The deal marks a strategic milestone for Tillomed and will strengthen the company's product offerings, expand its market reach, and enhance its ability to meet the evolving needs of patients.

Commenting on the development, Ajit Srimal, CEO Tillomed said, "Through the acquisition of Manx's established and high-quality products portfolio, we reinforce our commitment to delivering accessible healthcare solutions. The acquired assets will help diversify our portfolio and strengthen our market presence."

Eli Lilly launches Mounjaro (tirzepatide), offering new option for treatment of obesity and type 2 diabetes

New Delhi, India: Eli Lilly and Company (India) announced the launch of Mounjaro in single-dose vial presentation following the marketing authorization from the Central Drugs Standard Control Organization (CDSCO). It is a first-of-its-kind treatment for obesity, overweight, and type 2 diabetes that activates both GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (glucagon-like peptide-1) hormone receptors.

Mounjaro is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 kg/m2 or greater (obesity) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition.

"The dual burden of obesity and type 2 diabetes is rapidly emerging as a major public health challenge in India. Lilly is committed to collaborating with the government and industry to promote awareness and improve the prevention and management of these diseases," said Winselow Tucker, President and General Manager, Lilly India.

Tirzepatide was evaluated in two robust global clinical development programs: the SURMOUNT - 1 trials for chronic weight management and the SURPASS trials for type 2 diabetes.

In SURMOUNT-1, a study in 2,539 adults with obesity, or excess weight and weight-related medical problems not including diabetes, people taking Mounjaro as an adjunct to diet and exercise experienced substantial weight loss compared with placebo at 72 weeks. At the highest dose (15 mg), people taking Mounjaro lost on average 21.8 kg, while at the lowest dose (5 mg), people lost on average 15.4 kg (compared to 3.2 kg on placebo). Additionally, 1 in 3 patients taking Mounjaro at the highest dose lost over 26.3 kg (25% of body weight), compared to 1.5% on placebo, according to data not controlled for type 1 error.1,2 In summary, Mounjaro significantly reduced weight by up to 21.8 kg in the SURMOUNT-1 study.

Alembic Pharmaceuticals announces USFDA Final Approval for Pantoprazole Sodium for Injection

Mumbai, India: Alembic Pharmaceuticals Limited announced that it has received Final Approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Pantoprazole Sodium for Injection, 40 mg/vial (Single-Dose Vial). The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Protonix I.V. for Injection, 40 mg/vial, of Wyeth Pharmaceuticals LLC.

Pantoprazole sodium for injection is indicated for treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 10 days in adults. It is also indicated for the treatment of pathological hypersecretion conditions including Zollinger-Ellison (ZE) Syndrome in adults. Refer label for a detailed indication.

Pantoprazole Sodium for Injection, 40 mg/vial (Single-Dose Vial) have an estimated market size of US$ 48 million for twelve months ending December 2024 according to IQVIA. Alembic has a cumulative total of 221 ANDA approvals (195 final approvals and 26 tentative approvals) from USFDA.

Morepen Laboratories plans to add 1,000 professionals

New Delhi, India: Morepen Laboratories Ltd., one of India's leading pharmaceutical companies, today announced a bold expansion plan aimed at deepening its connect with doctors, patients, pharmacies, and healthcare professionals across the country. As part of this strategic initiative, the company will add more than 1,000 professionals to its salesforce over the next three years, with over 200 team members expected to join in FY26 alone.

Following consistently encouraging growth in the segment, this move marks a significant step in strengthening Morepen's formulations business in the market, reinforcing its commitment to building a stronger domestic footprint and aligning with India's vision of affordable, accessible healthcare for all.

"This expansion represents a pivotal moment in Morepen's journey as we sharpen our focus on the expanding domestic finished dosage market," said Mr. Sushil Suri, Chairman and Managing Director of Morepen Laboratories. "With the leadership in our high value APIs, this significant increase in our salesforce and enhanced reach to doctors, pharmacies, and patients, we are setting the stage for getting a bigger pie in the Indian pharmaceutical market valued at ₹2.38 lakh crore, yielding higher gross margins and better returns for stakeholders in the long run."

Currently, Morepen's formulation business stands at approximately ₹325 crore, and the company is targeting a ₹1,000 crore finished dosages business within the next five years. This goal will be supported by an aggressive expansion of its medical representative network and deeper market penetration across urban and rural India, with major growth expected from new products that the company is already producing at highly competitive costs.

Eris Lifesciences designates Gopal Agrawal and Nita Borkar in leadership roles

Mumbai, India: Eris Lifesciences Limited, a leading Indian branded formulations manufacturing company has designated Gopal Agrawal and Nita Borkar in leadership roles in its flagship Domestic Branded Formulations business.

Gopal Agrawal has joined Eris as Vice President and will head up the Renal Care, Branded Injectables and Market Access business segments. Prior to joining Eris, Gopal was Director, Market Access at Takeda. Prior to Takeda, Gopal has worked with Shire Plc and Eli Lilly. He brings over three decades of rich experience in areas such as Sales, Market Access, Key Account & Tender Management, Pricing & Reimbursement, Public Affairs & Public Health Systems, Patient Advocacy & Services and Patient Support Programs. He holds a Bachelors' degree in Science, a Masters' degree in Electronics from Lucknow University and an MBA in Marketing from IGNOU.

Nita Borkar is the co-founder of Oaknet Healthcare and became part of the Eris organization following the acquisition of Oaknet by Eris in May 2022. Another pharma industry veteran, she co-founded Oaknet in Apr 2015, secured private equity funding for the business and built it into a successful player in the Dermatology space before divesting it to Eris back in 2022.

Welcoming Gopal and Nita into their new roles, Amit Bakshi, Chairman and Managing Director, Eris Lifesciences said, "It is a real pleasure to have Gopal and Nita on board and taking on leadership roles in the business. Along with Murari who joined us last month to head the Cardiometabolic business, I am confident that our three new BU Leaders will bring their experience and expertise to bear and enable us to turbocharge the growth of our Domestic Formulations business over the next few years."

Gennova Biopharmaceuticals expands partnership with CEPI

Oslo, Norway: A pioneering self-amplifying mRNA (saRNA) vaccine candidate against the deadly Nipah virus will be developed by Pune-based Gennova Biopharmaceuticals Limited, as part of expanded funding from CEPI worth up to USD 13.38 million.

To accelerate development of a Nipah vaccine candidate, Gennova will also team up with US-based Houston Methodist Research Institute (HMRI), also a CEPI partner, to use their cutting-edge AI technology to optimise the properties of proteins derived from the virus that could stimulate the immune system and serve as optimal vaccine targets for Gennova to investigate in the lab and in the clinic.

Nipah virus belongs to the Paramyxovirus family. It is one of the deadliest pathogens known to infect humans. So far, Nipah outbreaks have been confined to South and Southeast Asia, but the fruit-bat vector is found in large geographical areas across the globe covering a population of more than 2 billion people.

"With no vaccines or specific therapeutics approved for human use against Nipah, CEPI is leading the charge to protect the world against this deadly virus committing over US$100 million to its Nipah programmes and advancing the first ever Nipah vaccine candidates into Phase 1 studies and through to completion", said Dr Kent Kester, Executive Director of Vaccine Research and Development at CEPI. "Gennova's work will not only help establish the suitability of the saRNA platform for use against Nipah but also its suitability as part of a wider group of RNA technologies that could enable rapid responses to future Disease X threats, potentially within 100 days of identification."

Dr. Sanjay Singh, CEO of Gennova Biopharmaceuticals Limited, shared optimism about the collaboration with CEPI and HMRI, viewing it as a significant advancement in the fight against the Nipah virus. "By harnessing the cutting-edge capabilities of our saRNA platform, we are committed to developing a revolutionary next-generation vaccine. This partnership not only sets a new standard for the rapid development of mRNA vaccines but also ensures equitable access and strengthens global health security", said Singh.

Avendus Spark initiates coverage on Suven Pharma with "ADD" rating

Mumbai, India: Avendus Spark has initiated coverage on Suven Pharma with "ADD" rating and a target price of Rs. 1,290.

Avendus Spark estimate a 21% revenue CAGR and a 24% EBITDA CAGR over FY25-27E (proforma for Cohance, Sapala, and NJ Bio), driven by strong growth in the core Pharma CDMO segment, recovery in Specialty Chemicals, and capability/capacity enhancements & synergies from the Sapala/NJ Bio acquisitions.

The report speaks on the Supply Chain Diversification & India's CRDMOs: China+1 diversification has boosted investor interest in Indian CRDMOs, despite the uncertain BIOSECURE act. We estimate a 21% revenue CAGR and 24% EBITDA CAGR from FY25-27E, driven by Pharma CDMO growth, Specialty Chemicals recovery, and synergies from Sapala/NJ Bio acquisitions. Avendus Spark value the stock at 35x FY27E EBITDA, with a ~22% EBITDA CAGR from FY25-29E, stated Avendus Spark.

Avendus Spark expects Suven, unlike most Indian CDMOs, aims to be a technology-driven CDMO, expanding its capabilities beyond conventional small molecules. Suven Pharma has identified Antibody-Drug Conjugates (ADCs) and oligonucleotides as key growth drivers and is strategically building expertise in these segments. The Suven-Cohance merger is expected to close in 1QFY26, and we assess financials & valuations on a proforma basis.

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Steris Healthcare announces strategic expansion plans

Mumbai, India: Steris Healthcare Pvt Ltd, a Mumbai-headquartered pharmaceutical leader with operations in Navi Mumbai, has announced a ₹50 crore multi-pronged growth strategy, including a major expansion into South India, a doubling of production capacity, and plans to launch its Initial Public Offering (IPO) in FY 2026-27. The company, which recently crossed ₹100 crore in annual sales, aims to solidify its national presence and enhance its ability to deliver innovative, affordable healthcare solutions.

As part of its strategic expansion, Steris Healthcare will establish a state-of-the-art manufacturing facility in South India, targeting key markets in Kerala, Tamil Nadu, Hyderabad (Telangana), and Bengaluru (Karnataka). This move is designed to streamline supply chains and strengthen the company's reach in high-demand regions. The new plant will double Steris' production capacity by 100%, adding (XX) units to its existing infrastructure, enabling the company to meet growing domestic and international demand while adhering to stringent quality standards.

In addition to scaling operations, Steris Healthcare will launch new medications and healthcare products aimed at addressing critical therapeutic needs. This initiative reflects the company's unwavering commitment to innovation and bridging gaps in medical care. The expansion is also expected to generate 800 new jobs across manufacturing, R&D, sales, and logistics, fostering economic growth in South India.

Jeevan Kasara, Director & CEO of Steris Healthcare, shared his vision for the company's future: "This ₹50 crore expansion and our upcoming IPO in FY 2026-27 mark a defining chapter in Steris' journey. By deepening our roots in South India and investing in cutting-edge therapies, we are poised to serve millions more patients while creating long-term value for our stakeholders. Our focus remains on making healthcare accessible without compromising on innovation."

Sai Life Sciences sets up Peptide Research Center in India

Hyderabad, India: Sai Life Sciences Limited , an innovator focused Contract Research, Development, and Manufacturing Organization (CRDMO), has inaugurated a dedicated Peptide Research Center at its integrated R&D Campus in Hyderabad, India.

Announcing the launch, Krishna Kanumuri, CEO & Managing Director, Sai Life Sciences, said: "As the pharmaceutical industry evolves from small molecules to emerging modalities like peptides, we are expanding our capabilities to stay ahead. Our new Peptide Research Center reflects this commitment—designed to meet the growing demand for complex peptide synthesis and conjugation. With this investment, we reinforce our role as a trusted partner in advancing next-generation therapeutics."

The Peptide Research Center is designed to support innovator pharma and biotech companies with specialized services across peptide synthesis, discovery, and advanced modalities, including complex conjugates. The facility integrates automation, advanced liquid handling, robotics, and high-throughput systems, enhancing precision, scalability, and efficiency in the development of novel peptide-based therapeutics.

Maneesh Pingle, Head of Discovery Services, said: "The demand for peptide-based therapeutics is rising rapidly, driven by their high specificity, biocompatibility, and lower risk of off-target effects. At Sai Life Sciences, we have a seasoned team of scientists with years of experience successfully delivering peptide discovery and development projects. Combined with our expanding capabilities, this expertise positions us strongly to support our clients' evolving needs as they advance peptide therapies across diverse therapeutic areas."

The new Peptide Research Center will be integrated with Sai Life Sciences' end-to-end discovery services, spanning synthetic and medicinal chemistry, biology, DMPK, and toxicology. This holistic approach ensures seamless transitions across different stages of drug discovery, accelerating timelines and enhancing success rates for peptide-based drug development.

India must collaborate with academia to strengthen CRDMO innovation: Peter Bains

Mumbai, India: India stands at a pivotal moment in time regarding the evolution of her CRDMO industry. With a market share of only 2–3% of a global market valued at USD 140Bn+ in 2024, the market potential & opportunity ahead is enormous & attractive. Momentum is on India's side with a CRDMO CAGR growth from 2019–2024 of 15%, double that of the global growth rate of 7–8%.

With global customers diversifying supply chains from China & seeking value driven outsourcing, geopolitics & geoeconomics provide strong tailwinds for India's CRDMO industry. However, to sustain momentum & seize this opportunity, the industry must address internal challenges & drive critical reforms in government, academia, & financial markets. To stay competitive, Indian CRDMOs must advance up the value & innovation curve, positioning themselves as leaders in new modalities rather than settling for a supporting role.

To strengthen CRDMO innovation & competitiveness, India must collaborate with academia to scale its scientific talent pool, engage with the government to build a world-class regulatory & economic ecosystem, & ensure financial markets provide the capital needed for growth. Failing to act risks losing global competitiveness & market opportunities.

If the Indian CRDMO sector mobilizes with a competitive sense of urgency to secure these initiatives, it has every potential to become a global leader, catalyzing a new era for India's biotechnology & innovation landscape. This report delves into the key drivers, challenges, & imperatives shaping the sector's future, providing a strategic framework for stakeholders to navigate & seize emerging opportunities.

Akums launches Ripasudil + Timolol Combination for Glaucoma Treatment and Ocular hypertension

Sanjeev Jain, Managing Director of Akums Drugs & Pharmaceuticals

New Delhi, India: Akums Drugs & Pharmaceuticals Ltd., India's leading contract development and manufacturing organization (CDMO), has announced the launch of a pioneering Ripasudil-Timolol combination therapy for glaucoma treatment. This DCGI-approved product represents a significant advancement in ophthalmic care, with Akums becoming the first Indian CDMO to receive approval for this innovative formulation.

The new combination therapy offers a dual mechanism of action for superior intraocular pressure (IOP) control: Ripasudil enhances aqueous humor outflow through the trabecular meshwork, while Timolol reduces aqueous humor production. This synergistic approach delivers more substantial and sustained IOP reduction compared to single-drug treatments.

Sanjeev Jain, Managing Director of Akums Drugs & Pharmaceuticals Ltd., states, "This innovation integrates two distinct mechanisms of action to improve glaucoma treatment. By enhancing efficacy and ease of use, we aim to offer a more practical and patient-friendly solution. Our focus is on better clinical outcomes, reducing disease progression, and ultimately improving the quality of life for those affected. With a patient-first approach and a commitment to Make in India, we continue to develop solutions that are of high-quality, and aligned with global standards.

The single combination drop formulation significantly simplifies treatment regimens, addressing a major challenge in glaucoma management—patient adherence. By combining two medications into one product, patients benefit from enhanced convenience and potentially improved compliance.

"With the rising prevalence of glaucoma in India, introducing therapies that enhance efficacy and patient compliance is crucial," added Sandeep Jain, Managing Director of Akums Drugs & Pharmaceuticals Ltd. "This launch marks a significant step in making high-quality and effective treatment more accessible."

Sovereign Pharma achieves EU approval for Aseptic and Terminally sterilized injectable products

Mumbai, India: Sovereign Pharma, a leader in high-quality injectable manufacturing, proudly announces its milestone: EU approval for aseptic and terminally sterilized products, including vials, ampoules, cartridges, and pre-filled syringes (PFS) for both liquid and lyophilized formulations. This achievement is a significant step in the company's commitment to quality, safety, and global healthcare excellence.The EU approval joins ANVISA (Brazil) and MHRA (UK) certifications, all three secured over the course of a year.

With these three prestigious approvals, Sovereign Pharma has strengthened its global presence, ensuring its products meet the highest international regulatory standards.

"At Sovereign Pharma, quality is not just a standard—it's the foundation of everything we do," said Kairus Dadachanji, Founder of Sovereign Pharma. "This EU approval reaffirms our dedication to manufacturing excellence, ensuring that every vial, ampoule, cartridge, and syringe we produce meets the strictest levels of safety, efficacy, and reliability."

In addition to the EU approval, ANVISA, the regulatory body under Brazil's Ministry of Health, granted approval for aseptically processed and terminally sterilized small volume parenteral solutions. Likewise, the UK's MHRA approved the company's terminally sterilized small volume liquids for vials. These certifications, coupled with WHO-GMP certifications and many others (held since 2006), reinforce Sovereign Pharma's dedication to time-tested and globally trusted manufacturing standards.

With an established footprint in over 50 countries, Sovereign Pharma is set to expand, leveraging these new approvals to penetrate additional markets. This milestone enables the company to manufacture both terminally sterilized and aseptically filled injectables, catering to the evolving needs of the global healthcare sector.As part of its strategic approach, Sovereign Pharma has already begun upgrading its manufacturing facility to integrate Isolator lines, ensuring compliance with the latest technological and regulatory advancements.

Furthermore, the company has invested an additional 30 million euros to upgrade its existing facilities. This investment includes the installation of isolator filling lines with auto lyophilised loading & unloading, fully automated packing lines, and the development of a dedicated building for PFS and cartridge filling that meets global standards. The facility is set to be in line for production by the end of 2025. ■

AGI Greenpac board approves ~₹700 Crore for a new Container Glass Plant in Madhya Pradesh

Mumbai, India: AGI Greenpac Limited, India's largest manufacturer of container glass, announced setting up of a state-of-the-art greenfield, high-output and high-efficiency manufacturing plant in Madhya Pradesh with capital expenditure outlay of ~₹700 Crore. This expansion will increase the company's container glass manufacturing production capacity by ~25% to meet the rising demand for high-quality glass packaging products.

The new plant, designed with a planned daily production capacity of 500 tonnes, will produce commercial glass for key sectors including alcoholic beverages, pharmaceuticals, and food. AGI Greenpac anticipates commencing commercial production within 24 months. The timeline demonstrates the company's commitment to efficient project execution and rapid market responsiveness.

Madhya Pradesh provides AGI Greenpac a strategic advantage through its central location, robust infrastructure, and readily available raw materials. These combined benefits will significantly enhance AGI Greenpac's container glass production capabilities and support its strategic expansion across India.

Commenting on the investment, Sandip Somany, Chairman and Managing Director of AGI Greenpac Limited, stated, "Madhya Pradesh's favorable business environment and strategic location aligns with our growth strategy. This state-of-the-art plant will enable us to meet the rising demand for tailored glass packaging solutions, providing our customers with enhanced quality products and will further expand our share in the Indian container glass market."

The facility will expand AGI Greenpac's geographical spread, integrating advanced manufacturing technologies and sustainable practices, demonstrating the company's commitment to environmental responsibility and long-term growth. This expansion strengthens the company's manufacturing footprint, complementing its existing glass plants in Telangana. Beyond its production benefits, the new plant is projected to create over 1,000 direct and indirect employment opportunities, acting as a catalyst for regional economic development and fostering a vibrant manufacturing ecosystem.

Johnson & Johnson increases US investment to over $55 bn over next 4 yrs

Mumbai, India: Johnson & Johnson announced manufacturing, research and development and technology investments of more than USD55 billion in the U.S. over the next four years.

This represents a 25 per cent increase in investment compared to the previous four years and builds upon the Company's already elevated US investment levels resulting from the passage of the 2017 Tax Cuts & Jobs Act.

"Today's announcements accelerate our nearly 140-year legacy as an American innovation engine tackling the world's toughest healthcare challenges," said Joaquin Duato, Chairman and Chief Executive Officer of Johnson and Johnson. "Our increased US investment begins with the ground-breaking of a high-tech facility in North Carolina that will not only add US-based jobs but manufacture cutting-edge medicines to treat patients in America and around the world."

The Company's increased investment in the US over the next four years includes three new advanced manufacturing facilities and the expansion of several existing sites across the Company's Innovative Medicine and medtech businesses. ■

INTERVIEW

“We focus on advancing drug formulation, process optimization, and cutting-edge excipient technologies”

Aditya Sharma
Head of Process Solutions, India Region
Merck Life Science

Aditya Sharma, Head of Process Solutions, India Region, Merck Life Science emphasizes about the Formulation and Technology Centre in Turbhe, Navi Mumbai. He also discussed about the collaborative opportunities that this facility offers for academia, research institutions, and pharmaceutical companies.

Brief us about the newly inaugurated Formulation and Technology Centre in Turbhe, Navi Mumbai, and highlight the key advancements and new capabilities introduced in the facility.

Merck Life Science continues to push the boundaries of R&D, driving innovation in the life science industry. In line with this commitment, we have recently inaugurated the Formulation & Technology Centre in Turbhe, Navi Mumbai, a next-generation facility that is a key part of Merck’s global R&D network. Designed as a hub for industry collaboration, it is equipped with cutting-edge tools to optimize drug formulation, overcome complex challenges, and accelerate time-to-market across India, APAC, the Middle East, LATAM and Africa.

This expanded facility is not just a lab, it’s a collaborative space where customers can engage with Merck’s global R&D expertise, gain hands-on training, and accelerate their drug development pipelines. With state-of-the-art equipment, including spray drying, Wurster coating, and Hot melt extrusion, alongside research tools like Melt Prep®, NIR spectroscopy, particle size analyzers, rheometers, and predictive formulation tools, the centre is designed to expedite drug discovery and formulation research.

As an integral part of Merck’s global innovation ecosystem, this centre reinforces our commitment to industry-academia partnerships, customer-driven

solutions, and sustainable pharmaceutical development. By working alongside our customers, we are not just supporting their formulation needs, we are co-creating the future of drug development, ensuring the delivery of high-quality, effective therapies to market faster.

How does the Formulation and Technology Centre address challenges in complex drug formulations and delivery?

The Indian pharmaceutical industry is evolving at an unprecedented pace, with breakthroughs in therapeutics and cutting-edge manufacturing technologies redefining the landscape. In this dynamic environment, formulation scientists are constantly looking for smarter ways to navigate patent challenges, develop novel excipients, and bring high-quality generics to market.

The Merck Formulation & Technology Centre has been established to address these complexities. More than just a laboratory, it serves as a collaborative hub, bringing together researchers, manufacturers, and industry experts to develop high-quality formulations that meet stringent quality, regulatory and therapeutic requirements. The centre provides technical consultations, hands-on training, and tailored solutions to support the development of robust, scalable formulations.

Furthermore, the centre underlines Merck's commitment to scientific excellence and technological advancement, enabling pharmaceutical companies to enhance drug stability, optimize delivery mechanisms, and streamline their development processes.

Brief us about the global R&D network?

Merck's global R&D network is built on a foundation of scientific excellence, industry collaboration, and customer-driven innovation. With state-of-the-art facilities across key markets, we focus on advancing drug formulation, process optimization, and cutting-edge excipient technologies to support pharmaceutical manufacturers worldwide. Merck has three customer-centric R&D labs globally. The R&D headquarters is located at Darmstadt, Germany followed by collaborative and application R&D centres in Navi Mumbai, India and later in Shanghai, China.

These labs are well equipped with advanced technologies and capabilities to cater solid drug developments. These centres are dedicated to prioritizing customer needs by creating a space where end users can engage directly with subject matter experts. It offers opportunities to explore cutting-edge technologies, gain insights into Merck's diverse portfolio of excipients, and access specialized training programs aimed at skill development.

The Formulation & Technology Centre is a key part of this ecosystem. It bridges the gap between research and commercialization, blending global expertise with local market insights to create smarter, more efficient drug development strategies. By working closely with pharmaceutical companies, Merck helps accelerate innovation, tackle industry challenges, and ultimately, bring better medicines to market.

Our global research network is designed to collaborate closely with customers, providing customized raw materials, APIs, and advanced formulation solutions to address evolving industry challenges.

What are the collaborative opportunities that this facility offers for academia, research institutions, and pharmaceutical companies?

The Merck Formulation & Technology Centre is a driving force in industry-academia collaboration, bridging research and innovation with practical application.

For academia and research institutions, the centre serves as a knowledge hub, offering specialized training programs, hands-on learning, and research support. It actively engages students through plant training, helping them transition from theoretical study to industry practice. Additionally, Merck's experts contribute to seminars and conferences, ensuring continuous learning and knowledge exchange within the scientific community.

For pharmaceutical companies, the centre provides technical consulting, process optimization, and access to cutting-edge formulation technologies—enabling seamless progression from early-stage research to pilot-scale production. With advanced equipment and expert support, it helps address complex formulation challenges, enhance drug delivery, and accelerate product development. Over the years, it has benefited more than 1,000 scientists from leading pharmaceutical companies, reinforcing its role in driving scientific advancement and industry innovation.

By fostering cross-sector collaboration, the Centre strengthens Merck's commitment to empowering the pharmaceutical ecosystem, equipping researchers and manufacturers with the expertise and tools needed to develop next-generation therapies. ■

Innovation in Pharmaceutical Packaging

Innovation is often used but with contrastive meaning. Innovation is a process of transforming ideas into new products, services or improved products and services offered to customers. Innovation is crucial for organizations that offer products or services in a highly competitive marketplace to survive, sustain and be successful.

Chandi Prasad Ravipat, Head - Packaging Development, Aurobindo Pharma stated that innovation in Pharmaceutical Packaging is becoming paramount for Pharmaceutical Industry.

Chandi Prasad Ravipat
Head - Packaging Development
Aurobindo Pharma

Packaging emerged as a pivotal tool of attracting consumers where multiple brands of FMCG, Food, Beverages and electronic goods are flooded into the market for reasons such as Affordability, Awareness of IoT, E-Commerce and Millennials and dominating young population

Pharmaceutical Packaging is a different gamut that requires superior quality packaging for these reasons:

- Complexity of molecules
- Product characteristics such as dosage form and route of administration
- Longer shelf life compared to FMCG, Food and Beverages
- Highly Regulated industry
- Regulations by country where medicines are sold

Importance of Packaging in Indian Pharmaceutical Industry started two and half decades back due to advent of exports to regulated markets especially the USA and Europe. The technological advancement in pharmaceutical packaging during this period is phenomenal. From importing 100% of primary packaging materials required for drug products these markets for a decade (Year 2000 to 2010) to becoming

Made in India having Drug Master Files with best quality management systems for primary packaging materials catering to 90% demand of pharmaceutical industry. This is one of the best examples of partnership between pharmaceutical and packaging industry innovation ecosystem.

As per USFDA guidelines, all primary packaging materials should be sourced from Drug Master File (DMF) holders. From 2000 to 2005, almost 100% of primary packaging materials were imported from DMF sources. Today Indian Packaging Industry is capable of manufacture and supply 90% of demand having acquired DMF with best quality management systems. This is one of the best examples of partnership between pharmaceutical and packaging industry ecosystem.

The foremost importance of pharmaceutical packaging is given to establish and demonstrate conformance to suitability, protection, compatibility, safety and performance. The stringent requirements to comply are ever changing which is the most challenging aspect to the packaging technologists. This made pharmaceutical packaging a scientific branch and vital department in all pharmaceutical organizations doing inland, regulated and emerging markets business.

Innovation is key for today's self-sufficiency to manufacture resins and primary packaging materials inland by the packaging industry.

Factors driving innovation in pharmaceutical packaging

Generic Drug Products: While innovator or brand leader enjoys premium price for drug products in regulated markets, generic drug products are sold at 5 to 10% of innovator products. Innovation in packaging by design results in reduction of the cost and improvement in productivity and help organizations to sustain in business.

Trends in Formulation Development: It is vital to adapt to ever changing trends in new drug delivery systems, new complex drug products in many therapeutic segments and drug innovation are driving packaging novelty for new plastics and packaging components to switch over from traditional packs. Some of them are

- New dispensing/dosing devices for patient convenience and compliance
- Advantages of blow-fill-seal system compared to conventional filling, stoppering and sealing
- COC vials in place of glass vials
- Glass tube replaced by plastic tube for PFS
- Blow-Fill-Seal Technology in large volume parenterals in Medical grade PVC in place of glass bottles and polyolefins for small volume parenterals replacing glass ampoules/vials
- Conventional bottle and measuring devise replaced by closure with dose-metering
- Preference of unit dose for parenterals to multi-dose
- Biodegradable plastics

User Centric Packaging: The new aspect becoming more prominent and imminent to comply with is user compliance and safety i.e., patient and hospital administering staff. User compliance and safety features in packaging add cost. Innovative ideas help to optimise the cost and add high value to the users. Packaging technologists should focus on therapeutic category of drug products, general age of patients using a particular medicine, its dosage form, frequency of medication, requirements of hospital staff administering parenterals or disperse medicines to patients, expectations of patients. All the ideas are converged to bring a best possible solution of a safety device or communication that brings delight to user.

Smart Packaging & Digital Integration: With the advancements of information technology, using digitization which comes at very nominal cost, smart packaging enhances connectivity to the patients or medical professionals across the globe with the product. Usage of QR Codes on packages with critical information connect to user's electronic devices and can access the information including alarm for dosage regiment and when refill is required. This will largely help in adherence of dosage regiment and help patients to be healthier.

Inclusive Packaging: Packages should be designed particularly for differently abled and geriatric patients aged above 65 for ease of opening the packs, taking prescribed dose.

Sustainability Pharmaceutical Packaging: This is the new requirement, and many countries are bringing legislations tom follow sustainability in pharmaceutical packaging. Non-compliance will attract hefty penalties

and can even block those organizations exporting medicines. Packaging Industry and pharma industry are working together to bring biodegradable plastics in place of conventional plastics, eliminate unwanted packaging and downsizing packages.

Innovation of Packaging Machinery: Innovation is required in designing pharmaceutical packaging machinery. There is huge scope of automation in pharma industry to avoid manual intervention as minimum as possible. Automation brings more flexibility on packing lines, integration with Artificial Intelligence ensures compliance to avoid packing and labeling errors which result in 70% of market complaints and recalls.

Authenticity of Drug Products to Users: Spurious and counterfeit medicines are prevalent despite many anti-counterfeit overt and covert features implemented in packaging. Regulated markets in the USA and Europe have implemented serialization and aggregation for drug products to ensure security of genuine medicines in the entire supply chain from manufacturers to pharmacies. Major emerging markets also implemented Track & Trace regulations to provide authenticity of drug products to the patients.

To conclude, the growth factor for any economy is innovation with its multiple advantages of increasing output with the same resources, edge over competition with novel improvements in products and services. An innovation ecosystem is a network of relationships through which information and talent flow through systems of sustained value co-creation. ■

Ensuring Quality and Innovation - A Key to Success

The global pharmaceutical Industry is known for its high degree of innovation, research & development and following stringent regulatory standards to deliver safe and efficacious medicines of highest quality. India has established globally as Pharmacy of the World.

Kaushik Desai, Executive Committee Member, Industrial Pharmacy Section FIP and Dr. Satish Desai, Quality Consultant emphasizes that the pharmaceutical industry is rapidly transforming due to technological advancements and encompasses revolutionary innovations that reshape the fundamental aspects of healthcare.

Quality and Innovation are vital components of any successful organisation. By integrating it in pharma environment, the innovation processes are expected to -

- enhance customer satisfaction and trust,
- drive operational efficiency,
- foster a culture of continuous improvement,
- stimulate growth and expansion,
- create a competitive advantage.

Quality plays a critical role in ensuring patient safety, product efficacy, and regulatory compliance in meeting the patient needs.

QUALITY is the backbone of INNOVATION

Ensuring both quality and innovation in the pharmaceutical industry requires a multifaceted approach, including fostering a culture of continuous improvement, leveraging technology, embracing agility, and nurturing a culture that values robust quality management systems, rigorous quality control specifications, stringent quality assurance checks, adherence to regulatory guidelines and continuous improvement in manufacturing processes and technologies, all while developing a culture of innovation and actively seeking and evaluating new ideas while balancing risk and reward.

10 Key Enablers Ensuring Quality and Innovation are :

Fostering a Culture of Quality and Innovation

- Embrace Continuous Improvement
- Encourage Creativity and Idea Generation
- Promote Collaboration by encouraging cross-functional teams to work together
- Emphasise Customer Focus

Implementing Robust Quality Management Systems

- Define Clear Quality Standards like measurable quality metrics
- Implement Quality Control Measures
- Conduct Regular Audits and Inspections
- Establish Feedback Loops

Quality Control and Assurance

- Good Manufacturing Practices (GMP)
- Quality Management Systems (QMS)
- Rigorous Testing and Analysis

- Documentation and Traceability
- Audits and Regulatory Compliance
- Validation and Qualification
- Focus on errors and defects Prevention
- Continuous Improvement through data analysis

Driving Innovation

- Identify Opportunities for Improvement
- Evaluate Innovation Ideas
- Embrace Experimentation and Prototyping
- Learn from failures to improve future innovation efforts
- Consider Design Thinking

Fostering Innovation

- Investing in Research and Development through Collaboration and Partnerships
- Digital Transformation through Embracing technologies
- Continuous Manufacturing
- Intellectual Property (IP) Protection
- Data Integrity and Compliance
- Innovation in Manufacturing Processes

Continuous Improvement & Process Innovation

- Lean Manufacturing principles
- Six Sigma methodology
- Kanban System
- Vendor Managed Inventory (VMI)

Technology & Analytics

- AI-powered Quality Control
- Data Analytics for Quality
- IoT for Real-time Monitoring

Agile Methodologies & Rapid Innovation

- Agile Development
- Rapid Prototyping
- Iterative Development

Fostering a Culture of Innovation

- Cross-functional Teams
- Open Communication & Idea Sharing
- Recognising and Rewarding Innovation
- Embracing Customer-Centricity
- Innovation Culture fosters a culture of continuous learning and remains at the forefront of technological advancements.

Quality Practices in Innovation

- Understanding the Importance of Quality
- Adopt a Customer-Centric Approach in Quality practices
- Implementing Rigorous Testing Procedures for product's quality, reliability and
- Encouraging Employee Training and Development
- Leveraging Cutting-Edge Technology
- Ensuring Compliance with Industry Standards
- Incorporating Continuous Improvement Strategies
- Promoting a Culture of Innovation
- Utilising Predictive Analytics for QUALITY
- Establishing a Robust Feedback Mechanism

PHARMACEUTICAL INNOVATIONS AND TRENDS

- **Precision Medicine and Personalised Therapies**

Precision medicine introduces a novel paradigm in healthcare. Instead of applying uniform treatments universally, medical practitioners utilise a person's genetic information, lifestyle, and medical background to create a personalised treatment strategy. This approach involves scrutinising genetic variations associated with disease, employing sophisticated technology to decode genes, and identifying telltale indicators within the body. The researchers are focusing more on oncology and biologics where demand is highly specific and patient centric.

The 3D printing is one such technology that offers a novel approach to drug delivery, enabling the creation of personalised and complex dosage forms with precise control over drug release and shape. 3D-printed pharmaceuticals have largely been relegated to niche markets and prototyping due to limited scalability and reliance on technicality of manufacturing processes. This innovation permits the creation of tablets that

can regulate the release of medication, ensuring the most effective therapeutic outcomes. To date, one 3D printed drug Levetiracetam, a rapidly dissolving tablet product has been approved by the US Food and Drug Administration (FDA) for human use. In February 2021, Triastek have received US FDA approval for a clinical study using a 3D printed drug for patients with rheumatoid arthritis. 3D printing has great potential to advance personalized medicine with patient centricity that enables customized doses for a specific patient population.

Sustainability and Green Initiatives

The pharmaceutical industry is embracing sustainability and green initiatives to minimise its environmental impact. This involves reducing carbon emissions through energy-efficient manufacturing and renewable energy sources, implementing waste reduction strategies, adopting eco-friendly packaging materials, developing greener chemical synthesis methods, and conserving water in manufacturing processes. Globally these initiatives are taking momentum to reduce carbon footprint. The newer manufacturing facilities are now adopting green lighthouse principles.

mRNA Vaccines Development : The success of mRNA vaccines against COVID-19 has proved that mRNA technology is a versatile platform for developing vaccines against a wide range of diseases, including cancer, Zika, autoimmune diseases etc.

Immunotherapy Advancements: Immunotherapy represents a unique approach to treating illnesses by leveraging the body's natural defenses. CAR-T cell therapy, a method that involves modifying a person's immune cells to target cancer cells effectively. These modified cells are reintroduced into the body, resulting in a direct and potent attack on cancer cells. CAR-T treatments have demonstrated remarkable efficacy in blood cancers. Scientists are exploring its potential applications. The research areas also include gene therapy.

Digital Therapeutics: Digital therapeutics are healthcare programs that Patient may utilise on personal phone or computer. They provide sound scientific guidance on how to deal with various health issues. Patient can use them in addition to their normal therapies. These technical applications can encourage patients to follow prescribed treatment regimens, diets, and exercise routines. The digital wearable devices are much in demand and ensures patient compliance to dose regime.

Continuous Manufacturing: Continuous manufacturing changes how medicines are made, making them faster and smoother. Usually, medicines are made step by step, in a batch process which takes a long time. But with evolvement of continuous manufacturing, everything happens continuous by negligible process contamination and real time monitoring of quality parameters are done during the entire integrated process ensuring higher with less product recalls and lower risk of contamination. quality of finished drug in much lesser time. This supports in smooth uninterrupted supply of medicines. Pharmaceutical companies are making a conscious effort to reduce their carbon footprint by initiating continuous manufacturing in their development plan.

Automation and Digitisation : Automation and robotics are being used to streamline manufacturing processes, enhance efficiency, improve product quality & safety, minimise human errors, minimise contamination, reduce costs, decrease waste, and ensure regulatory compliance. The pharma 4.0 concept which is a combination of digitization and automation is the new game changer.

The goal of a digital transformation, as outlined in the new McKinsey book 'Rewired: A McKinsey Guide to Outcompeting in the Age of Digital and AI (Wiley, June 20, 2023)', is be to build a competitive advantage by continuously deploying technology at scale to improve patient experience and lower costs. It is a journey of continuous improvement. Robotics although in nascent stage today, it is going to be the future of technological advances for pharma processing and packaging operations. The application of digitization tools like AI, Machine Learning, Internet of Things (IoT) coupled with automation will support innovative companies to grow and be a market leader globally.

Nanotechnology in Drug Delivery: Nanotechnology is revolutionising medication delivery by using nanoparticles and nanomaterials to deliver medicinal compounds to particular parts of the body with extreme accuracy. Nanotechnology is considered a new and rapidly emerging area in the pharmaceutical and medicinal field. Nanoparticles, as drug delivery systems, impart several advantages concerning improved efficacy as well as reduced adverse drug reactions. These microscopic particles can be precisely

manufactured to release drugs in a regulated manner, ensuring optimal drug concentration at specific targeted sites while minimising impact on healthy tissues.

Portable Diagnostic Devices: Portable medical diagnostic devices have transformed the way healthcare is delivered, making it possible for professionals to perform tests anywhere—from a patient's home to remote villages. These devices are compact, lightweight, and user-friendly instruments that allow healthcare professionals to perform diagnostic tests outside traditional clinical settings. It helps in saving time, reduce the burden on hospitals, and provide real-time data, all of which contribute to better patient outcomes.

Shipping Containers for thermolabile medicines: Specialised shipping containers are being developed to ensure the safe and efficient transport of temperature-sensitive medicines and biologics. Technological advancements are revolutionizing cold chain management, enabling real-time monitoring, enhanced traceability, and improved efficiency through tools like IoT, blockchain, AI, and smart packaging. Cold chain management in supply chain is very critical for biologics and vaccines storage and distribution.

CHALLENGES INVOLVED IN INNOVATION

Despite life-saving Innovations to improve quality of life, pharmaceutical industry faces various challenges that require careful consideration and mitigation.

- High Risk and Cost pressure
- Ethical Considerations
- Collaboration, Partnerships, and innovation confidentiality
- Patents and Licensing for cost of innovation
- Ensuring the costs of developing biotechnology innovations are covered through patents and licensing deals.
- Stringent regulatory compliance
- Ensuring consistent supply chain through Quality Maturity
- Counterfeit drugs
- Trust and open environment
- Skilling, upskilling and reskilling

KEY INNOVATIONS ON THE HORIZON

Few quality innovations to modernise the manufacture of drug substances and drug products are as under –

- **Drug Discovery and Development –** Artificial Intelligence (AI) is accelerating drug discovery by analysing vast datasets, identifying potential drug candidates, and predicting their efficacy, leading to faster and more efficient drug development. The various regulatory bodies have developed guidelines on the use of AI to protect the interest of patients.

- **New routes to drug substances -** Innovations in manufacturing technology to synthesise active pharmaceutical ingredients (APIs) or drug substances include photochemical and electrochemical approaches, biocatalysis, cell-free protein synthesis, and cell-based biosynthesis that uses alternative hosts.

- **Co-processed APIs -** An innovation in the manufacture of APIs is the addition of a non-active excipient or carrier to improve efficacy of drug or to manipulate attributes of a process stream to achieve a desired outcome. Co-processed APIs might be advantageous in particle formation, crystallisation, or drying operations to improve the stability of a desired solid state or to tailor Physico-chemical properties of the drug substance.

- **Process intensification -** Technological advancements that foster more efficient and higher-yielding processes, while also allowing for smaller manufacturing spaces and lowering both capital and operating expenses, are referred to as process intensification.

- **Advanced process control and automation -** The advances are being made in sensor technology, data analytics, and system modeling, and manufacturers will increasingly rely on these innovations to design, understand, and control complex processes.

- **Modular systems -** Modular systems are composed of interconnected unit-operation "modules" that can be arranged and adapted to enable a single facility to manufacture a large array of drug products.

- **Data analytics -** This has brought new opportunities in Biotechnology Innovation. With Data analytics

increasing, the speed of development process can be considerably expedited and researchers are able to accessing more biological, social, and environmental insights, improved and more sustainable products which could be on the horizon in future.

- **Predictive Analytics for QUALITY -** Predictive analytics implementation in quality is about leveraging data to forecast potential issues, thus enabling preemptive action. This strategic approach not only helps in identifying problems before they surface but also in understanding patterns that could give rise to them. When data is abundant, predictive analytics effectively turns data into actionable insights and drives decisions that enhances the product quality and customer satisfaction.

- **Regulatory Evolution -** Regulatory authorities are developing adaptive approval processes for novel medicines. There are innovative approaches like hybrid inspection and digitization which were positive outcome of COVID pandemic. The regulatory bodies encourage paper less submissions of documents for faster decisions. The number of guidance documents are developed supporting innovations in technology and processes.

Considering the importance of innovation and to have upper edge globally, the Indian government has undertaken several industry friendly initiatives to encourage innovation in research. The Government has launched Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) Scheme which aims to transform India into a global R&D hub, with a focus on strengthening research infrastructure and promoting industry – academia collaboration. This is expected to nurture quality research and enable research and innovation for future health challenges. There will be establishment of Centers of excellence at seven National Institutes of Pharmaceutical Education & Research (NIPERs) and there will be significant investment in the R&D ecosystem within the pharma sector. The need is felt to inculcate creative and innovative mind set during early days of teaching. The day is not very far to see positive outcome from such collaborative approach between Government, Industry and Academia. The beginning has been made but we have a long way to go to catch up with developed countries in Innovation front.

India aims to become global hub not only for supplier of affordable quality medicines but also a key growth driver in path breaking technological advances by the year 2047 with active involvement of all stakeholders. ■

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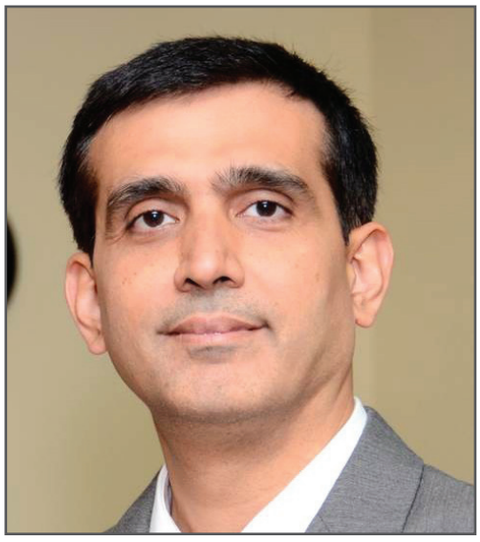
Pharmaceutical Packaging: Inspired by Nature's Innovations

Pharmaceutical packaging is a critical aspect of the healthcare industry, ensuring drug safety, stability, and usability. As technology advances, packaging solutions must evolve to be more efficient, sustainable, and intelligent. Nature, with billions of years of evolutionary design, offers inspiration for innovative pharmaceutical packaging. From self-cooling mechanisms to tamper-evident barriers, nature's packaging solutions provide valuable lessons for modern pharmaceutical needs.

Dharmesh Kharwar, Director, NGB Laboratories Pvt. Ltd emphasizes about the pharmaceutical packaging innovations. He also spoke about the sustainable and biodegradable packaging.



Dharmesh Kharwar
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ANALOGIES FROM NATURE IN PACKAGING

Nature has perfected the art of packaging by creating structures that protect, preserve, and indicate quality. Several natural examples can inspire pharmaceutical packaging innovations.

The Banana Peel: Built-in Freshness Indicator

A banana's peel serves as an ideal packaging, protecting the fruit while also signaling its ripeness through color changes. Similarly, pharmaceutical packaging can incorporate smart indicators that change color when drugs are past their expiry date or have been exposed to unfavorable conditions.

Example in Pharma:

Companies have developed smart labels that change color based on exposure to temperature or air, indicating the freshness and potency of pharmaceuticals. Additionally, temperature-sensitive packaging is used for vaccines, where color changes indicate improper

storage conditions. In Zone IV climatic conditions like India and similar markets, it's a good investment for higher cost products to start with on pilot basis for patient protection . Here the appropriate TOR (Time out of Refrigeration) is incorporated and exceeding that the indicators will activate. There are digital and GPS enables version also commercially available for critical thermolabile products .

The Coconut: Tough and Transport-Friendly

The coconut's hard outer shell shields the soft, delicate interior, much like glass vials or blister packs protect sensitive medications. The fibrous husk provides shock absorption, similar to tamper-proof and impact-resistant packaging for pharmaceuticals in transit.

Example in Pharma:

Blister packs with multiple layers of polymer and aluminum provide high impact resistance and moisture control, ensuring safe drug transportation. Alu-Alu blister packaging, commonly used for moisture-sensitive drugs, is inspired by coconut's protective structure.

The Peapod: Perfect Unit-Dose Packaging

A peapod naturally separates its contents into compartments, just like blister packs keep pills in individual pockets to ensure easy dispensing, correct dosage, and contamination prevention.

Example in Pharma:

Unit-dose packaging for tablets and capsules, by one company, follows this principle by providing individually sealed doses that improve patient adherence for oral dosage forms. Single-dose eye drop packaging, used for medications like artificial tears and glaucoma treatments, is another example inspired by nature.

The Eggshell: Lightweight Yet Protective

An eggshell is fragile yet strong, protecting the yolk inside while allowing airflow. This structure mimics breathable pharmaceutical packaging that protects moisture-sensitive medications while ensuring proper ventilation.

Example in Pharma:

Modified Atmosphere Packaging (MAP) is used for pharmaceutical storage, where gas permeability is controlled to maintain stability, mimicking the natural permeability of eggshells. This is especially useful for probiotic supplements and biologics that require controlled atmospheres.

The Pinecone: Responsive to Environmental Conditions

A pinecone opens and closes based on humidity levels, an adaptive feature that could be replicated in pharmaceutical packaging that responds to environmental conditions.

Example in Pharma:

Humidity-sensitive blister packs that release moisture when necessary or seal in dryness are being explored for temperature-sensitive drugs and biologics. Companies are developing smart packaging materials that mimic this natural responsiveness.

SELF-COOLING PACKAGING INSPIRED BY NATURE

Temperature-sensitive pharmaceuticals, such as biologics and vaccines, require cooling solutions. Nature provides excellent self-cooling mechanisms that can be adapted for pharmaceutical packaging.

Desert Beetle: Moisture-Harvesting Cooling

The Namib Desert beetle collects moisture from the air to regulate temperature. This principle can inspire moisture-harvesting pharma packaging that passively cools medicines by utilizing condensation.

Example in Pharma:

A company uses evaporation-based cooling in remote areas to maintain product integrity without electricity, a technique that could be adapted for vaccine packaging. Similarly, self-cooling insulin carriers, such as the pack with smart sensor, use evaporative cooling to keep insulin at the right temperature.

Termite Mounds: Passive Cooling with Ventilation

Termites construct mounds with ventilation tunnels that maintain stable internal temperatures. Pharmaceutical packaging can incorporate self-ventilating designs to regulate temperature-sensitive drugs without external cooling sources.

Example in Pharma

One cooling system, inspired by termite mounds, maintains consistent refrigeration without power, suitable for vaccines in remote areas. Some temperature-controlled shipping containers also use passive cooling designs for biologics transport.

SUSTAINABLE & BIODEGRADABLE PACKAGING

Sustainable Forest-Sourced Paper Packaging

Many pharmaceutical companies are adopting FSC-certified paper-based packaging to reduce environmental impact. Companies that care for environment have introduced recyclable paper-based pill boxes to replace plastic-based packaging.

Biodegradable Polymer Packaging

Biodegradable alternatives for tablet blister packs, liquid solutions, and injectable packaging are being developed. PHA-based and PLA-based polymers, derived from natural sources, are increasingly used to replace petroleum-based plastics. Some of them are are leaders in biodegradable pharma packaging solutions.

Conventional blister packaging often consists of materials like aluminum and polyvinyl chloride (PVC), which pose challenges for biodegradability and recycling. This has resulted in significant environmental waste, with countless blister packs being discarded in landfills and oceans annually. These packs can take centuries to degrade, breaking down into harmful microplastics and nanoplastics over time. The prevalence of traditional blister packs has become a growing concern for both pharmaceutical companies and environmentally conscious consumers. Cyclic olefin copolymer (COC) is a transparent, high-performance plastic widely used in healthcare, optics, packaging, and electronics. Its applications range from insulin delivery systems and food-safe films to smartphone and tablet displays. Renowned for its versatility, COC is often the material of choice, and its comprehensive global regulatory compliance simplifies development processes. Glass transition temperature up to 180 °C ▪ Excellent moisture and aroma barrier ▪ High stiffness and strength ▪ Easy to extrude and thermoform ▪ Resists hydrolysis, polar organics, acids and alkalis ▪ High transparency and gloss ▪ Broad global food and healthcare regulatory complianceBeing on higher price range , the adoption is slow however companies can invest in this for sustainability.

It contains only carbon and hydrogen; no chlorine or other halogens are present. When combusted completely, it yields carbon dioxide and water and releases over 23,000 kJ/kg (10,000 BTU/lb)

POLICY ASPECTS IN PHARMACEUTICAL PACKAGING

Incentivizing R&D in Pharmaceutical Packaging

All governments should incentivize R&D in pharmaceutical packaging, similar to drug development. Tax credits and grants for eco-friendly packaging innovation are being provided in EU's Green Deal and the US FDA's Sustainable Packaging Initiative.

Safe and Effective Return & Disposal of Expired Medication

Expired medications contribute to antimicrobial resistance, drug toxicity to aquatic life, and pollution. Countries like Sweden and Canada have national take-back programs, incentivizing consumers to return unused drugs for safe disposal.

CONCLUSION

Nature provides an abundance of inspiration for pharmaceutical packaging innovations, from protective and tamper-proof designs to self-cooling and sustainable materials. By mimicking nature's smart packaging solutions, the pharmaceutical industry can develop more efficient, environmentally friendly, and user-friendly packaging systems.

By integrating biomimicry into packaging design, the future of pharmaceuticals can ensure safer, longer-lasting, and more accessible medicines while reducing environmental impact. As technology advances, the fusion of nature's intelligence with human innovation will redefine the possibilities in pharmaceutical packaging. ■

The Importance of Packaging in the Pharmaceutical Industry

In the pharmaceutical industry, packaging plays a far more critical role than simply containing a product. It serves as a crucial line of defence in ensuring drug safety, maintaining efficacy, enhancing patient adherence and meeting regulatory requirements. Pharmaceutical packaging is required to meet stringent standards while accommodating the evolving needs of manufacturers, healthcare professionals, and most importantly - consumers. As the sector continues to advance, innovations in packaging materials, design, and technology are reshaping how medicines are protected, distributed, and consumed.

Rajesh Khosla, CEO, AGI Greenpac Limited emphasizes about the role of packaging in the pharmaceutical industry. He also spoke about the regulatory compliance and industry standards in the pharmaceutical industry and shift towards sustainable packaging solutions.

Ensuring drug safety and stability

One of the most fundamental roles of pharmaceutical packaging is to safeguard the integrity of the drug throughout its lifecycle. Medications are highly sensitive to external elements and factors such as light, moisture, and temperature fluctuations, which can degrade their potency and effectiveness. Certain active pharmaceutical ingredients (APIs) require absolute protection to prevent oxidation or contamination, which is why high-barrier packaging materials such as glass, aluminum foils, and specialised polymers are commonly used. Glass, in particular, remains a preferred material due to its inert nature, ensuring no interaction between the material of the container and the drug, which preserves its stability.

Tamper-evident packaging also plays a crucial role in ensuring product safety and integrity. Features such as breakable seals, child-resistant closures, indicator bands, etc. prevent accidental ingestion or deliberate adulteration.

In crucial formulations such as vaccines and injectables, packaging is designed to maintain sterility from production to administration, ensuring that the medicine remains free from contamination of any kind. The importance of safety features in packaging cannot be overstated, as they directly impact patient health and the reliability of pharmaceutical products.

Regulatory compliance and industry standards

The pharmaceutical sector, as we all know, is governed by some of the most stringent regulations worldwide, with organisations such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and India's Central Drugs Standard Control Organization (CDSCO) setting precise, stringent and enforceable standards for packaging safety, labelling, and traceability. Ensuring compliance with these regulations is essential not only to ensure consumer safety but also to prevent counterfeit medicines from entering the supply chain and making their way to stockrooms and store shelves.

Building upon the foundation of general regulatory compliance, specific aspects of packaging are subject to particularly rigorous scrutiny. Labelling is one of the most strictly controlled parts of pharmaceutical packaging regulations. Clear, legible, and standardised labelling helps both healthcare professionals and patients understand important information such as dosage instructions, expiry dates, and safety warnings. In addition, global regulatory bodies mandate serialization and track-and-trace systems, which use

barcodes and unique identifiers to authenticate and trace products from production to distribution. These systems significantly reduce the risk of counterfeit drugs entering the market, a growing concern in many regions.

Beyond the critical aspects of labelling and traceability, accessibility presents another key dimension of pharmaceutical packaging. Packaging accessibility is another key factor for consideration.. Child-resistant packaging is essential for preventing accidental ingestion by children, while packaging designs must remain user-friendly for elderly patients, ensuring they can easily open and consume their medication.

It is also vital to recognize the dynamic nature of these regulatory frameworks. The regulations evolve to address emerging risks and concerns, requiring manufacturers to remain agile in adapting their products and production to maintain compliance.

Improving patient adherence and user experience

Beyond regulatory compliance, pharmaceutical packaging plays a crucial role in enhancing patient adherence. Poor adherence to prescribed medications continues to be a major challenge across the world, often leading to ineffective treatment and increased medical costs. Packaging solutions that facilitate correct dosage and encourage compliance can significantly improve treatment outcomes.

User-friendly designs, such as blister packs with pre-measured doses or colour-coded compartments, help patients take the right medication at the right time – especially in areas with lower literacy or awareness rates. Single-dose packaging solutions are particularly effective in ensuring precise dosage, reducing the risk of medication errors. For patients managing chronic illnesses, easy-to-use multi-dose packaging and clear instructional labelling can improve adherence by eliminating confusion regarding dosage schedules.

Advancements in smart packaging are also contributing to better patient compliance. The integration of QR codes, RFID tags, and Near Field Communication (NFC) technology enables patients to access instructions, medication reminders, and real-time support digitally through devices such as smartphones. These innovations are a bridge between packaging and digital health, ensuring that patients receive the necessary guidance to follow their prescribed treatment plans accurately.

The shift towards sustainable packaging solutions

As with most other industries, sustainability has also become a key consideration when it comes to pharmaceutical packaging.

Historically, the industry relied heavily on plastic due to its cost-effectiveness and durability. However, environmental concerns and regulatory changes are driving the sector towards more sustainable alternatives. Within this shift, glass is emerging as a critical material, offering a compelling blend of sustainability and performance. The transition to eco-friendly packaging is complex and needs to balance protective properties while reducing environmental impact.

Glass remains a leading choice for sustainable packaging due to its recyclability and non-reactive nature, making it particularly suitable for high-value medications and injectables. Its inert properties ensure drug stability and prevent leaching, a vital consideration for sensitive pharmaceuticals.

While advancements in biodegradable plastics are being explored, glass stands out for its well-established recycling infrastructure and closed-loop potential. It can be endlessly recycled without loss of quality, significantly reducing waste and resource depletion.

Meanwhile, efforts to optimise packaging design, such as reducing excess materials and adopting lightweight packaging, are contributing to lower carbon footprints in production and transportation. Lightweight glass innovations are further enhancing its sustainability profile.

The pharmaceutical sector is also increasingly embracing the principles of a circular economy, where, in certain cases, packaging materials are designed for reuse and efficient disposal. Refillable glass vials, returnable packaging models, and enhanced recycling infrastructure are proving to be viable solutions to address waste management challenges. As sustainability goals become more ambitious, companies across the pharmaceutical supply chain must collaborate to implement packaging strategies that balance functionality, safety, and environmental responsibility.

Technological innovations shaping the future of packaging

The widespread digital transformation has also touched the pharmaceutical sector. Smart packaging solutions that incorporate real-time monitoring capabilities are improving drug safety by ensuring that temperature-sensitive medications, such as vaccines and biologics, remain within required storage conditions.

Blockchain technology is also being explored to strengthen supply chain transparency and combat counterfeit drugs. By creating immutable records of a drug's journey from manufacturer to end-user, blockchain can significantly enhance patient safety and regulatory compliance. Meanwhile, automation in pharmaceutical packaging production is streamlining manufacturing processes, enabling greater precision and scalability, particularly in the era of personalised medicine. For instance, automated labelling and precise filling systems ensure accuracy and efficiency in production.

As the industry advances, the role of packaging will extend beyond containment and protection, serving as an even stronger bridge between pharmaceuticals, healthcare providers, and patients. The integration of digital tools into packaging will continue to revolutionise medicine delivery, ensuring greater accessibility and adherence while maintaining the highest standards of safety and compliance.

Pharmaceutical packaging is a cornerstone of the healthcare industry, ensuring drug safety, regulatory compliance, patient adherence, and environmental sustainability. As the sector evolves, packaging innovations must align with emerging challenges, from counterfeit prevention and digital integration to sustainability and accessibility.

By embracing new materials, technological advancements, and user-centric designs, pharmaceutical packaging can contribute to a more efficient, secure, and patient-friendly healthcare ecosystem. We must remember that the role of packaging in the pharmaceutical industry is not merely about containment - it is about creating solutions that enhance the entire healthcare experience, ensuring medicines reach patients safely and effectively while minimising environmental impact. With a forward-thinking approach, the industry can continue to drive meaningful change and set new benchmarks in pharmaceutical packaging excellence. ■

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Pharma Packaging Industry and Challenges

The pharmaceutical industry is undergoing a major transformation, where regulatory frameworks are intensifying, accelerating the adoption of automation and minimising human interaction in drug production and aseptic filling. While this is becoming more evident each day, it doesn't stop at core operations—because we see that it even extends to secondary processes like packing. **Rishad Dadachanji, Managing Director, Dadachanji Group** emphasizes about the shift towards automation in Pharma Packaging and future trends in Pharma packaging.

The Shift Towards Automation in Pharma Packaging

Today, packaging in many pharmaceutical factories is still handled manually, leaving room for human error. A simple mistake—like forgetting to include a leaflet inside a medication box—could have serious consequences. If a doctor, especially one using a product for the first time, does not receive critical instructions, patient safety may be at risk.

To address such concerns, the industry is rapidly transitioning toward automated packaging lines and cartoners. Automation enhances precision, minimises errors, and ensures compliance with stringent regulatory requirements. However, this shift also comes with new challenges.

Challenges in Automated Packaging

Unlike manual operators who intuitively adjust packaging components, automated machines require highly stable and uniform input materials. For instance, a cartoning machine expects properly folded and rigid cartons for smooth operation. If the packaging material quality is inconsistent, it can lead to disruptions in the line.

A key issue arises when cartons or boxes have high moisture content. Increased moisture makes the material softer, causing problems during pickup and processing in automated lines. As more companies adopt high-speed automation, suppliers of packaging materials—including boxes, trays, leaflets and various others—must adapt and improve their standards.

The Role of Packaging Material Suppliers

Automation in pharmaceutical packaging depends heavily on the quality and consistency of input materials to function reliably. Consider an example of leaflet insertion: in

automated systems, sensors verify whether a leaflet has been correctly placed inside a carton before sealing, significantly reducing the risk of omission. In manual packaging, this verification step is often missing, increasing the chances of human error. Another example is carton quality—automated lines require cartons with precise creasing and consistent material properties to ensure smooth folding and accurate assembly. Variations in rigidity or improper creasing can cause machine stoppages or misalignment. Similarly, vials, ampoules, syringes, and cartridges must meet stringent standards for dimensions, to ensure efficient processing. These are just a few examples of how critical high-quality inputs are to maintaining the integrity and efficiency of automated pharmaceutical packaging lines.

Future Trends in Pharma Packaging

As the pharmaceutical industry continues to evolve, so too must every link in the supply chain. From seemingly simple components like cartons and leaflets to complex systems like medical devices and drug delivery formats,

every element must be designed with automation compatibility in mind. The examples discussed are just a glimpse into the broader transformation underway. Future-ready pharma packaging demands more than just innovation—it requires a deep alignment between technology, compliance, and manufacturing excellence. As automation, personalization, and regulatory expectations grow, suppliers must rise to the challenge, driving forward a new era of smarter, safer, and more efficient pharmaceutical packaging. ■

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Indian Clinical Trials Market

There is a continual quest by mankind for the advancement in medical knowledge as well as patient care, and clinical research plays a pivotal role in this pursuit. This has resulted in incremental increase in the number of clinical trials conducted across the globe and the Indian scenario is no different.

The Indian clinical trials market has been growing significantly over the past few years, driven by several factors such as a large patient pool, cost-effective operations, and a well-established pharmaceutical industry.

Sujay S. Salvi, Head – Clinical Trial Supplies Management, Siro Clintech Pvt Ltd emphasizes about the Indian Clinical Trials Market and how it fares compared to the global clinical trials market.

Global Clinical Trials Market

Market size and growth: The global clinical trials market was valued at approximately USD 50 billion in 2023 and is projected to grow at a CAGR of around 6% through 2032 at approximately USD 85 billion as per Straits Research.

North America (particularly the U.S.) dominates the global market, followed by Europe and Asia-Pacific.

Dominated by large pharmaceutical companies (e.g., Pfizer, Novartis, Roche etc.) and CROs (e.g., IQVIA, Parexel, Syneos Health etc.).

Global Market Drivers:

- High R&D spending by pharmaceutical and biotech companies.
- Focus on decentralized trials and personalized medicines.
- Increasing prevalence of chronic diseases (e.g., cancer, diabetes).
- Adoption of advanced technologies (e.g., AI, blockchain, and wearable devices).
- Growth in biologics and gene therapies.

Global Market Challenges:

- High costs of conducting trials in developed countries.
- Stringent regulatory requirements leading to longer approval timelines.
- Difficulty in patient recruitment and retention, especially for rare diseases.

Global Market Opportunities:

- Growth in decentralized and virtual clinical trials.

- Expansion of trials in emerging markets (e.g., Asia-Pacific, Latin America).
- Increasing focus on rare diseases and orphan drugs.

Global Trends:

- Adoption of decentralized clinical trials (DCTs) using digital tools.
- Increased use of real-world evidence (RWE) and artificial intelligence (AI).
- Focus on patient-centric trials and personalized medicine.

Indian Clinical Trials Market*:

Market size and growth:

India accounts for a smaller but rapidly growing share of the global market, valued at around USD 2 billion in 2024 and is projected to grow at a CAGR of around 8% through 2030 at approximately USD 3 billion as per Techsci Research.

India holds 8% of the global clinical trial market and represents about 10-15% of global clinical trial recruitment.

Presence of both international and domestic experienced CROs (e.g., IQVIA, SIRO etc.).

**Pharma/Devices/Biologics*

Presence of majority of global pharma giants (e.g. Pfizer, Novartis, Abbott, Novo Nordisk, Roche etc.)

Growing participation of Indian pharmaceutical companies (e.g., Wockhardt, Biocon, Cipla, Dr. Reddy's, Sun Pharma etc.) in clinical research.

Indian Market Drivers:

Cost Efficiency: Conducting clinical trials in India is generally more cost-effective compared to Western countries. This includes lower costs for patient recruitment, clinical site management, and labour.

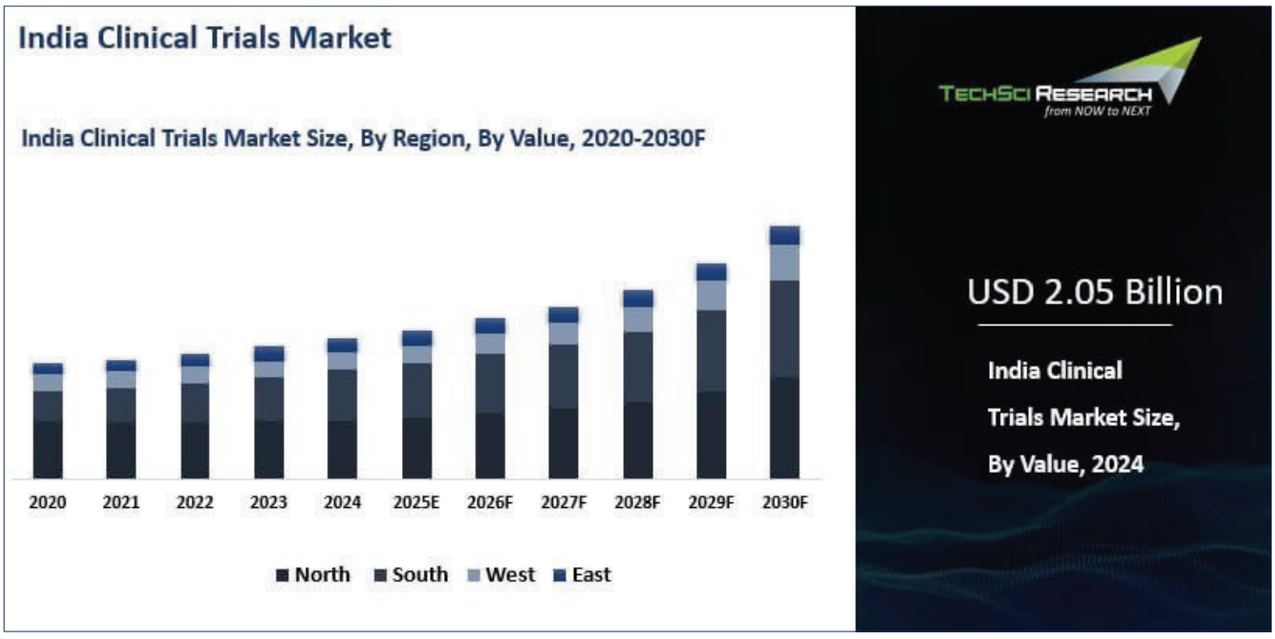
Large and Diverse Patient Pool: India's population of over 1.4 billion provides access to a wide range of disease conditions and faster recruitment.

Regulatory Reforms: The Indian government has implemented several regulatory reforms to streamline the clinical trial process, making it more attractive for global pharmaceutical companies. The "New Drugs and Clinical Trials Rules, 2019" streamlined approvals and improved transparency.

Skilled Workforce: India has a large pool of highly skilled medical professionals and researchers, which is crucial for conducting high-quality clinical trials.

Indian Market Challenges:

Regulatory Delays: Despite reforms, delays in approvals and queries persist.



Ethical Concerns: Ensuring informed consent and protecting vulnerable populations.

Compliance: Concerns over data integrity & GCP adherence.

Infrastructure Gaps: Limited clinical trial infrastructure in rural areas.

Patient retention and awareness: Dropout rates due to lack of awareness in rural areas.

Compensation Disputes: Ambiguities in compensation for trial-related injuries or deaths.

Indian Market Opportunities:

Cost Advantage: Lower operational costs attract global sponsors.

Diverse Population: Enables trials for a wide range of ethnicities and genetic profiles.

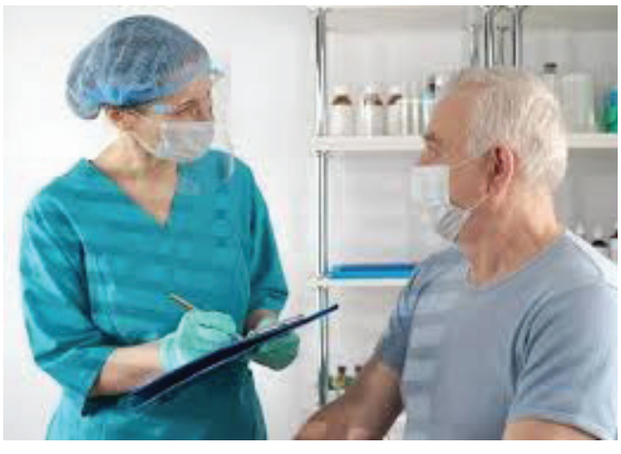
Government Initiatives: Policies to promote India as a global hub for clinical research.

Emerging Sectors: Growth in Biosimilars, Vaccines, Medical Devices and Ayurvedic drug trials.

Indian Trends:

Rising number of multicentric trials involving global sponsors. Growth in contract research organizations (CROs) and clinical trial sites. Increasing focus on biosimilars, generics, and vaccines.

The global clinical trial market is larger and more mature, with advanced technologies and stringent regulations driving innovation. The Indian clinical trial market, while smaller, is growing rapidly due to cost advantages, a large patient pool, and regulatory reforms. India is increasingly becoming a preferred destination for global clinical trials, particularly for generics, biosimilars, and vaccine research. Both markets face challenges, but opportunities for growth and collaboration are significant, especially with the rise of digital technologies and patient-centric approaches.



Experts anticipate significant growth in India's clinical trials market, driven by various strategic initiatives and inherent advantages.

Here are some key points about the Indian clinical trials market:

Market Segmentation:

By Phase: Clinical trials are typically segmented into Phase I (FIH, BA/BE), Phase II, Phase III, and Phase IV (PMS/RWE).

By Therapeutic Area: Key therapeutic areas include oncology, cardiovascular diseases, diabetes, infectious diseases, and central nervous system disorders.

By Sponsor: The market is segmented into MNC and domestic pharmaceutical companies, contract research organizations (CROs) and academic and government institutes.

By Study Design: Randomized controlled trials, Observational & real-world evidence studies, Decentralized trials etc.

By Services: Clinical Operations, Data Management, Medical Writing, Biostats, Pharmacovigilance, Clinical Trial Supply and logistics, Laboratory Services etc.

Regulatory Environment:

India's clinical trial regulatory framework has evolved significantly, with a focus on patient safety, ethical conduct, and streamlined approvals.

Key Regulatory Bodies:

Central Drugs Standard Control Organization (CDSCO), operates under the Ministry of Health and Family Welfare):

The national regulatory authority responsible for approving clinical trials, new drugs, and medical devices.

Headed by the Drugs Controller General of India (DCGI).

Ethics Committees (ECs):

Institutional or independent committees that ensure the protection of participants' rights, safety, and well-being.

Must be registered with the CDSCO.

Indian Council of Medical Research (ICMR):

Provides ethical guidelines for biomedical research, including clinical trials.

Manages the Clinical Trials Registry – India (CTRI), ensuring transparency and public accessibility of trial information.

In addition, Ministry of AYUSH is the primary governing body overseeing Ayurvedic research and trials. They have published GCP-ASU (Good Clinical Practice for Ayurveda, Siddha, Unani) guidelines, which provide a framework for conducting trials involving these products.

Medical Devices Trials need to follow the Medical Devices Rules, 2017 (amended in 2020 & 2024) under the CDSCO.

Recent Developments:

Recent reforms include the introduction of the New Drugs and Clinical Trials Rules, 2019 & 2023 amendments, which aim to streamline the clinical trials approval process and ensure patient safety.

Mandated compensation for trial-related injuries or deaths.

Fast-track approvals for trials involving drugs for unmet medical needs or life- threatening conditions.

Online submission of applications through the SUGAM portal. Increased transparency and efficiency in the approval process. All trials must be registered in the Clinical Trials Registry - India (CTRI) before enrolment begins. All Clinical Research Organizations to be registered with the CDSCO.

Future Outlook:

In addition, the below latest and upcoming government initiatives are expected to boost growth in this sector.

National Digital Health Mission (NDHM): Improving Patient Data Accessibility.

Draft Pharma Policy: Encouraging innovation and R&D investments.

PLI (Production Linked Incentive) Scheme for Pharma: Promoting domestic manufacturing and clinical research.

Experts have urged India to revise its clinical trial regulations to capture a larger share of the global market, where it currently holds 8% compared to China's 29%.

Recommendations include expediting regulatory processes to attract more sponsors.

The market is expected to continue growing, driven by increasing R&D investments, rising prevalence of chronic diseases, and ongoing regulatory improvements.

The adoption of advanced technologies such as artificial intelligence and big data analytics in clinical trials is also expected to boost market growth.

Decentralized Clinical Trials (DCTs): Post COVID there is a growing trend towards decentralized clinical trials, which leverage digital technologies to conduct trials remotely.

Increased Focus on Rare Diseases: There is an increasing focus on clinical trials for rare and orphan diseases, driven by both regulatory incentives and unmet medical needs.

Collaborations and Partnerships: Strategic collaborations between pharmaceutical companies, CROs, and academic/government institutions are becoming more common to leverage complementary strengths. For example, India's first indigenously developed COVID -19 vaccine (Covaxin by Bharat Biotech) involved collaboration between ICMR/NIV and industry.

AI is playing a crucial role in modernizing India's clinical trial sector by enhancing data analysis, operational efficiency, and personalized patient care. These advancements are positioning India as a major hub for innovative clinical research.

In summary, the Indian clinical trials market is poised for a substantial growth, supported by a favourable regulatory environment, cost advantages, digital initiatives and a large patient pool. However, challenges related to ethical concerns, GCP compliance and regulatory complexities need to be addressed to fully realize the market's potential. ■

Author

Sujay S. Salvi
Head – Clinical Trial Supplies Management
Siro Clintech Pvt Ltd

Injection Filter Needle Market to reach USD 1.73 billion in 2025

With chronic diseases on the rise and medical treatments advancing rapidly, the need for precision in drug administration has never been greater. This challenge is also an opportunity. At Terumo, we see it as our responsibility to lead — to set new standards in safety, innovation, and patient care. The global filter needles market is poised for continued growth, expanding from USD 1.59 billion in 2024 to $1.73 billion in 2025, at a CAGR of 9.0%. This growth is fueled by several factors, including growing emphasis on patient safety and infection control, rising chronic disease prevalence, regulatory developments, healthcare infrastructure expansion, and increasing global healthcare spending.

Ashit Sikka, Senior Director – Pharmaceutical Solutions Division (PSD), APAC, Terumo India emphasizes about how technological advancements in medical devices are transforming the landscape of drug delivery.

Meeting India's Healthcare Needs with Innovation

India's rapidly expanding healthcare sector is reflecting global trends, driving the injection filter needle market. The country's growing burden of chronic diseases, including diabetes, cardiovascular diseases, and cancer, has led to a surge in demand for injectable medications. Insulin delivery through pen needles, an essential type of filter needle, has become vital in diabetes management. India houses the world's largest number of diabetic patients, highlighting the critical role of filter needles in ensuring safe and effective drug delivery. The increasing adoption of injectable biologics for treating autoimmune diseases, cancer, and chronic inflammatory conditions is further driving the demand for high-performance filter needles that minimize contamination and enhance medication delivery efficiency.

Beyond the Needle: Why Surgical Procedures Are Fueling Demand

The rising volume of surgical procedures, both elective and emergency, is also contributing to the increasing demand for filter needles. Modern surgical interventions require precise and sterile medication delivery to minimize the risk of infections and complications. Filter needles prevent contamination from glass particles and other impurities when drawing medication from ampules, commonly used in hospital settings. This is especially critical in intensive care units (ICUs) and operating rooms, where even a minor lapse in sterility can lead to serious infections. As more patients undergo complex surgical procedures, the need for advanced drug delivery systems, including high-quality filter needles, is becoming more pronounced.

A Clearer Vision: Tackling Eye Diseases with Precision

Eye diseases, particularly those requiring intravitreal injections, are driving a significant portion of the demand for filter needles. Neovascular age-related macular degeneration (nAMD), diabetic retinopathy, and diabetic macular edema are becoming more prevalent in India due to an aging population and rising diabetes rates. Approximately 35 million people in India are visually impaired, and about 4.95 million people (0.36% of the population) are blind.

Intravitreal injections are the primary treatment for

these retinal conditions, requiring precise drug delivery directly into the eye. Filter needles play a crucial role in this process by preventing contamination and minimizing tissue damage, thereby improving clinical outcomes and reducing patient discomfort. In 2020, approximately 196 million people experienced age-related macular degeneration (AMD) globally, a figure that is predicted to rise to 288 million by 2040, underscoring the growing importance of safe and effective injection techniques.

The Invisible Threat: How Filter Needles Are Combating Contamination

Medication contamination remains one of the most overlooked yet significant risks in drug administration. Glass ampules, commonly used for storing injectable medications, can release tiny glass particles when opened. If these particles enter the bloodstream, they can trigger serious complications, including embolism and inflammation. Filter needles are designed with fine mesh filters that capture these particles, ensuring that only pure medication reaches the patient. Terumo's injection filter needles feature a five-micrometer mesh filter that prevents both intrinsic and extrinsic particles from entering the body. This not only improves patient safety but also enhances the overall efficiency of drug delivery by reducing the chances of clogging and inconsistent flow.

Terumo's Edge: Setting New Standards in Injection Technology

Terumo, a global leader in medical technology, has been at the forefront of innovation in the injection filter needle market. The company's K PACK™ 30G extra wall needles are equipped with a specialized five-micrometer mesh filter that ensures a flow rate over four times higher than that of regular needles. This high-flow rate design reduces injection time and minimizes patient discomfort, improving both clinical efficiency and patient experience. Additionally, Terumo's hub design ensures a secure connection between the needle and syringe, eliminating the risk of leakage or detachment during administration. These innovations are particularly beneficial in high-stakes procedures such as intravitreal injections and critical care drug delivery, where precision and reliability are paramount.

Smart Injections: How Technology Is Redefining Drug Delivery

Technological advancements in medical devices are transforming the landscape of drug delivery. Needle-free injection systems and smart syringes are gaining traction, but the need for precision, sterility, and patient comfort continues to drive demand for high-quality filter needles. Innovations such as ultra-thin wall needles, ergonomic designs, and integrated safety features are enhancing the performance and user experience of filter needles. Furthermore, the integration of digital health solutions with drug delivery systems provides real-time monitoring and feedback, improving patient adherence and clinical outcomes.

Policy and Infrastructure: The Backbone of Market Growth

Government initiatives and healthcare infrastructure development are playing a crucial role in supporting the growth of the filter needle market. In India, the government's push to strengthen the healthcare sector through investments in hospital infrastructure, medical training, and drug safety regulations has created a favorable environment for market expansion. The increasing availability of healthcare services in rural and underserved areas is also driving the demand for affordable and high-quality medical devices. Moreover, the rise in medical tourism and the growing number of accredited healthcare facilities in India are contributing to the increased use of advanced drug delivery systems, including filter needles.

The Rise of Biosimilars: New Opportunities for Filter Needle Innovation

The increasing adoption of biosimilars and specialty drugs is creating new opportunities for innovation in filter needle technology. Biosimilars require precise and consistent drug delivery to achieve the desired therapeutic effect, making filter needles a critical component of the drug administration process. The shift towards personalized medicine and targeted therapies is further driving the need for advanced injection systems that can deliver small, highly concentrated drug volumes with minimal waste and maximum patient comfort.

Future Outlook: Why the Market Is Just Getting Started

As the global healthcare landscape continues to evolve, the injection filter needle market is set to maintain its growth momentum. The increasing burden of chronic diseases, rising demand for injectable biologics, growing surgical volumes, and technological advancements in drug delivery systems will continue to drive market expansion. The Asia-Pacific region, with its rapidly growing healthcare infrastructure and rising healthcare expenditure, is expected to be a key growth driver. Terumo's commitment to innovation and quality ensures that its products remain well-positioned to meet the evolving needs of healthcare providers and patients. The future of the injection filter needle market lies in enhancing patient safety, improving clinical efficiency, and supporting better health outcomes through advanced drug delivery technology. ■

Author

Ashit Sikka
Senior Director – Pharmaceutical Solutions Division (PSD), APAC, Terumo India

Beyond the Pill: A Holistic Approach to Combating Antimicrobial Resistance

India is confronting a grave public health emergency—antimicrobial resistance (AMR). With the highest incidence of bacterial infections and widespread, in many cases unregulated, application of antibiotics, the emergence of drug-resistant "superbugs" has become a significant concern.

Devvesh Shrivastav, Country President & Global HR Director, Centrient Pharmaceuticals emphasizes that Antibiotics are essential tools in modern medicine, preventing and treating bacterial infections. He also spoke about how Pharmaceutical companies also play a significant role in controlling AMR.

According to the World Health Organization (WHO), AMR is a top global health threat, responsible for 1.27 million deaths worldwide in 2019 and contributing to another 4.95 million deaths. A sharp rise in mortality from bacterial AMR is predicted, with 39 million deaths expected between now and 2050—an average of three deaths per minute.

Unless checked, the world economy could lose as much as USD 3.4 trillion each year by 2030. In India, the sales of over-the-counter antibiotics, self-medication, and the lack of public awareness have only aggravated the situation. The increasing inefficacy of life-saving medicines for ailments such as pneumonia, urinary tract infections, and even surgical site infections proves that India requires a more extensive, holistic approach to AMR—apart from new antibiotics alone.

Why AMR is a Growing Threat in India

AMR doesn't just make infections harder to treat—it also puts routine surgeries and life-saving treatments at risk. When antibiotics fail, even minor infections can be fatal. Antibiotics are essential tools in modern medicine, preventing and treating bacterial infections, saving lives, and reducing risks in surgeries, childbirth, and chemotherapy. However, overuse and misuse of antibiotics—such as prescribing them unnecessarily or using the wrong antibiotic—are the main drivers of AMR. According to a study published in 2022 by the Indian Council of Medical Research (ICMR), most patients in India are no longer responding to carbapenems, a potent last-line antibiotic reserved for critical patients. 42% of E. coli infections and 35% of Staphylococcus aureus infections are resistant to third-generation cephalosporins and methicillin, respectively, worldwide, as per WHO reports.

India's high antibiotic consumption is a big part of the problem, especially with weak regulations allowing over-the-counter sales and poor infection control in healthcare settings. Beyond human health, overuse of antibiotics in livestock and agriculture contributes to resistance. Additionally, pharmaceutical manufacturing has played a role, as the release of antibiotics into the environment from waste products encourages the development of resistant bacteria. The economic consequences are severe—the World Bank estimates that AMR could add USD 1 trillion in annual healthcare costs by 2050 and cause GDP losses of up to $3.4 trillion per year by 2030. To address these

challenges, we need a more holistic strategy that goes beyond just prescribing antibiotics.

What Can Be Done: Better Surveillance, Smarter Use, and More Awareness

A key part of fighting AMR is improving surveillance—tracking where and how resistance is spreading. India should invest in a national AMR database that collects data from hospitals, clinics, and local healthcare providers to detect trends and help policymakers make better decisions. Using advanced technologies like AI can further improve this monitoring process.

Antibiotic stewardship programs are another critical tool. Such programs ensure that antibiotics are prescribed only when absolutely needed, and patients complete their entire course of the drug to avert resistance developing. Hospitals should also emphasize more infection control measures, such as providing sterile surroundings and encouraging hand hygiene, in order to avert infections in the first place.

Public education plays an equally key role. Many individuals are unaware that antibiotics cannot cure viral infections such as the common cold, and stopping antibiotics too early contributes to resistance. Additionally, responsible disposal of unused antibiotics is crucial to minimizing environmental contamination. Adhering to WHO's One Health model—interrelating human, animal, and environmental health—is crucial to confronting AMR on all fronts.

The Role of Responsible Manufacturing in Combating AMR

Pharmaceutical companies also play a significant role in controlling AMR. Responsible manufacturing practices must be followed to ensure antibiotics do not enter the environment through waste discharge. The AMR Industry Alliance has developed a science-based standard known as the Predicted No-Effect Concentration (PNEC), which sets discharge limits for antibiotic manufacturing. A few leading manufacturers have already implemented stringent wastewater treatment processes to comply with these targets.

Looking Ahead

India's battle against AMR must be multi-faceted. In addition to gearing up regulations and enhancing public education, India must invest in sustainable waste management to avert contamination by pharmaceuticals and enhance vaccinations in animal husbandry to minimize the use of antibiotics. Hospitals must implement tighter infection control practices, and policymakers must put their foot down on selling antibiotics over the counter.

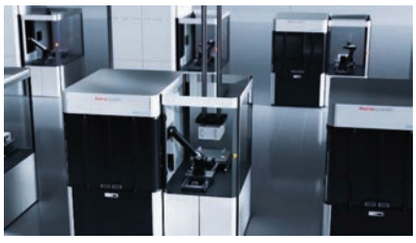
International collaboration is also key. The AMR Industry Alliance, which includes over 100 biotech, diagnostics, generics, and research-based pharmaceutical companies, has been instrumental in setting standards for responsible manufacturing and encouraging collaboration between governments and industry.

Through prevention and education, India can truly make headway in the battle against AMR. It's not merely a matter of creating new medicines; it's a matter of creating a system that prevents resistance in the first place. ■

Author

Devvesh Shrivastav
Country President & Global HR Director
Centrient Pharmaceuticals

Thermo Fisher Scientific introduces Vulcan Automated Lab



WALTHAM, Mass: Thermo Fisher Scientific Inc, the world leader in serving science, today announced the launch of the Thermo Scientific Vulcan™ Automated Lab, a groundbreaking solution designed to drive a new era of process development and control in semiconductor manufacturing. The seamlessly integrated system is designed to enhance productivity, increase yield and reduce operating costs for semiconductor manufacturers.

The rapid evolution and miniaturization of semiconductor technology is leading to unprecedented demand for atomic-scale transmission electron microscopy (TEM) metrology data. Manufacturers now face the challenge of scaling laboratory operations quickly, while maintaining high efficiency and productivity to meet the growing global need for semiconductors that power everything from consumer electronics to autonomous vehicles.

"The increasing complexity of digital technologies, which requires more sophisticated semiconductors, provides us with an incredible opportunity to enable the success of our semiconductor customers through advanced imaging analysis technology," said Marc N. Casper, chairman, president and chief executive officer of Thermo Fisher. "By leveraging our deep expertise in electron microscopy and auxiliary instruments with artificial intelligence capabilities, our new solution is well-positioned to help semiconductor manufacturers drive efficiencies in their operations."

The solution has also been designed to help address the time-to-data gap resulting from traditional TEM analysis methods. By streamlining metrology data collection using a combination of materials handling automation and data connectivity, the Thermo Scientific Vulcan Automated Lab accelerates the data collection process and creates an integrated workflow between the semiconductor lab and the fabrication facility. ■

DuPont launches Liveo Pharma TPE Ultra-Low Temp tubing for Biopharma Industry

WILMINGTON, Del: DuPont announced it has launched DuPont Liveo Pharma TPE Ultra-Low Temp Tubing, a new thermoplastic elastomer tubing designed to withstand the low temperatures required for many of today's biopharmaceutical processing applications.

Sterilizable, weldable, sealable Liveo™ Pharma TPE Ultra-Low Temp Tubing is an ISO Class 7 cleanroom-manufactured tubing that offers improved elastomer toughness and ductility down to -86 °C; resistance to bend, crush and impact at -80 °C; good pumpability and low spallation; and excellent burst pressure resistance and chemical resistance. The phthalate-free tubing's purity and regulatory data include USP Class VI standards, extractables USP <665>, elemental impurities USP <232> and Biocompatibility ISO 10993 (part 5, 6, 11, 23), among others. A comprehensive data package is available to facilitate qualification and validation.

"In recent years, there's been increasing demand for high-purity materials that can meet the biopharmaceutical processing industry's needs for low-temperature exposure," said Diana Salvadori, DuPont Global Senior Product Marketing Manager for Biopharma Processing. "With our new Liveo™ Pharma TPE Ultra-Low Temp Tubing, DuPont is offering an additional thermoplastic elastomer tubing option for fluid transport and single-use bioprocessing applications, facilitating adoption and compatibility with alternative TPE tubing offerings."

Liveo Pharma TPE Ultra-Low Temp Tubing is the second TPE tubing product launched by DuPont in recent years, joining Liveo™ Pharma TPE Tubing in the company's portfolio of solutions for biopharma processing applications – which also includes numerous silicone-based tubing and overmolded assembly (OMA) products.

"DuPont's TPE tubing products complement our silicone-based Liveo™ Pharma range – and they are produced under the same high-quality principles as our products that already are known and trusted by the biopharma industry," Salvadori said. ■

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FACT & FIGURES 2024

- **750** EXHIBITORS FROM 15+ COUNTRIES
- **25871** VISITORS FROM 53 COUNTRIES
- **8** TECHNICAL CONFERENCES
- **250+** GLOBAL SPEAKERS
- **1500+** BUSINESS DELEGATES
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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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