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the business of Bio & Health Sciences

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25 Transformative Years of BIOSIMILARS

"The biosimilar developers are eagerly awaiting revised CDSCO regulations that might lead to simplification of the development pathway for biosimilars"

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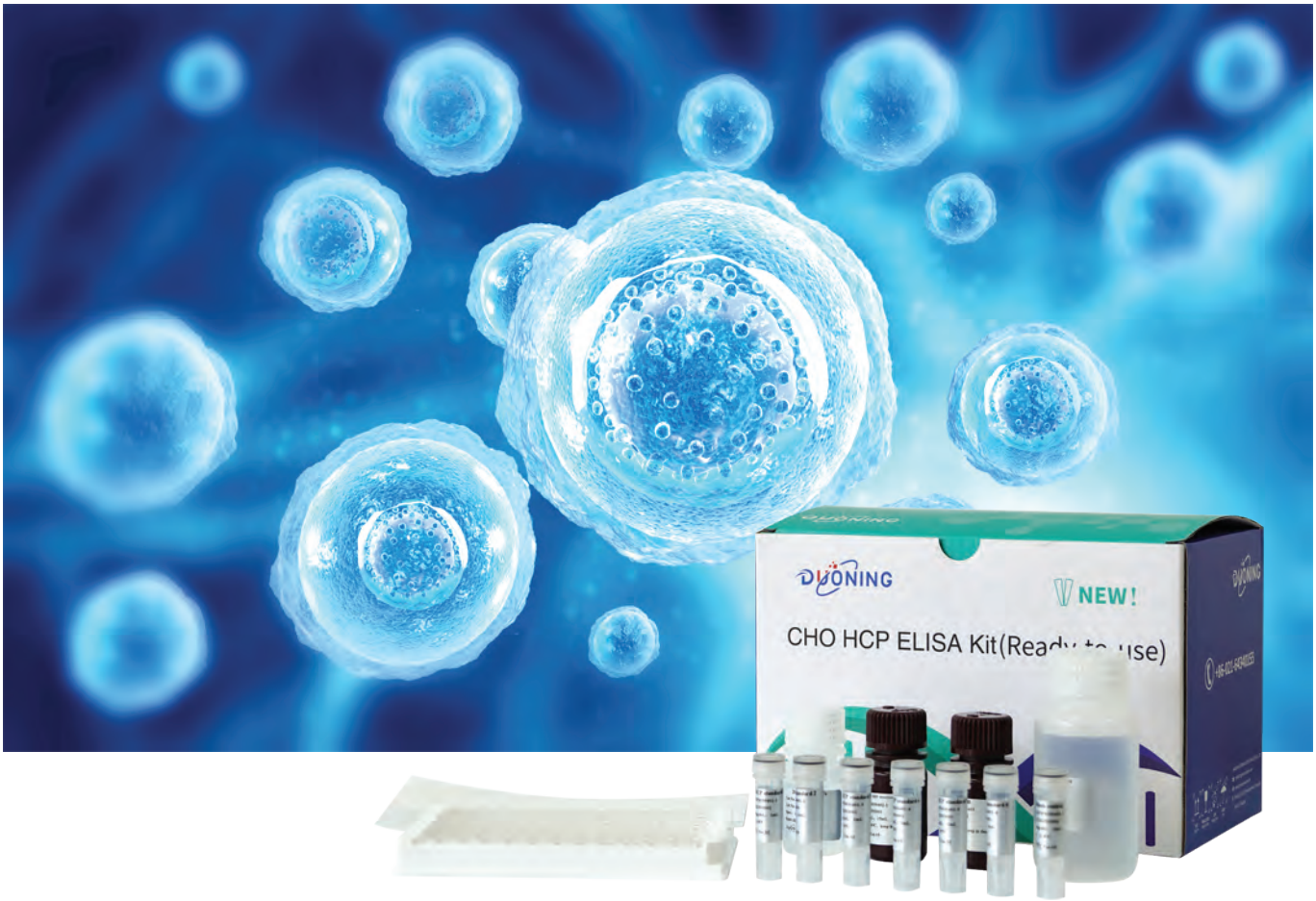

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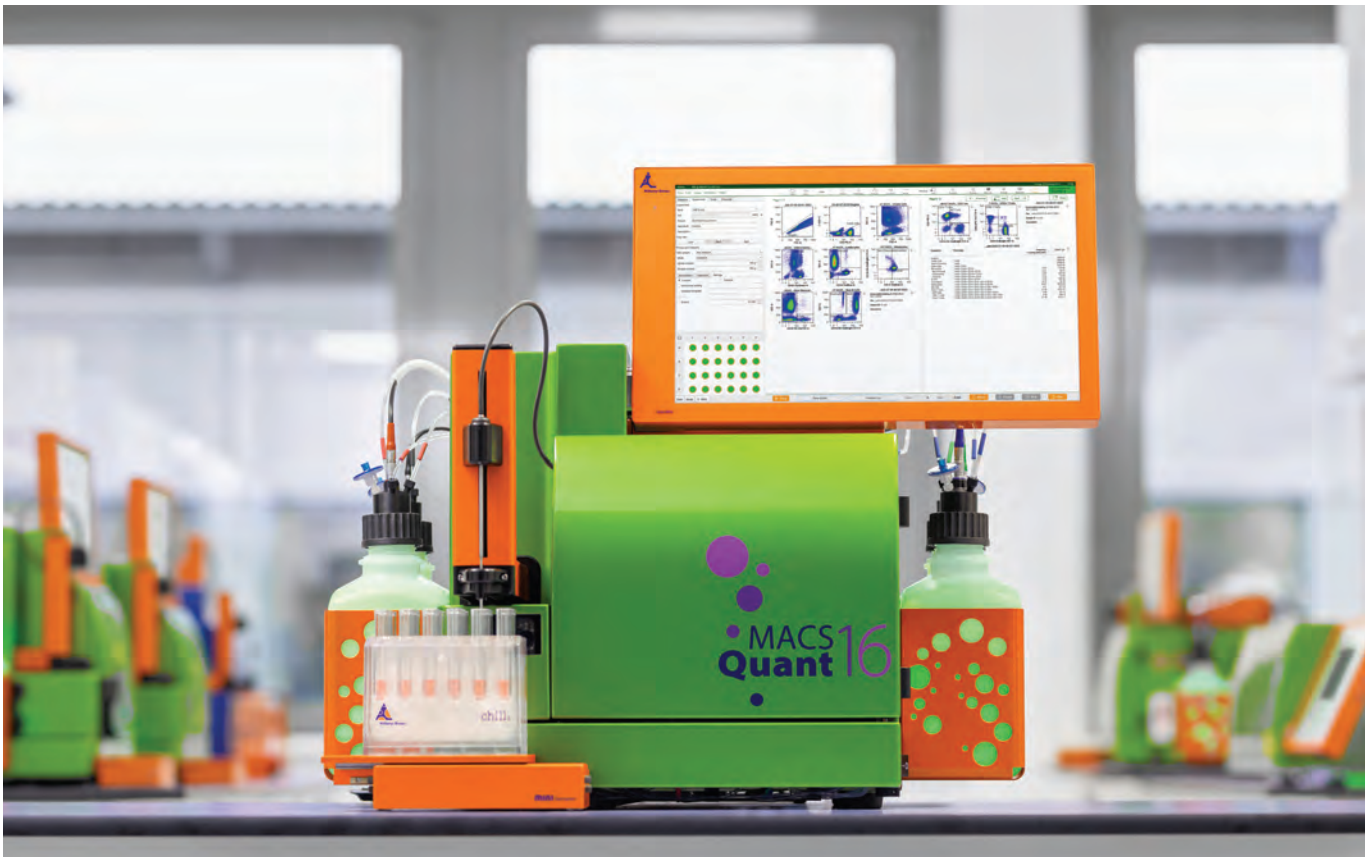

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Acknowledgement/ Feedback

Thank you for the opportunity to participate in the cover story about the 'current tax cuts on cancer drugs'.

-Dr Ranjana Sarma, Hyderabad

The Indian CRDMO sector is seeing rapid growth and has demonstrated immense potential in the face of global disruptions and a volatile market. However, there are few key barriers that will need to be overcome for the sector to leverage its full potential.

-Manni Kantipudi, Hyderabad

Thank you for featuring an interview with RNT Health Insights. We truly appreciate BioSpectrum's support!

-Tanmaya Gulati, Chandigarh

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
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Dear Readers,

India has a thriving biosimilar ecosystem in comparison to other countries, and because of that, Indian pharmaceutical companies have risen as the global market leaders in biosimilars. India approved its first biosimilar much before the United States (2015) and Europe (2006). The first biosimilar was approved and marketed in India in 2000 for hepatitis B, although no specific guidelines were available at that time for the development and marketing of biosimilars in India. Then there is no looking back. So far, the country has approved 135 biologics for manufacturing and marketing and 301 biologics for import and marketing between January 2000 and 2025. The lead story throws light on how the first 25 years of India's biosimilar journey focused on building domestic capacity and regulatory frameworks. With growing expertise and shifting geopolitical dynamics, Indian biosimilar companies are poised to seize a bigger piece of the pie. The next 25 years are set to be Bharat's biosimilar moment on the world stage.

According to the Indian BioEconomy Report 2025, the number of biotech startups has more than doubled from 4,237 in 2020 to 10,075 in 2024. On a year-on-year basis, the biotech startup sector has shown a decrease in growth rate in 2024 compared to previous years between 2020 and 2023. Our correspondent has tried to identify the factors that govern these fluctuations, such as market saturation, increased competition, emerging new technologies, or limited funding.

India has become a significant force in the global biopharmaceutical market, and with the swift growth of biologics and biosimilars, the importance of local biosuppliers has reached new heights. Additionally, with a financial backing of Rs 1500 crore from the Biotechnology Research Innovation and Entrepreneurship Development (Bio-RIDE) scheme by the government, aimed at advancing high-performance biomanufacturing and biofoundry assistance to the industry, the demand for decreasing reliance on imported research tools, consumables, and raw materials is becoming increasingly prominent. In an article, we are discussing how the emergence of emerging technologies like artificial intelligence (AI), generative AI, automation, etc., might bolster the self-sufficiency of the domestic biosupplier sector in the near future.

In recent years, research has increasingly focused on discovering and validating novel biomarkers to overcome the limitations of traditional tests. Emerging biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL) and kidney injury molecule-1 (KIM-1) have shown significant promise for the early detection of kidney injury. These biomarkers are particularly sensitive indicators of tubular injury and are capable of detecting renal damage at stages when conventional markers remain within normal limits. In an opinion piece, an expert, despite their potential, stresses that further research is needed to validate these biomarkers in large-scale, long-term clinical trials.

The Indian small molecule Contract Development and Manufacturing Organisations (CDMOs) market generated a revenue of $6.8 billion in 2023, and a compound growth rate of 9 per cent is expected by 2030. The Indian large molecule CDMO market is set to double over the next few years, from a revenue of just below $1 billion in 2023 to $2 billion by 2030. An expert points out that digital platforms that can be tailored to the specific requirements of the varied Indian pharmaceutical market present tremendous potential to maximise R&D for both large and small molecules, hence enhancing India's position in this dynamic global pharma industry.

I am sure you will find this edition a great read.

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

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25 Transformative Years of BIOSIMILARS

2025 marks 25 years since India first ventured into the biosimilar space. Over the past quarter-century, the country has consistently solidified its position as a global leader in biosimilar approvals, with 135 approvals till January 2025. Initially focused on simpler biologics, the field now includes developing and approving complex monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), a diversified therapeutic focus, and a growing number of innovative players entering the field. As the industry celebrates this silver jubilee, we reflect on the journey that has not only transformed India's biotechnology sector but has also played a pivotal role in making life-saving treatments more accessible and affordable worldwide.

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Dr Vidhi Bhanushali, Chief Executive Officer of scanO shares details about the current oral health landscape of the country.

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Senior Field Application Specialist, Revvity Signals Software Team

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Leveraging Genomic Data

While the entire pharma world is still grappling with the issue of tariffs by the US and its impact on the US consumers as well as various other countries (though there is 90-day relief on the issue), India has achieved a significant step in the healthcare and medicines sector. There is encouraging news from the Genome India project that has the potential to advance the precision medicines field.

Preliminary findings of the Genome India project, which were revealed last month, show that it has uncovered over 180 million genetic variants. These 180 million unique differences in DNA have been uncovered from the genome data of 9,772 individuals from diverse populations across India. A gene variant is a permanent change in the DNA sequence that makes up a gene. The genetic variations among individuals are considered to be crucial for understanding our disease predispositions and rare inherited disorders.

Along with the genome data of these individuals, this database includes over 30 health indicators for each of them. They include weight, height, blood pressure, blood sugar, lipid levels and liver and kidney functions. This is expected to help the researchers to understand how our genomes connect to our health. With 4.5 petabytes of data generated through this project, India is described as the world's largest genetic lab. Such a large biological data was gathered in just five years.

The Genome India project was launched in 2020 to collect 10,000 samples and conduct whole genome sequencing. The sequencing of over 99 ethnic groups was done by 20 Indian institutions under the leadership of the Indian Institute of Science (IISc) in Bengaluru. The project was completed in 2024, and the sequencing data was released in January 2025 at a function held in Delhi. The data was later published in the journal Nature Genetics in April 2025. In the next steps, the researchers are finding out the implication of the variants, which are related to diseases, associated with therapeutic responses and constructing a panel of variants that would be useful for finding missing data in the future small-scale genotyping. Correcting disease-genetics associations among the Indian population is one more utility of this data.

The availability of such a diverse and in-depth genome data, along with unique differences, biochemistry and anthropometry data, will find many crucial applications in healthcare. It will facilitate the creation of a variant panel useful for future small-scale studies linking genes to diseases in the Indian population. The information on variants associated with specific diseases will be useful for developing low-cost diagnostic kits. It will further kickstart the precision medicines efforts by diagnosis and predicting genetic basis of drug responses.

Biobanks play an important role in precision medicine. It is a repository of biological samples like blood, DNA, cells, tissues, and/or organs alongside their genetic data. Large and diverse data is always helpful in therapies. Such a large and diverse biological data stored in the biobanks help in making the use of precision medicine widespread. We have 19 registered biobanks hosting biological specimens. The addition of the new data available from the Genome India project will help in making the biobanks richer in diversity and numbers, too. Its significance is even more pronounced since it has captured genetic diversity in 83 population groups that have been underrepresented till now in global genome studies.

However, experts point out that having merely very diverse data is not enough. Biobank regulations are also important in gathering and using the data and the development of precision medicine. On this count, there are some gaps in Indian regulations, particularly related to the rights of individual and public trust. That is believed to be restricting the exploitation of the potential of precision medicine.

We have crossed one major hurdle and gathered the requisite critical data. Now, the right approach towards regulation will be required by aligning it to global standards. That will encourage people to share their data to make faster developments in precision medicines. BS

Dr Milind Kokje
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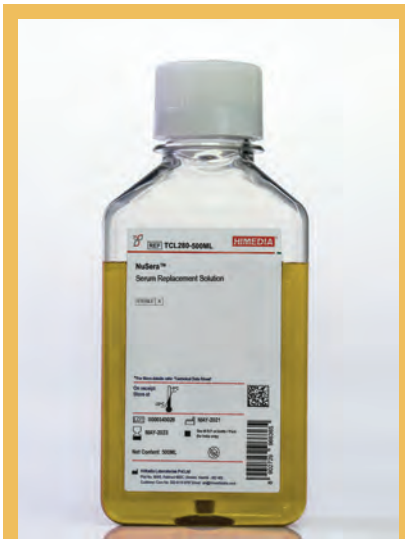

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Health Ministry releases national guidelines on medical oxygen management

The Ministry of Health and Family Welfare, Government of India, has released the National Guidelines on Medical Oxygen Management at a workshop held at the All India Institute of Medical Sciences (AIIMS), Delhi. The workshop also marked the launch of the National Capacity Building Programme on Oxygen Management, which will be led by the Department of Hospital Administration at AIIMS, Delhi. The release of National Guidelines on Medical Oxygen Management marks a significant step toward strengthening the country's medical oxygen infrastructure

and ensuring uniform best practices in oxygen management across healthcare facilities. The comprehensive guidelines provide a framework for the efficient procurement, storage, and administration of medical oxygen, with a focus on patient safety, capacity building, and emergency preparedness. The National Capacity Building Programme on Oxygen Management is an initiative led by the Disaster Management Cell of Ministry of Health and Family Welfare in collaboration with AIIMS, New Delhi. It aims to train around 200 master trainers across the country which in turn shall undertake capacity building of hospital administrators and medical officers across the country in proper handling and utilisation of medical oxygen, reducing wastage and improving clinical outcomes.

Cuba explores partnership with India focusing on biomanufacturing and science

India and Cuba have reaffirmed their commitment to expanding bilateral cooperation in science and technology, particularly in biotechnology and biomanufacturing, as Cuba Deputy Prime Minister Dr Eduardo Martínez Díaz recently called on the Union Minister of State (Independent Charge) for Science and Technology Dr Jitendra Singh. The meeting explored avenues to deepen collaboration in medical research, vaccine development, and sustainable biomanufacturing. During the discussions, Dr Jitendra Singh emphasised that collaborative research is indispensable for a science-driven society to have a global influence at scale. He noted that joining hands with the best in the world and pursuing complementary, targeted research will propel India's scientific community to the next level of innovation, transformation, and skill development.

S&T Minister announces completion of 10,000 genome sequences of Mycobacterium TB

In a significant breakthrough in the fight against tuberculosis (TB), Union Minister Dr Jitendra Singh announced the completion of genome sequencing of 10,000 isolates of Mycobacterium tuberculosis. The achievement marks a major stride in India's commitment to eradicating TB ahead of the World Health Organization's (WHO) 2030 targets. The genome sequencing initiative is part of the Dare2eraD TB programme (Data Driven Research to Eradicate TB), launched on March 24, 2022, which focuses on data-driven research to eradicate TB. A key component of this initiative is the Indian Tuberculosis Genomic Surveillance (InTGS) Consortium, spearheaded by the Department of Biotechnology (DBT), the Council of Scientific and Industrial Research (CSIR), and the Indian Council of Medical Research (ICMR), in collaboration with major clinical institutions. The programme aims to sequence over 32,000 TB isolates to identify drug resistance mutations and improve treatment outcomes.

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Ankura Hospitals secures Rs 165 Cr funding from ADB

Hyderabad-based Ankura Hospitals, a leading healthcare provider specialising in super-specialty tertiary and quaternary care services for women and children, has secured Rs 165 crore in funding from the Asian Development Bank (ADB). This strategic investment will support Ankura's ambitious expansion plans and is aligned with its long-term vision to strengthen its market presence and enhance healthcare accessibility across India. As part of its expansion strategy, Ankura Hospitals is focused on establishing new state-of-the-art facilities in key cities across India. Ankura Hospitals specialises in providing world-class care in maternity and gynaecology, offering services such as normal deliveries, cesarean sections, fertility treatments, high-risk obstetrics, and comprehensive prenatal and postnatal care. The hospital also features advanced surgical solutions in gynaecology, including laparoscopic surgeries and treatment for various gynaecological conditions.

Emcure's European subsidiary Tillomed buys strategic pharma portfolio from Manx for £19.7 M

Tillomed Laboratories, a subsidiary of Pune-based Emcure Pharmaceuticals, and a leading European pharma company, has entered into an Asset Purchase Agreement (APA) with UK-based Manx Healthcare and its subsidiaries Manx Pharma and Manx Generics. 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 million (including £ 4.7 million for inventory) of which £ 6.2 million 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. Headquartered in Luton, UK, Tillomed operates across multiple European markets, ensuring access to cost-effective healthcare solutions. As an Emcure subsidiary, Tillomed leverages world-class research, manufacturing, and distribution expertise to bring innovative and affordable medicines to patients.

Eureka Analytical Services acquires majority stake in Teena Biolabs

Eureka Analytical Services, a subsidiary of the GBA Group, has acquired a majority stake in Teena Biolabs, a leading pharmaceutical analytics service provider in India. The acquisition is another important step in the GBA Group's global expansion strategy. Through the merger with Teena, Eureka will become a leading service provider for pharmaceutical analysis in India with a total of two US-FDA approved sites. With its current ~200 employees across the main site in Hyderabad and the second laboratory in Panchkula, Teena has built up long-standing customer relationships and a very good reputation in the market over the last few years. Teena laboratory at Hyderabad has a US-FDA inspected status and can therefore support pharmaceutical companies both for the local Indian market and for export to the USA or Europe.

Kotak Alts injects Rs 1,050 Cr in Tirupati Medicare to support expansion plans

Kotak Alternate Asset Managers Limited (Kotak Alts) has announced an investment of Rs 1,050 crore in Himachal Pradesh-based Tirupati Medicare Limited. This investment will facilitate a complete exit for the existing investor and support Tirupati's expansion plans. Founded in 2005, Tirupati is a leading player in the nutraceutical, pharmaceutical, and Ayush contract development and manufacturing sectors in India. The company boasts of long-standing relationships with global industry leaders such as Herbalife, Glanbia, Abbott, Haleon, Cipla, Dr. Reddy's, Torrent, Macleods, Pfizer, Lupin, Dabur, and others. Tirupati manufactures renowned brands including Optimum Nutrition, PediaSure, Centrum, Endura Mass, Montair LC, Azee, Softovac, and others. It holds the distinction of having the largest installed capacity for oral solids and powders among Indian nutraceutical contract manufacturers.

AGI Greenpac Limited invests Rs 700 Cr in greenfield manufacturing plant in MP

AGI Greenpac Limited, India's largest manufacturer of container glass catering to the food, pharmaceutical industries, has 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 Rs 700 crore. This expansion will increase the company's container glass manufacturing production capacity by ~25 per cent 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. 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.

DCDC Kidney Care raises Rs 150 Cr from ABC Impact

DCDC Health Services, which operates dialysis centres under the DCDC Kidney Care brand, has secured a significant investment of Rs 150 crore from Singapore-based ABC Impact, the Asia-focused impact investor backed by Temasek. Founded in 2009, DCDC operates more than 200 centres across India and is one of the foremost operators of dialysis clinics, both under public-private partnerships (PPP) and company-owned standalone clinics. The investment from ABC Impact will support Delhi-based DCDC's expansion plans, facilitating the rollout of over 150 new clinics across the country in the coming months. On average, patients in India must travel up to 50 kilometres to access a dialysis centre. This expansion will help address the growing need for accessible, affordable dialysis services for those with end-stage renal disease (ESRD) in-line with the Ayushman Bharat Yojna.

Rx Propellant unveils new research and innovation campus in Genome Valley

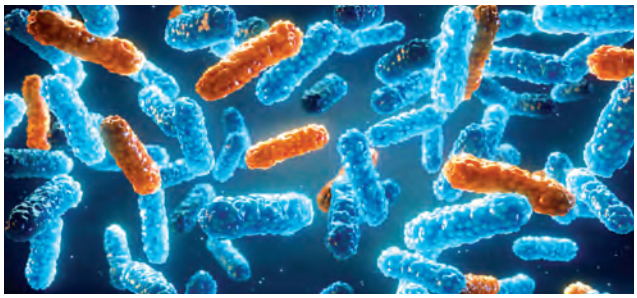
Rx Propellant, India's premier life sciences infrastructure platform backed by Actis, has unveiled 1GV, a cutting-edge 136,000 sq. ft. research and innovation campus built over 1.8 acres in Genome Valley, Hyderabad. This launch marks another milestone in Rx Propellant's unwavering commitment to advancing India's life sciences ecosystem and shaping its future. Over the years, this campus has been instrumental in scientific breakthroughs, witnessing and contributing to the evolution of India's pharmaceutical, biotech, and contract research industries. This campus is a continuation of the legacy of the evolution of the Indian pharmaceutical and biotech industry, as 1GV is built on the historical grounds of the first construction in Genome Valley. 1GV is a beacon of modern life sciences infrastructure, designed to integrate sustainability at its core. With LEED Platinum & IFC EDGE Advanced Pre-Certification, the campus reflects a commitment to environmentally responsible development. Its world-class facilities are built for adaptability, scalability, and long-term growth, providing an optimal environment for life sciences enterprises. Beyond infrastructure, 1GV offers a suite of collaborative spaces designed to enhance connectivity, comfort, and well-being.

Alcon introduces India's first fully personalised Lasik treatment

Alcon, the global leader in eye care, has announced the launch of wavelight plus, India's first fully personalised Laser-Assisted In Situ Keratomileusis (LASIK) treatment. Alcon is a leader in refractive vision correction and its next-generation wavelight plus technology introduces a new era of precision in refractive surgery, with unprecedented levels of personalisation offering patients visual outcomes with minimal risk and excellent predictability. Wavelight plus has received Central Drugs Standard Control Organisation (CDSCO) India approval, CE Mark and recently received US Food and Drug Administration (FDA) approval. Unlike conventional Lasik treatment, wavelight plus uses Ray Tracing Technology to create a Digital Eye Twin, a highly detailed 3D model of each patient's eye. This allows surgeons to simulate, test and optimise a fully customised treatment plan before surgery, ensuring a high level of accuracy and personalised vision correction. By considering the complete optical system rather than just the cornea, this innovation enhances surgical precision, safety and visual outcomes, often enabling patients to achieve vision beyond 20/20.

Sai Life Sciences sets up Peptide Research Centre in Hyderabad

Sai Life Sciences Limited, a Contract Research, Development, and Manufacturing Organisation (CRDMO), has inaugurated a dedicated Peptide Research Centre at its integrated R&D Campus in Hyderabad. The Peptide Research Centre is designed to support innovator pharma and biotech companies with specialised 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. The new centre 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.



Venus Remedies & AdjuTec Pharma partner to combat AMR

AdjuTec Pharma AS, a Norway-based startup developing antibiotic resistance breakers, has entered into a research collaboration agreement with Panchkula-based Venus Remedies Limited. Venus Remedies 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 programme, which is presently in phase 1 clinical trials. As a frontrunner in antimicrobial resistance (AMR) research, Venus Remedies 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 will test APC-148 in combination with various antibiotics against its extensive library of clinical isolates collected through the GASAR study.

Ireland's T-Pro opens new India offices to meet demand for AI-driven clinical documentation

T-Pro, a global leader in artificial intelligence (AI)-powered speech recognition and clinical documentation solutions, has announced the opening of its new offices in Chennai and Bengaluru, reinforcing its commitment to leveraging India's rich talent pool to drive healthcare innovation worldwide. This strategic move further solidifies T-Pro's presence in India, allowing it to better serve its growing customer base across India, Malaysia, Singapore, Australia, and New Zealand. By harnessing the power of artificial intelligence, T-Pro's solutions streamline clinical documentation, reduce the administrative burden on healthcare professionals, and improve patient outcomes. With a workforce of over 350 employees and contractors in India, T-Pro has experienced a steady 20 per cent year-on-year growth since 2021. The newly established offices in Chennai and Bengaluru will initially house more than 20 full-time professionals across software development, helpdesk support, and operations, with further expansion plans in the pipeline.

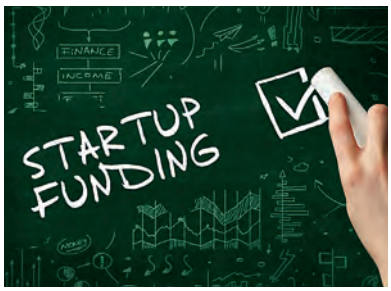
Gennova Biopharma accelerates development of Nipah virus vaccines using mRNA technology

Pune-based Gennova Biopharmaceuticals, a subsidiary of Emcure Pharmaceuticals, is advancing the development of a pathbreaking self-amplifying mRNA (saRNA) vaccine against the deadly Nipah virus. This critical initiative is supported by an expanded partnership with Norway-based Coalition for Epidemic Preparedness Innovations (CEPI), with funding of up to $13.38 million. 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. In August 2023, CEPI initially provided up to $3.6 million to support the optimisation of Gennova's saRNA-platform technology to develop vaccine candidates against unknown pathogenic threats, also referred to as Disease X.

Govt approves funds worth Rs 10,000 Cr to boost deep-tech and early-stage innovation

The union Minister of Commerce & Industry Piyush Goyal has announced that the Second Fund of Funds for Startups (FFS) with a corpus of Rs 10,000 crore, has been approved by Prime Minister Narendra Modi. This year, Rs 2,000 crore will be disbursed to Small Industries Development Bank of India (SIDBI) as the first installment. A significant portion of the fund will be reserved for seed funding of small startups and to support deep-tech innovation. The objective is to provide early-



stage financial support to budding entrepreneurs who often face challenges in accessing traditional forms of capital. This allocation will empower startups working on disruptive technologies by enabling them to scale prototypes, undertake research and development, and accelerate go-to-market strategies. The fund will especially focus on startups operating in cutting-edge domains such as artificial intelligence, machine learning, quantum computing, robotics, precision manufacturing, biotech, and semiconductor design, where long gestation periods and high capital requirements often pose hurdles.

Tvaster Genkalp raises $1.25 M to advance liquid biopsy cancer diagnostics

Chennai-based molecular diagnostic startup Tvaster Genkalp has raised $1.25 million in a Pre-Series A funding round led by Ideaspring Capital. Existing investors include Invigo Softwares and Prof. Mohamed Rela, a globally renowned liver transplant surgeon. The fresh investment will accelerate expansion and commercialisation of Episcreen Liver, a pioneering methylation-based liquid biopsy test for early liver cancer detection. Co-founded in 2021 by Dr Srikar Raman and K Sreedurgalakshmi, Tvaster is transforming molecular diagnostics and precision oncology through advanced epigenetic screening technologies. The company develops proprietary, high-accuracy genetic solutions, setting a new benchmark in non-invasive cancer detection. The startup is forging partnerships with leading diagnostic companies. Tvaster is also advancing its oncology diagnostics pipeline with Episcreen Bile, a novel test for Cholangiocarcinoma, an aggressive bile duct cancer with limited early detection options. Additionally, the company has developed Episcreen HBResist, the first-ever chemotherapy resistance test for paediatric hepatoblastoma, addressing a critical gap in childhood cancer treatment.

Stance Health secures $1 M funding to transform musculoskeletal care in India

Bengaluru-based startup Stance Health, an innovator in musculoskeletal (MSK) care, has secured $1 million in pre-seed funding. The round was led by General Catalyst, with participation from Antler, DEVC, EX Capital (Founders of Sword Health), and prominent angel investors such as Sriharsha Majety and Nandan Reddy, co-founders of Swiggy, along with Kulin Shah, co-founder of Onsurity. This funding will enable Stance Health to scale its structured, technology-driven MSK care model in India, addressing a traditionally unorganised market. The investment will support the development of its proprietary technology platform and the expansion of its team and multidisciplinary MSK centres across Bangalore and other major Indian cities. By leveraging advanced analytics and personalised therapeutic interventions, the company aims to create an integrated ecosystem that enhances the entire patient journey—from diagnosis to complete recovery.

25 Transformative Years of BIOSIMILARS

2025 marks 25 years since India first ventured into the biosimilar space. Over the past quarter-century, the country has consistently solidified its position as a global leader in biosimilar approvals, with 135 approvals till January 2025. Initially focused on simpler biologics, the field now includes developing and approving complex monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), a diversified therapeutic focus, and a growing number of innovative players entering the field. As the industry celebrates this silver jubilee, we reflect on the journey that has not only transformed India's biotechnology sector but has also played a pivotal role in making life-saving treatments more accessible and affordable worldwide.

The first 'similar biologic' was approved and marketed in India for a hepatitis B vaccine in 2000, well ahead of the EMA's (European Medicines Agency) approval in 2006 and the US FDA's (United States Food and Drug Administration) approval in 2015 for biosimilars for export. Since then, the biosimilars landscape in India has grown leaps and bounds. As of January 2025, India has approved 135 biosimilars across various continents, far surpassing the approvals in the US FDA and EMA. The Indian biosimilars market was valued at approximately Rs 4.37 billion in 2024 and is expected to grow at a compound annual growth rate (CAGR) of 14.2 per cent, reaching around Rs 16.49 billion by 2034 as per Expert Market Research.

Talking about therapeutic trends, ***Dr Cyrus Karkaria, President – Biotechnology at Lupin,*** said, "Around 75 per cent of the biosimilars approved by Central Drugs Standard Control Organisation (CDSCO) are primarily used for cancer treatment & supportive care. Filgrastim, pegfilgrastim, rituximab, trastuzumab, & bevacizumab are some of the most commonly prescribed biosimilars in these fields. Other key therapeutic areas where biosimilars have made a difference include adalimumab, etanercept, & infliximab for autoimmune disorders like rheumatoid arthritis, as well as epoetin alfa & darbepoetin alfa for anaemia associated with chronic kidney disease.

Key Milestones in India's Biosimilar Journey

- **2000 –** Launch of Biovac-B for Hepatitis B, India's first approved biosimilar.
- **2007 –** Approval of Wockhardt's Insulin Glargine (100 IU), one of India's first biosimilars for a long-acting insulin analogue.
- **2012 –** Introduction of India's first official regulatory framework for biosimilars, formalising the approval pathway for similar biologics.
- **2013 –** Biocon, in partnership with Mylan, received Indian approval for its trastuzumab biosimilar of Herceptin, the world's best-selling breast cancer drug — a major milestone in oncology biologics.
- **2014 –** Zydus Cadila became the first company in the world to receive approval for a biosimilar of AbbVie's Humira, the top-selling drug globally at the time.
- **2016 –** CDSCO issued revised guidelines to strengthen the biosimilar regulatory framework in India.
- **2017 –** Biocon became the first Indian company to receive U.S. FDA approval for a biosimilar — Trastuzumab, for the treatment of breast and gastric cancers.
- **2021 –** Zydus Cadila launched the world's first biosimilar Antibody-Drug Conjugate (ADC), Trastuzumab Emtansine, for HER2-positive breast cancer.

Ranibizumab biosimilars are transforming the treatment of wet age-related macular degeneration, while biosimilars of insulin glargine & recombinant human insulin are improving the accessibility & affordability of diabetes mellitus treatment. These cost-effective alternatives have significantly improved access to essential biologic therapies for patients across the country. However, there are still numerous unmet needs in disease areas such as asthma, allergy, dyslipidemia, & others, & India has the potential to address these requirements effectively."

Indian companies are credited with many industry firsts. In 2013, Biocon, in partnership with Mylan, received approval for its trastuzumab biosimilar of Herceptin, the world's best-selling breast cancer drug at the time, marking a major milestone in oncology biologics. Zydus Cadila, another frontrunner, became the first company to receive approval for a biosimilar of AbbVie's Humira, the top-selling drug worldwide in 2014. In another breakthrough, Zydus also launched the world's first biosimilar antibody-drug conjugate (ADC) — Trastuzumab Emtansine — for HER2-positive breast cancer in 2021. Between 2000 and 2025, the big five Indian companies—Biocon, Intas, Dr. Reddy's, Zydus, and Lupin—captured the lion's share of biosimilar approvals and launches. However, in recent years, smaller companies and emerging biotech firms have begun to make their mark, driving innovation and expanding the landscape of India's biosimilars sector. The Indian biosimilars that include vaccines, blood products, recombinant therapeutics (rDNA), stem cells and cell based products, landscape between 2000 and 2025 can be broadly categorised into two phases: the foundational period (2000–2013) and the accelerated growth phase (2014–2025). The early years were marked by approvals of relatively simpler biologics. The later phase saw the emergence of complex molecules such as monoclonal antibodies (mAbs), a more diversified therapeutic focus, and a significant increase in the number of companies entering the biosimilars space.

India has manufacturing capabilities of these biologics and also allowed multinationals to import and market in the country. The Central Drugs Standard Control Organisation (CDSCO) gave its first approval to Ethnor Limited to import and market r-hu-EPO in 1993 for Anaemia due to chronic renal failure. From 1993 to 2019 the CDSCO approved 197 biologics for import and marketing in the country. From 2020 till January 2025 another 104 biologics (r-DNA origin) received regulatory approval for marketing in India. The Genetic Engineering Appraisal Committee (GEAC) under the Ministry of Environment and Forestry responsible for appraisal of activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle gave approvals for 38 recombinant therapeutics products for marketing in India. The CDSCO has granted permission for manufacturing of 88 biologics from 2007- 2019 and 81 biologics from 2020 to January 2025 under MF and Bulk permission numbers. Wockhardt Limited got first approval for Insulin Glargine 100 IU on February 22, 2007 for the treatment of type -I and Type -II diabetes mellitus patients who required basal (long acting) insulin for the control of hyperglycemia.

Reflecting on the sector's rapid progress, ***Dr Sridevi Khambhampaty, CEO, Shilpa Biologicals*** noted, "We've gone from just 1 per cent of eligible patients using biologics or biosimilars in the 2000s to around 40 per cent today. That number could rise to 60 per cent as more products from companies like Hetero, Enzene, MJ Pharma, and Shilpa Biologics enter the market."

Approved Biosimilars (Recombinant Therapeutics) between 2000 & 2025

No	Name of the firm	Date of Permission	Name of the Drug
1	Wockhardt Limited	2000	Biovac-B
2	Intas Pharmaceuticals	01 Aug 2005	Epofit/Erykine
3	Wockhardt Limited	22 Feb 2007	Insulin Glargine 100 IU
4	Dr. Reddy's Laboratories Ltd.	23 Mar 10 & 20 Jul 10	Darbepoetin alfa
5	Gennova Biopharmaceuticals Ltd.	29 Jan 2010	Pegfilgrastim (peg-r-hu-GCSF)
6	Gennova Biopharmaceuticals Ltd.	16 Mar 2010	Filgrastim (r-hu- GCSF)
7	Virchow Biotech Pvt Ltd	28 Apr 2010	rh-PDGF-BB + β- TCP
8	Reliance Life Sciences Pvt Ltd	30 Apr 2010	Recombinant Follicle stimulating hormone (r-Hu- FSH)
9	Cadila Healthcare Ltd	28 Apr 2010	r-Hu-EPO Lyophilized injection
10	Intas Biopharmaceuticals Ltd	01 Nov 2010	Teriparatide [r- Hu-Parathyroid Hormone(1-34)].
11	Dr. Reddy's Laboratories Ltd.	28 Jan 2011	Pegfilgrastim
12	Reliance Life Sciences Pvt Ltd	04 May 2011	Recombinant Interferon Beta 1a
13	Cadila Healthcare Ltd	21 Jun 2011	PegINF alfa 2b (lyophilized) (Subcutaneous)
14	Reliance Life Sciences Pvt Ltd	22 Jun 2011	r-Hu- Choriogonadotro pin alfa
15	Gland Pharma Ltd	09 Aug 2011	1. Biphasic Isophane Injection IP, 30% Soluble Insulin and 70% Isophane insulin. 2. Biphasic Isophane Insulin Injection IP, 50% soluble Insulin and 50% Isophane insulin. 3. Soluble Insulin injection IP. 4. Isophane Insulin Injection IP
16	Bioviz Technologies pvt Ltd	09 Aug 2011	Erythropoetin (r- HU-EPO) injection
17	USV Limited	13 Aug 2012	Teriparatide
18	Cadila Healthcare Ltd	21 Aug 2012	Teriparatide
19	Virchow Biotech Pvt Ltd	28 Aug 2012	Rasburicase injection
20	USV Limited	06 Sep 2012	Teriparatide
21	Zenotech Laboratories	27 Feb 2013	Rituximab
22	Intas Biopharmaceuticals	26 Feb 2013	Rituximab
23	Lupin limited	05 Mar 2013	filgrastim
24	Reliance Life Sciences Pvt Ltd	23 Apr 2013	Abciximab
25	Intas Biopharmaceuticals	25 Apr 2013	Pegylated Recombinant Human Interferon alfa 2b
26	Intas Biopharmaceuticals	14 May 2013	Recombinant human Follicle stimulating hormone (Follitropin alfa)
27	Zenotech Laboratories	15 May 2013	Recombinant human granulocyte macrophage colony stimulating factor (Molgramostim)
28	USV Limited	03 Jun 2013	Recombinant human growth hormone
29	Lupin limited	03 Sep 2013	Pegfilgrastim
30	Cadila Pharmaceuticals	22 Oct 2013	Filgrastim
31	Biocon limited	23 Oct 2013	Trastuzumab 150 mg/vial & 440 mg/vial
32	Shantha Biotechnics Limited	14 Nov 2013	Human insulin(Rapid)
33	Biocon Limited	18 Nov 2013	Nimotuzumab
34	Hetero Drugs Limited	06 Jan 2014	Darbepoetin alfa
35	Reliance Life Sciences Pvt Ltd	21 Mar 2014	Infliximab
36	Gennova Pharmaceuticals	29 Apr 2014	Tenecteplase
37	Intas Pharmaceuticals	30 Sep 2014	Etanercept
38	Cadila Healthcare Ltd.	25 Sep 2014	Adalimumab
39	Cadila Healthcare Ltd	14 Oct 2014	r-Human Erythropoeitin Conc. Solution
40	Shantha Biotechnics Limited	07 Nov 2014	Insuman basal
41	Scigen Biopharma Pvt ltd	03 Feb 2015	Recombinant Human Insulin
42	Eli Lilly and Company India Pvt. Ltd	03 Feb 2015	Zinc Insulin Crystals Human, Proinsulin derived (r-DNA)
43	Reliance Life Sciences Pvt Ltd	12 Feb 2015	Rituximab
44	Intas Pharmaceuticals Ltd	20 Feb 2015	Ranibizumab
45	Wockhardt Limited	25 Feb 2015	Pegfilgrastim (Peg-GCSF)
46	Bharat Serum & vaccines (BSV)	02 Mar 2015	Human tetanus Immunoglobulin (HTIG) Injection
47	Hetero Drugs Limited	25 Mar 2015	Rituximab
48	Intas Pharmaceuticals Ltd	13 Apr 2015	Peg-EPO
49	Cadila Healthcare Ltd	12.May.2015	Peg-GCSF (Filgrastim)
50	Reliance Life Sciences Pvt Ltd	02 Jun 2015	Trastuzumab
51	Reliance Life Sciences Pvt Ltd	26 Jun 2015	Adalimumab
52	Cadila Healthcare Pvt. Ltd.	14 Jul 2015	Filgrastim
53	Bharat Serum & vaccines Pvt Ltd	20 Jul 2015	Human tetanus Immunoglobulin (HTIG) Injection
54	Cadila Healthcare Pvt. Ltd.	28 Oct 2015	Trastuzumab
55	Reliance Life Sciences Pvt Ltd	05 Jan 2016	Bevacizumab
56	Reliance Life Sciences Pvt Ltd	13 May 2016	Pegfilgrastim (Peg-GCSF)
57	Hetero Drugs Limited	13 May 2016	Bevacizumab
58	Reliance Life Sciences Pvt Ltd	14 Jun 2016	Darbepoetin alfa
59	Intas Pharmaceuticals Ltd	23 Jun 2016	Bevacizumab
60	Cadila Pharmaceuticals limited	09 May 2016	Filgrastim Concentrate soloution (BULK)
61	Serum Institute of India	07 Jun 2016	Rabies Human Monoclonal antibody (Rabishield)
62	Syngene International Limited	20 Dec 2016	Recombinant streptokinase (BULK)
63	Biocon Limited	01 May 2017	Bevacizumab
64	Cadila Healthcare Ltd	12 May 2017	Bevacizumab
65	Serum Institute of India	15 May 2017	Rabies Human Monoclonal antibody (Rabishield)
66	Bharat Serum & vaccines Pvt Ltd	23 May 2017	Recombinant Human Chorionic Gondatropin for injection (r- HCG)

No	Name of the firm	Date of Permission	Name of the Drug
67	Hetero Drugs Limited	26 Jul 2017	Adalimumab
68	Cadila Healthcare Ltd	10 Jan 2018	Follitropin alfa
69	Intas Pharmaceuticals Ltd	10 Jan 2018	Denosumab 60mg/ml PFS
70	Dr. Reddy's Laboratories Ltd.	06.Mar.2018	Trastuzumab
71	Reliance Life Sciences Pvt Ltd	21 Mar 2018	Tenecteplase
72	Intas Pharmaceuticals Ltd	06 Apr 2018	Trastuzumab
73	Reliance Life Sciences Pvt Ltd	07 05 2018	Etanercept
74	Reliance Life Sciences Pvt Ltd	21 May 2018	Somatropin
75	MJ Biopharma pvt ltd	14 Jun 2018	Human Insulin, IP/Ph. Eur (As 30% Soluble Insulin Injection and 70% as Isophane Insulin Injection) 40 IU and 100 IU
76	Dr. Reddy's Laboratories Ltd.	04 Sep 2018	Bevacizumab
77	Lupin Limited	05 Mar 2019	Etanercept drug substance (r- DNA origin)
78	Reliance Life Sciences Pvt Ltd	21 Feb 2020	Omalizumab powder for solution for Injection
79	Reliance Life Sciences Pvt Ltd	30 Mar 2020	Ranibizumab Injection
80	Mylan	07 Jan 2021	Etanercept
81	Cadila Healthcare	12 Jan 2021	Trastuzumab emtansine
82	Enzene Biosciences	28 Jan 2021	Teriparatide
83	Cadila Healthcare	23 Apr 2021	Pegylated Interferon alfa- 2b
84	Epygen Biotech	21 May 2021	Biphasic Isophane Insulin Injection IP
85	Enzene Biosciences	01 Jul 2021	Romiplostim injection
86	Enzene Biosciences	20 Jul 2021	Denosumab 60mg/ml (r- DNA origin)
87	Intas Pharmaceuticals	22 Aug 2021	Denosumab
88	Hetero	03 Oct 2021	Tocilizumab
89	Lupin	29 Oct 2021	Ranibizumab
90	BioGenomics Limited	29 10 2021	Recombinant Insulin Aspart I.P. (r-DNA origin) drug substance
91	Cadila Healthcare	30 Dec 2020	Trastuzumab Emtansine
92	Virchow Biotech	29 Dec 2021	Pegylated Recombinant Human Granulocyte Colony Stimulating factor injection
93	Dr Reddy's	29 Dec 2021	Rituximab
94	BSV	19 Jan 2022	Recombinant Human Follicle Stimulating Hormone
95	Dr Reddy's	20 Apr 2022	Bevacizumab Formulated Drug Substance in Liquid & Frozen form (r- DNA origin)
96	Lupin	17 Jun 2022	Ranibizumab
97	Intas Pharmaceuticals	06 Jul 2022	Ranibizumab
98	BSV	22 Aug 2022	Recombinant Human Follicle Stimulating Hormone
99	Enzene Bioscience	28 Oct 2022	Adalimumab (r-DNA Origin)
100	Enzene Bioscience	08 Dec 2022	Teriparatide
101	Reliance Life Sciences	19 Dec 2022	Denosumab (r-DNA Origin)
102	Enzene Bioscience	16 Jan 2023	Cetuximab
103	Hetero Biopharma	31 Jan 2023	Tenecteplase
104	Wockhardt	14 Feb 2023	Erythropoietin
105	Enzene Biosciences	21 Feb 2023	Bevacizumab
106	Sun Pharma	24 Mar 2023	Ranibizumab
107	Enzene Biosciences	10 Apr 2023	Denosumab injection
108	Reliance Life Sciences	26 Apr 2023	Golimumab Injection
109	Reliance Life Sciences	26 Apr 2023	Ustekinumab
110	Shilpa Biologicals	22 Jun 2023	Adalimumab
111	Enzene Biosciences	29 Aug 2023	Ranibizumab Injection
112	Levim Biotech	24 Aug 2023	Liraglutide
113	Zenotech Laboratories	05 Oct 2023	Ranibizumab
114	Gennova Biopharmaceuticals	27 Oct 2023	Tenecteplase
115	Reliance Life Sciences	29 Nov 2023	Bevacizumab
116	Enzene Biosciences	08 Jan 2024	Ranibizumab
117	Sun Pharma	18 Jan 2024	Ranibizumab
118	M.J. Biopharm	19 Jan 2024	Liraglutide
119	Enzene Biosciences	30 Jan 2024	Bevacizumab
120	M.J. Biopharm	27 Mar 2024	Recombinant Insulin Glargine, Drug Substance IP/USP/Ph. Eur
121	M.J. Biopharm	27 Mar 2024	Insulin Glargine Injection
122	Curateq Biologics	27 Mar 2024	Trastuzumab
123	Zydus	04 Apr 2024	Pertuzumab
124	Enzene Biosciences	29 Apr 2024	Adalimumab Injection
125	Biocon	30 Apr 2024	Etanercept Injection
126	Reliance Life Sciences	09 Jul 2024	Ranibizumab
127	Zydus	27 Aug 2024	Pertuzumab
128	BSV	15 Oct 2024	Trinbelimab
129	Reliance Life Sciences	25 Oct 2024	Golimumab
130	Cadila	27 Nov 2024	Biphasic Isophane Insulin Injection (30/70) IP
131	Hetero Biopharma	20 Dec 2024	Denosumab
132	Reliance Life Sciences	23 Dec 2024	Ustekinumab
133	Zydus	27 Dec 2024	Nivolumab
134	Intas Pharmaceuticals	17 Jan 2025	Pertuzumab, drug substance and drug product
135	Shilpa Biologicals	17 Jan 2025	Adalimumab

Let's take a closer look at these past years in detail.

Tracing 25 Years of India's Biosimilar Journey

2000-2010: The Foundational Years

The period from 2000 to 2010 marked the beginning of India's entry into the biosimilars space, with a series of first-time approvals for recombinant biologics across therapeutic areas.

The Indian biosimilars landscape began with Biovac-B for hepatitis B, led by Wockhardt, a critical first step in local biologics manufacturing. The early 2000s saw leading firms like Intas, Wockhardt, Dr. Reddy's, Gennova, and Reliance Life Sciences enter the space, focusing on recombinant hormones and growth factors.

Next approval came five years later, in August 2005, when Intas Pharmaceuticals received authorisation to market Epofit/Erykine, a biosimilar of epoetin alfa, for treating anaemia linked to cancer, chronic kidney disease, and chemotherapy. Another significant milestone occurred in February 2007 when Wockhardt obtained approval for Insulin Glargine (100 IU), marking one of India's earliest biosimilar approvals for a long-acting insulin analogue.

The year 2010 saw a sharp increase in the number of biosimilar approvals, with several companies entering the space. In March 2010, Dr. Reddy's Laboratories received approval for Darbepoetin alfa, a long-acting erythropoiesis-stimulating agent (ESA) used in the treatment of anaemia associated with chronic renal failure and chemotherapy. The product was cleared for use in both dialysis and non-dialysis patients, as well as in non-myeloid cancer patients receiving chemotherapy.

Gennova Biopharmaceuticals received approval for two granulocyte colony-stimulating factor (G-CSF) products: Pegfilgrastim in January and Filgrastim in March. Both were designed to prevent neutropenia in cancer patients undergoing chemotherapy, marking Gennova's entry into oncology supportive care.

In April 2010, Virchow Biotech Pvt Ltd. gained approval for a combination biologic—recombinant human PDGF-BB + β-TCP, targeted at treating periodontal defects like intrabony defects and gingival recession, standing out in regenerative dentistry applications. Reliance Life Sciences Pvt Ltd. also received approval for recombinant human follicle-stimulating hormone (r-hu-FSH) to treat female infertility. Cadila Healthcare Ltd. (Zydus) followed with the approval of r-hu-EPO lyophilised injection, indicated for maintaining haemoglobin levels in patients with chronic renal failure.

Closing out the year, Intas Biopharmaceuticals secured approval in November 2010 for Teriparatide [r-hu-Parathyroid Hormone (1-34)], a biosimilar used in postmenopausal women with osteoporosis who are at high risk for fractures. This represented one of the earliest biosimilar entries into the osteoporosis segment in India. Altogether, India approved 10 biosimilars across key therapeutic areas such as nephrology, endocrinology, reproductive health, and bone metabolism.

2011-2015: The Boom Phase

This period was marked by several key milestones. In 2012, India introduced its biosimilar policy, laying the foundation for a more structured regulatory environment. In 2013, Biocon, in partnership with Mylan, received approval for its trastuzumab biosimilar to Herceptin, the world's best-selling breast cancer drug. In 2014, Zydus Cadila became the first company to receive approval for a biosimilar of AbbVie's Humira, the world's top-selling drug at the time. The formalisation of CDSCO's biosimilar evaluation process in 2012 helped improve regulation. Between 2011 and 2015, India saw a sharp rise in biosimilar activity, with 44 approvals.

A notable trend in this period was the increasing number of complex biologics like trastuzumab, rituximab, and adalimumab entering the Indian market, indicating growing capabilities in monoclonal antibody production. Among all molecules, filgrastim emerged as the most commonly approved biosimilar across different manufacturers—Lupin, Cadila, and Hetero Drugs. Most approvals targeted prevalent conditions in India:

Top Companies producing Biosimilars

- Biocon
- Intas Pharmaceuticals
- Dr. Reddy's Laboratories
- Reliance Life Sciences
- Zydus Cadila Healthcare
- Lupin Limited
- Wockhardt Limited
- Hetero Biopharma
- Bharat Serums And Vaccines (acquired by Mankind Pharma in 2024)

Biosimilar approvals

Year	Approval
2000-2010	10
2011-2015	44
2016-2020	25
2021-2025	56

India's Biosimilars Revolution

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

The increasing incidence of chronic illnesses such as cancer, diabetes, and autoimmune disorders, which necessitate long-term biologic therapies, is driving the growth of the biosimilar market in India. Since introducing the "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India" in 2012, which was later revised in 2016, the Indian biosimilar industry has made significant strides. With a robust pharmaceutical sector, India is now a leader in biosimilar production, boasting approximately 100 domestically approved biosimilars. Several Indian companies have also received approval for Biosimilars in the US and Europe. Indian companies have catered to the local market and emerged as global frontrunners in biosimilars, playing a crucial role in enhancing the accessibility of biological therapies. Biosimilars are notably impacting various therapeutic areas in India, particularly in oncology, autoimmune disorders, and diabetes. In the oncology sector, biosimilars such as Trastuzumab, Bevacizumab, Rituximab, and Cetuximab are effectively treating a substantial patient population across multiple cancer types. Additionally, there is a robust pipeline of biosimilars in the oncology field. For Rheumatoid Arthritis, biosimilars for Etanercept and Adalimumab have been approved, expanding treatment options for many patients. The introduction of biosimilar insulins in the Indian healthcare landscape is crucial for improving access to insulin for all diabetes patients. The growing availability of insulin biosimilars is expected to enhance accessibility and potentially reduce costs for individuals with diabetes. Furthermore, several other biosimilars have been approved for conditions such as neutropenia, anemia, and multiple sclerosis. These cost-effective alternatives significantly improve access to vital biologic therapies for patients nationwide.

- **Oncology:** Trastuzumab, rituximab, and later, bevacizumab.
- **Autoimmune Diseases:** TNF inhibitors like etanercept and adalimumab.
- **Haematology:** Filgrastim, epoetin for anaemia and neutropenia.

2016-2020: Evolving regulations and expansion into international markets

The glory days of previous years continued into this period, marked by several important milestones for Indian companies and the country's biosimilar space in general.

In 2016, Biocon's Insulin Glargine became the first biosimilar from India to be commercialised in Japan. In December 2017, Ogivri, a biosimilar of Trastuzumab co-developed by Biocon and Mylan, became the world's first biosimilar of Herceptin to be approved in the US. In 2018, Fulphila (Pegfilgrastim), another biosimilar co-developed by Biocon and Mylan, became the first biosimilar of Neulasta to be approved in the US. In 2016, the CDSCO revised its guidelines, providing clearer regulations for biosimilars, which helped streamline the approval process. From 2016-2020, India saw over 25 biosimilar approvals across various therapeutic areas, including oncology, immunology, and nephrology. These approvals were for both monoclonal antibodies and other biologics, marking a significant increase in India's biosimilar market activity. Companies such as Reliance Life Sciences, Intas Pharmaceuticals, Hetero Drugs, and Dr. Reddy's Laboratories were key players in bringing these therapies to market.

Bevacizumab emerged as a frequently approved biosimilar, with multiple companies launching versions for colorectal cancer, lung cancer, and ovarian cancer. Pegfilgrastim, adalimumab, and etanercept were also prominent, with approvals for treating conditions like chemotherapy-induced neutropenia, rheumatoid arthritis, and psoriasis. The sector continued to grow, with the approval of biosimilars for more specialised conditions such as chronic kidney disease, macular degeneration, and chronic urticaria.

2021-2025: Diversification and push toward global standards

From 2021 to 2025, India's biosimilar industry continued to build on the momentum of previous years, experiencing rapid growth. During this period, 56 approvals were granted, with significant

advancements in oncology, autoimmune diseases, ophthalmology, diabetes care, and rare conditions. This phase also saw the emergence of newer players such as Enzene Biosciences, Shilpa Biologicals, etc.

The therapeutic dominance of oncology & autoimmune conditions continued, with recurring approvals for trastuzumab, bevacizumab, adalimumab, & rituximab from both new entrants & legacy players. India also ventured into rare and niche therapies, with Trinbelimab for maternal health, marking a new frontier for biosimilars in specialised fields. Several companies secured approvals for updated formulations, additional indications, or second-generation biosimilars of earlier-approved molecules, demonstrating maturing portfolio strategies.

What next?

The impending patent cliff presents a significant opportunity for biosimilar companies worldwide. Between 2025 and 2032, 39 high-value biologics are set to lose patent exclusivity. Five of these molecules generate over $10 billion each in global annual revenues, creating a substantial opening for Indian biosimilar manufacturers. Indian companies are gearing up to capture a larger piece of this pie. Many top firms are investing heavily in R&D, expanding their manufacturing capacities, and building robust product pipelines, with over 40 biosimilars currently in development, according to Bain & Company. However, it won't be without challenges. India faces stiff competition from China and South Korea, which are leading in US FDA biosimilar approvals.

India has built a robust domestic biosimilars market, but its international presence remains limited. Dr Cyrus Karkaria points out that progress in global markets has been relatively slow.

"Of the biosimilars manufactured by Indian companies, approximately 17 have received approval in Europe, while only 9 have been approved in the US," he noted.

As a result, India's share in the global biosimilars market remains modest. Indian pharmaceutical firms currently hold less than 5 per cent of the global market, with biosimilar exports valued at approximately $0.8 billion as per Bain and Company.

It doesn't help that some experts feel that the CDSCO has taken a lenient approach to biosimilar approvals. There are concerns that misalignment between CDSCO and FDA/EMA on clinical trial requirements for biosimilars may also hinder domestic manufacturers from participating on a global scale. That said, reforms are underway. The Drug Controller General of India (DCGI) has indicated that revised biosimilar guidelines will soon be released, aiming to align India's regulatory framework with global standards. The Indian government is also pushing forward with public initiatives like the National Biopharma Mission and PLI schemes to bolster the sector. Indian companies are also scaling up—investing in R&D, expanding manufacturing capacity, and forging strategic partnerships to strengthen their global presence. Looking ahead, experts are bullish about India's potential to take on a larger role in the global biosimilars market.

"Leveraging its strengths in developing cost-effective Biosimilars, India is well poised to become a key player in the global biosimilar Industry. Indian biosimilar exports are currently valued at ~$0.8 billion and projected to grow fivefold to $4.2 billion by 2030, and reach $30-35 billion by 2047. Key factors driving growth in exports include global trends such as the simplification of biosimilar approval pathways in the US and Europe, including interchangeability, extrapolation of Indications and waiver on phase 3 clinical trials. In addition, Indian manufacturers have already embarked on building world class manufacturing facilities and generating value through CDMOs, where just like generics, we would be the high quality and affordable biosimilar producers for the world Navigating through regulatory complexities, fostering collaboration with global pharmaceutical companies and leveraging technology will be the key to advancing R&D and achieving leadership in global biosimilar space," said Dr Karkaria.

Dr Sridevi echoes similar sentiments, "Again in a few words I would say 'growing massively'. We now have some 25 years of pedigree in developing and launching these therapies, and therefore a very well-trained workforce with an excellent understanding of global requirements. This, coupled with recent proposed changes to biosimilar regulations globally [waiving phase 3 studies], means we are potentially removing the large investment barrier required for new approvals. Therefore, it will open-up opportunities to develop biosimilars for indications which previously required large and expensive phase 3 studies (like antibodies for migraine etc.). So my view is that India will be contributing at least 15-20 per cent of global biosimilars moving forward – especially if we can leverage the opportunity of the new regulatory paradigm."

The first 25 years of India's biosimilar journey focused on building domestic capacity and regulatory frameworks. The next 25 years will centre on global expansion. With growing expertise and shifting geopolitical dynamics, Indian biosimilar companies are poised to seize a bigger piece of the pie. The next 25 years are set to be Bharat's biosimilar moment on the world stage. BS

Ayesha Siddiqui

"The biosimilar developers are eagerly awaiting revised CDSCO regulations that might lead to simplification of the development pathway for biosimilars"

In an interaction with BioSpectrum, ***Dr Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC),*** *reflects on the evolution of India's biosimilars sector and shares his insights on the country's growing role in the global biosimilars landscape over the next decade.*

How has India's biosimilars landscape evolved over the past 25 years, and what have been the most significant milestones? Can you share insights into the number of biosimilars approved for domestic use vs. exports?

India approved its first biosimilar, Biovac-B for hepatitis B in 2000 which was launched by Wockhardt Limited. Since then, several biosimilars have been developed and marketed in India by various biopharmaceutical companies. Department of Biotechnology (DBT), India announced the release of regulatory guidelines for 'similar biologics' on 19 June 2012 and these guidelines were implemented on September 15, 2012. The guidelines outline a simple abridged procedure for evaluation of 'similar biologics' which have been approved and marketed in India, Europe or USA for more than four years. These guidelines were then revised and updated, with new guidelines, which came into effect in August 2016.

Apart from the streamlined regulations, DBT and its public sector enterprise Biotechnology Industry Research Assistance Council (BIRAC) have made sustained efforts through funding, policy advocacy, new initiatives, capacity building, and promoting innovation and infrastructure creation in research institutions, small and medium size companies, and large firms. The schemes of BIRAC like the Biotechnology Industry Partnership Program (BIPP), Small Business Innovation Research Initiative (SBIRI) and Promoting Academic Research Conversion to Enterprise (PACE) launched between 2008 and 2012 are to assist small and medium-sized biotech firms in the creation of biosimilars.

In 2017, the Government of India, DBT with co-funding from World Bank, launched the National Biopharma Mission (NBM), an Industry-Academia Collaborative Mission for accelerating discovery research to early development for Biopharmaceuticals, implemented by BIRAC. One of the focused mandates of the Mission is to accelerate the biosimilar development to bring them closer to market.

Under these schemes, BIRAC has supported several biosimilars including Trastuzumab, Insulin Glargine, Insulin Lispro, Bevacizumab, Ramicirumab, Liraglutide, Aflibercept, Pertuzumab, Romiplastim, Ustekinumab, Insulin Aspart, Pembrolizumab, Golimumab, and Pegloticase. Many of these biosimilars are also developed by startups. Of these, Biosimilar Liraglutide for type 2 diabetes was developed by Levim Biotech LLP, and launched in the market by Glenmark (Levim's marketing partner) in January 2024 under the brand name "Lirafit", and is the first biosimilar of Liraglutide in market and introduced at ~65 per cent discount over the innovator's price. Many other biosimilars supported by NBM and BIPP and other schemes of BIRAC will be ready for market launch in the next 1-2 years.

The NBM has also contributed in establishing regulatory-compliant, accessible facilities to cater to services for bio-analytical and functional testing, immunogenicity testing and cGMP manufacturing of clinical trial lots, to support domestic industry and startups to accelerate the development of biosimilars to improve accessibility and affordability. In addition, NBM also supported indigenous production of raw materials such as culture media, resins and Single-Use Bioreactors which will further reduce the manufacturing costs of biosimilars and other biologics.

The biosimilar landscape in India is characterised by a multitude of bio-pharmaceutical entities actively involved in the production and distribution of biosimilar products. Prominent players include Intas Biologicals, Biocon, Dr. Reddy's Laboratories, Zydus Lifesciences, Reliance Life Sciences, Lupin Pharma, Cipla, Wockhardt Ltd. Apart from these, Gennova Biopharmaceuticals, Enzene Biosciences, Hetero Biopharma, Torrent Pharmaceuticals also have several approved biosimilar products for Indian and some for global markets. The startups who

have ventured into biosimilars space include Levim Lifetech, Genext Genomics Pvt. Ltd, Lamark Biotech, Bycus Therapeutics, etc.

The biosimilar domestic market is projected to grow to ~$40 billion by 2030. Till date there are > 100 biosimilars for ~ 40 Reference Products (RP) approved from India, for oncology, hematological, immunological, toxicology, musculoskeletal and metabolic, hormonal, neurological disorders, ophthalmic diseases, infectious diseases, cardiovascular and respiratory diseases, and women health. Out of these ~ 20 (RP) biosimilars are exported to developed and emerging markets, mostly to USA, Europe, Brazil, Belgium, Netherlands, and Africa mostly by the Indian companies Biocon, Dr. Reddy's, Intas, Hetero and Lupin.

Which therapeutic areas have seen the most approvals?

Oncology has seen the most approvals, followed by haematological and immunological disorders.

How do you see India's role in the global biosimilars industry in the next 10–15 years?

Indian companies currently hold less than 5 per cent of the global biosimilars market, but with increasing R&D investments and an expanded product pipeline, biosimilar exports are expected to grow from $0.8 billion now, to $4.2 billion (£3.3 billion) by 2030, and $30-35 billion by 2047. Over the next seven years, about 100 drug patents valued at a total of $180 billion are expected to expire, creating a good opportunity for Indian companies.

As per the landscaping exercise done by BIRAC, large companies in India are trying to be vertically integrated in-house – i.e. Clone development to Manufacturing and aiming at the global markets from conceptualisation stage. The companies are also licensing tie-ups at an early stage or taking the co-development route. On August 31, 2024, Science &Technology Minister Dr. Jitendra Singh released the BioE3 Policy. The policy, which is jointly implemented by DBT and BIRAC, aims to foster high-performance biomanufacturing in India. It seeks to develop and commercialise bio-based products through the establishment of BioEnablers like Bio-AI Hubs, Biofoundries, and Biomanufacturing Hubs, which will give a major boost to the biosimilars sector.

India's biotech ecosystem includes more than 800 core biotech companies, over 100 bio-incubators, and ~ 10,000 biotech startups. This investment, along with the focus on innovation, will encourage the growth of Indian biopharma capabilities. The 2024 Indian Bioeconomy Report prepared by the Make in India Facilitation Cell of BIRAC with research support from the Association of Biotechnology Led Enterprises (ABLE), highlights that India's BioEconomy achieved a landmark value of $151 billion in 2023, reflecting impressive double-digit growth. The report also gives hope that India is in the right direction to cross the $300 billion mark by 2030. On the regulations side, on April 10, 2025, the FDA announced the plans to phase out animal testing requirements for monoclonal antibodies and other drugs. The biosimilar developers are eagerly awaiting revised CDSCO regulations which might lead to simplification of the development pathway for biosimilars with improved accessibility and affordability. The BioSecure Act is also expected to benefit India. All of this will support the growth of smaller Indian companies into key players in the global biosimilar industry and help establish India as a leading contributor to the international biosimilar market over the next 10 to 15 years. BS

Ayesha Siddiqui

The biosimilar domestic market is projected to grow to ~$40 billion by 2030. Till date there are > 100 biosimilars for ~ 40 Reference Products (RP) approved from India, for oncology, hematological, immunological, toxicology, musculoskeletal and metabolic, hormonal, neurological disorders, ophthalmic diseases, infectious diseases, cardiovascular and respiratory diseases, and women health. Out of these ~ 20 (RP) biosimilars are exported to developed and emerging markets, mostly to USA, Europe, Brazil, Belgium, Netherlands, and Africa mostly by the Indian companies Biocon, Dr. Reddy's, Intas, Hetero and Lupin.

Ensuring Biotech Startup Success Stories

According to the Indian BioEconomy Report 2025, the number of biotech startups has more than doubled from 4237 in 2020 to 10,075 in 2024. However, there has been a 13.1 per cent decline in 2024 with new startup registrations, as compared to the previous years. While the number of new startups kept increasing between 2020 and 2023, ranging between 26 and 30 per cent, 2024 saw only a 16-18 per cent rise in the number. Does this new trend suggest a potential stabilisation of the existing startups or a funding crunch for the new entrants? Or the growth of biotech startups in the country is simply following a numbers game. Let's find out.

In 2024, the bioeconomy of India reached a value of $165.7 billion, reflecting strong growth across biopharma, bioindustrial production, research services, and agricultural biotechnology. The India Bioeconomy Report 2025, prepared by the Association of Biotechnology Led Enterprises (ABLE), states that in 2023, the bioeconomy registered a 10 per cent growth, while in 2024, it registered a 9.7 per cent growth.

The report also reveals that the biotech startup sector has shown a decrease in growth rate in 2024 compared to previous years between 2020 and 2023. A similar dip was witnessed back in 2019 after considerable jumps from 2016 to 2018.

On the other hand, in 2022, biotech startups saw 31 deals totalling $938.8 million, while 2023 saw a dip with only 16 deals worth $199.6 million. The year 2024 further witnessed recovery and is estimated to close at $700 million with over two dozen deals.

These fluctuations might be governed by factors such as market saturation, increased competition, emerging new technologies, or limited funding.

As a recent development to harness the biotech potential in different parts of the country, the government has announced the development of regional Biotechnology Industry Research Assistance Council (BIRAC) centres across India, as a collaboration between the Centre and States.

"The rapid rise of biotech startups over the last 10 years demonstrates India's growing leadership in biotechnology and its potential to revolutionise the global bioeconomy. A new trend also lies in the observation that innovative startups are now growing in other areas of the country, such as Jammu, Haryana, and the Northeastern region, which were less explored before. There is a need for comprehensive mapping of states based on their biotech potential", said ***Dr Jitendra Singh, Union Minister of State (Independent Charge) Ministry of Science and Technology, Government of India.***

Failure of funding?

While the Department of Biotechnology (DBT) and BIRAC in India are actively supporting and promoting biotech startups through various funding opportunities, not many innovations are translating into successful products in the market every year. Budding entrepreneurs continue to face challenges in accessing capital in different stages of their venture journey, and this might be a reason for the dip in the number of new startups entering the biotech sector in 2024.

Sharing his thoughts, ***Dr Manish Diwan, Mission Director - Make in India & Head-Biofoundry,*** said, "Very little government funding has reached entrepreneurs in 2024 due to in progress implementation of the new finance system of zero balance account. This has had a direct impact on fresh entrepreneurs onboarding as grant recipients and hence affecting new startup incorporation."

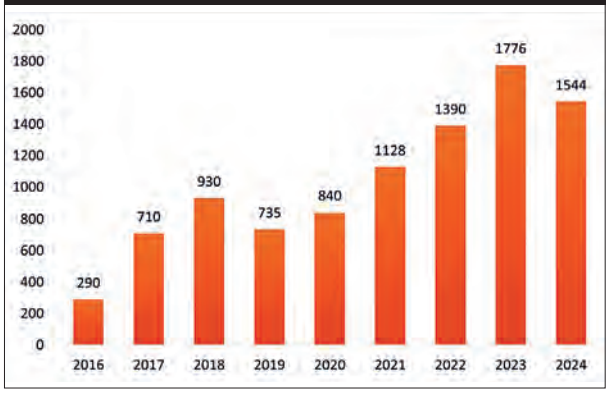
At the Startup Mahakumbh 2025 event, held between April 3 and 5 in Delhi, ***Union Minister for Commerce and Industry Piyush Goyal*** urged Indian investors to strengthen the startup ecosystem with more domestic capital. The Minister also mentioned

that the Second Fund of Funds for Startups (FFS) with a corpus of Rs 10,000 crore has been approved by Prime Minister Narendra Modi. "This year, Rs 2,000 crore will be disbursed to Small Industries Development Bank of India (SIDBI) as the first installment. A significant portion of the fund will be reserved for seed funding of small startups and to support deep-tech innovation. Through this fund, we aim to foster the development of cutting-edge technologies like AI, robotics, quantum computing, machine learning, precision manufacturing and biotech", said Goyal.

Focusing particularly on the biotech startups' funding scenario, ***Padmaja Ruparel, Co-founder, Indian Angel Network (IAN),*** said, "While early-stage investors are willing to fund and nurture the biotech startups, the lack of growth-stage capital in India is a major hurdle. Without larger funding pools, we risk losing promising companies to overseas markets through acquisitions or relocations. Addressing this gap is critical. Another key insight from an investor's perspective is that while many entrepreneurs have strong expertise in deep science and technology, they often lack knowledge in business and finance. Understanding these aspects is essential for building long-term value. Entrepreneurs must either acquire these skills themselves or bring in co-founders, mentors, or advisors who can bridge this gap. Without a solid grasp of finance and business strategy, scaling a startup becomes significantly more challenging."

Adding another perspective to this current scenario restricting the growth of biotech startups in the country, ***Dr Taslimarif Saiyed, Director, Centre for Cellular and Molecular Platforms (C-CAMP),*** said, "The rise in the number of startups doesn't automatically reflect the depth of innovation. There seems to be less emphasis on sustained support and monitoring. The focus should shift towards nurturing long-term, science-driven entrepreneurship rather than just counting startup numbers. A strong innovation ecosystem depends on a steady and accessible funding pipeline. Even if 1,000 startups begin each year, around 200 may hold real potential, highlighting the importance of a broad base to support a strong top. Reintroducing dedicated early-stage funding will be essential. At the same time, as new technologies emerge, regulatory frameworks must evolve to strike a balance between innovation and safety. Policymakers have a crucial role in anticipating these changes. Equally important is investing in education and scientific literacy, not just relying on a young population, but ensuring they're equipped with the knowledge and skills needed for the future."

Number of new biotech startup registrations from 2016 to 2024



Source: Association of Biotechnology Led Enterprises (ABLE)

As technology is maturing faster within the startup ecosystem, many biotech and deeptech startups are exploring the use of artificial intelligence (AI) while building new solutions. But these innovations require a strong skilled workforce, financial support, and effective regulatory guidelines to see the light of the day. The deployment of new technologies alone will not ensure success and profitability for the biotech startups in the years to come.

Focusing on critical factors, experts of the biotech industry strongly recommend establishment of strategic funds that can provide patient capital, supportive manufacturing hubs and bio-foundries, strengthening mentorship programmes such as the new BioSaarthi programme launched by the government in March this year, increasing availability of risk capital for biotech ventures with particular focus on early-stage funding, and creation of specialised accelerator programmes for biotech startups that account for longer development timelines. Designed as a six-month cohort, BioSaarthi will facilitate structured mentor-mentee engagements, offering personalised guidance to emerging entrepreneurs in the biotech sector. Thereafter, we hope to see a number chart of successful biotech startups getting highlighted year after year. BS

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Can technology uplift the Indian BioSuppliers ecosystem?

The bioindustrial and biopharma segment have emerged as the two key sectors contributing majorly (82 per cent) to India's bioeconomy which stands at $165.7 billion in 2024. The development of new drugs, vaccines, cell therapies by Indian companies are further strengthening these segments, thereby enhancing the innovation potential of our country. But these innovations require a strong domestic biosupplier ecosystem which is currently dominated by foreign players. However, with the advent of new technologies such as artificial intelligence, generative AI, automation etc, can we expect self-reliance within the domestic biosupplier sector anytime soon? Let's find out.

India has emerged as a key player in the global biopharmaceutical industry, and with the rapid expansion of biologics and biosimilars, the role of domestic biosuppliers has never been more crucial. Also, with a funding support of Rs 1500 crore under the Biotechnology Research Innovation and Entrepreneurship Development (Bio-RIDE) scheme by the government, for promoting high performance biomanufacturing and biofoundry support to the industry, the call for reducing the dependence on imported research equipment, consumables and raw materials is getting strongly established.

According to the India Bioeconomy Report 2025, developed by the Association of Biotechnology Led Enterprises (ABLE), the bioindustrial segment, representing nearly half of the bioeconomy valued at $165.7 billion, stands at $78.2 billion. Its dominance reflects the growing adoption of bio-based solutions across sectors such as biofuels, chemical, bioplastics and enzymes. Likewise, with a significant 35.2 per cent share, valued at $58.4 billion, the biopharma segment is growing stronger with development of new drugs, vaccines, and therapies by the Indian companies.

In order to reach the bioeconomy target of $300 billion by 2030, or before, all stakeholders must come together to overcome the challenges currently facing the domestic biosupplier sector, namely regulatory compliance, stringent quality standards, expertise, and policy support. While efforts are being made by the local players to overcome these challenges, the key probably lies in the implementation of emerging new technologies such as artificial intelligence (AI), generative AI, automation etc.

Suggesting a few solutions to these existing challenges, ***Martin Wilfried Pichler, Chief Executive Officer, Zeta India*** said, "Meeting stringent regulatory requirements is crucial and can be time-consuming and costly. However, early and continuous engagement with regulatory bodies can ensure compliance. Implementing robust quality management systems and using advanced analytics to monitor compliance can also be beneficial. Also, high initial costs for new technologies and the risk of financial loss if the technology fails to deliver expected results can pose a big challenge. But conducting detailed cost-benefit analyses and phased implementation can help manage costs. Exploring funding opportunities and partnerships can also mitigate financial risks."

Relying positively on new technologies, Thane-based biosupplier PharmNXT Biotech has emerged as a key player in the domestic market leveraging advanced automation across critical stages of bioprocessing, including design, prototyping, and scalable production.

"The rise of next-generation therapies, including mRNA, cell and gene therapies, and Antibody-Drug Conjugates (ADCs), will require more sophisticated containment and processing solutions. However, the industry faces significant hurdles in achieving economies of scale, primarily due to regulatory complexities and the dominance of larger global players. The key to overcoming these challenges lies in streamlining regulatory frameworks, subsidising equipment manufacturing, and implementing equitable procurement policies. Also, automated design and prototyping can enable precision engineering, ensuring that products meet the highest safety and operational standards. Automation extended to manufacturing, thereby reducing production costs by 35-40 per cent while maintaining global quality benchmarks is the need of the hour. We are focusing on self-

sufficiency in consumables and critical raw materials to provide just-in-time solutions, reducing reliance on imported materials with long lead times", said ***Ankush Kapoor, Co-founder and Chief Executive Officer, PharmNXT Biotech.***

Another key player establishing itself in the domestic biosupplier market is Chennai-based VFL Sciences. The company has recently developed and launched a range of bioreactors and fermenters for the biopharma industry, with a particular focus on biomanufacturing. With new offerings in the pipeline this year and beyond, VFL Sciences is building products of global standards, and with new technologies.

"The overall biosupplier market is growing very well, however the competition is very intense. Opportunities around Cell and Gene Therapy (CGT) as well as synthetic biology are increasing. Government spending on capital instruments is muted, however, we expect that to grow faster in the coming years. The government procurement through GeM (Government e market) is a challenge especially for startups and small companies. Scientific instrument purchase is more complicated and doing this through a system of GeM is cumbersome for scientists as well as companies. We hope to be a better alternative to the leading global brands. Our team of engineers and scientists are working to understand the needs of the customers better and offer products that are made with the concept of affordable excellence", said ***V Sankaranarayanan, Managing Director, VFL Sciences.***

Speaking about how deployment of new technologies can uplift the local biosupplier sector, he further adds, "Artificial intelligence is being tried and used by different biosuppliers. Since several of the bio instruments are made for repeated use of the same protocols, applying GenAI will be very useful to automate the analysis. We expect more of this to come in major analytical and life sciences instruments."

Ahmedabad-based supplier Shree Biocare is another player at the forefront of technological advancements, developing and installing large-scale automatic media preparation and dispensing systems (bioreactors) and fermentors for the life sciences industry. Likewise, OmniBrx Biotechnologies, also based in Ahmedabad, has designed single-use bioreactors for vaccines, gene therapies, and biologics production.

Attending to the growing use of new technologies, Mumbai-based HiMedia Laboratories, one of the oldest players of the Indian biosuppliers sector, has recently opened a state-of-the-art Centre of Excellence (CoE) for 3D Cell Culture Laboratory, where cutting-edge technologies and pioneering research is converging to shape the future of cell culture methodologies. This facility is also serving as a catalyst for developing novel solutions and driving breakthroughs in 3D cell culture and bioprinting technologies.

On the global front, biosuppliers have been implementing new technologies to their products as fast as possible. For instance, Thermo Fisher has recently launched Krios 5 Cryo-Transmission Electron Microscope (TEM) with enhanced optics and AI-enabled automation, while Agilent has acquired US-based startup Sigsense Technologies, which uses AI and power monitoring to help optimise lab operations. Likewise, Eppendorf SE and DataHow AG have announced a strategic collaboration to advance bioprocess data management using AI; while Qiagen has launched an AI-extension of Ingenuity Pathway Analysis for automatic interpretation of biological data.

Although the use of technology can prove to be beneficial for the domestic biosupplier industry to strengthen its presence, and come at par with the global competitors, it will require a skilled workforce for efficient handling. This will in turn require comprehensive training programmes to be organised by the local players, with support from other stakeholders, to help bridge the knowledge gap.

"Vision towards becoming the global biopharma powerhouse demands close collaboration between all members of the ecosystem i.e. organisations focusing on research and manufacturing, biosuppliers, academia, and policymakers. While the biosupplier market is currently dominated by global players, a stronger nationwide presence of high-quality domestic suppliers will be essential to drive innovation in emerging biopharma technologies", concludes ***Dr Cyrus Karkaria, President, Biotechnology – Lupin.*** BS

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"Evolving regulatory requirements, heightened scrutiny from regulatory agencies, and geopolitical uncertainties pose challenges"

« **Neeraj Sharma,** CEO & Managing Director, OneSource Specialty Pharma

Strides Pharma Science demerged its Contract Development and Manufacturing Organisation (CDMO) business into OneSource Specialty Pharma Ltd, following approval by the National Company Law Tribunal (NCLT) in 2024. OneSource Specialty Pharma, was listed on January 22, 2025 on the National Stock Exchange (NSE) and Bombay Stock Exchange (BSE). With a revenue generation of around Rs 1500 crore during FY 2024-25, the company is providing seamless end-to-end offerings across all verticals (biologics, drug-device combinations, sterile injectables and Softgel capsules). In an interaction with BioSpectrum India, Neeraj Sharma, CEO & Managing Director, OneSource Specialty Pharma, upbeat about the growth of the CDMO sector, reveals more about the company's major focus areas in the coming years. ***Edited excerpts:***

What have been the major highlights for this fiscal, and what are your upcoming plans?

This fiscal has been marked by significant milestones, namely the successful merger of the three incoming businesses, fundraising with participation from marquee investors, successful listing on the NSE and the BSE and significant addition to our customer base. The listing of OneSource Pharma on the NSE and BSE this year, marks a significant milestone in our journey, one that began with a vision to build a one-stop shop for the CDMO sector. Listing will increase our visibility among partners and stakeholders, opening up more opportunities for strategic collaborations and business ventures. It will also support the recruitment of talent from around the globe. The group is known for its strong corporate governance. We now have over 60 customers across all modalities and now we collaborate with 20 customers in the GLP-1 space. We have initiated our first new biological entity (NBE) programme with the top three animal health companies. Additionally, we are supporting seven potential new chemical entity (NCE)-1 programmes.

We remain fully committed to reinforcing our position as India's first specialty pharma CDMO by expanding our capabilities, advancing quality standards, and strengthening customer partnerships. A key strategic focus is our leadership in drug-device combination (DDC) fill-finish and assembly, particularly as several customers prepare for commercial-scale GLP-1 supplies between 2025 and 2026. To support this, we are making significant investments to expand our manufacturing capacity, ensuring we are well-positioned to meet the needs of our partners. Additionally, we are broadening our sterile injectable capabilities, both by scaling existing infrastructure and introducing new capabilities to support a wider customer base.

In biologics, we are leveraging our deep expertise and robust infrastructure in the microbial segment to position ourselves as a key player in this high-growth segment with limited CDMO providers. In line with our commitment to expansion and innovation, we have already tripled our soft gel manufacturing capacity to 2.4 billion capsules per year and launched CDMO offerings for this segment.

Beyond capacity expansion, quality and compliance remain at the core of our operations, demonstrated by 36 successful regulatory and customer inspections of our sites in 2024. Our flagship site operates with digitalised, paperless systems, allowing us to enhance efficiency, ensure regulatory excellence, and scale operations seamlessly. We are driving a transformational shift in quality management, evolving from quality as a compliance necessity to quality as a competitive differentiator.

What are the significant challenges facing the CDMO sector in India? How do you plan to address those?

The CDMO sector in India is experiencing strong growth, driven by increasing outsourcing trends and a well-established track record in pharmaceutical

manufacturing. India's drug development, manufacturing, and regulatory compliance capabilities have positioned it as a preferred partner for global pharmaceutical and biotech companies. Additionally, the rising demand for specialised areas such as DDCs and biologics presents significant growth opportunities for well-invested CDMOs.

However, evolving regulatory requirements, heightened scrutiny from regulatory agencies, and geopolitical uncertainties pose challenges to the industry. To navigate these complexities, CDMOs must demonstrate robust quality systems, technological advancement, and operational excellence. We have proactively addressed these challenges by investing heavily in technology, talent, and processes, ensuring that we remain ahead of regulatory expectations. Our comprehensive compliance framework is designed to meet global regulatory standards, allowing us to maintain operational excellence and deliver high-quality solutions across all stages of production.

Talent crunch is a major worry for the CDMO sector. What needs to be done to bring in the right talent? Do you think more investment is needed in academic institutions?

India has a very strong legacy and history of pharmaceutical manufacturing development, especially in the area of chemistry, where we have been doing this for over three decades. The talent is available but there is a large pool of opportunities available to them today, significantly more than what was the case say 10-15 years ago. Therefore, it is important to get to the talent early and give them the right opportunity.

At OneSource, we approach talent in several ways. One is getting talent at the senior level. We are able to recruit people who are experts in their arenas and have spent many years in markets such as the US, Europe and are looking to come back. These leaders also attract others to come back as well.

We are also able to get a lot of good talent from other companies. What also helps us is that we are based in Bengaluru, which is an innovation hub. We have excellent institutions here, and specifically for us, we have built a very strong funnel through our apprenticeship programme, which has been ongoing for some years now. Under the programme, we recruit young graduates from pharmacy and engineering colleges for our sites in good numbers and give them training for a year. Post that, we absorb as many as we can. If you get talent early, they stay with you and they progress with you.

There is one area where we need to focus more, which is in the field of biologics. We are very strong in chemistry, but we need to do more in the arena of biologics. Some of our Indian educational institutions are already focusing on that area.

Pharma is a highly regulated industry, not just in India but globally. If companies are not able to keep compliance levels, there is a challenge. We have seen companies from across the globe who have had to face the wrath of the US FDA and other regulatory agencies. Especially in the area of sterile injectables, since it is very complex, keeping compliance is not easy. Compliance has been the most important aspect in our business, and we have a very strong record. It is also very important that the leadership, whether at the site or the company, always focus on quality without any compromise.

What kind of regulatory issues are currently plaguing the CDMO sector, and how can the issues be addressed? Also, what are your views on the newly established CRDMO body, Innovative Pharmaceutical Services Organization (IPSO)?

Pharma is a highly regulated industry, not just in India but globally. If companies are not able to keep compliance levels, there is a challenge. We have seen companies from across the globe who have had to face the wrath of the US FDA and other regulatory agencies. Especially in the area of sterile injectables, since it is very complex, keeping compliance is not easy. Compliance has been the most important aspect in our business, and we have a very strong record. It is also very important that the leadership, whether at the site or the company, always focus on quality without any compromise. That is what we have done at OneSource, and it is appreciated by our customers. Because the single most important thing in a CDMO, which customers look for, is the compliance track record. A trade body such as IPSO can be very helpful because it gives a platform for the industry, even though we compete with each other. There are many areas where we, as an industry, can collaborate, and collaborate with the government, mainly to make India a very strong CDMO base. BS

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"Govt initiatives and private sector investments are boosting adoption of NGS technologies for various applications"

« **Varun Raj,** Regional Marketing Manager - India and Southeast Asia, Illumina

Illumina, a global leader in DNA sequencing and array-based technologies, recently launched the MiSeq i100 and MiSeq i100 Plus Systems. These two powerful, compact benchtop sequencers incorporate more than 140 invention disclosures and 60 patent families. The Illumina MiSeq i100 Series is its first customer-installable instrument since the iSeq. The MiSeq i100 Series builds on the legacy of the original benchtop MiSeq System, which Illumina customers have used since 2011 to power a host of genomic discoveries. Completely redesigned and incorporating the groundbreaking technology and chemistry of the NovaSeq X Series, the MiSeq i100 will help fuel the next generation of genomics growth and discovery. In an interaction with BioSpectrum Varun Raj, Regional Marketing Manager - India and Southeast Asia, Illumina shared more details about the series and how the company will take this product to end users and more. ***Edited excerpts;***

Which are the industry challenges that the MiSeq 100 will solve for the benefit of the scientific community?

Our customers in the scientific community told us they need a faster, smaller, and easy-to-use instrument, and that's what we're delivering with the MiSeq i100.

Whether an established next-generation sequencing lab or a lab looking to start sequencing for the first time, our latest benchtop instrument adds the 'plug-and-play' flexibility that today's labs are seeking.

MiSeq i100 is empowering customers to unlock powerful insights through an affordable, comprehensive solution that is simple to understand and use, even for those with limited NGS expertise. Room-temperature storage and shipping enable labs to sequence on demand, with no delays for thaw time and same-day sample-to-analysis.

The MiSeq i100 Series builds on the legacy of the original benchtop MiSeq System, which Illumina customers have used since 2011 to power a host of genomic discoveries. Completely redesigned and incorporating the groundbreaking technology and chemistry of the NovaSeq X Series, the MiSeq i100 will help to fuel the next era of genomics growth and discovery.

What are the USPs of the MiSeq 100 compared to similar products in the market?

The MiSeq i100 Series brings Illumina's powerful XLEAP-SBS chemistry innovation even further—for the first time, harnessing the potential of room-temperature storage and shipping, which provides customers greater flexibility in how they plan and execute their projects while reducing their environmental impact.

Key features of MiSeq 100 include Room-temperature shipping and storage for reagents (Eliminating the cold chain and allowing for greater flexibility to sequence on demand without the need to thaw reagents, which is critical for running urgent samples); Sustainability (An 85 per cent reduction in packaging waste compared to the MiSeq System supports a lower carbon footprint); Speed (Dramatic reduction in run times: as fast as four hours, with same-day results (4× faster than MiSeq)); Cost efficiency (Cost-effective consumables enable more affordable sequencing); Turnkey workflows (18 proven end-to-end workflows across 10 applications) Simplicity (Simpler, streamlined operations for various levels of sequencing experience) and Integrated Data Analysis (The MiSeq i100 includes onboard data analysis with preconfigured DRAGEN pipelines, minimizing the need for external data processing and analysis tools).

How do you see the market potential for the MiSeq 100 in India?

According to industry reports, the Next-Generation Sequencing (NGS) market in India

is expanding rapidly and is expected to grow at a compound annual growth rate (CAGR) of around 11 per cent through 2033. This growth indicates a strong demand for advanced sequencing technologies. The market potential for the MiSeq i100 in India looks promising, driven by increasing market awareness and growing investment in healthcare and genomic research. Government initiatives and private sector investments are boosting the adoption of NGS technologies for various applications, including clinical diagnostics, oncology, and personalised medicine. Combined with these macro-environmental tailwinds, as well as the speed, simplicity, scalability, sustainability, and cost-effectiveness it offers, the MiSeq i100 is well poised to unlock the potential for genomics growth and discovery in India.

How does the MiSeq 100 fit into India's growing genomics landscape?

The MiSeq i100 fits well into India's rapidly evolving genomics landscape, addressing several key needs and opportunities. With its speed, simplicity, flexibility, and cost-effectiveness, it has the potential to empower every lab, everywhere, making NGS accessible and affordable to a broader range of laboratories, including smaller research institutions and hospitals. This democratisation of NGS is crucial for expanding genomic discoveries and research across the country, especially for clinical applications, where genomic insights can impact patient care and treatment decisions. The MiSeq i100 is well-positioned to contribute to India's genomics revolution, supporting advancements in personalised medicine, genetic research, and biotechnology.

Who among the public and private sectors will be your target audience for the MiSeq 100 series?

The MiSeq i100 series is suitable for a wide range of applications, addressing the needs of a diverse group of users across multiple segments in both the public and private sectors.

In the public sector, it can fit well within academic and research institutions conducting genomic studies and projects, government health agencies involved in public health surveillance, epidemiology, and disease control, as well as public hospitals and diagnostic labs focusing on personalized medicine, oncology, and genetic testing. In the private sector, the MiSeq i100 can effectively serve the needs of hospitals and medical centres offering genetic testing and precision medicine services, biotechnology companies involved in drug development and vaccine discovery, and environmental and agricultural research firms studying environmental genomics, biodiversity, crop improvement, and animal genetics.

The Next-Generation Sequencing (NGS) market in India is expanding rapidly and is expected to grow at a compound annual growth rate (CAGR) of around 11 per cent through 2033. This growth indicates a strong demand for advanced sequencing technologies, according to industry reports. Government initiatives and private sector investments are boosting the adoption of NGS technologies for various applications, including clinical diagnostics, oncology, and personalised medicine. Combined with these macro-environmental tailwinds, as well as the speed, simplicity, scalability, sustainability, and cost-effectiveness it offers, the MiSeq i100 is well poised to unlock the potential for genomics growth and discovery in India.

How do you reach out to a large customer base in India, considering its vast geographical area?

With more than 200 employees, we have established a strong market presence in the country. In parallel, our long-standing collaboration of over 18 years with our trusted channel partner, Premas Life Sciences, has enabled us to support the Indian market, providing access to next-generation sequencing technology and genomic solutions to various institutions, healthcare providers, and research organizations across India.

In 2024, we established our Global Capability Center in Bengaluru as an investment to expand our technology workforce in support of both global and local customer bases. Additionally, we opened our Illumina Solutions Center in Bengaluru, which features a state-of-the-art genomic sequencing lab and offers training and educational opportunities to practitioners nationwide, thereby expanding our products and services footprint in India. BS

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Medical Device Classification and FDA Approval: What Startups Need to Know

« **Aishwarya Varpe,** Associate-Regulatory Services, Venture Center

For many innovators, the United States represents a key market, being the world's largest for medical devices. However, entering the US market requires navigating the US Food and Drug Administration's (FDA) stringent regulatory landscape, where accurate device classification is crucial. To assist innovators, the Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune has released a whitepaper early this year that offers practical insights, featuring examples of devices developed by Venture Center-supported startups to illustrate how medical devices are categorised based on risk.

Under the FDA, the Center for Devices and Radiological Health (CDRH) oversees the regulation of medical devices. It ensures that patients and healthcare providers have timely and sustained access to safe, effective, and high-quality medical devices, including radiation-emitting products.

To assist innovators, the Regulatory Information and Facilitation Center (RIFC) at Venture Center has released a whitepaper titled "Classification of Medical Devices in the US", providing a simplified step-by-step guide in the form of a flowchart on determining device classification (Class I, II, III), regulatory pathways (510(k), De Novo, PMA), and key compliance requirements with examples. The whitepaper also offers practical insights, featuring examples of devices developed by Venture Center-supported startups to illustrate how medical devices are categorised based on risk.

Determining whether a product qualifies as a medical device and identifying its risk classification become important when navigating the FDA approval process. A product is classified as a medical device only if it meets the FDA's definition, which can be ambiguous and often requires further evaluation. This is because medical devices may closely resemble drugs, combination products, or wellness products, each following distinct regulatory pathways. Accurately classifying a device is crucial as it determines the level of regulatory scrutiny and the appropriate market approval process.

Fallout of Misclassification

Misclassifying a medical device can lead to additional efforts, increased costs of rework and delays in the approval process. A clear example provided by the CDRH is the distinction between infant diapers and adult diapers. An adult diaper is designed for individuals with incontinence, a medical condition that affects bladder or bowel control. Since it is intended to manage a health issue, the FDA classifies it as a medical device. In contrast, an infant diaper is a standard part of baby care, as infants naturally lack bladder or bowel control. Because it does not treat a medical condition, it is not classified as a medical device. In fact, according to FDA regulation 21 CFR 876.5920, adult diapers fall under the category of "protective garments for incontinence"—designed to protect clothing from leaks. The regulation even makes it clear that this does not include infant diapers. The whitepaper further explores similar examples, demonstrating how a product's intended use and the manufacturer's claims can impact its classification as a medical device.

The US FDA Classification System employs a risk-based approach to classify medical devices into three categories: Class I, Class II, and Class III, with Class I (Low risk) having the least regulatory requirements and Class III (High risk) undergoing the most rigorous review through the Premarket Approval (PMA) pathway. Devices may require a 510(k) clearance, a De Novo request, or PMA submission, depending on their novelty and risk. The classification is determined by the intended use of the device, its indications for use, and the potential risks it poses to patients and users. FDA applies regulatory controls (general controls and special controls), which are essential for ensuring the safety, effectiveness, and quality of medical devices.

Once the product is confirmed to be a medical device, the next step is to identify similar devices. The FDA product classification database, an online

tool, allows manufacturers to search for devices by name, intended use, or Product Code. This database provides information on the class of a device, applicable regulations, and any predicate devices already cleared by the FDA to confirm the risk-based classification. Venture Center's whitepaper serves as a guide for innovators, offering insights on how to navigate these pathways effectively.

Reclassification of Medical Device

Classifying a medical device and obtaining approvals is not the final step. A device may be reclassified in case of updates that affect its safety and performance. The change in classification depends upon the updated risk profiles due to technological, non-technical modifications and the recent clinical data concerning the subject device. Reclassification ensures that the modified device remains subject to appropriate regulatory controls and continues to meet safety and effectiveness standards. If the FDA receives a petition for reclassification, it may refer the request to a device classification panel for review. After evaluating all relevant information, the FDA will issue an order either approving or denying the petition. Before 2012, if a medical device received a "not substantially equivalent" (NSE) decision, it was automatically placed in Class III. However, after section 513(f)(2) of the FD&C Act was amended by Section 607, an alternative reclassification process allows such devices to be classified under De Novo, and this process does not require a 510(k) submission first. Between 2020 and 2024, the FDA has reclassified seven medical devices through this alternate process.

With evolving technologies like Software as a Medical Device (SaMD) and AI-driven healthcare tools, regulatory landscapes are continuously adapting. New regulatory frameworks and flexible approaches to reclassification will continue to play an important role in fostering innovation. Manufacturers must stay informed about FDA guidance and classification databases to navigate compliance efficiently and align with the latest regulatory expectations.

As regulatory pathways evolve to accommodate emerging technologies, they are expected to become more streamlined and tailored, enabling faster market entry while maintaining patient safety, device quality and efficiency. Understanding these evolving trends will be critical for manufacturers as they navigate the future regulatory landscape. BS

(With inputs from Akash R Dhade, Chetna Dharmawat-Dabi and Dr Pinky Raychaudhuri at Venture Center)

Medical devices are categorised into three classes based on risk

FDA Class	Risk Level	Examples*
Class I	Low	- Noninvasive traction component - Dental hand instrument - Specimen transport and storage container - Limb orthosis
Class II	Moderate	- Resorbable calcium salt bone void filler device - Creatinine test system - Interactive rehabilitation exercise device - Low-energy DC-defibrillator (including paddles)
Class III	High	- High-energy DC-defibrillator (including paddles) - Intraocular lens - Intravascular occluding catheter - Resurfacing cemented prosthesis

*Examples given are the devices developed by the Venture Center supported startups.

FDA's medical device reclassification

- Section 513(e) of the FD&C Act allows the FDA to reclassify a device type that is already classified based on new information by the Commissioner. The FDA commissioner may initiate the reclassification or respond to the petition of an interested person to reclassify the device.
- Section 513(f)(1) of the FD&C Act automatically classifies medical devices into class III that were not available for commercial distribution before May 28, 1976.
- Section 513(f)(2) of the FD&C Act allows an alternative pathway to classify medical devices automatically placed in class III after a "not substantially equivalent" (NSE) to De Novo classification without first being required to submit a 510(k).
- Section 513(f)(3) allows the FDA, manufacturer, or importer to initiate a reclassification. If the FDA receives a petition, it may request that the device classification panel to review the information and provide a recommendation. The FDA will then issue an order that either approves or denies the petition.

Specialised Skill Development for GCCs in India

« **Sudeep Krishna,**
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Healthark Insights

India is a key hub for Life Sciences and Healthcare (LSHC) Global Capability Centers (GCCs). With over 280,000 professionals, 40 per cent are focused on clinical research and using AI for healthcare advancements. The AI talent pool in India is projected to grow to 633,000 by 2025, emphasising the need for specialised skills and continuous learning to maintain its reputation as a top destination for LSHC GCCs.

India has solidified its position as a pivotal hub for Global Capability Centers (GCCs), especially in the Life Sciences and Healthcare (LSHC) sectors. These centres are instrumental in driving advancements in research and development, digital transformation, regulatory compliance, pharmacovigilance, clinical trial analytics, and supply chain management for global pharmaceutical and healthcare enterprises. To sustain this momentum, developing a workforce with specialised skills is essential. Currently, LSHC GCCs in India employ over 280,000 professionals. Of this talent pool, 43 per cent are engaged in core healthcare and R&D, 16 per cent specialise in IT, and 41 per cent focus on business process management.

This article delves into the initiatives undertaken for skill development, the contributions of industry leaders, emerging competencies, and the role of GCC consortiums in fortifying the talent pipeline for LSHC GCCs in India.

Escalating Demand for Specialised Skills in LSHC GCCs

As India cements its status as a preferred destination for LSHC GCCs, there is an escalating demand for professionals proficient in Regulatory Affairs & Compliance for navigating guidelines from authorities such as the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Central Drugs Standard Control Organisation (CDSCO) of India for drug approvals; Clinical Research & Data Management for executing clinical trials, analysing real-world evidence, and managing extensive healthcare datasets.

Currently, 40 per cent of the GCC talent pool is engaged in clinical research, Digital Health & AI/ML Applications for leveraging artificial intelligence for drug discovery, diagnostics, and personalised medicine. India's AI and big data analytics talent base is projected to reach approximately 633,000 professionals by 2025, with a broader goal of 30 million digitally skilled professionals by 2026; Pharmacovigilance & Medical Writing for ensuring drug safety through monitoring adverse events and preparing scientific regulatory documents.; and Healthcare Supply Chain & Operations for overseeing procurement, logistics, and employing predictive analytics to enhance supply chain efficiency.

To bridge the skill gap, a concerted effort involving government bodies, industry leaders, academic institutions, and GCC consortiums is underway, implementing structured programmes to upskill professionals in these critical domains.

Strategic Initiatives for Skill Development

1. Government-Led Programmes- Recognising the potential of LSHC GCCs, the Indian government has launched several initiatives to cultivate a highly skilled workforce:

Skill India Mission & National Skill Development Corporation (NSDC): These programmes offer specialised courses in clinical research, medical coding, and pharmaceutical manufacturing, aiming to enhance employability in the LSHC sector.

Life Sciences Sector Skill Development Council: Established by NSDC, the initiative aims to empower approximately 6.15 million skilled professionals in the sector within the next decade.

Biotechnology Industry Research Assistance Council (BIRAC) Initiatives: Focused on R&D skill enhancement in biopharma and life sciences, BIRAC supports startups and enterprises in developing innovative solutions. Under the National Biopharma Mission, BIRAC has conducted 43 training programmes, trained approximately 7,000 professionals.

Healthcare Sector Skill Council (HSSC): Provides targeted training in healthcare technology, diagnostics, and regulatory affairs to ensure alignment with industry standards.

AI & Digital Health Upskilling: The Ministry of Electronics and Information Technology (MeitY)

collaborates with healthcare firms to offer AI training tailored to medical applications, fostering digital transformation in healthcare.

LSHC GCC Consortium: The Government of Telangana has facilitated the formation of India's first-of-its-kind GCC Consortium with 40 LSHC companies, which is dedicated to developing a highly skilled workforce to meet industry demands.

2. Industry-Led Initiatives

Corporate Training Programmes (CTPs)- Life sciences and healthcare companies are proactively investing in skill development through CTPs. Companies such as Roche, AstraZeneca, and Biocon have established specialised internal training modules focusing on R&D, regulatory compliance, and clinical research to enhance employee competencies.

Centres of Excellence (CoEs)- Organisations like Johnson & Johnson have established CoEs dedicated to skill development in pharmaceutical innovations and medical technology, fostering continuous learning and innovation.

Healthcare-Academia Partnerships- Collaborations between global healthcare firms and academic institutions facilitate certification programmes, hands-on training, and workshops for clinical and regulatory professionals, bridging the gap between academia and industry.

Startup Engagement & Incubation Support- Many leading healthcare companies are investing in incubators focused on AI-driven diagnostics, medical devices, and drug discovery, nurturing innovation and entrepreneurship.

3. Initiatives by Leading Companies- Several multinational and Indian companies are undertaking targeted efforts to enhance skill development in the LSHC GCC sector. In collaboration with universities, **Pfizer** runs workforce upskilling programmes focusing on clinical research and regulatory affairs, aiming to align academic curricula with industry requirements. Through its generative AI programme, **AstraZeneca** enhances the digital capabilities of its employees, focusing on data science and machine learning applications in healthcare. **Biocon** conducts hands-on training programmes in biopharmaceutical manufacturing and quality control, ensuring adherence to global standards and best practices. **Cipla** has launched the "Cipla University" to provide continuous learning and development opportunities for its employees. **Merck** in collaboration with CSIR-IMTECH, has established a High-Tech Skill Development Centre to address employability gaps by offering specialised training in advanced technologies. **GE Healthcare** runs skill enhancement programmes for medical device engineering and healthcare technology management, addressing the evolving needs of the medical technology sector.

4. Role of GCC Consortiums- The government of Telangana has enabled a one-of-its-kind LSHC GCC Consortium in India to further nurture and accelerate the ecosystem. GCC consortiums play a pivotal role in building talent pipelines by Specialised Training Programmes with a focus on areas such as molecular chemistry, data sciences, and regulatory sciences. Companies like Dr. Reddy's Laboratories provide specialised training at institutions like Young India Skills University.

Industry-Academia Collaboration brings together 40 life sciences companies to enhance skill development in Telangana.

Technology Integration focuses on incorporating Artificial Intelligence (AI) and advanced technologies into life sciences education.

Hybrid Course Development designs courses that blend traditional science education with modern technology skills.

Curriculum Enhancement collaborates with universities to include emerging niche areas in academic programmes.

Bridging Skill Gaps ensures students graduate with industry-relevant skills, creating a steady pipeline of skilled professionals.

5. Industry-Academia Collaborations

Strategic partnerships between LSHC GCCs and academic institutions are instrumental in aligning educational outcomes with industry requirements,

Joint Degree & Certification Programmes: Institutions such as the National Institute of Pharmaceutical Education and Research (NIPER) offer specialised courses in biomedical informatics, regulatory sciences, and data analytics, developed in collaboration with industry stakeholders.

Internship & Apprenticeship Models: Companies like Novartis, Pfizer, and Johnson & Johnson provide structured internship programmes, offering students hands-on experience in GCC operations and bridging the gap between theoretical knowledge and practical application.

Corporate Training Centres: Several multinational healthcare firms have established dedicated training centres within universities to enhance R&D and regulatory skill sets, fostering a culture of continuous learning and innovation.

As India continues to solidify its position as a global leader in LSHC GCCs, investing in skill development is crucial for sustaining innovation and growth. Government policies, industry-led initiatives, academia collaborations, and GCC consortium-driven strategies are collectively shaping a future-ready workforce. BS

Biomarkers in Kidney Health: Enhancing Early Detection and Treatments

« **Dr Ajay A Phadke,**
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Emerging biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL) and kidney injury molecule-1 (KIM-1) have shown great potential in the early diagnosis of kidney injury. These biomarkers are extremely sensitive indicators of tubular injury, and they can detect renal damage at stages when conventional markers are still within normal ranges. While these novel biomarkers have high sensitivity and specificity, incorporating them into ordinary clinical practice raises several problems. Despite its potential, more study is needed to validate these biomarkers in large-scale, long-term clinical studies.

Doctors rely on assessing kidney function to diagnose and manage kidney disease. For years, medical professionals have used traditional indicators such as serum creatinine, blood urea nitrogen (BUN), and the calculated estimated glomerular filtration rate (eGFR) to check and track kidney health. These tests are widely accessible and useful for monitoring the gradual loss of kidney function. However, they have a significant limitation: they often fail to detect problems until substantial kidney damage has already occurred. This is particularly concerning in glomerular diseases, where early damage may go unnoticed until the kidneys are severely impaired.

For patients at high risk of kidney problems—such as those with diabetes, high blood pressure, or a family history of kidney disease—the urinary microalbumin-to-creatinine ratio has become an important tool. This measurement can detect early kidney damage, even when blood creatinine levels appear normal by identifying small increases in albumin excretion in the urine. Early detection allows doctors to begin treatment sooner, potentially slowing the progression of chronic kidney disease (CKD) and reducing the risk of cardiovascular complications.

Cystatin C, a low molecular weight protein produced by all nucleated cells, has also gained attention as a biomarker for kidney function that may be more accurate than creatinine. Unlike creatinine, cystatin C levels are less influenced by factors such as muscle mass, age, or diet. This makes it especially valuable in populations where serum creatinine may be unreliable, such as the elderly or individuals with low muscle mass. Despite its advantages, cystatin C has yet to become a routine part of clinical practice due to higher testing costs, variability in laboratory measurements, and the lack of standardised reference ranges.

In recent years, research has increasingly focused on discovering and validating novel biomarkers to overcome the limitations of traditional tests. Emerging biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL) and kidney injury molecule-1 (KIM-1) have shown significant promise for the early detection of kidney injury. These biomarkers are particularly sensitive indicators of tubular injury and are capable of detecting renal damage at stages when conventional markers remain within normal limits.

NGAL is produced by renal tubular cells when they are damaged by factors such as ischemia (lack of blood flow) or exposure to harmful substances. Its levels in urine and blood can rise dramatically within hours of kidney injury, allowing for earlier detection than serum creatinine. Similarly, KIM-1, a protein minimally expressed in healthy kidneys, becomes highly elevated in the urine following

injury to proximal tubular cells. Monitoring KIM-1 levels provides valuable insights into acute kidney injury (AKI) and the severity of renal damage.

While these novel biomarkers demonstrate excellent sensitivity and specificity, integrating them into routine clinical practice presents several challenges. Standardising assay methods and establishing universally accepted reference ranges are essential to ensure consistency across laboratories. Additionally, kidney diseases are complex and can arise from various causes, meaning no single biomarker can provide a complete picture of renal health. A more effective approach may be to combine traditional tests with newer biomarkers such as NGAL, KIM-1, and cystatin C. This combination could enable earlier detection and more accurate risk stratification.

There is also great potential for these biomarkers to play a key role in personalised medicine. As our understanding of the molecular pathways involved in kidney diseases improves, targeted therapies could be developed for specific types of renal injury. For example, elevated NGAL levels might indicate the need for immediate interventions aimed at protecting the renal tubules, while increased albuminuria might prompt strategies to preserve glomerular function. By incorporating a panel of biomarkers into individualised treatment plans, healthcare providers could slow disease progression and reduce the risk of complications such as cardiovascular disease.

In addition to aiding diagnosis, novel biomarkers can serve as valuable tools for monitoring treatment effectiveness. Traditional markers like serum creatinine typically do not change until significant kidney function has been lost, potentially delaying critical treatment decisions. In contrast, biomarkers such as NGAL and KIM-1 can reflect improvements or worsening of kidney injury much earlier. This timely feedback allows clinicians to adjust therapies proactively, optimising outcomes and potentially preventing permanent kidney damage.

Despite their potential, further research is needed to validate these biomarkers in large-scale, long-term clinical trials. Studies must assess their utility across diverse patient populations and determine whether they can reliably predict adverse outcomes such as end-stage renal disease (ESRD) or cardiovascular events. Additionally, strategies for integrating these markers into existing clinical workflows, especially complex decision-making processes, must be explored.

Future research may also focus on identifying additional biomarkers that reflect other key aspects of kidney disease, such as inflammation, fibrosis, or cellular damage. Combining biomarkers that indicate different pathogenic mechanisms could provide a more comprehensive assessment of renal health and help identify patients at risk of rapid disease progression. For example, integrating markers of inflammation such as interleukin-6 (IL-6) or tumour necrosis factor-alpha (TNF-α) with NGAL and KIM-1 could offer deeper insights into the role of inflammation in kidney injury.

Future research may also focus on identifying additional biomarkers that reflect other key aspects of kidney disease, such as inflammation, fibrosis, or cellular damage. Combining biomarkers that indicate different pathogenic mechanisms could provide a more comprehensive assessment of renal health and help identify patients at risk of rapid disease progression. For example, integrating markers of inflammation such as interleukin-6 (IL-6) or tumour necrosis factor-alpha (TNF-α) with NGAL and KIM-1 could offer deeper insights into the role of inflammation in kidney injury.

Moreover, advances in fields such as genomics, proteomics, and metabolomics offer exciting new opportunities for biomarker discovery. These cutting-edge approaches may reveal novel molecular signatures associated with kidney damage and help clarify the underlying causes of disease. As these technologies become more accessible and cost-effective, they could help bridge the gap between laboratory research and clinical practice, enabling highly personalised and effective treatments for kidney disease.

While traditional markers like serum creatinine, BUN, and eGFR have long been the mainstays of kidney health assessment, they are limited in their ability to detect early disease. Emerging biomarkers, such as microalbumin-to-creatinine ratio, NGAL, KIM-1, and cystatin C, represent a promising frontier in nephrology. By incorporating these tools into clinical practice, healthcare providers can improve early detection, refine risk stratification, and enhance treatment strategies—ultimately offering better outcomes for patients with kidney disease. BS

Unlocking Future of Large and Small Molecule Pharma R&D with Science-Driven Digital Solutions

« **Dr Manish M Khandagale,** Senior Field Application Specialist, Revvity Signals Software Team

Digital platforms that can be tailored to the specific requirements of the varied Indian pharmaceutical market present tremendous potential to maximise R&D for both large and small molecules, hence enhancing India's position in this dynamic global pharmaceutical industry.

As pharmaceutical companies expand their R&D operations globally, Indian Contract Development and Manufacturing Organisations (CDMOs) are attracting significant investment.

In recent years, India has emerged as a leader in the production of generic small molecules. In 2023, the India small molecule CDMO market generated a revenue of $6.8 billion, and a compound growth rate of 9 per cent is expected by 2030. However, large molecules, also known as biologics, are now also taking root. Attracting considerable investment, the development of biologics and biosimilars (highly similar copies of approved biologics) is creating new streams of revenue generation in India. The Indian large molecule CDMO market is set to double over the next few years, from a revenue of just below $1 billion in 2023 to $2 billion by 2030.

Key Digital Technologies Empowering Pharma R&D

Digital transformation has become a cornerstone for advancing pharmaceutical R&D over the last few years. By integrating advanced digital platforms, pharma companies can reduce costs, increase response time, enhance stakeholder communication, and create robust chains of identity and custody. These digital tools also deliver new insights that were previously unavailable, providing data that helps executives drive continuous improvement. Given the global nature of the industry, digital platforms are now essential for both efficiency and scalability.

The technological revolution in drug discovery has generated vast and complex datasets, which can be mined and analysed for multiple purposes. To make this possible, digital platforms that can aggregate R&D data from multiple sources and then provide a unified resource that can be analysed and interpreted will offer significant competitive advantage, helping streamline drug development from discovery through to market.

Alongside data handling, fully integrated platforms also support automation of the time- and cost-intensive experimental processes and workflows. Solutions include automating liquid handling, synthesis/bioreactor processes, and high-throughput screening, to name but a few. These techniques offer the potential to reduce development time and cut operational costs while simultaneously improving research quality and enhancing reproducibility.

Advanced data analytics, AI, and machine learning are increasingly being used to optimise production processes, interpret data, identify novel drug targets, and assess molecules under development. Real-world deployments are already showing how digital modelling can accelerate production timelines and create efficiencies in areas such as identifying promising drug candidates, drug molecular design, retrosynthetic analysis, or information flow between clinical trial and manufacturing units.

Benefits of Science-Driven Digital Transformation

Digital transformation delivers measurable benefits in pharmaceutical drug discovery R&D, including:

Accelerated development timelines: By automating many of the manual and routine R&D tasks, digital platforms help to vastly accelerate the "Design-Make-Test-Decide" cycle in drug discovery. These advances have the potential to reduce human error, improve quality control, and free up researchers' time for more complex and critical tasks.

Improved candidate targeting: The availability of real-time data insights, based on the integration of automation, instrumentation, and analysis of vast data sets, enables precise molecule targeting. With an improved focus on likely drug candidates, companies can accelerate research programmes, cutting costs and reaching the market more rapidly.

Business scalability: Cloud-based digital

solutions enable R&D projects to be rapidly scaled up and down to address very high computational demands.

Cost efficiency: Digital solutions can automate routine tasks such as data entry and report generation, streamline workflows, and help researchers to share data securely and efficiently to learn from others' progress.

Enhanced compliance and traceability: Digital solutions enable automated real-time documentation with improved reproducibility and data integrity to facilitate compliance. Technologies that can track batch genealogy help overcome the challenges of monitoring product genealogy in today's complex production environment. For small molecules, this might mean monitoring synthesis schemes, process routes, associated materials consumption tracking, and/or analytical data. For large molecules, it can include tracking processes from cell-line development and fermentation through to the downstream processing and purification stages.

Analysis of vast data stores: Digital solutions can access, store, and analyse huge quantities of data from multiple sources to create entirely new insights. Modern platforms that adhere to F.A.I.R. data principles (findable, accessible, interoperable, and reusable) help to deliver the maximum possible benefit from historic and current research, exploiting data assets to drive future drug discovery.

Artificial Intelligence (AI) and Machine Learning (ML): AI and ML rely on copious amounts of well-curated data to identify patterns and predict the efficacy of potential drug candidates, enabling researchers to prioritise the most promising compounds. Digital platforms, from automation to data warehousing, deliver the critical resources that fuel AI and ML innovation.

Collaborative data sharing and integration: Integrated digital platforms enable robust, reliable, and secure data exchange between pharma firms, CROs, CDMOs, and a multitude of international partners—in real time.

Case Studies and Applications in Indian Pharma

Hyderabad-based NATCO Pharma Limited, an industry leader in generic pharmaceuticals, selected Revvity Signals Notebook to unify its R&D processes, accelerate product development, and improve data audit trails. Signals Notebook provides a complete digital platform for NATCO. For example, the solution includes project codes and unique tracking numbers for new projects, inventory tracking, document management (such as R&D control procedures, protocols, and standard operating procedures), collaboration workflows (such as task and request management with review approval), and much more. The solution delivers immediate visibility of inventories for raw materials, control of instrumentation, and access to references and working standards. Signals Notebook integrates data from other digital tools, for example, permitting bidirectional data exchange with Empower instruments for high-pressure liquid chromatography (HPLC) and gas chromatography.

Also in Hyderabad, Dr. Reddy's Laboratories (DRL) set up its biotechnology R&D business unit in 1999 and launched the first biosimilar product, Filgrastim, within 2 years, and many more biosimilars followed. DRL uses advanced simulation and modelling software to test new drugs virtually, digital twin technology to run virtual experiments and find the optimal production methods, and AI-enhanced standard operating procedures. By adopting digital tools, DRL has improved its operations and set a standard for innovation in healthcare.

Addressing Challenges with Present and Future Digital Integration

Competing in the global marketplace affects multiple business areas, from operational efficiency to process scalability, from collaboration to compliance. Digital solutions provide the flexibility, integration, and security to drive productivity, cut costs, and accelerate innovation—all key factors in gaining competitive advantage.

With the advent of cloud-based solutions, transitioning from paper and manual processes and from multiple independent systems to a unified platform is now considerably more cost-effective than in the past, with zero on-site deployments and no capital costs. In addition, these solutions offer a full audit trail, data backups, role-based data privileges, and compliance with certifications such as SOC 2 Type 2 and ISO 27001, helping to ensure security, confidentiality, and information security in the management of customer data.

Finally, as AI and ML in pharma R&D continue to gain momentum, enhanced data management will be an essential focus. Simultaneously, there will also be pressure to meet new standards laid down by regulators. To strengthen India's role in this vibrant global pharma sector, digital platforms, which are customisable to the needs of the diverse pharma landscape of the Indian market, offer enormous potential to optimise large and small molecule R&D. Sustained digital transformation can foster a shift toward data-centric thinking among scientists, and position Indian pharma as a global leader in large and small molecule pharmaceutical R&D. BS

BiomatiQ Inaugurates State-of-the-Art, Fully Automated Production Line for Ready-to-Use Culture Media

Hyderabad, India - BiomatiQ, a leading life science products distribution company, has marked a significant milestone with the inauguration of its state-of-the-art, fully automated production line for ready-to-use culture media. Founded in 2017, BiomatiQ has established a strong presence in the industry with a team spread across India. This latest advancement marks a pivotal transition into manufacturing, underscoring the company's commitment to delivering high-quality products and services.

A Grand Inauguration Ceremony

The grand ceremony featured a ribbon-cutting by Sri K.V.G.K. Raju, an esteemed figure, known for his immense contributions to the scientific and industrial domains. The momentous ribbon-cutting was followed by the ceremonial lighting of the inauguration diya, signifying a bright and prosperous beginning for this new phase in BiomatiQ's journey. The diya was lit by Sri K.V.G.K. Raju, along with Sri Pavan Kumar, Sri Natarajan, Sri Jean-Francois Jochim from Biokar Diagnostics, Sri Rakesh Aggarwal and Sri Omkaranath, symbolizing unity, collaboration, and enlightenment.

The presence of respected dignitaries and industry leaders added gravitas to the event, highlighting the importance of this new facility not only for BiomatiQ but for the life sciences eco-system.

A Facility Built on Quality and Compliance

BiomatiQ's new greenfield facility has been meticulously designed with a strong foundation in Quality by Design (QbD) principles. The infrastructure supports unidirectional men and material flow, ensuring minimal risk of cross-contamination. At the heart of the facility lies a Grade A/B cleanroom, dedicated to the aseptic filling of RTU media. Every component and layout decision has been made to comply with cGMP and WHO standards.

The seamless integration of design, compliance, and technology ensures not just regulatory adherence, but also operational excellence. BiomatiQ's investment in this facility reflects its commitment to raising the bar for quality in the Indian manufacturing landscape.

Automated Processes for Enhanced Quality

The centrepiece of the facility is a fully automated, Grade A aseptic filling line, built to deliver high-precision, contamination-free RTU culture media. The production workflow includes fully automated plate loading, stacking, silica sachet application, gamma label application, triple wrapping, and packaging. All plates undergo gamma irradiation, followed by 100% batch incubation and visual inspection, ensuring only products that meet the highest quality standards are dispatched to customers.

This rigorous and automated process reduces human intervention, thereby minimizing contamination risk and improving batch-to-batch consistency—a key requirement for customers in regulated industries like pharmaceuticals, biotechnology, and healthcare.

Advanced Equipment for Smart Manufacturing

The facility is equipped with cutting-edge equipment, including filling lines, media preparation and sterilization vessels, incubators, and autoclaves, all of which are 21 CFR Part 11 compliant. This ensures secure, electronic records and controlled access to critical systems.

Each system is integrated with a centralized data acquisition setup for timely monitoring and analysis, allowing for proactive quality control, assurance and trending. The equipment is designed to support the company's commitment to quality, regulatory compliance and traceability.

State-of-the-Art Contract Testing Laboratory

In addition to the production line, BiomatiQ is also setting up a state-of-the-art contract testing laboratory for microbiology testing. The laboratory will cater to the testing requirements of the pharmaceutical, biopharma, and food industries, with services aligned to national and international standards.

What sets this lab apart is its planned adoption of

Rapid Microbiological Methods (RMM), enabling faster turnaround times, enhanced traceability, and better compliance with regulatory expectations. The lab will also offer routine testing, environmental monitoring services, and validation studies for manufacturing clients.

Bridging the Academia-Industry Gap

Beyond its production and testing capabilities, BiomatiQ is committed to bridge the gap between academia and industry. BiomatiQ plans to offer training programs, imparting essential skills to industry entrants and aspiring students. By doing so, BiomatiQ aims to foster a new generation of professionals equipped with the knowledge and expertise required to excel in the life sciences industry. These training programs empower aspirants to meet and exceed expectations, transitioning seamlessly from classroom learning to cleanroom applications.

Building a Complete Life Science Business Eco-System

BiomatiQ is creating a comprehensive life science ecosystem. From product distribution and manufacturing to testing and training, the company provides a one-stop solution for researchers, manufacturers, students, and regulatory bodies. This integrated model is designed to bring synergies across the value chain, improving efficiency, reducing dependency on imports, and enabling innovation at every level. In doing so, BiomatiQ is opening infinite possibilities for collaboration, advancement, and sustainable growth.

Strengthening India's Life Sciences Sector

With this new facility and laboratory, BiomatiQ is poised to become a significant player in the life sciences industry. The company's aim is to produce high-quality products and services that meet international standards, with a strong focus on regulatory compliance and robust Quality Management Systems (QMS).

Directors' Vision

Sri Omkaranath B., the founding director and Sri Rakesh Aggarwal (director), bring extensive industry experience to BiomatiQ. With a strong background in microbiology and technical expertise, they have built a team with the technical know-how to handle daily operations efficiently. The company's focus on quality, compliance, and customer satisfaction is a reflection of its founding directors' vision.

The inauguration of BiomatiQ's state-of-the-art facility marks a significant milestone in the company's journey. With its commitment to quality, compliance, and building a complete life science business eco-system, BiomatiQ is well-positioned to become a leading player in the global life sciences industry.

Looking Ahead

The inauguration of this state-of-the-art facility is more than a celebratory event—it is a powerful statement of intent. BiomatiQ is ready to lead the change in how life science products are manufactured, tested, and delivered.

As the diya was lit and the facility officially came to life, it is the dawn of a new era for BiomatiQ. An era defined by automation, compliance, innovation, and above all, a commitment to quality.

For more details contact :

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Nagaland University announces undergraduate programme in Basic Sciences

Nagaland University is launching a new undergraduate programme in Basic Sciences from the Academic Year 2025-26. The University also plans to launch a Multidisciplinary Research Centre that will offer more programmes in Basic Sciences. Initially, this new centre will offer 3-year/ 4-year Undergraduate programmes in Botany, Chemistry, Mathematics, Physics and Zoology. The University also plans to offer more programmes in Basic Sciences in the coming

years, including integrated Postgraduate programmes in Botany, Chemistry, Mathematics, Physics, and Zoology; PhD programmes in all sciences and social sciences with an emphasis on the topics of multidisciplinary research; integrated PhD (PG + PhD) programmes in all sciences and social sciences with an emphasis on the topics of multidisciplinary research. The Undergraduate/ Integrated Postgraduate programmes will start with an intake capacity of 50 students across all the disciplines (Botany, Chemistry, Mathematics, Physics, and Zoology) during the academic year 2025-26.

H.E.L Group signs research agreement with ICT in Mumbai

H.E.L Group, a global developer and manufacturer of innovative laboratory tools for process optimisation, safety, and scale-up, has announced a research agreement with the Institute of Chemical Technology (ICT) in Mumbai to advance process safety in the chemical synthesis industry. The three-year strategic alliance will focus on H.E.L's Process Safety Hub combined with ICT Mumbai's academic leadership and research acumen in the field of chemical sciences, engineering and allied fields. As part of the agreement, H.E.L will provide ICT Mumbai with a Simular Process Development Reaction Calorimeter, designed for applications including adiabatic calorimetry, autocatalysis, and batch and semi-batch reactors. By leveraging the derived thermodynamic and kinetic information of a reaction, the system enables optimisation of process conditions, determination of safest conditions, and provides accurate and reliable measurements for precise process control.

RED Health opens global centre of excellence in allied healthcare education

Marking a bold step toward reshaping allied healthcare education, Hyderabad-based startup RED Health, Asia's only JCI-accredited and India's largest emergency medical care company, has introduced its dedicated education and training arm, RedVersity. As the demand for skilled healthcare professionals continues to rise, RedVersity aims to empower aspiring medical professionals, working clinicians, and corporate partners through a diverse range of globally accredited programmes. These programmes, delivered through the recently acquired RED TACT Academy for Clinical Training, will provide internationally recognised certifications such as Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), and Pediatric Advanced Life Support (PALS) from the American Heart Association (AHA) as well as Advanced Trauma Life Support (ATLS) from the American College of Surgeons (ACS). In addition to short-duration certifications, RedVersity will offer medium-duration industry readiness programmes, including EmergePro, a specialised finishing school designed to prepare undergraduate and postgraduate students for careers in emergency medical services and allied healthcare.

Ameera Shah steps in as new President of NATHEALTH

NATHEALTH, an apex body representing the Indian healthcare industry, has announced Ameera Shah, Promoter and Executive Chairperson, Metropolis Healthcare as its new President for FY 2025-2026. Ameera takes charge from the erstwhile president Abhay Soi, Chairman and Managing Director, Max Healthcare Institute. Ameera is the Promoter & Managing Director of Metropolis Healthcare. For the last 20 years, she has focused on delivering sustained growth, built and led corporate functions, including finance, strategy, business process optimisation, innovation, investor relations etc. Under her leadership, Metropolis raised the bar of diagnostic accuracy, technological equipment, customer experience and research driven, empathetic service. In addition to being a propagator of organisational empathy and gender sensitivity, Ameera is also an active financial investor and a business mentor. Passionate about the women leadership and empowerment, she has been committed to supporting budding women entrepreneurs.

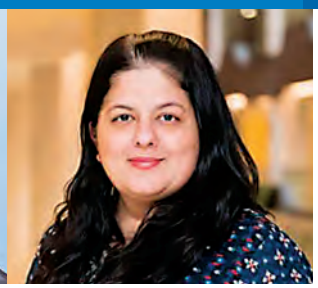
Entod Pharma names Balasubramanian K Pillai as Chief Financial Officer

Mumbai-based Entod Pharmaceuticals has announced the appointment of Balasubramanian K Pillai as its new Chief Financial Officer (CFO). With over 26 years of experience, he brings expertise in financial planning, risk management, and business growth across various industries and global markets. As CFO, he will oversee financial strategy, budgeting, and risk management, helping Entod strengthen its financial position and achieve its growth goals. Pillai has held leadership roles in Reliance Group, Globacom Africa, Petroleum Development of Oman, and Akums Group. He has worked across India, MENA, Europe, and Africa in industries such as telecom, technology, education, pharmaceuticals, and manufacturing. His experience in managing financial operations, improving efficiency, and driving business success will be a great asset to Entod.

Dr Shivkumar Kalyanaraman assumes charge of CEO of Anusandhan National Research Foundation

Secretary, Department of Science and Technology (DST) Professor Abhay Karandikar who was acting as Chief Executive Officer (CEO) of Anusandhan National Research Foundation (ANRF) has handed over the charge to Dr Shivkumar Kalyanaraman who has been appointed the CEO. Dr Shivkumar who earlier held the post of Chief Technology Officer (CTO), Energy Industry, Asia at Microsoft is a Distinguished Alumnus Awardee of IIT Madras & Ohio State University (2021). He is also a Fellow of the IEEE (2010), Fellow of Indian National Academy of Engineering (2015), ACM Distinguished Scientist (2010), Microsoft Gold Club (2024) and Technology Review TR100 young innovator (1999). ANRF will act as an apex body to provide high-level strategic direction of scientific research in the country as per recommendations of the National Education Policy (NEP).

Gopal Agrawal



Nita Borkar

Eris Lifesciences designates Gopal Agrawal and Nita Borkar in leadership roles

Mumbai-based Eris Lifesciences, 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, Agrawal was Director, Market Access at Takeda. Prior to Takeda, he has worked with Shire Plc and Eli Lilly. Nita Borkar is the co-founder of Oaknet Healthcare and became part of the Eris organisation following the acquisition of Oaknet by Eris in May 2022. Another pharma industry veteran, she co-founded Oaknet in April 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. She has now taken on a larger role in Eris and will spearhead the Dermatology, Neuropsychiatry and vitamins/minerals/nutrients (VMN) businesses.

Devesh Choudhari steps in as Director-Finance at Abbott India

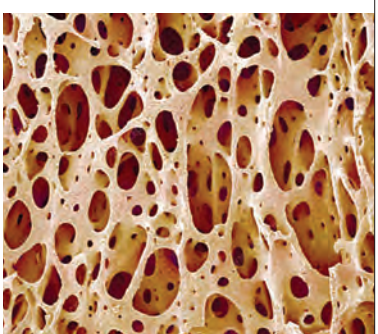
Abbott India has announced the appointment of Devesh Choudhari as Director - Finance effective April 1, 2025. He will be a part of the Senior Management team of the company. Choudhari is a seasoned finance professional specialising in Finance, Accounting, Structuring, M&A, Fundraising, and Controls and has 18 years of experience. He brings a wealth of knowledge and a proven track record in leading complex financial projects. In his most recent role, Choudhari joined Perfect Day, to lead their Indian manufacturing business following the acquisition of Sterling Biotech. Prior to this, Choudhari spent nearly a decade at the Piramal Group, gaining hands-on experience in multi-segment, multi-location manufacturing setups, as well as equity raises totalling over $1.5 billion.

Algorithmic Biologics appoints Hiranjith GH as Chief Business Officer

Bengaluru-based startup Algorithmic Biologics, a pioneer in molecular computing, enabling faster, cost-effective, and highly accurate molecular testing by embedding artificial intelligence (AI) directly into the test tube, has announced the appointment of Hiranjith GH as Chief Business Officer (CBO) to lead the company's commercial operations and its expansion globally, primarily in the US. With decades of experience in the pharmaceutical and life sciences industries, Hiran brings valuable experience and expertise in go-to-market strategy for the US, business development, solution development, and cross-border team leadership. Based in the San Francisco Bay Area, Hiran most recently served as the Vice President and Site Head for MedGenome USA, launching and scaling its commercial operations in the US. Prior to that, he held various corporate leadership and business roles at MedGenome since its incorporation as an independent entity.

NIT Rourkela develops natural bio-ink for 3D bioprinting of bone tissue

A team of researchers at the National Institute of Technology (NIT) Rourkela has developed a bioink made from natural materials for 3D bioprinting of bone-like structures. This bioink is designed to address challenges in bone grafting and implants, which are commonly used to treat bone defects caused by injury or disease. The research focuses on improving existing bone repair techniques by developing a bioink that is biocompatible, easy to use, and supports bone regeneration.



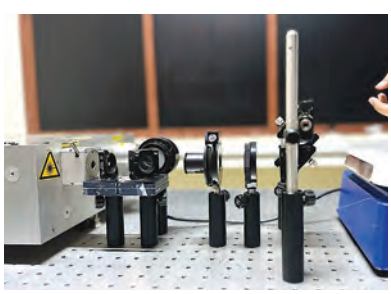
3D bioprinting is being explored as an alternative method for bone repair. It involves printing bone-like structures using bio-inks that contain cells and supportive biomaterials. A major challenge with the existing bioinks is that they require an extended preparation period in laboratory conditions before they can be implanted. The printed tissue must be maintained in a controlled environment for cells to grow and form functional bone before it can be used for treatment. This makes the process slow and difficult to implement in clinical settings.

Potential new autism therapy to help patients become self-sufficient

Researchers from Bengaluru-based Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), an autonomous institute of the Department of Science and Technology (DST), have found a potential therapy for patients suffering from Autism / Intellectual Disability (ID) that will enable the patient to lead a life less dependent on others. Current therapeutics prescribed to treat Autism Spectrum Disorder (ASD) / ID are mostly related to alleviating the symptoms rather than correcting the phenotypes observed in neurodevelopmental disorders, especially after brain development. JNCASR team has found that in mice with mutated syngap gene (Syngap1+/- mice) which resembles humans with mutated syngap gene (present in autistic patients) the acetylation of DNA-associated proteins, histones or proteins that provide structural support for chromosomes is repressed in the brain. The epigenetic enzyme behind this acetylation seems to be KAT3B or p300. The study provides a new potential therapeutic option by targeting epigenetic modifications in Syngap1-related ID/ASD that can restore the deficits to an extent that will enable the patient to lead a life less dependent on others.

IISc suggests blood glucose detection through painless photoacoustics

Blood glucose is usually measured using invasive methods involving pricking small needles into the skin. But people suffering from diabetes have to test their glucose levels many times in a day. This repeated use of needles is inconvenient and can increase the risk of potential infections. A new study by researchers at the Department of Instrumentation and Applied Physics (IAP), Indian Institute of Science (IISc) in Bengaluru offers an alternative solution via a technique called photoacoustic sensing. In this



technique, when a laser beam is shined on biological tissue, the tissue components absorb the light and the tissue heats up slightly. This causes the tissue to expand and contract, creating vibrations which can be picked up as ultrasonic sound waves by sensitive detectors.

In the current study, the team exploited this approach to measure the concentration of a single molecule, namely glucose. They used polarised light – a light wave that oscillates only in a specific direction. Glucose is a chiral molecule, which means that it has an inherent structural asymmetry that causes polarised light to rotate its orientation of oscillation when it interacts with the molecule.

Alamar Biosciences expands commercial support in APAC region

Alamar Biosciences, a US-based company powering precision proteomics to enable the earliest detection of disease, has announced the signing of five new distribution partners to expand its global presence. The company has partnered with established industry leaders across key international markets to enhance access to its innovative proteomics technologies. The newly signed distribution partners include GeneWorks – Australia and New Zealand; Genomax – Singapore; PhileKorea – South Korea; Scrum Inc. – Japan; and Spinco – India. Alamar's technology empowers scientists to achieve groundbreaking insights in biomarker discovery, drug development, and disease research. Through these new partnerships, researchers in Asia-Pacific (APAC) will now have enhanced access to Alamar's cutting-edge platforms and technical support. The company's proprietary NULISA Platform along with the ARGO HT System work seamlessly with the latest advances in genomics to achieve single digit attomolar detection sensitivity, greatly surpassing the most sensitive protein detection technology on the market today.

Copeland opens engineering and technology centre in Pune

US-based Copeland, a global provider of sustainable climate solutions serving the pharma, healthcare sectors among others, has inaugurated a new state-of-the-art Engineering and Technology Centre in Pune, Maharashtra, as part of its broader Rs 500 crore India investment plan. Leveraging India's STEM talent pool and aligned with India's ambition to become a global innovation hub, the Copeland Engineering and Technology Centre will strengthen the company's innovation ecosystem with state-of-the-art engineering labs spanning 9 countries to advance its engineering, research and development efforts locally and globally. The new facility spans over 15,000 square meters and is the hub for over 320 engineers specialising in engineering, research and development, as well as software and firmware development. Copeland's Pune Engineering and Technology Centre will help Copeland accelerate in-country innovation and product development, allowing the team in India to leverage their proximity to the company's customer base and anticipate and respond to evolving market requirements to develop future-forward sustainable solutions.

BiomatiQ Group inaugurates world-class manufacturing facility in Hyderabad

BiomatiQ Group has announced the inauguration of its state-of-the-art fully automated manufacturing facility in Hyderabad, a significant milestone in the Group's mission to build a self-reliant and innovation-led life science business ecosystem in India. This new unit reinforces BiomatiQ's commitment to the Make in India initiative by offering locally manufactured, globally benchmarked products for the pharmaceutical, biotechnology, and research sectors. Strategically designed to support high standards of quality, compliance, and scalability, the new facility will focus on the manufacturing of Ready-to-Use (RTU) microbiological media plates and Laboratory essential products tailored for regulated environments. The facility is equipped with fully automated Grade A aseptic filling line for high-precision, contamination-free RTU media; GMP-compliant manufacturing zones with ISO-certified operations; In-house microbiology and quality control laboratories, designed to support 21 CFR Part 11 compliance; and scalable and sustainable production infrastructure with a focus on data-driven operations and minimal human intervention.

Qiagen introduces QIAprep Plasmodium kit to strengthen malaria research efforts

Qiagen N.V. has announced the launch of the QIAprep Plasmodium Kit and two companion assays to support malaria research and surveillance efforts. This new solution combines sample preparation and quantitative PCR (qPCR) into a single workflow, providing a rapid and accessible tool for detecting malaria-causing parasites from blood samples. Qiagen's QIAprep technology – originally developed for COVID-19 research – integrates liquid-based sample preparation with qPCR into a streamlined and cost-efficient workflow. It offers

high sensitivity, detecting as little as one parasite per microliter, and is compatible with both liquid and dried blood samples. The accompanying assays further enhance malaria research detection and differentiation.

The Qiagen Pf/Non-Pf Detection Assay is a single-reaction screen for the most common cause of malaria in humans involving Plasmodium falciparum, while the Qiagen Pv/Pm/Po/Pk Detection Assay helps distinguish between the remaining four common species that cause malaria – P. vivax, P. malariae, P. ovale, and P. knowlesi – allowing scientists to track mixed infections, study parasite evolution during vaccine rollouts and ensure that comprehensive epidemiological surveillance data is available when designing response measures.

ABEC unveils single use bioreactor technology for cell therapy manufacturing

ABEC, a global leader in engineered solutions and services for biotech manufacturing, has introduced its Advanced Therapy Bioreactor (ATB) – a revolutionary platform poised to transform cell expansion for Advanced Therapy Medicinal Products (ATMPs). Designed to overcome the limitations of currently available systems, the ATB delivers unprecedented process control and scalability from bench to commercial scale. The ATB redefines cell culture by mimicking the human circulatory system. Its proprietary hollow fiber membrane networks enable localised nutrient delivery and waste removal, ensuring optimal conditions for every cell. Unlike conventional systems that rely on bubbles and mechanical agitation, the ATB's oscillation-based mixing and diffusion-based gas and nutrient/waste transfer maintain an optimum cell growth environment for sensitive cell lines.

Waters expands Alliance iS Bio HPLC product line with photodiode array detector

Waters Corporation has announced the expansion of the Alliance iS Bio HPLC product line with integrated photodiode array (PDA) detection, advancing the capabilities of the next-generation intelligent HPLC platform designed for development and Quality Control (QC) laboratories. The Alliance iS HPLC Platform has been purposefully designed to simplify laboratory workflows by reducing the risk of out-of-specification results and the need for troubleshooting. Default system parameters provide over threefold improvement in day-to-day reproducibility and reduce carryover by up to two orders of magnitude, compared to other systems on the market. Additionally, with MaxPeak Premier columns, the Alliance iS Bio HPLC System enhances out-of-the-box sensitivity by up to 80 times compared to traditional systems and columns. Waters now offers four configurations of the Alliance iS HPLC Platform to support routine quantitative analysis and expanded spectral analysis of small and large molecules in development and QC.

Mushrooming Generics Turn Affordable Lifeline

The Indian pharmaceutical market is witnessing a dramatic transformation following the patent expiry of Empagliflozin (sold under the brand name Jardiance by Boehringer Ingelheim) on March 11, 2025, used for treatment of adults with type 2 diabetes mellitus, as an adjunct to diet and exercise to improve glycemic control and to reduce the risk of cardiovascular death in patients with established cardiovascular disease. Jardiance (empagliflozin), a sodium-dependent glucose co-transporter 2 (SGLT2) inhibitor, was approved in 2014 for type 2 diabetes and later expanded to include heart failure and kidney disease indications. In 2023, the drug generated $8 billion in global sales, according to reports. The drug remains the leader in the SGLT2 inhibitor market, holding a substantial 31.2 per cent market share in 2025.

Following the patent expiry of Empagliflozin, multiple branded generics have flooded the Indian market in a short span, signaling one of the most competitive post-patent scenarios in recent years. For instance, on March 12, Alkem Laboratories announced the launch of Empanorm in India, a generic version of empagliflozin, for the treatment of type-2 diabetes mellitus, chronic kidney disease (CKD), and chronic heart failure (HF). The product is priced approximately 80 per cent lower than the innovator drugs, making it more accessible to patients.

Simultaneously, March 12 saw Glenmark Pharmaceuticals launching Empagliflozin, under the brand name Glempa (Empagliflozin 10/25 mg), along with its fixed-dose combinations (FDCs)—Glempa-L (Empagliflozin 10/25 mg + Linagliptin 5 mg) and Glempa-M (Empagliflozin 12.5 mg + Metformin 500/1000 mg), to improve glycemic control in adults with type 2 diabetes while also reducing cardiovascular outcomes. Later, on March 18, USV announced the launch of Xenia (Empagliflozin and its combinations) for glycemic control, heart failure and chronic kidney care in people with Type 2 diabetes. Joining this list are other pharma companies, such as Mankind, Corona Remedies, Morepen, etc.

On the other hand, before the patent expiry of empagliflozin, a few Indian pharma companies had signed agreements with Boehringer Ingelheim to co-market the anti-diabetic drug. Back in 2020, Cipla and Boehringer Ingelheim India had announced a partnership in India to co-market three oral anti-diabetics drugs Oboravo (Empagliflozin), Oboravo Met (Empagliflozin+Metformin) and Tiptengio (Empagliflozin+Linagliptin).

In December 2024, Torrent Pharma agreed to acquire brands Cospiaq (empagliflozin), Cospiaq Met (empagliflozin + metformin) and Xilingio (empagliflozin + linagliptin) from Boehringer Ingelheim International GmbH (BI). The acquisition was expected to be completed in March 2025. Torrent has been marketing these brands since 2022 as part of an existing co-marketing agreement with Boehringer Ingelheim India.

2024 also witnessed the High Court of Himachal Pradesh granting an interim injunction in the patent infringement case filed by Boehringer Ingelheim International GmbH against Eris Lifesciences (EL). BI sought an interim injunction to prevent Eris from manufacturing, selling, or marketing Empagliflozin tablets, claiming that EL's product sold under the brand name Linares-E infringes its patent. A similar legal issue had erupted back in 2021, when Dr. Reddy's had launched Empagliflozin under the brand name Vicra, priced at a one-third cost charged by Boehringer. MSN had also introduced Empagliflozin tablets under the brand name Empaone within a price range of Rs 15-19.

But post-patent expiry, the rapid proliferation of generic Empagliflozin has intensified competition among pharmaceutical companies, prompting strategies such as multi-brand approaches and extensive distribution networks to capture market share. The coming quarters will reveal how this Empagliflozin wave reshapes diabetes care delivery, patient adherence, and the economics of chronic disease management in India. Simultaneously, the upcoming patent expiry of a few other diabetes drugs, such as Farxiga (dapagliflozin) by AstraZeneca and Humalog (insulin lispro) by Eli Lilly, indicates a period of heightened competition with significant implications for pricing, market share, and patient access. The entry of cost-effective alternatives will mark an opportunity to enhance access to life-saving therapies. BS

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- **Infrastructure** — Plug & Play, Brownfield Development....
- **Bio-Industrial** — Bioplastics, fermentation-based products...
- **Bio-Agriculture** — Bio-fertilizers, Bio-pesticides, Plant Tissue culture..
- **Healthcare** — Biologics, Biosimilars, Probiotics, Med Devices..

BIOTECH UNITS ENGAGED IN ...

SETTING UP NEW UNIT	EXPANSION / DIVERSIFICATION	SPECIAL PROJECTS	ECOSYSTEM STRENGTHENING PROJECTS	SMART & FUNCTIONAL PROTEINS	PRECISION BIOTHERAPEUTICS

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*Note: For details, please refer Biotech policy 2022-27

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