An MM ACTIV Sci-Tech Communications Publication

BioSpectrum

the business of Bio & Health Sciences

PUNE ▪ Volume 22 ▪ Issue 8 ▪ August 2024

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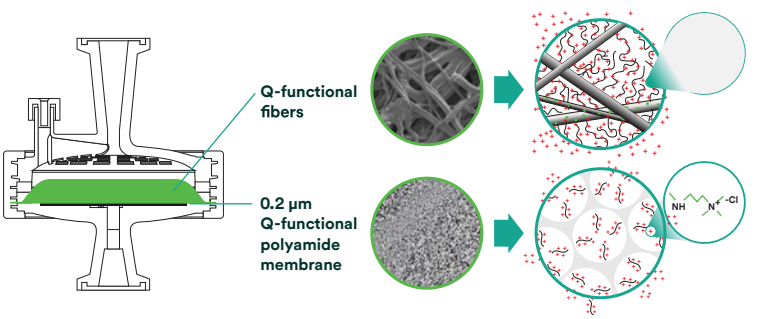
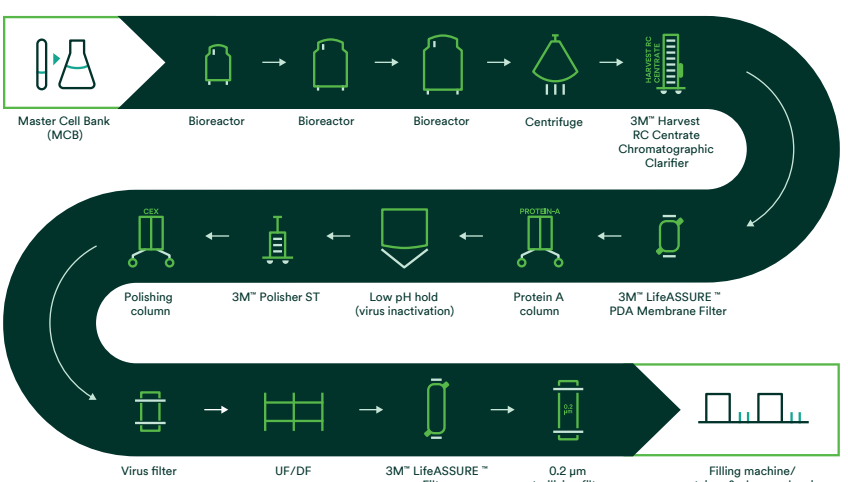


Centrate clarification simplified:



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Vol 22; Issue 7; July 2024

Acknowledgements/ Feedback

The whole initiative of 'Make in India' must become a reality. Government should take actions in the direction of discouraging imports of medical devices in general.

- Dr Sudhir Srivastava, Gurugram

To elevate the landscape of vaccine research in India, adopting modern immunology-vaccinology research approaches is imperative.

- Dr Pragya Yadav, Pune

Thank you BioSpectrum for publishing the story on Orchid Pharma and exploring a conversation about the urgent topic of Antimicrobial Resistance.

- Aayushi Sharma, Gurugram

BioSpectrum

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Vol 22; Issue 8; August 2024

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'BioSpectrum' monthly publication is owned by MM Activ Sci-Tech Communications Pvt. Ltd., **Published and Printed by** Ravindra Boratkar, **Printed at** Spectrum Offset, D2/4, Satyam Industrial Estate, Behind CDSS, Erandawana, Pune - 411 038. and **Published at** 'Ashirwad', 36/A/s, S. No. 270, Pallod Farms, Baner Road, Near Bank of Baroda, Pune - 411 045. **Editor:** Narayan Kulkarni.
Website: www.biospectrumindia.com Reprinted for private Circulation

Letter from Publisher

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

Since 2000, the momentous year when the first biosimilar was introduced in India, a vaccine for hepatitis B, the development and utilisation of "biosimilars or similar biologics" have undergone significant growth in the country. At present, the Indian biologics and biosimilars market is growing rapidly, from $6 billion in 2022 to a projected $12 billion by 2025.

With over 55 blockbuster branded biologics going off-patent from 2022 to 2032 globally, the McKinsey report in August 2022 pointed out that the Indian biosimilars manufacturers can grab this opportunity to bring in not just affordable biosimilar products in place of costly branded biologics, but also leverage the huge business potential offered by the global markets for biosimilars products. Despite the considerable potential and high expectations for India, there are substantial challenges that India must overcome to maintain its leadership position.

To realise its full potential and sustain its global leadership, Indian biopharmaceutical companies must enhance their technological capabilities and enhance the skills of their workforce. This will require a supportive environment from both the government and regulatory agencies.

Our team has spoken to industry leaders and experts as to how India can work to achieve the growth in the biosimilar market that holds immense potential, with opportunities to innovate and develop complex molecules. Overcoming regulatory challenges, fostering collaborations, and leveraging advanced technologies will be key to advancing R&D in biosimilars and achieving global leadership in this field.

Technologies like Artificial Intelligence (AI) and Machine Learning (ML) are being deployed in bioreactors to make bioprocessing systems score higher in their performance thereby increasing production of biopharma products at a faster rate. As India's biopharma market is booming, the convergence of Information Technology and Biotechnology is spurring a huge demand in developing automated bioprocess equipment. An article, in this edition, touches upon how these bioreactors are becoming automated leading to improved efficiency and consistency, offering better product yields and higher speed-to-market.

India's pharmaceutical industry is globally recognised for its capabilities in research and manufacturing and for its skilled workforce. The country's attractiveness as a destination for Global Capability Centres (GCCs) is underpinned by several key factors, including cost-efficiency, a vast talent pool, robust infrastructure, and strong regulatory support.

Presently there are over 38 GCCs in India from healthcare and life sciences companies. The future of these hubs in India's pharmaceutical sector appears promising. We have an expert column that sheds light on how these hubs provide ample opportunities to explore emerging technologies and foster collaborations, leading to breakthrough discoveries and continuing to solve the healthcare challenges of India.

BioSpectrum India is hosting the biotechnology industry's most anticipated event, the Biotech Innovations & Suppliers Conclave 2024, on August 23, 2024, at the CIDCO Exhibition Centre, in Mumbai. It promises to bring together the brightest minds and leading companies in the biotech suppliers' sector to showcase groundbreaking innovations and forge strategic partnerships. It's my pleasure to invite industry leaders, innovators, and suppliers for a transformative event showcasing the latest advancements and forging strategic partnerships for the growth of the biotechnology industry.

I am sure that, as usual, you will find this edition a great read.

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

COVER 18

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Why INDIA must turn BIOSIMILAR POWERHOUSE by 2030

Biosimilars could potentially enhance patient access to treatment of various malignant and nonmalignant conditions by reducing costs. Since the introduction of the first biosimilar in 2000 in India, a vaccine for hepatitis B, the development and utilisation of "biosimilars or similar biologics" have experienced significant growth. Each year, regulatory bodies are approving numerous similar biologics for the management of both cancerous and noncancerous illnesses. India has firmly positioned itself as a key player in the global production of similar biologics, benefiting from its large population. Despite the considerable potential and high expectations for India, there are substantial challenges that must be overcome to maintain this leadership position. To realise their full potential and sustain their global leadership, Indian biopharmaceutical companies must enhance their technological capabilities and enhance the skills of their workforce. This will require a supportive environment from both the government and regulatory agencies.

Dr Sudhira H S,
Director, Gubbi Labs

Surbhi Gupta,
Industry Principal, Healthcare & Lifesciences, Frost & Sullivan

Union Budget 2024-25

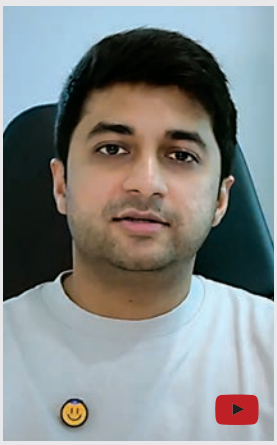
Bioreactors

Speaking With

GCCs

Pathology

Top Video



Rishi Tandulwadkar, Founder, ALIV lays focus on the potential applications of regenerative medicine that spans multiple medical fields.

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Strategies to scale healthcare innovations- A perspective by Srinath Rao, Senior Vice President, Citius Tech.

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Regulars

‘Quality’ is the MANTRA

If closure of the number of pharmaceutical units by the Central Drug Standard Control Organisation (CDSCO) over the quality concerns is an indicator, then the issue of drug quality in the country appears to have reached an alarming level.

The Drugs Controller General of India (DCGI) Dr Rajeev Singh Raghuvanshi, disclosing the number at a pharma event in Mumbai recently, remarked, “I am not very happy to say that 36 per cent of the 400 pharma manufacturing units have been shut down during CDSCO’s one and half year drive of risk-based inspection”.

The closed production facilities are mainly in the MSME sector and had to be shut down as they realised that they cannot meet the expectations of the regulators. Prior to this, just two months back, 52 drug samples failed the quality test. During this entire drive of risk-based inspection, in November 2023, nearly 65 per cent of the pharma firms which were MSME units, were found to be producing not of standard quality (NSQ) drugs. Medicine samples of nearly 68 per cent MSME companies failed in that drive.

All these figures lead to one direction, lack of quality and lacunae in good manufacturing practices (GMPs) at the production centres. The problem is compounded when such substandard drugs, when exported, do damage in other countries - causing sickness or even fatality. They are then recalled or banned, damaging the reputation of the Indian pharma industry. To overcome this, the drug regulator had taken back the authority to issue manufacturing licences for new drugs meant for exports.

In 2018, the drug regulator had authorised state drug controllers to issue NOCs. Those powers of the states have now been withdrawn and CDSCO has once again been made the sole licensing authority for drugs to be exported. This will surely bring uniformity leading to quality assurance which is required for export.

The regulator has launched four programmes to tighten the screws to improve quality assurance on the domestic front also. Two new digital platforms are being developed. CDSCO is launching its digital platform covering the entire regulatory value chain and bringing every stakeholder to the platform. Similarly, Indian Pharmacopoeia Commission (IPC), an autonomous body under the Ministry of Health and Family Welfare, is also creating a digital platform for IP.

Digitalisation makes the organisations and their processes democratic and transparent, which is, no doubt, important in moving towards quality improvement. But, digitalisation alone does not guarantee quality improvement. For that, some on-ground steps too are required. The drug regulator is moving in that direction too.

First and foremost, it is planning to improve its internal working. CDSCO has appointed an internationally renowned consultancy firm to examine its internal processes. Realising the need for improvement in the internal processes itself is a very important step. CDSCO has even gone beyond that and initiated action for corrections and changes. Similarly, another consultancy firm will look into the Drugs and Cosmetics Act, 1940. However, one problem in appointing international firms is that they lack the practical ‘on the ground’ knowledge and make their recommendations which may be ideal but impractical. Hence, the drug regulator and the government will have to look into this particular aspect of the Act. It is also not clear as to what will be the status of the new planned Drugs, Medical Devices and Cosmetics Bill, set to replace 83-year-old Drugs and Cosmetics Act.

Another important step is the launch of the Revamped Pharmaceuticals Technology Upgradation Assistance Scheme (RPTUAS) which provides financial assistance to upgrade the manufacturing facilities. Sixty small firms have joined the scheme. This is a good initiative since merely regulatory tightening would not ensure quality, but handholding of the companies and joint efforts will help in improving the quality.

Improving quality is paramount for Indian pharma. Otherwise, as per Japanese media reports, quality lapses in Indian pharma are compelling the US to turn to China. Shortcuts taken by the Indian drug makers, if any, will help China in the final analysis. BS

Dr Milind Kokje
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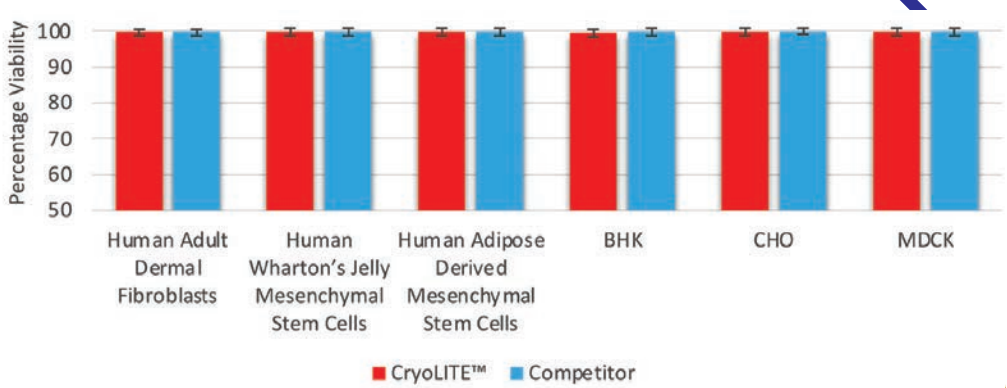

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Ministry of Ayush strengthens standardisation protocols to ensure safety of ayurvedic medicines

In a significant development aimed at advancing the field of Indian Medicine and Homoeopathy, a Memorandum of Understanding (MoU) was signed between the Central Council for Research in Ayurvedic Sciences – Captain Srinivasa Murthy Central Ayurveda Research Institute (CSMCARI), Chennai, under the Ministry of AYUSH, Government of India and the Commissionerate of Indian Medicine and Homoeopathy (CIM&H), Arumbakkam, Chennai, Tamil Nadu. The MoU outlines a collaborative framework for Testing Services, Imparting Training, and executing a Collaborative Project on 'Research Studies for the Standardisation and Evaluation of Toxicity Studies for the Preparation of Selected Higher Order Medicines.' The primary objectives of this MoU include to carry out testing of selected raw drugs and finished products for the purpose of standardisation of medicine; and providing NABL Accreditation Training guidance to the Laboratory of CIM&H. Joint research projects will focus on evaluating the toxicity of selected higher-order medicines, contributing valuable data to the scientific community.

Kerala to launch Institute of Organ Transplantation in Kozhikode

The Government of Kerala has decided to establish an Institute of Organ and Tissue Transplant at Kozhikode. It is being established as an Apex Institute for research, training and patient care in the area of organ transplantation and allied activities. This Apex Institute with skilled doctors, researchers and health workers can be developed as a Centre of Excellence. The total cost of setting up the Institute of Organ and Tissue Transplant will be Rs 558.68 crore (Phase I Rs 373.68 crore + Phase II Rs 185 crore). Funds will be procured from the Kerala Infrastructure Investment Fund Board (KIIFB) to establish the Institute according to a Master Plan within a 25- acre campus, and implement the scheme. The Institute is proposed as a Super Specialty Centre with a 489 bedded hospital which includes 219 general beds, 42 special ward beds, 58 ICU beds, 83 HDU beds, 16 Operation Rooms, Dialysis Centre and a Centre for Transplantation Research. Currently only the USA and China have dedicated transplant centres. The Institute of Organ and Tissue Transplant at Kozhikode will be the first of its kind in the country.

Health Ministry unveils National STOP Diarrhoea Campaign 2024

The Union Minister of Health and Family Welfare, Jagat Prakash Nadda launched the National STOP Diarrhoea Campaign 2024, in New Delhi. He was joined by Anupriya Patel and Jadhav Prataprao Ganpatrao, Union Ministers of State for Health and Family Welfare. The dignitaries also released Information, Education and Communication (IEC) materials like logo, posters, radio spots and audio visuals for the campaign and distributed oral rehydration salts (ORS) and zinc tablets to children on the occasion. The goal behind the STOP Diarrhoea Campaign 2024 is to attain zero child deaths due to childhood diarrhoea. While the existing diarrhoea strategy entailed a 2-week campaign with pre-positioning of ORS to under-5 children and limited IEC, the new strategy involves a 2-month long campaign with pre-positioning of 2 ORS packets and zinc as a co-packaging to under-5 children.

AstraZeneca invests Rs 250 Cr to grow Global Innovation and Technology Centre in India

AstraZeneca India has announced an investment of Rs 250 crore ($30 million) to expand its Global Innovation and Technology Centre (GITC) in Chennai, Tamil Nadu, which includes close to 1,300 roles focused on driving innovation, enhancing efficiency, and streamlining operations across the company globally. The investment marks a significant milestone in AstraZeneca's growth story in India as it celebrates its 45th year in the country this month. With the highly skilled roles to be brought in by 2025, the expanded GITC will propel the company's vision to leverage technologies such as enterprise platforms, artificial intelligence, machine learning, data science, and supply chain analytics to shape healthcare outcomes. The expanded facility was inaugurated in a ceremony officiated by Dr TRB Rajaa, Minister of Industries, Tamil Nadu; Christina Scott CMG, British Deputy High Commissioner to India; Sylvia Varela, AstraZeneca, Vice President, as well as AstraZeneca's leadership team in the country.

Dr. Reddy's buys Nicotine Replacement Therapy business from Haleon for Rs 5276 Cr

Hyderabad-based Dr. Reddy's Laboratories has announced that its subsidiary Dr. Reddy's Laboratories SA has signed a definitive agreement with Haleon plc, a leading consumer healthcare company, for purchase of shares of Northstar Switzerland SARL, a Haleon group company, to acquire Haleon's global portfolio of consumer healthcare brands in the Nicotine Replacement Therapy (NRT) category outside of the United States. Dr. Reddy's will acquire the share capital of Northstar Switzerland SARL for a total consideration of GBP 500 million (Rs 5276 crore) with an upfront cash payment of GBP 458 million and performance-based contingent payments of up to GBP 42 million, payable in 2025 and 2026. The portfolio to be acquired consists of Nicotinell, a global leader in the NRT category with an extensive footprint in over 30 countries spanning Europe, Asia including Japan, and Latin America, and local market-leading brand names of the product – Nicabate in Australia, Thrive in Canada, and Habitrol in New Zealand and Canada.

Pulsus Group to establish Rs 300 Cr pharma healthcare IT hub in Ameenpur

Pulsus Group, headquartered in Hyderabad, has announced the creation of an artificial intelligence (AI)-based pharma healthcare IT hub in Ameenpur, Sangareddy, Telangana, at an estimated cost of Rs 300 crore. This project, announced by Dr Srinubabu Gedela, CEO and MD, Pulsus Group, at the 73rd Indian Pharmaceutical Congress held in Hyderabad, is set to revolutionise the healthcare and IT landscape while generating a significant economic impact by creating approximately 50,000 jobs. Early projections indicate the hub will create 10,000 direct positions within the facility itself and an estimated 40,000 indirect jobs through supporting industries and services. Key features of the project include innovative AI applications across all aspects of pharma, from research and development to healthcare delivery. The hub will generate substantial employment opportunities for local residents, enriching the region's economy. Located within the designated IT/ITeS Zone in Ameenpur, the hub, benefits from exceptional infrastructure and connectivity.

Horiba invests Rs 200 Cr to open medical equipment and consumables manufacturing facility in Nagpur

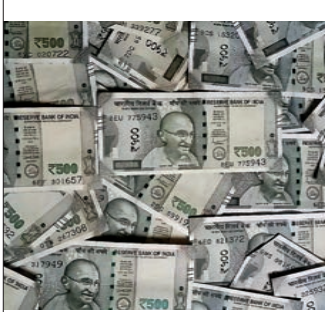
Horiba India, a group company of Kyoto based Japanese leader in analytical equipment and measurement solutions, has inaugurated its state-of-the-art medical equipment and consumables manufacturing facility in Butibori, Nagpur. With an investment of approximately Rs 200 crore, in a phased manner, the Nagpur facility is poised to serve over 30,000 diagnostic labs and hospitals across India and represents Horiba's third significant investment in India, reinforcing its commitment to generating employment opportunities in tier-2 cities. Global business revenue of Horiba Ltd is $2.3 billion. This state-of-the-art manufacturing facility, covering 50,000 square metres, includes a medical equipment production unit for blood diagnostics, clinical chemistry equipment, and medical consumables and reagents.

Navin Molecular injects $35 M for expanding manufacturing capabilities

Navin Molecular, a Madhya Pradesh-headquartered Contract Development and Manufacturing Organisation (CDMO), has announced a significant investment of Rs 288 crore (approximately $35 million) to expand its GMP manufacturing plant in Dewas. The new 9,000-square-metre facility will nearly double the site's overall capacity to 420 cubic metres, supporting existing commercial-scale projects and meeting future demand as the company continues to grow its global customer base. The multi-purpose facility will add 200 cubic metres of manufacturing capacity, incorporating various vessel types including stainless steel, glass-lined, Hastelloy, and Inconel. It will handle a wide range of chemistries, including hazardous processes such as direct fluorination, cyanation, azide chemistry, cryogenic reactions, and high-pressure hydrogenation. The plant will feature a high level of automated control, including a distributed control system (DCS), enhancing efficiency and minimising risks to employees and the environment. Navin Molecular, launched in 2023 as the CDMO division of Navin Fluorine, supports global pharmaceutical innovators.

HCG buys Mahatma Gandhi Cancer Hospital & Research Institute in Vizag for Rs 414 Cr

Bengaluru-based HealthCare Global Enterprises Limited (HCG), one of the largest cancer care networks in India, has announced the acquisition of Mahatma Gandhi Cancer Hospital & Research Institute (MGCHRI) in Vizag, Andhra Pradesh, for an Enterprise Value of Rs 414 crore. HCG will have an initial 51 per cent stake in MGCHRI, with plans to complete the acquisition of the additional 34 per cent stake over the next 18 months. This strategic move entails leadership in a highly attractive micro-market with high quality primary catchment supported by large draining secondary catchment from neighbouring states. This acquisition is poised to significantly bolster HCG's annual EBITDA by Rs 3 per share and gain a leadership position with a dominant share in the Vizag region. The partnership aims to address the significant demand-supply gap in radiation therapy equipment, which has a penetration rate of less than 0.6 per million in Andhra Pradesh and Orissa.



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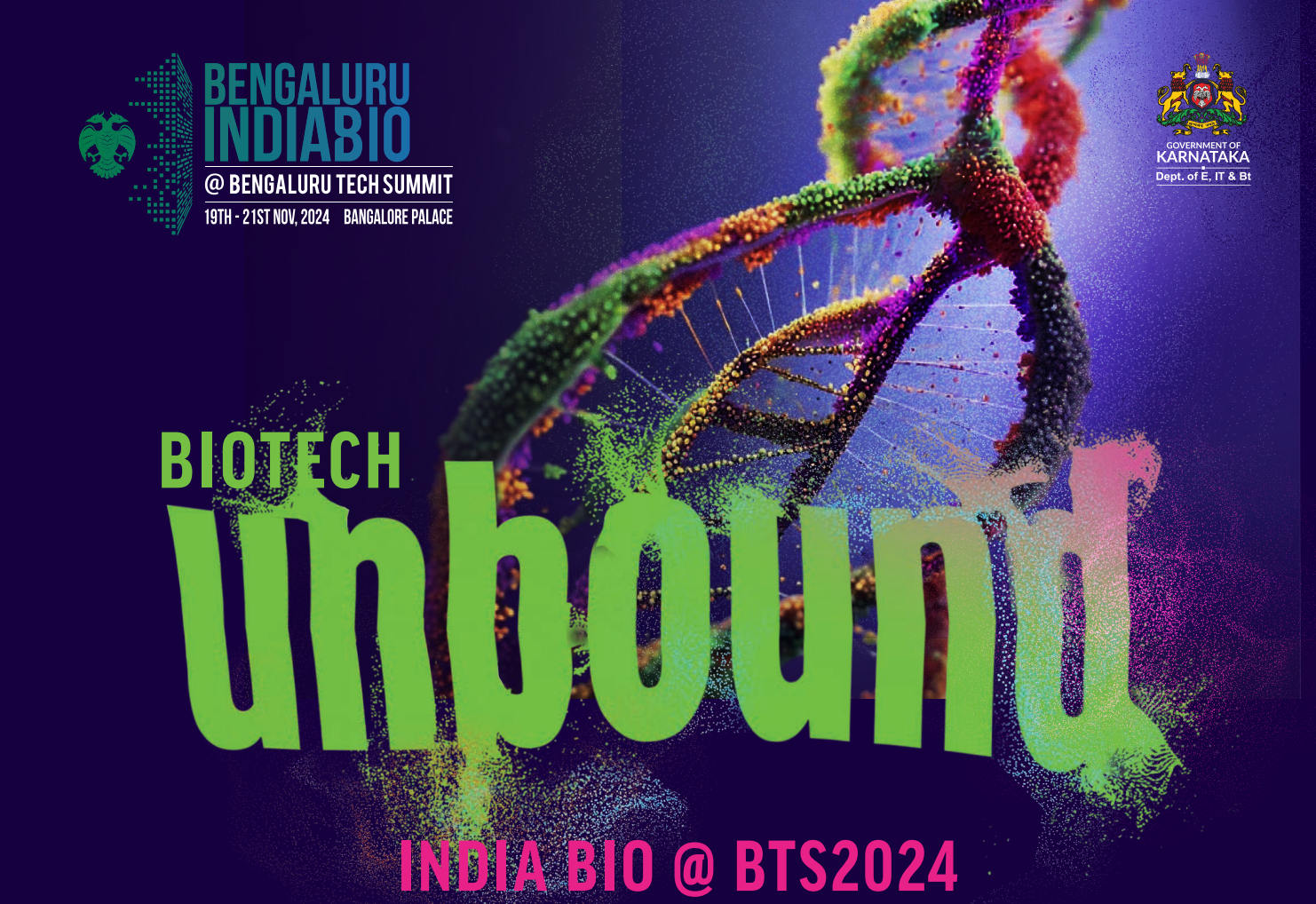

BIOTECH unbound

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Join us at the Bengaluru Tech Summit 2024 for an extraordinary exploration of the Biotech & Healthtech sector. The **India Bio Track** invites industry leaders, researchers, startup founders and professionals from the sector on an epic journey of knowledge, discovery and business growth through a diverse range of programs. Come, join us and **be unbound!** Organized by the Department of Electronics, Information Technology & Biotechnology, Government of Karnataka, BTS 2024 is scheduled from November 19-21, 2024, at Bangalore Palace.

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- Bio Posters Showcase
- National IT & Bio Quiz
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- World Leaders Dinner
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Wipro 3D and Nikon SLM Solutions partner to accelerate additive manufacturing in India

Wipro 3D, a leading Additive Manufacturing (3D Printing) solution provider in India delivering many end-use functional components for medical, space, aviation, and many other sectors, and Nikon SLM Solutions have announced a strategic partnership to accelerate the adoption of Additive Manufacturing in India. By combining Wipro 3D's extensive infrastructure and technical expertise with Nikon SLM Solutions' advanced selective laser melting technology, this collaboration aims to provide superior quality Additive Manufacturing services in the Indian market and enhance manufacturing processes across multiple sectors. The partnership brings together Nikon SLM Solutions, renowned for its wide portfolio of integrated metal Additive Manufacturing solutions with Wipro 3D's deep expertise and established presence in the Indian market. Together, they aim to foster innovation, optimise production processes, and drive widespread adoption of Additive Manufacturing across all industries in India.

Takeda signs patent licence agreement with Cipla, Sun Pharma to commercialise GERD drug in India

Mumbai-based pharmaceutical firms Cipla and Sun Pharma have signed a non-exclusive patent licence agreement with Takeda Pharmaceutical Company for 'Vonoprazan' for the Indian market for treating acid-related illnesses among patients. This deal is meant to commercialise the drug in India under Cipla's own trademark brands, while Sun Pharma will commercialise Vonoprazan tablets 10 mg, 20 mg in India under the brand name 'Voltapraz'. Vonoprazan (oral tablets) is a novel potassium-competitive acid blocker (P-CAB), used for the treatment of related disorders - Gastroesophageal Reflux Disease (GERD). Vonoprazan was discovered and developed by Takeda. With a novel mechanism of action, Vonoprazan inhibits the binding of potassium ions to H+K+ATPase (proton pump) in gastric parietal cells in the stomach thereby suppressing basal and stimulated gastric acid secretion. The drug is approved in India for treatment of adults with Reflux esophagitis and other acid peptic disorders.

Meril introduces advanced surgical robotic technology MISSO

Vapi-based medical device company Meril has announced the launch of its advanced surgical robotic technology, MISSO. MISSO is a high-quality robotic system entirely made in India that provides surgeons with real-time assistance during knee replacement procedures with unparalleled accuracy. Indian hospitals currently depend on imported robotic technology for knee replacement surgeries which requires a significant investment. MISSO will reduce this investment by ~66 per cent, making these surgeries more accessible and affordable. The versatile technology of MISSO can be adapted for other joint surgeries in the near future. Knee replacement surgery is necessary for patients who suffer from severe osteoarthritis. This condition is highly prevalent in India, occurring in around 22 to 39 per cent of the population. Today about, ~5.5 lakh people undergo total knee replacement in India every year, which is 2.5 times the number of such procedures conducted annually about five years ago. MISSO has received approval from CDSCO and is queued up for CE and US FDA approvals in times to come.

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Union Budget Drives Home 'VIKSIT BHARAT' MANTRA

Presenting the Union Budget for the seventh time in a row on July 23, the Union Minister for Finance and Corporate Affairs, Nirmala Sitharaman proposed to abolish 'angel tax' for all classes of investors and announced several measures like operationalisation of the Anusandhan National Research Foundation (ANRF) for basic research and prototype development and setting up a mechanism for spurring private sector-driven research and innovation at commercial scale with a financing pool of Rs 1 lakh crore in line with the announcement in the interim budget. The Budget has enhanced the allocation to the Department of Scientific and Industrial Research (DSIR) from Rs 5746.51 crore in 2023-24 to Rs 6323.41 crore 2024-25 marking an increase of 10.03 per cent, of which Rs 6265.80 crore has been earmarked for Council of Scientific & Industrial Research (CSIR).

The Union Budget 2024-25 is focussed on driving the growth and development of entrepreneurship, employment and skilling, making India a manufacturing hub of the world and boosting primary and secondary healthcare in the country – factors by and large being hailed by leaders and experts as keystones on India's path of 'Viksit Bharat' to become one of the world's biggest economy. The Prime Minister asserted "Today's budget has brought new opportunities, new energy, new employment and self-employment opportunities. It has brought better growth and a bright future."

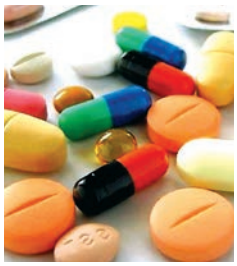
Healthcare/medtech

The government has increased the budget allocation for the healthcare sector by 15 per cent compared to the previous year. This increase aims to improve healthcare infrastructure and services across the country. Three cancer drugs namely Trastuzumab Deruxtecan, Osimertinib and Durvalumab have been fully exempted from custom duty, to make cancer treatment more affordable in the country. The budget has also introduced schemes to enable changes in Basic Customs Duty (BCD) on X-ray tubes & flat panel detectors for use in medical X-ray machines under the Phased Manufacturing Programme. Although the announcements have been welcomed by the healthcare sector, experts opine that customs duty reduction on finished goods is still a pending demand.

Kiran Mazumdar Shaw, Chairperson, Biocon & Biocon Biologics said, "The removal of customs duty on three cancer drugs will provide relief to cancer patients. However, the government needs to consider GST exemption for all cancer drugs to make cancer care more affordable for patients." "The exemption of customs duty on cancer medicines is a significant step towards making healthcare more accessible and affordable. As an oncologist, I feel that the government needs to look toward high-end treatments like Radiation Therapy, and Bone Marrow Transplant and make these within the reach of the common man", said Dr Raj Nagarkar, MD & Chief of Surgical Oncology & Robotic Services, HCG Manavata Cancer Centre.

Himanshu Baid, Managing Director, Poly Medicure Ltd and Chairman - CII Medical Technology Division said, "The Finance Minister's proposed changes in customs duty aimed at synchronising domestic capacity addition for X-ray tubes and flat panel detectors is worthy. This measure will bolster local manufacturing capabilities in medical technology, fostering self-reliance and enhancing accessibility to critical diagnostic equipment." Referring to one of the core focusses of National Medical Devices Policy-2023 to reduce medical device import dependence, AiMeD Forum Coordinator, Rajiv Nath said that the Central government must also consider income tax benefits, specifically tailored for capital expenditure (CAPEX) and research and development (R&D) investments within the medical devices sector.

Pavan Choudhary, Chairman, Medical Technology Association of India (MTaI) commended the budget's outlook on harnessing both the domestic and international currents to optimally forge the path ahead, and its facilitation of FDI. He also said, "We do hope that tariff barriers on finished MedTech products which are not import substitutable in the short to mid-term, will eventually come down. This would further patient affordability and foster competition and quality."



Dashed Pharma Expectations

The Union Budget has increased allocation for R&D, particularly through the ANRF– an announcement that is largely being commended by the industry as a welcome step for clinical research and pharma sector's growth. Experts have emphasised on the implications of simplifying regulatory processes and reducing operational hurdles in creating a more conducive environment for pharmaceutical companies to operate, innovate, and expand.

Sanjay Vyas, Executive Vice President and Managing Director, Parexel said, "Government's push for digital infrastructure under the Jan Vishwas Bill will significantly enhance the operational efficiency of clinical trials. Moreover, the budget's emphasis on skill development and women's empowerment will contribute to a robust talent pipeline for the life sciences sector. These measures collectively position India as a more attractive destination for Global Capability Centers (GCCs)."

Although new incentives and schemes introduced in the Union Budget are being lauded by the pharma sector for its pro-innovation stance, industry leaders have opined on lacunae that need to be addressed as well. Anil Matai, Director General, Organisation of Pharmaceutical Producers of India (OPPI) said, "While we appreciate the positive strides taken in the Union Budget 2024, we were also hoping that the government could announce incentives for pharma companies to develop medications for rare diseases affecting small populations. We were hoping for focused measures like the establishment of more CoEs for the management of rare diseases. We were also hoping for the stricter and unambiguous enforcement of IP regulations required for Pharma MNCs to introduce newer innovative therapies for Indian patients." Industry leaders are also expressing the unmet need for focus on areas of API manufacturing and reducing import dependence. Ashutosh Gupta, Director of Medicamen Organics Limited and former Chairman Pharmexcil Export Promotion Council of India said, "There is not much for the pharmaceutical sector in Budget 2024. We were expecting some more announcements to promote the API sector. We also expected some announcements on R&D."

Further Push for Startup Ecosystem

This Budget is heavily focussed on boosting the country's R&D, and innovation ecosystems through implementation of schemes and initiatives like the ANRF, eliminating "Angel Tax", extension of the limit of mudra loans to Rs 20 lakh from the current Rs 10 lakh, and a reduction of corporate tax on foreign companies from 40 to 35 per cent to invite investments.

Dr Jitendra Singh, the Union Minister of State (Independent Charge) for Science and Technology said "Budget 2024-25 will boost StartUps and the StartUp ecosystem through bold and innovative proposals like ending "Angel Tax" and introducing paid Internship". Hailing the abolition of the angel tax, Dr Premnath, Director, Venture Center, a Pune-based deep tech incubator, said, "It appears that Angel Tax will not apply to other investors, including non-resident investors or those not meeting criteria listed in the previous exemption. This will definitely help give comfort to many more investors in investing in startups."

Sharing his views on the implications of the budget's announcements, Dr Vishal Gandhi, Founder & CEO, BIORx Venture & Indian Healthcare Angels, said, "A major milestone achieved! The unconditional removal of the angel tax will alleviate the financial burden on startups raising capital, bolstering investor confidence and fostering innovation in the biotech and pharma sector particularly. High risk investments must translate into high rewards for investors and founders. This will be great motivation to encourage R&D to drive better economic impact in the near future."

Additionally, the Union Budget has made announcements in the areas of generating employment, skilling, and youth empowerment, which will also hold potential in advancing India's healthcare, pharma and life sciences sectors. The Budget is also focussed on boosting MSMEs. In this regard, a highlight of this Budget also includes e-commerce export hubs - E-Commerce Export Hubs to be set up under public-private-partnership (PPP) mode for MSMEs to sell their products in international markets.

All-in-all a forward-looking Budget, it holds the potential to advance India's healthcare, pharma and life sciences sector through enhancements in R&D, innovation, competent entrepreneurship strategies and youth upskilling. BS

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Why INDIA must turn BIOSIMILAR POWERHOUSE by 2030

Biosimilars could potentially enhance patient access to treatment of various malignant and nonmalignant conditions by reducing costs. Since the introduction of the first biosimilar in 2000 in India, a vaccine for hepatitis B, the development and utilisation of "biosimilars or similar biologics" have experienced significant growth. Each year, regulatory bodies are approving numerous similar biologics for the management of both cancerous and noncancerous illnesses. India has firmly positioned itself as a key player in the global production of similar biologics, benefiting from its large population. Despite the considerable potential and high expectations for India, there are substantial challenges that must be overcome to maintain this leadership position. To realise their full potential and sustain their global leadership, Indian biopharmaceutical companies must enhance their technological capabilities and enhance the skills of their workforce. This will require a supportive environment from both the government and regulatory agencies.

As Indian biopharma sector already proved its mettle in the manufacture of biosimilars and captured vast global markets as one of the key supplier of low cost, high quality medicines for various therapeutics, industry leaders and lead scientists opined that country's biotech industry stands at a pivotal juncture of dynamic transformation from current capabilities of a mere replicator of existing original brands to becoming innovator in developing new and complex molecules by giving renewed push to its R&D sector.

With more than 55 blockbuster branded biologics going off patent from 2022 to 2032 globally, according to McKinsey report August 2022 the Indian biosimilars manufacturers can grab this opportunity to bring in not just affordable biosimilars products in place of costly branded biologics but can also grab the huge business potential offered by the global markets for biosimilars products. At present, the Indian biologics and biosimilars market is rapidly growing, from $6 billion in 2022 to a projected $12 billion by 2025.

To achieve these growth statistics, Dr Ramesh Mathur, Senior Vice President R&D from Biological E Limited, while highlighting how India had come a long way in exhibiting its success in the biosimilars segment during the past two decades, noted that it is high time that all stakeholders of the industry must give a new push towards research and development (R&D) and take measures towards bringing in innovations in biotech sector to develop innovator molecules rather than going after the low hanging fruits just to make easy profits with little efforts.

Dr Mathur further emphasised India's evolution from a manufacturing hub to an innovation-driven force in biosimilars and stressed the need to move beyond replication towards developing novel molecules and complex biomolecules. He posed critical questions on fostering an ecosystem conducive to such innovations, underscoring the shift from reliance on existing products to pioneering new entities.

Growth Drivers

Talent pool: India's market for biosimilars is driven by the country's preference for effective production. The nation has access to a sizable pool of highly qualified scientific and technical employees, and its production facilities are less expensive than those in other countries.

Rising demand for affordable healthcare: Increased demand for cost-effective healthcare solutions is a primary driver of the biosimilar market in India. Biosimilars offer more economical treatment options compared to originator biologics, making them preferable for patients and healthcare providers seeking accessible therapies.

Patent expirations and market opportunities: The impending expiration of patents on several biologic drugs creates significant market opportunities for biosimilar manufacturers in India. With patents reaching their expiry, it paves the way for the development and commercialisation of biosimilar products, enabling companies to introduce more affordable alternatives.

Growing chronic disease burden: Another major growth driver in India is the growing incidences of chronic diseases including cancer, hypertension, and diabetes is rising, which is fuelling an increase in demand for biosimilars across the country.

Regulatory environment: A strong regulatory environment is also regarded as catalysts for the growth of the biosimilars sector in India. Constantly upgraded regulatory system is helping the production of quality and efficacious biosimilars products.

Source: Invimeds Health

Growth in India

With fast changing dynamics in the life sciences industry globally, currently India stands as a pioneer in the global biosimilars market. In fact, India is the first country in the world to approve a biosimilars product way back in the year 2000 for Hepatitis B, over two decades ago.

According to a report from India Brand Equity Foundation (IBEF), the Indian biosimilars market is estimated to grow at a compounded annual growth rate (CAGR) of 22 per cent to become $12 billion by 2025. This would represent almost 20 per cent of the total pharmaceutical market in India.

Sharing his views Ravi Uday Bhaskar, Former Director General of Pharmaceutical Export Promotion Council of India (Pharmexcil) said that India has a huge potential to tap into the global biosimilars market. “India is the 3rd largest producer of Active Pharmaceutical Ingredients (API) accounting for an 8 per cent share of the global API industry touching exports worth $27.8 billion in 2023-24 and projected to touch $31 billion by 2025. The country has huge potential to tap the global biosimilars market, which is fast emerging. As India is regarded as the global pharmacy of the world with its supply of affordable high quality generic medicines to the world, India can equally gain the same reputation in the biosimilars space. Already India is meeting more than 60 per cent of global vaccine demand and given the huge off patent regime ahead for branded biologics, I feel India has the potential to grab this opportunity and can lead the world in biosimilars space as well,” said Uday Bhaskar.

India boasts an impressive portfolio of over 98 approved biosimilars domestically (as of September 2019), a feat unrivalled by any other nation, underscoring its formidable presence in the biosimilars arena. The biosimilar landscape in India is characterised by a multitude of pharmaceutical entities actively involved in the production and distribution of biosimilar products. The key players in the biosimilars segment in India include, Biocon Ltd, Intas Pharmaceuticals Ltd, Dr. Reddy's Laboratories Ltd, Reliance Life Sciences Pvt. Ltd, Zydus Cadila Healthcare Ltd, Lupin Limited, Wockhardt Limited, Panacea Biotec Ltd, Emcure Pharmaceuticals Ltd and Torrent Pharmaceuticals Ltd are among others.

Regulatory Advancements

To address the issues and challenges associated with the development of biosimilars and similar biologics, Central Drugs Standard Control Organisation (CDSCO) in collaboration with the Department of Biotechnology (DBT) had developed “Guidelines for the Regulatory Requirements for Marketing Authorisation in India” in 2012 and has revised it in 2016. These guidelines address the regulation of manufacturing processes as well as quality, safety, and efficacy of similar biologics in the country.

However, experts from the industry are of the view that despite amendments into the drug regulatory rules and regulations, the lack of proper understanding of the subject among the regulators has become a big challenge causing regulatory hurdles and blockade in the way of new approvals of biosimilars products. For instance biosimilars companies who approach for approval of clinical trials for orphan drugs are told to conduct trials on a large number of subjects, while the orphan disease population may not even cross 20-30 people among the vast population. Dr Sreenivasu Karra, Director

R&D at Clonz Biotech Pvt Ltd, while pinpointing regulatory challenges and the need for stronger industry-academia collaborations, he emphasised the role of regulatory agencies in adapting to the evolving biopharma landscape, particularly in enabling the development of new biological entities through collaborative efforts with academia and with better understanding of existing situations.

Echoing a similar opinion expert, Dr Satish Sadagopan, Head of Biologicals, Senior General Manager from Anthem Biosciences said that more flexible regulations would further enable more companies to venture investing into new areas of research for finding innovative solutions and new drug molecules that could help treat even orphan diseases.

Apart from top 20 leading biopharma companies including Biocon Ltd, Intas Pharmaceuticals Ltd, Dr. Reddy's Laboratories Ltd, Reliance Life Sciences Pvt. Ltd, Zydus Cadila Healthcare Ltd, Lupin Limited, Wockhardt Limited, Panacea Biotec Ltd, Emcure Pharmaceuticals Ltd, Torrent Pharmaceuticals Ltd, Pfizer Inc., Novartis International, Roche Holding, Sanofi S.A., Merck & Co., Inc., GlaxoSmithKline plc, AstraZeneca plc, Johnson & Johnson, Boehringer Ingelheim GmbH and Fresenius SE & Co. KGaA, that are already producing and marketing their biosimilars across the globe, there are over 100 companies are standing in queue to grab the off patent opportunity in the coming 5-10 years.

"It is estimated that over 100 biopharma companies in the country are working on various platforms to produce biosimilars products to treat deadly diseases like cancer, diabetes, hepatitis, orphan and other autoimmune diseases. As per official records more than 98 biosimilars products have already been given approval by the CDSCO as on September 2019 in India," informed Dr Uday Bhaskar.

Highlighting about the efforts of the Department of Biotechnology and the Ministry of Health in India, Kiran Mazumdar-Shaw, Chairperson & Managing Director, Biocon Limited, stated that the Indian government had established a strong foundation with a clear regulatory pathway ensuring safe and effective biosimilars, with an emphasis on affordability. Many of these biosimilars are supplied to highly regulated markets in North America, Europe, and Japan. With the advent of Ayushman Bharat, India's universal healthcare programme, these life-transforming biosimilars are now accessible to the poorest patients in the country suffering from cancer, diabetes, and other immune-mediated diseases. Global Bio India serves as a platform to showcase India's growing stature as an emerging hub for biologics and biosimilars.

"There's great potential for the Indian biotech sector to become a global hub for manufacturing of biologics; innovating globally competitive, novel, affordable - vaccines, biosimilars and advanced immunotherapeutic, that is accessible to all for India and the world."

Dr Rajesh S Gokhale,
Secretary, Department of Biotechnology, Government of India

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Kiran Mazumdar-Shaw,
Chairperson & Managing Director, Biocon

"It is high time that all stakeholders of the industry give a new push towards R&D and take measures towards bringing in innovations in biotech to develop innovator molecules rather than going after the low hanging fruits just to make easy profits with little effort."

Dr Ramesh Mathur,
Senior Vice President R&D, Biological E

"Flexible regulations would further enable more companies to invest into new areas of research to find innovative solutions and new drug molecules that could even treat orphan diseases."

Dr Satish Sadagopan,
Head of Biologicals, Senior General Manager, Anthem Biosciences

"There's still much to understand about biosimilars. Reverse-engineering of biosimilars involves deducing DNA from the protein product and optimising it for production. Automation, machine learning, and robotics accelerate this process. However, advanced instrumentation and skilled professionals are often lacking in India."

Dr Pratima Srivastava,
Vice President, Discovery Biology Solutions, Aragen Life Sciences

"There is a need for comprehensive understanding and characterisation of biosimilars, from genetic sequences to clinical efficacy, utilising advancements in technology such as next-generation sequencing and automation."

Dr Tathagata Dutta,
President and Chief Technology officer, Jodas Expoim

"The regulatory agencies should adapt to the evolving biopharma landscape, particularly in enabling the development of new biological entities through collaborative efforts with academia and with better understanding of existing situations."

Dr Sreenivasu Karra,
Director R&D, Clonz Biotech

"India is already meeting more than 60 per cent of global vaccine demand and given the huge off-patent regime ahead for branded biologics, I feel India has the potential to grab this opportunity and lead the world in biosimilars space as well."

Ravi Uday Bhaskar,
Former Director General, Pharmaceutical Export Promotion Council of India (Pharmexcil)

Government Support

The Department of Biotechnology (DBT) and its public sector enterprise Biotechnology Industry Research Assistance Council (BIRAC), under the Ministry of Science and Technology have made sustained efforts through funding, policy advocacy, new initiatives, capacity building, human resource development, promoting innovation and infrastructure creation in research institutions, small and medium size industries, large industries as well as nurturing emerging enterprises.

The National BioPharma Mission (NBM), a joint initiative of the World Bank and DBT, is further solidifying the country's foundation in this field. Collectively, these initiatives are positioning India's biotech sector for its next level growth phase. "I see that there is a great potential for Indian biotech sector to become a global hub for manufacturing of biologics; innovating globally competitive, novel, affordable - vaccines, biosimilars and advanced immunotherapeutic, that is accessible to all for India and the World," stated Dr Rajesh S Gokhale, Secretary, Department of Biotechnology, Government of India.

Off-patent of Original Biologics

According to McKinsey's analysis, more than 55 blockbuster drugs that will lose exclusivity in the United States and Europe from 2022 to 2032 will collectively have more than $270 billion in expected peak sales. By 2025, 19 global blockbuster brands are set to lose exclusivity. From 2026 to 2032, the pace quickens, with 39 blockbusters set to lose it. This group includes at least five megabrands with annual sales exceeding $10 billion will lose their exclusivity.

Between 2020 and 2022, more than 91 drugs have gone off patent globally, says GreyB report. Similarly, it adds that from 2022 to 2027, 31 blockbuster biological drugs are expected to go off-patent providing a huge scope for the Indian biopharma firms to invest and venture into the biosimilars manufacturing markets. The imminent expiration of biological product patents accounts for combined revenue of $60 billion, in the next two to three years.

As per a report from World Health Organization (WHO), currently, high prices of biological drugs are restricting the healthcare systems from providing affordable, population-wide access to such medicines. This creates a huge space for generic companies to manufacture biosimilars of the originator biologics whose patents have expired.

In particular the Indian firms supported by the Department of Biotechnology are expected to

take advantage of the off patent regime and further penetrate into the global biosimilars markets providing low cost high quality medicines to treat deadly diseases like, cancer, autoimmune diseases, and diabetes treatments account for over 60 per cent of the biologics market.

The pipeline for biosimilars in India is robust, fueled by the government's initiative to offer subsidies to the local biosimilars manufacturers. This growth is also driven by the expiration of existing biologics patents and the Central Drugs Standard Control Organisation (CDSCO)'s aligning guidelines closely with global regulators, including the United States Food and Drug Administration (USFDA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

Challenges and Scope

The major challenge for biosimilar development in India is the high cost of clinical trials and regulatory hurdles. The development of biosimilars in India costs around $10-20 million due to stringent regulatory procedures required for their approval. Unlike generic drugs, biosimilar manufacturers face numerous problems in development, clinical improvement, manufacturing, registration, and product marketing.

"Though biosimilars benefit from the initial work done by innovators", observed Dr Pratima Srivastava, Vice President, Discovery Biology Solutions, Aragen Life Sciences, "there's still much to understand". "Reverse-engineering of biosimilars involves deducing DNA from the protein product and optimising it for production. Automation, machine learning, and robotics accelerate this process. However, advanced instrumentation and skilled professionals are often lacking in India", added Dr Pratima.

Delving into the intricacies of reverse engineering of biosimilars, Dr Tathagata Dutta, President and Chief Technology Officer, Jodas Expoim highlighted the rigorous analytical processes involved in ensuring equivalence to originator products. He stressed the importance of comprehensive understanding and characterisation of biosimilars, from genetic sequences to clinical efficacy, utilising advancements in technology such as next-generation sequencing and automation.

Talking about innovation and collaboration among biopharma firms, Dr Kripa Murzello, Head R&D Biologicals at Bharat Serum and Vaccines Ltd, highlighted the evolving mindset towards Indian biopharma capabilities and emphasised the importance of collaboration between industry and academia. She underscored the transformative impact of such partnerships in advancing research capabilities and overcoming commercial constraints.

Therapeutic Areas

Oncology: Approved biosimilars of monoclonal antibodies like trastuzumab (Herceptin), bevacizumab (Avastin), and cetuximab (Erbitux) are effectively treating different cancer types in India. Indian pharmaceutical firms exhibit a strong commitment to developing biosimilars tailored to oncological treatments, evident from their extensive pipeline in this domain.

Autoimmune diseases: Biosimilars of biologics such as adalimumab (Humira) and etanercept (Enbrel) have gained approval for managing autoimmune disorders like rheumatoid arthritis in India. These approved biosimilars have notably enhanced treatment accessibility for individuals grappling with autoimmune conditions across the nation.

Diabetes: Approved biosimilars of insulin glargine (Lantus) are effectively utilised for diabetes management within India. The introduction of these biosimilar insulin options has substantially broadened treatment avenues and affordability for diabetes patients nationwide.

Other therapeutic areas: Biosimilars of recombinant proteins like filgrastim (Neupogen) and epoetin alfa (Epogen) are approved for addressing conditions such as neutropenia and anaemia in India. Biosimilars of interferon beta-1a (Avonex) are approved for managing multiple sclerosis within the country.

Source: Invimeds Health

Future Prospects

With emerging trends like cell and gene therapy, oligonucleotides, and the role of artificial intelligence (AI) in biotechnology, the future prospects and technological advancements are very bright for the biosimilars sector in India. Industry experts expressed optimism about India's potential to lead in these areas, provided there is continued investment in technological infrastructure and talent development.

India's biosimilars market holds immense potential, with opportunities to innovate and develop complex molecules. Overcoming regulatory challenges, fostering collaborations, and leveraging advanced technologies will be key to advancing R&D in biosimilars and achieving global leadership in this field. BS

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Cementing India's place as global leader in biosimilars

« **Dr Sudhira H S,**
Director,
Gubbi Labs

Over the past decade, biologics and biosimilars have taken centre stage in medical advancements. Their potential in treating diseases previously considered untreatable, such as certain types of cancer, autoimmune disorders, and rare genetic conditions, has changed the face of healthcare. India, with its robust biotechnology and information technology sectors, has embraced this shift and is making significant strides in the development and manufacturing of biological drugs.

Biosimilars, also known as follow-on biologics, are the subsequent versions of innovative biological medicine that are introduced after the expiry of the original medicine's patent. The development of biosimilars is a complex and expensive process, but it has potential to improve the accessibility of life-saving treatments. Emerging technological trends in the biosimilar sector are redefining the way these medicines are developed, evaluated, and marketed. Given that India is a global hub for generic medicine, it is critical to examine the country's role in the rapidly evolving biosimilars landscape.

In recent years, the market for biosimilars or similar biologics, has seen significant expansion, particularly in India. India's biosimilars market size was valued at $349 million in 2022 and is estimated to expand at a compound annual growth rate (CAGR) of 25.2 per cent from 2022 to 2030 and will reach $2108 million by 2030.

India is one of the leading manufacturers of biosimilars, and has observed an increase in their use, improving the health of many patients suffering from a wide variety of diseases. The most significant advantage of biosimilars is that they cost less than the original drugs that they replicate.

An article noted that the expiration of patents on many key biologics by 2020 would provide a sizable opportunity for the development and use of biosimilars. With over one hundred biopharmaceutical companies engaged in the manufacturing and marketing of biosimilars, India has emerged as a global market leader in this segment. It was the first to approve a biosimilar back in 2000 for the treatment of hepatitis B- much before Europe and the United States.

Since then, several biosimilars have been developed and marketed in India by various biopharmaceutical companies. Given the country's high potential, Indian biopharma industries are striving to maintain leadership in this rapidly expanding sector. Companies in India are upgrading their technology and improving their human resource skills to stay competitive.

Globally, a remarkable reduction in the overall cost of treatment using biosimilars has already been seen. A US study predicted that over a decade, biosimilars could save $54 billion. India has a thriving biosimilar ecosystem compared to other countries. Enabling this, has been the notification of specific guidelines for the approval process.

The Central Drugs Standard Control Organisation (CDSCO), in collaboration with the Department of Biotechnology (DBT), developed “Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorisation in India” in 2012, which were revised in 2016.

Till date, there are more than one hundred biosimilars approved in India. The biosimilars approved for use in India include vaccines, monoclonal antibodies, insulin, and recombinant proteins.

Technological Trends in Biosimilars

One of the most significant technological trends in the biosimilar sector is the use of big data analytics. Big data in biosimilars entail collecting, analysing, and interpreting vast quantities of structured and unstructured data. As more biosimilars are introduced to the test market, big data can provide valuable insights into their effectiveness, potential side effects, and other salient characteristics. This

granular data can aid in improving the efficiency of clinical trials and ensuring the safety of the biosimilar product.

Adoption of advanced analytical techniques is playing a key role in developing highly similar biosimilars. These include protein characterisation using mass spectrometry, chromatography, and high-resolution imaging techniques. In addition, cell line development is enhancing the processes to be effective. The establishment of optimal cell lines is critical for efficient biosimilar production. Improvements in cell line engineering, media optimisation, and bioreactor design have led to enhanced yield and productivity.

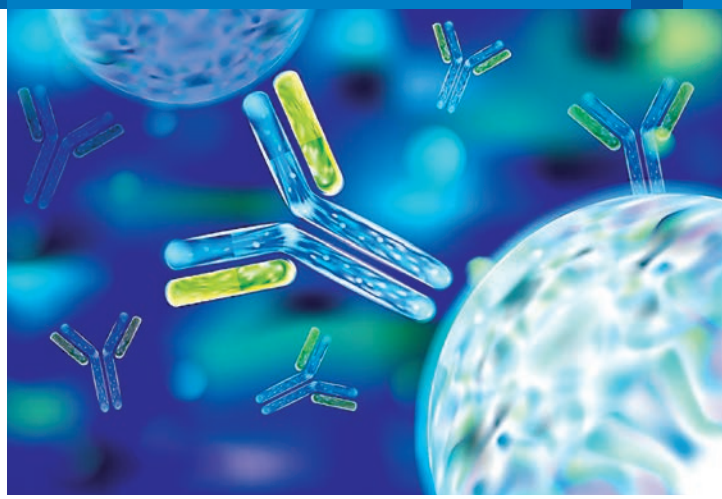
Furthermore, process optimisation measures through advanced techniques like perfusion culture, continuous manufacturing, and bioprocessing models have contributed to the reduction in production costs and improved scalability of biosimilars. Another critical technology trend in the sector is the rising adoption of personalised medicine and precision health, made possible by advancements in genomics, bioinformatics, and artificial intelligence. Personalised medicine addresses both efficacy and safety as it enables treatments to be tailored to the genetic makeup of the individual.

Future of Biosimilars in India

Clearly, the future of biosimilars in India appears promising. Despite a compelling need for a stronger intellectual property rights regime, the biopharma industry involved in biosimilars are getting to benefit with streamlined regulatory procedures, heightened research and development capacity, and greater public awareness about biosimilars.

India, with its vast pharmaceutical sector and expertise in generic medicine, has exhibited great leadership in the biosimilar market. Several domestic firms are making substantial strides in the global biosimilar market. Companies like Alembic, Biocon, Dr. Reddy's Laboratories, Enzene Biosciences, Indoco Remedies, Lupin are some have made their presence felt internationally, with many of their biosimilar products gaining approval from exigent health agencies like the US FDA, and the European Medicines Agency (EMA). For instance, Biocon's Insulin Glargine, a biosimilar for diabetes, has been widely accepted across several countries.

Besides, biopharmaceutical companies the Contract Development and Manufacturing Organisations (CDMOs) play an indispensable role in biologics and biosimilars production and their supply chain in India. Indeed, the country is transitioning from being primarily a generics powerhouse towards becoming a hub for high-value drugs.



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Moreover, using cutting-edge technological trends is proving beneficial for India in unlocking the potential of the biosimilar sector. Technologies such as big data analytics, artificial intelligence, and personalised medicine can fast-track the development, testing, and delivery of safe and effective biosimilars.

The confluence of rapidly progressing technology and India's unique positioning as a global pharmaceutical hub provides remarkable opportunities. This has allowed for accessibility and affordability of biosimilar drugs, both domestically and globally. A strategic focus on technological adaptation, regulatory support, and capacity building is heralding an era of affordable and accessible healthcare solutions, cementing India's place as a global leader in the biosimilar market. BS

This article is an excerpt of a larger report created by Gubbi Labs in collaboration with Cactus Communications

Addressing Rare Disease Treatments with Biosimilars and Orphan Drugs

« **Surbhi Gupta,** Industry Principal, Healthcare & Lifesciences, Frost & Sullivan

Approximately 10,000 rare diseases (RDs) impact about 400 million people worldwide, with 30 million in the United States alone. In Europe, the European Medicines Agency estimates that up to 36 million people are diagnosed with an RD. However, approximately 5 per cent of RDs have US FDA-approved treatment options, while up to 15 per cent have at least one drug that exhibits potential for treatment, diagnosis, or prevention. The growing number of unaddressed RD needs is a major catalyst for R&D. There is a need for novel medicine to treat RDs that currently have limited therapeutic choices. Let's explore further.

Governments across the world have regulatory incentives to support orphan drug (OD) development. It is more appealing for pharmaceutical firms to engage in R&D for RDs because of these incentives, which include prolonged exclusivity, tax benefits, and simplified and expedited regulatory procedures and approvals.

Recent advancements in precision medicine and informatics, such as big data analytics, multi-omics, nanomedicine, gene-editing techniques, and next-generation diagnostics, have created opportunities to develop specific and individualised therapies for RDs. The convergence of cancer and RDs is becoming evident. Precision oncology and tailored medicine for rare tumours are emerging as prominent themes in the discipline, facilitating the OD industry's expansion.

There are multiple challenges restraining the development and adoption of orphan drugs. Owing to low awareness of RDs, many patients go undetected for extended periods. Apart from diagnosis, both prognostics and therapy are seeing significant gaps that must be filled. Challenges in prognosis assessment are due to the absence of reliable parameters to measure improvement and/or biomarkers as well as a lack of knowledge of underlying pathophysiological pathways. Furthermore, a limited patient sample size prevents the derivation of statistically significant parameters.

The development of orphan medication may be economically onerous due to RDs' intricacies, restricted patient groups, and the need for specialised R&D endeavours, resulting in higher expenditure that is sometimes not justified by industry potential. The high cost of developing and manufacturing next-generation biologics, such as Cell and Gene Therapy (CGT) and Ribonucleic acid (RNA) therapies, often presents considerable challenges in terms of pricing and reimbursement. Pharmaceutical firms may find it difficult to justify OD costs, and payers may hesitate to provide coverage, limiting patient access to these drugs.

Repurposing existing compounds offers significant advantages for small and emerging biotechnology companies. For instance, it helps them to better coordinate their economic and financial concerns with their medical and scientific goals. In addition, it enables them to enter an industry not currently occupied by large pharmaceutical companies and accelerates the validation of their drug development platforms. Examples of such companies include NovaBiotics, a Scottish biotechnology firm, and Healx, a computational drug repurposing firm that integrates omics and phenotyping.

Self-care advocacy organisations and patient support initiatives help propel the orphan drug market in developed countries. Compared to the US, India has fewer organisations to assist firms develop treatments or undertake clinical studies. Ad hoc patient access schemes are financed by philanthropic programmes like Sanofi's India Charitable Access Program ((INCAP), which gives free enzyme replacement medicine to lysosomal storage disease patients. Novartis is making significant investments in its rare diseases drug portfolio in response to the growing market demand in India and has 17 ongoing clinical programmes dedicated to rare diseases in India.

Some orphan drugs are at the tail-end of their market exclusivity as well as patent life, and therefore

will become vulnerable to biosimilar and generic competition. Even though competition from generics for orphan drugs stands low because of lower addressable population size, off-label use of products for various indications often impacts the overall sales of existing products. Given the infrequency of these diseases and the difficulties in finding patients, it is crucial to extrapolate to other rare disease indications to get regulatory clearance for biosimilars. Biologics serve as a major therapeutic approach for many rare diseases. Nevertheless, their growing use stands as a key catalyst for the rise of healthcare expenditures. But from an economic perspective, it is essential to consider the financial implications of paying for biologics treatments out of pocket or with a co-pay instead of adopting biosimilars.

A monoclonal IgG2/4k antibody called eculizumab RP (Soliris, Alexion) has been introduced in Russia as the first biosimilar for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). PNH is a rare haematological illness that is characterised by hemolytic anaemia, thrombosis, and peripheral blood cytopenias. Multiple firms such as Amgen, Samsung Bioepis and Biocad are now engaged in the development of biosimilars for eculizumab.

Biosimilar versions of biologics, such as eculizumab RP, that have been licensed for rare disorders may provide significant cost reductions and enhance accessibility. Non-clinical animal investigations may be omitted if there is limited variance in the analysis of the two molecules or if there is no accessible animal species that is pharmacologically relevant. Animal experiments were not performed during the preclinical evaluation of ABP 959, a potential biosimilar of eculizumab RP, due to its targeting of human complement protein 5. In addition, modelling and simulation may be used to enhance the design of more effective comparative clinical trials, a crucial aspect in the advancement of biosimilars for rare disease indications.

Biosimilar producers face resistance from originator companies, healthcare providers, and payers. Formulary restrictions, the bundling of reference products, and rebate strategies impede market expansion and increase entry barriers. It is imperative for pharmaceutical companies to dexterously navigate the balance between safeguarding their biologic products and nurturing an environment conducive to biosimilars, which inevitably contribute to a thriving competitive milieu. The implementation of robust regulatory frameworks to mitigate anticompetitive practices can expedite the entry of biosimilars into the market, encouraging enhanced accessibility. The evolving landscape of regulatory agencies has introduced certain waivers for animal testing and, in specific instances, clinical efficacy testing and interchangeability studies requirements.

Government authorities and nonprofit institutions provide financial resources and subsidies to facilitate the advancement of R&D efforts focused on RDs. These monetary incentives compensate for the exorbitant expenses involved in the development of medicines for RDs. The acceptance and use of biosimilars are increasing as patients and healthcare stakeholders enhance their understanding and awareness driven by biosimilar manufacturers and regulators. As the availability of information and practical data supporting the safety and effectiveness of biosimilars rises, both patients and healthcare professionals are developing a greater level of confidence in these medications.

Partnerships among pharmaceutical and biotechnology companies, research institutes, and patient advocacy organisations are gaining prominence. These collaborations use complementary knowledge and resources, promoting innovation. Often, government authorities and nonprofit institutions provide financial resources and subsidies to facilitate the advancement of R&D efforts focused on RDs. These monetary incentives compensate for the exorbitant expenses involved in the development of medicines for RDs. The acceptance and use of biosimilars are increasing as patients and healthcare stakeholders enhance their understanding and awareness driven by biosimilar manufacturers and regulators. As the availability of information and practical data supporting the safety and effectiveness of biosimilars rises, both patients and healthcare professionals are developing a greater level of confidence in these medications. BS

Why Automate Bioreactors?

Automation and controlled monitoring have made in-roads to modernize several industries. Bioreactors too became more automated and heavily monitored using diagnostic sensors, leading to improved efficiency and consistency offering better product yields and higher speed-to-market. Technologies like Artificial Intelligence (AI) and Machine Learning (ML) are deployed in bioreactors to make bioprocessing systems score higher in their performance thereby increasing production of biopharma products at a faster rate. As India's biopharma market is booming, let's look into the market scenario for automated bioreactors in the country.

Bioreactors are used extensively in biopharmaceutical space to produce biological drugs (such as, proteins/peptides, antibodies, or vaccines). Automation, thus, offers vast potential in optimal design, monitoring, and control of biopharmaceutical manufacturing. Advanced software integrated into bioreactors enables real-time monitoring, data analysis, and process control. This allows for precise adjustment of parameters such as temperature, pH, agitation, and nutrient supply, optimizing bioproduction processes for higher yields, quality, and efficiency.

Several market research reports indicate that the driving forces for adoption of AI/ML techniques include the growing global demand for biotherapeutics and the shift towards Industry 4.0 spurring the rise of integrated process platforms and continuous processes that require intelligent, automated supervision.

"Automation stands as the beacon of efficiency and consistency in bioreactor operation," says Arun Luthra, Founder and CEO of Amerging Technologies, one of India's leading bioprocess equipment manufacturers. He says, "Unlike manual processes, which are prone to human error and variability, automation ensures precision and reproducibility at every stage. This reliability translates into enhanced productivity, reduced downtime, and ultimately, cost savings. Moreover, automation facilitates seamless data collection and analysis, empowering researchers with real-time insights into process parameters." According to Luthra, by harnessing automation capabilities, bioreactor operators can optimise conditions, troubleshoot issues promptly, and accelerate the pace of scientific discovery.

Bringing forth another critical perspective to the advantage of automating bioreactors, Kumarasamy K, Chief Technical Officer of India's well-recognised bpe manufacturer, Biotree, says, "Automation ensures that processes are performed consistently and reproducibly, reducing variability between batches by referring the previously executed golden batches. This consistency is critical in industries such as biologics, pharmaceuticals, where product quality and regulatory compliance are extremely important."

Elaborating further, Kumarasamy, says, "Automated bioreactor systems can collect and record vast amounts of data in real-time and archives the same for future analysis, providing insights into the fermentation process that would be difficult or impossible to obtain manually. This data can be analysed to optimise process parameters, identify trends, alarms, version control/audit trail and troubleshoot issues more effectively. The collected data will, hence, be readily available for auditors as and when required."

Speed to market

One of the significant reasons for a sudden spruce in bioreactor manufacturing was COVID-19. The high demand from governmental vaccination programmes and private entities to vaccinate large sections of the population required scientists to work under pressure to shorten the time-to-market of developed vaccines. And, procuring automated bioreactors offered significant advantages in accelerating the speed at which vaccines and other bioproducts reached the market.

Advanced automated bioreactors can facilitate continuous manufacturing, where production runs uninterrupted. This eliminates downtime between batches and significantly reduces overall production time. Thermo Scientific, for example, has deployed high-performance software control platforms, that enhances both user experience and data aggregation. A software-led distributed control platform facilitates easy integration of multiple bioreactors to streamline process control and data management from research to production. Thermo believes that this software interface helps to minimise the engineering effort and time spent when navigating through the process stages of production, especially vaccines, and biomanufacturing, when speed to market is very critical.

Similarly, Sartorius asserts that by incorporating software functionalities, its bioreactors have become more intelligent, accelerating R&D timelines for biopharmaceutical products. Sartorius' bioreactors are specifically designed and pre-engineered with software components from the ground up. The company has developed a configuration toolkit, which has a library of templates that provide standardised configuration. Using the library, the production teams can integrate several bioreactors into their control system quickly. This increased automation reduces the need for manual operation, which ultimately increases quality and speeding up time-to-market.

From the user point of view, Pfizer, one of the world's premier biopharmaceutical companies, uses ML and AI for near-real-time monitoring of its mammalian cell culture bioreactors to boost batch yield and reduce the risk of contamination. Using Amazon Web Services (AWS), the company developed Manufacturing Intelligence Edge (MI Edge), a platform that uses AI and ML for continuous monitoring of bioreactors at its global manufacturing sites. MI Edge increased the frequency of measurements from one sample per day to near-real-time monitoring every few seconds. This improved frequency, according to Pfizer, helps operators to adjust parameters as needed throughout the batch, resulting in greater yield, delivering more medicine for patients, faster.

Steadily progresses

The bioreactor market in India is expected to reach $164.8 million in 2027 from $94.6 million in 2018. The market is estimated to grow with a CAGR of 6.6 per cent from 2019-2027, according to Insight Partners' report. The growth of the bioreactors market is primarily attributed to the increasing number of bioreactors manufacturers, speedy evolution of pharmaceutical industry and aggressive pharmaceutical and biotechnological activities. Additionally, the growth is also contributed to factors such as opportunities to develop personalised medicine.

There are over 100 companies who are into manufacturing of bioreactors in the country, according to tradeindia.com. Some of the leading names in this space include Fermex Solutions, Shree Biocare Solutions, Uma Pharma, BPE Biotree, Prime Care Technology, Krishna Scientific Suppliers, Amerging Technologies, OmniBRx Biotechnologies, SM Biosystems, IMEMFLO, Biozeen, Bangalore Biotech Labs, Praj Hipurity Systems, Labindia Instruments, Thermo Fisher Scientific India, Merck Millipore India, Globe Scientific Inc, Solaris

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- Kumarasamy K,
Chief Technical Officer, Biotree

Some of the global and domestic bioreactor manufacturers

Indian Manufacturers

- Wipro GE Healthcare
- Fermex Solutions LLP
- Uma Pharma
- BPE Biotree
- Shree Biocare Solutios
- Amerging Technologies
- Prime Care Technology
- Krishna Scientific Suppliers
- OmniBRx Biotechnologies
- SM Biosystems
- IMEMFLO
- BIOZEEN

Global Manufacturers

- Applikon Biotechnology
- BioNet
- Cytiva
- Eppendorf
- Merck
- Ollital Technology
- Parr Instrument Company
- Sartorius
- Solaris Biotech
- Thermo Fischer

Potential advancements in bioreactor automation technologies

Advanced Process Control: AI and ML algorithms can enable advanced process control strategies in bioreactor automation. These algorithms can analyse real-time data from sensors and actuators to optimize process parameters dynamically, leading to improved productivity, efficiency, and product quality. Advanced control strategies such as model predictive control (MPC) and adaptive control can be implemented to adaptively adjust process conditions in response to changing environmental conditions and product requirements.

Predictive Maintenance: AI, ML and Digital twin techniques can be used to predict equipment failures and schedule maintenance proactively in bioreactor systems. By analysing historical data and sensor readings, predictive maintenance algorithms can identify early signs of equipment degradation or malfunction, allowing operators to take corrective actions before failures occur. This approach can minimize downtime, reduce maintenance costs, and prolong the lifespan of bioreactor systems.

AI and ML algorithms can optimize media and feed strategies in bioreactor systems to maximize product yield and minimize resource consumption. By analysing process data and historical performance, these algorithms can identify optimal nutrient compositions, feeding schedules, and feeding rates to enhance cell growth and product formation. This can lead to significant improvements in process efficiency and cost-effectiveness.

Real-time Quality Monitoring and Control: AI and ML techniques can enable real-time monitoring and control of product quality in bioreactor systems. By analysing sensor data and process parameters, these techniques can detect deviations from quality specifications and adjust process conditions accordingly to ensure consistent product quality. This can be particularly important in industries such as biopharmaceuticals, where product quality is critical for regulatory compliance and patient safety.

Integration with IoT and Cloud Computing: Bioreactor automation systems can be integrated with IoT (Internet of Things) devices and cloud computing platforms to enable remote monitoring, data analysis, and control. IoT sensors can collect real-time data from bioreactor systems, which can be transmitted to cloud-based platforms for analysis and visualization. This enables operators to monitor bioreactor performance remotely, collaborate with colleagues, and make data-driven decisions in real-time.

AI and ML algorithms can be used to optimise the operation of these bioreactor systems and analyse the large volumes of data generated. Overall, the integration of AI, ML, IoT, and other emerging technologies holds great promise for advancing the automation of bioreactors, leading to more efficient, reliable, and cost-effective bioprocessing operations in the future.

Source: BPE Biotree

Biotechnology, Infors HT (Labmate (Asia)), Eppendorf India, Sartorius Stedim Biotech India, Applikon Biotechnology, and GE Healthcare.

In the past few years, India has been witnessing significant investments in the development of modern bioreactors. In March 2023, bioprocess engineering company, OmniBRx Biotechnologies secured $5 million Series-A funding from SIDBI Ventures and others. OmniBRx used the funds to expand into overseas markets and strengthen its product portfolio of single-use bioreactors. The company noted that scalable and efficient bioprocessing technologies, specifically the single-use bioreactor platforms are in high demand worldwide for the production of vaccines and other biologicals.

Several reasons can be attributed to the demand for bioreactors. India's biopharmaceutical sector has been expanding rapidly due to increasing investments in R&D, rising demand for biologics, and a favourable regulatory environment. Bioreactors play a crucial role in the production of biopharmaceuticals such as vaccines, monoclonal antibodies, and recombinant proteins. The competitive landscape in India's biopharmaceutical industry is also pushing companies towards adopting automated bioreactors. And Indian biopharmaceutical companies are increasingly competing with established players globally.

"Automation also plays a critical role in meeting regulatory requirements for approval, ensuring consistency and reliability in production processes. It's crucial for providers to customize their offerings to meet the diverse needs of buyers, ensuring market expansion and long-term success," opines Arun Luthra.

It's safe to conclude that in India, the convergence of IT and BT is spurring a huge demand in developing automated bioprocess equipment. Hiring of candidates, in India, with specialization in process and mechanical design and fabrication of bioreactor equipment coupled with knowledge in software technologies will be trending for long. BS

Anusha Ashwin

"We recommend government for innovative economic models to incentivise antibiotic research"

Panchkula-based Venus Remedies, among the 10 leading fixed-dosage injectable manufacturers in the world, is expanding the reach of its products across the globe by obtaining regulatory approvals in multiple countries. Highlighting a primary focus on improving access to affordable medicines in India by strengthening its generics and institutional business nationally in 2024, Saransh Chaudhary, President, Global Critical Care, and Chief Executive Officer, Venus Medicine Research Centre spoke to BioSpectrum in detail about the company's business and growth plans. ***Edited excerpts-***

« **Saransh Chaudhary,** President, Global Critical Care, and Chief Executive Officer, Venus Medicine Research Centre

What are the major plans in store at Venus Remedies for FY 24-25 for the Indian and global markets?

We aim to establish a formidable presence in the injectable space and expand our on-ground presence to cover all districts in the country, over the next 2-3 years. We have already made significant strides in this space over the past three years by leveraging data and technology. Globally, we plan to fortify our presence in key markets such as Europe, Commonwealth of Independent States, Latin America, Asia and Africa. We will achieve this through strategic partnerships, joint ventures and enhancing our distribution network. Additionally, we are focusing on obtaining regulatory approvals for our pipeline products in multiple countries to facilitate smoother market entry and expansion.

How much revenue was generated by the company during FY 23-24? How much growth is expected this fiscal?

In financial year 2023-24, Venus Remedies generated consolidated revenue of Rs 601.45 crore. Of this, exports contributed 73 per cent, while 27 per cent came from our domestic business. Moving forward, we anticipate robust growth of 15-20 per cent in our domestic division due to increasing adoption of generics in both the hospital and institutional sectors. We also expect our export business to grow by around 15 per cent as we continue to expand our international presence, entering new markets and registering more products in existing key markets.

Are you exploring academic partnerships to strengthen pharma R&D in India? Please share some details.

We have always valued academic collaborations, having previously partnered with esteemed institutions such as IITs, AIIMS, NIPERs and the Institute of Microbial Technology on various projects. The recently announced Research Linked Incentives (RLI) by the government will further boost such collaborations. We are actively engaging with multiple institutions to identify synergistic areas for partnership, aiming to leverage scientific expertise, share resources and promote talent development through student engagement and training initiatives.

Pharma companies should invest more in R&D through public-private collaborations to create value based on cutting-edge research. The Central government's move to promote research and innovation in the pharmaceutical space through centres of excellence and making the Indian Council of Medical Research (ICMR) lab facilities available for private sector R&D will significantly boost collaborative research.

The company has recently received its first incentive under the government's Production-Linked Incentive (PLI) scheme. How would it be used further? How much more is to be received?

We have embarked on a journey to amplify our manufacturing infrastructure and expand our product portfolio, meeting the government's rigorous investment and sales criteria to qualify for the PLI scheme. This milestone will propel us to enhance our manufacturing capabilities further and contribute to

India's self-reliance goals. The first grant of Rs 7.5 crore, covering 75 per cent of the total incentive for FY 22-23, will be utilised to bolster manufacturing capabilities, foster product diversification and invest in R&D of complex generics and new drugs. We recently received the second instalment of Rs 2.5 crore, covering the remaining 25 per cent of the total incentive. The scheme permits a maximum of Rs 50 crore in cumulative incentives over the next five years, with annual payouts based on incremental sales of qualifying products, subject to an annual cap.

What are your key expectations from the government to enhance the growth of the pharma industry in India?

We expect the government to continue incentivising R&D and manufacturing to promote growth and innovation. Improving the baseline quality of manufacturing is critical for the industry's growth, requiring changes in the regulatory and oversight framework. Centralising new drug approval by withdrawing power from state licensing authorities is a step in the right direction, but should be supported by adequate manpower to avoid hindering review timelines. More therapy-specific guidelines would also be beneficial. In our area, we recommend innovative economic models to incentivise antibiotic research, such as market entry rewards and delinked subscription models. The Research-Linked Incentive scheme should help create a conducive ecosystem for collaboration, enabling R&D-driven pharma companies in India to compete globally.

What are your views on the current quality related challenges being faced by the Indian pharma sector? How is Venus Remedies working in this regard?

The Indian pharmaceutical industry, known as the "Pharmacy of the World," has achieved a significant share in global pharma supplies due to its adherence to stringent international quality standards. Despite these accomplishments, the industry faces several quality-related challenges, including compliance with international regulatory standards, adoption of advanced manufacturing technologies by smaller companies due to financial constraints and gaps in supply chain management caused by the complexity and scale of global networks.

To overcome these challenges, the industry needs increased investment in infrastructure, technology and human resources. However, a crucial element of this transformation is a comprehensive overhaul of regulatory and oversight processes. Currently, the lack of standardisation in drug quality and approval mechanisms creates a lack of a level playing field, resulting in discrepancies in drug quality and unhealthy market competition, which further impacts overall quality. This cycle must be broken through systematic interventions and positive regulation.

How do you view the growing partnerships between pharma companies and contract research organisations? Is the CRO/ CDMO space setting new trends for the pharma sector, especially with the advent of new technologies such as AI being implemented for key operations?

The growing partnerships between pharma companies and Clinical Research Organisations/ Contract Development & Manufacturing Organisations (CROs/ CDMOs) highlight a trend where companies outsource compliance responsibilities to external entities. This approach, although resulting in slightly lower gross margins, helps companies save on compliance and talent-related costs. CROs/CDMOs often find it easier to hire and retain talent due to their involvement in diverse projects across various industry verticals. This trend is particularly significant for manufacturing complex or novel drugs, allowing pharma companies to focus on their core expertise in drug development without heavy investment in scaling up production infrastructure.

The rise in biologics has further accelerated the growth of the CRO/CDMO sector, as common patterns and challenges emerge in biologics manufacturing. For CROs/CDMOs, the return on investment is higher when they can leverage their facilities to produce drugs for multiple companies.

CRO partnerships offer similar advantages, enabling pharma companies to remain agile with new product launches and quickly capitalise on off-patenting blockbuster drugs. Indian CROs, known for their high-quality service that meets international standards, remain cost-efficient as compared to Western markets for conducting large clinical trials. With recent regulatory reforms aimed at expediting approvals, India is emerging as a hub for clinical trials, leading to more global collaborations with domestic CROs. This collaborative ecosystem fosters knowledge exchange and innovation.

The adoption of new-age technologies like artificial intelligence offers CROs and CDMOs opportunities to scale operations, enhance efficiencies and improve trial processes. These advancements will further solidify India's position as a preferred destination for clinical trials and contract manufacturing, setting new trends in the pharmaceutical sector. BS

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"We look forward to collaborate with government initiatives to promote degree programmes in biomedical innovation"

Blockchain For Impact (BFI), established during the second wave of the COVID-19 pandemic in India, is continuing its trailblazing journey after announcing a monumental allocation of $15 million through its BFI-BIOME Virtual Network Program, aimed at propelling biomedical research forward in India. In the past three months, BFI has already allocated a substantial amount through strategic MoU's with elite research institutes and incubators, setting in motion its plans to revolutionise biomedical research and innovation in the country. BioSpectrum India spoke to Sandeep Nailwal, Founder of BFI, in detail about his vision for driving transformative change in the healthcare landscape. ***Edited excerpts-***

« **Sandeep Nailwal,** Founder, Blockchain For Impact (BFI)

Please highlight the recent collaborations signed by BFI for advancing biomedical research in India.

Blockchain For Impact (BFI) has been actively collaborating with eminent research institutions in India to vitalise progression in the field of biomedical research. Partnerships with institutions like the Indian Institute of Science (IISc) Bengaluru, Birla Institute of Technology and Science (BITS) Pilani, and Indian Institute of Technology (IIT) Bombay, Centre for Cellular and Molecular Biology (CCMB), Foundation for Neglected Disease Research (FNDR), and TCG Crest, will prove to be instrumental in fostering innovation, advancing scientific proficiency and building a biomedical network in the nation.

Additionally, through the BFI-BIOME Program, alliances with leading incubators such as Venture Center, Centre for Cellular and Molecular Platforms (C-CAMP), Startup Incubation and Innovation Centre - IIT Kanpur, Atal Incubation Centre (AIC)- CCMB, and IKP Knowledge Park have further solidified BFI's commitment to making a positive impact in the healthcare sector.

BFI has committed a significant sum of $15 million to its BFI-BIOME Virtual Network Program, aimed at driving forward biomedical research in India. Overall, this initiative by BFI represents a major step forward for the field of biomedical research in India, and it is sure to have a lasting impact on the healthcare landscape of the country. Another $200 million is committed towards this initiative which includes setting up a state-of-the-art biomedical research institute in India that will engage in developing cutting edge research activities related to biomedical and healthcare directly contributing to the ecosystem.

What are the key objectives that are to be achieved through these partnerships in India?

BFI has two primary domains, Biomedical Research and Innovation (BRI) and District Full Stack (DFS). Under BRI we are partnering with various prominent institutes, incubators and medical institutes of national importance (INIs) with an aim to support biomedical research and innovation across the nation. DFS works to identify the problem at the grass root level and provides tailormade solutions.

Developing a virtual network of researchers, innovators & industry experts. The aim is to construct multi sectoral collaborations to expedite biomedical innovation across the nation to tackle the present issues and anticipated gaps in the healthcare sector. Stimulating concentrated efforts towards upstream research, primarily Translational Research to convert upcoming inventive research into actual products & services that can be applied to public welfare.

The DFS program through its partnership with local NGOs, State and District administration, UN agencies like the United Nations International Children's Emergency Fund (UNICEF) and other health system players have adopted a health systems approach to tackle India's health challenges, aligning with the United Nations' Sustainable Development Goals (SDGs), particularly SDG 3: Good Health and Well-being. In this context The India Health and Climate Resilience Fellowship was launched in partnership with Partnering Hope Into Action Foundation (PHIA), UNICEF, and other NGO mentors

(the Centre for North East Studies and Policy Research (CNES), JSS, Vivekananda Girijana Kalyana Kendra (VGKK), MediCiti Hospital and Mediciti Institute of Medical Sciences (MIMS). It operates in 6 states across 18 districts with 24 Fellows on the ground.

Additionally, the programme along with state health departments supports the development of novel, climate-resilient healthcare delivery systems that enhance access for remote and vulnerable populations. In this context, BFI is supporting the construction and deployment of a Hospital Ship which will provide essential maternal and child healthcare services to communities in the flood-prone regions of lower Assam. This hospital ship will be operated in partnership with CNES and the Government of Assam. It will be a pioneer in India, featuring a fully functional Outpatient Department (OPD), operation theatre, comprehensive medical and paramedical departments, and 24/7 living quarters for doctors, nurses, medical officers, and crew members.

Are you planning to execute more partnerships & collaborations this year, & beyond?

Yes, we have just closed the call for funding biomedical innovations with Medical INIs. BFI announced $250,000, with $50,000 each going to 5 Institutes of National Importance for Biomedical Research in Public Health Preparedness. In the future, BFI-BIOME program along with its network of partners is expected to grow and enrich the network with more collaborations.

What are the major challenges before biomedical research sector? How is BFI addressing those challenges?

For the longest time, the scaleup of biomedical products and research outputs has proven to be one of the major challenges to the biomedical sector in India. The idea is to provide a means to open the doors of the laboratories and allow the novel research outputs to reach upscaling opportunities for the generation of inventive healthcare products and services. Thus, collaboration between the industry and academia is vital and should surely be encouraged to propel the actualisation of translational research outputs.

BFI utilising collaborative partnering with prominent institutions actively working in the domain of translational research is steadily constructing an elaborate network, where the researchers can connect with the innovators, other researchers, grantors, industrial experts, and entrepreneurial initiatives, to contribute to the foundation of biomedical innovation.

What initiatives do you have for startups, so that their innovation reaches the market faster?

Yes, some of the key initiatives include;

- BFI-BIOME Fellowships: Through our partners the designed fellowships provide funding, mentorship, and resources to promising researchers and entrepreneurs in the biotech and biomedical fields, through which the fellows can develop their ideas and bring them to market. Venture Centre has announced Rs 60,000 per month as the fellowship offered under this initiative, and like such C-CAMP has offered an amount of Rs 50,000 per month and AIC-CCMB an amount of Rs 50,000 per month.
- BFI-BIOME Kickstarter Initiatives: Our partners have launched initiatives to identify and support promising healthcare technologies that will benefit the public. For instance, AIC-CCMB has announced an amount of upto Rs 10 lakh for the Kickstarter initiative, C-CAMP an amount of up to Rs 11 lakh, and Venture center an amount of Rs 10 lakh.
- BFI-BIOME Events: The partner organisations are conducting a variety of events such as workshops, awareness sessions, mentoring clinics, and thematic campaign events. BFI will organise convening events as a support. These events are designed to provide the knowledge, networks, and skills needed to navigate the complex path to product formulation.
- Strategic Partnerships: Our partnerships, like the one with Venture Center, C-CAMP, IITs, etc. leverage combined expertise to create impactful programmes that support healthcare initiatives in developing and scaling their innovations.
- Funding and Investment: BFI has allocated substantial funding with the aim of supporting more than 100 projects across India running at the partner institutes under Biome programme.

Any major expectation from the government to promote biomedical research in India?

We as an organisation particularly look forward to collaborating with government initiatives that promote biomedical research in India.

- Promotion of more programmes/degree programmes that encourage younger generation to take an interest in biomedical innovation & translational research; programmes that incorporate industrial training/internship.
- Opportunities to connect over multidisciplinary discussions on promoting biomedical research in the nation.
- Promoting Public Private Partnerships collaborations. BS

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“In India, the snake antivenom market has historically been unregulated and often grouped under vaccine guidelines”

In India, around 50,000 deaths occur of an estimated 3-4 million snake bites annually which accounts for half of all snakebite deaths globally. Only a small proportion of snake bite victims across countries report to the clinics and hospitals and actual burden of snake bite is grossly underreported. As per the Central Bureau of Health Investigation (CBHI) reports (2016-2020), the average annual frequency of snakebite cases in India is around 3 lakhs and about 2000 deaths occur due to snakebite envenoming. BioSpectrum spoke to Siddarth Daga, Managing Director, Vins Bioproducts, a biotechnology company dedicated to developing life-saving antisera against snake bites since 1997 about the regulatory challenges and the growth and R&D plans of the company. ***Edited excerpts;***

« **Siddarth Daga,** Managing Director, Vins Bioproducts

Could you please share the journey of Vins Bioproducts? How did it all begin, and what was your initial objective?

We started in 1997 with a small facility on the Bombay Highway in Erdanoor. Initially, our capacity was about 20,000 vials per annum. Over the past 27 years, we've expanded significantly. Today, our installed capacity has grown from 20,000 vials to nearly 5 million doses annually, specifically for antisera. Our objective was to address rural health issues, which many multinationals overlooked due to the complexities involved in handling biological products. Our chairman was always keen on developing niche products, and our first licensed product was Indian Anti Snake Venom Serum (ASVS). Currently, we have over 25 licensed products from the Drugs Controller General of India (DCGI).

Apart from Anti-Snake Venom Serum, what are your other major products and what are the international standards that you follow for your products?

In addition to Anti-Snake Venom Serum, our major products include Anti-Rabies Serum, Anti-Diphtheria Serum, and Anti-Scorpion Venom Serum. While our products don't have a significant market presence in the US or Europe, they are imported into these regions under special permits. Our facilities are approved by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and several Southeast Asian countries, such as Thailand, Indonesia, and the Philippines. We also have a strong presence in African markets, with around 15 to 20 registrations.

What are the key regulatory challenges you face in India?

In India, the snake antivenom market has historically been unregulated and often grouped under vaccine guidelines, which isn't appropriate. Conducting clinical trials for snake antivenom, as required for vaccines, presents practical challenges since we can't predict or control snake bites. Additionally, the efficacy of our products is region-specific, necessitating customisation for different snake species across various geographies. Another significant challenge is the availability of venom, which is critical for production but is controlled by strict regulations under the Ministry of Forest and Environment.

Tell us about your manufacturing facilities and the technologies you use.

We have two main plants in Hyderabad; one for animal handling and another for farming, 45 kilometres away. We manage the entire process from plasma extraction to the final product. Our facilities are equipped with advanced chromatography setups for additional purification, making our products comparable to human monoclonal antibodies. We collaborated with institutions like the Indian Council of Medical Research (ICMR) and the Centre

for Cellular & Molecular Biology (CCMB) during COVID-19 to develop an indigenous antidote, demonstrating our technical capabilities.

How does Vins Bioproducts ensure ethical standards, particularly in animal handling?

We consider every equine (horse) a crucial part of our operations, so their health is paramount. We're regulated by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), ensuring compliance with animal welfare standards. Our processes, similar to human plasma donation, are designed to minimise harm and maximise care for the animals involved.

In fact at Vins Bioproducts, we adhere to rigorous ethical standards to ensure the welfare of our equines. We undergo frequent audits—at least two every month, each lasting three to four days—where auditors spend considerable time at our animal farms to inspect our practices. We grow our own fodder for about 2,000 horses using hydroponic farming techniques, which allows us to maintain a consistent and high-quality food supply. This practice also reduces our reliance on external suppliers who can be inconsistent. Additionally, we incorporate nutritious inputs such as 'chana' and barley to meet the protein requirements of our horses. Our focus is on minimising cruelty and enhancing the comfort of the animals through continuous technological advancements in their treatment.

How many animals do you have at your facilities?

We have around 650 animals at our main facility. At another location, about 40 kilometres from here, we have nearly 1,000 to 1,100 animals on a 100-acre farm.

Apart from equines, do you use any other animals for serum extraction?

No, we only use horses. Horses are easier to handle and are more human-friendly compared to larger animals like elephants, which are impractical to manage in large numbers.

Are you venturing into any new research areas? If so could you give us a brief on those developments and products in pipelines?

Yes, we are exploring several new research areas. During the COVID-19, we successfully developed a treatment platform, which we are now diversifying. We are currently focusing on treatments for Dengue and Gangrene. Our Dengue treatment is still in the proof-of-concept stage, but we are optimistic about its potential. We are also developing an anti-thymocyte product for aplastic anaemia and organ transplants.

"The Middle East, Southeast Asia, and certain parts of Africa are key markets for us"

« **Khushboo Daga,** CEO, Vins Bioproducts

What are your company's revenue models and where do you export your products and what are your market strategies?

We export to almost 100 countries globally and are registered in 40 to 50 countries across the globe. Our products are mainly procured through tenders, both in India and internationally. We are market leaders in anti-snake venom in India, supplying around 1.5 to 1.8 million doses annually. We also participate in global tenders and have a significant presence in West Africa with our tetanus antitoxin.

Revenue wise for the year 2022-23 we crossed Rs 150 crore mark with a profit margin

How much investment have you made in these new research areas? Are you partnering with any academic institutions or organisations to take forward your healthcare solutions?

We are looking to collaborate rather than solely fund these initiatives. We have identified experienced scientists and partnered with companies like Sanofi and GSK. The investment required for moving a product from development to clinical trials can range from $5 to $10 million, given the high costs associated with clinical trials.

During COVID-19, we collaborated with CCMB and closely worked with them to develop an anti-dote for COVID. Though we could not complete our clinical trials, we gained significant knowledge and

of 55 to 60 per cent, and we are expecting to witness a double digit growth and expecting to cross revenue beyond Rs 200 crore in the coming years ahead.

Which markets are more profitable for Vins Bioproducts?

It's challenging to pinpoint the most profitable markets, but we aim to grow new markets, which can be more profitable by reducing competition. Our strategy is to register our products in new markets as quickly as possible, although this process can take two to four years. The Middle East, Southeast Asia, and certain parts of Africa are key markets for us. In Africa, we are particularly mindful of pricing due to the economic constraints, as we produce life-saving drugs for poorer populations.

In India our primary supply of about 97-98 per cent is to the government, with the remaining distributed to the limited private market. Our product Anti-Snake Venom Serum is under Drug Price Control Order in India and supplied to all state government hospitals through a tender based supply system in India as well as in some of the world countries.

In West Africa we have developed our own private virgin market where we provide prefilled Tetanus Antitoxin in Ampoules, Syringes, and Vials. Though this is a much sophisticated presentation, we have succeeded in delivering it and sold more than 1.50 million doses only in West Africa. BS

will definitely use it whenever a similar pandemic breaks in future. We had also collaborated with the University of Hyderabad.

Regarding snake bite treatments, how do you address the lack of awareness and the reporting of cases in India?

Currently, snake bite is not a notifiable disease in India, which means it is not officially tracked on health information portals. Some state governments are beginning to recognise it as a notifiable disease. In the meantime, we engage in community awareness programmes, especially in regions with high incidence rates, such as Mahabubnagar district in Telangana, collaborating with local authorities to raise awareness and improve reporting.

Do you have any plans of expanding and upgrading your company either in India or internationally? Who are your competitors, both in India and globally, particularly in your product domain?

Currently, snake bite is not a notifiable disease in India, which means it is not officially tracked on health information portals. Some state governments are beginning to recognise it as a notifiable disease. In the meantime, we engage in community awareness programmes, especially in regions with high incidence rates, such as Mahabubnagar district in Telangana, collaborating with local authorities to raise awareness and improve reporting.

Fortunately, we have ample land available here, so we're currently focused on upgrading and expanding our existing facilities. Since our inception almost reached a growth of 5 million doses capacity. We're enhancing our filling line facilities, purification labs, quality control, and small animal labs. While we are considering expansion beyond India, it's still in the preliminary stages. We need to assess feasibility and logistics before making any concrete plans.

In India, we face competition from both government and private entities. The Central Research Institute (CRI) Kasauli in Himachal Pradesh and Bharat Serums & Vaccines and Haffkine Bio- Pharmaceutical Corporation (both from Mumbai) are notable competitors. Globally, government organisations in countries like Thailand and Vietnam also pose competition, as they have their own labs focused on similar products.

Finally, how do you perceive the overall growth prospects for the biotechnology sector in India, particularly in Telangana? Can you provide an overview of your opinion on the Indian pharma sector?

The pharmaceutical sector in India has been experiencing significant growth, with record exports reaching $27 billion this year. There's a growing awareness about health post-COVID, leading to increased demand for diagnostic testing and subsequent treatments. This surge in demand is driving business growth, prompting companies to invest more in research and collaboration. Overall, the future looks promising, and the sector holds great potential for India's economy. BS

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Why global pharma companies choose India for GCCs

« **Anil Matai,** Director General, Organisation of Pharmaceutical Producers of India (OPPI)

India's pharmaceutical industry is globally recognised for its capabilities in research and manufacturing and for its skilled labour. The country's attractiveness as a destination for Global Capability Centres (GCCs) is underpinned by several key factors, including cost-efficiency, a vast talent pool, robust infrastructure, and strong regulatory support.

India serves as a key global hub for development, attracting investments of more than $7 billion. Global pharmaceutical companies have established GCCs in India which serve as centres of excellence for drug discovery, formulation development, and healthcare solutions, while also supporting a strong ecosystem by employing talent and increasing the knowledge base.

For instance, Novartis has had a significant footprint in India since 1947, and in the last two decades, it has evolved to be an integral part of the development journey of many breakthrough medicines in various therapeutic areas like cardiovascular, oncology, immunology, neurology, and ophthalmology, amongst others. Similarly, MSD is primed to support the Indian government in protecting every woman through HPV vaccination with nearly 85 per cent of their products being manufactured locally.

In India, Novo Nordisk is conducting phase 2-4 clinical trials across major disease areas with over 3,000 enrolled patients. With 37 ongoing trials in various therapy areas, India accounts for 7-8 per cent of Novo Nordisk's global patient pool.

As GCCs have evolved to become centres for innovation and research, India has transformed into a hub for new product development for global enterprises. Consequently, over 50 per cent of the world's GCCs are now located in India, driven by factors that provide a competitive edge for businesses aiming to optimise operations and drive innovation.

Cost-efficiency of conducting business

India offers a compelling cost-quality ratio, making it financially advantageous for companies to establish their GCCs in the country. Labour costs in India are significantly lower than those in countries like North America and Europe, enabling companies to reduce operational expenses while maintaining profitability. According to a NASSCOM report, companies setting up GCCs in India could achieve average cost savings of 40-50 per cent compared to their home countries. These savings extend beyond salaries to include operational costs such as real estate, utilities, and infrastructure.

Bayer's Hyderabad centre has been selected as a key APAC hub as India has a significant talent pool to support global drug development and manufacturing initiatives. There are over 100 employees currently working here. The Novartis Corporate Centre serves as one of the key global hubs for development wherein scientists are providing support in the development of many chemical entities developed and commercialised by Novartis globally.

Extensive Talent Pool

India boasts a large pool of highly skilled professionals with the world's second-largest English-speaking youth population and the highest number of Science, Technology, Engineering, and Mathematics (STEM) graduates. The foundation of a thriving GCC model in India is the nation's abundant talent pool and expanding knowledge economy. The Indian talent is equipped to meet the demand because of its unique characteristics like generative artificial intelligence (GenAI) and cloud computing.

GSK's GCC in Bengaluru employs over 2,500 people in global business operations and R&D, with more than 50 per cent focusing on R&D in areas like safety science, regulatory, biostatistics, clinical operations, and more. Pfizer's Global Drug Development Centre in Chennai has emerged as a powerhouse of innovation, propelling the company's quest for groundbreaking medical solutions.

Bristol Myers Squibb's new facility in Hyderabad expands the company's global drug development and IT and digital capabilities. It is expected to be home

to over 1,500 employees, enhancing the company's workforce and impact on patients.

Robust infrastructure and regulatory support

The country has made substantial investments in modernising its infrastructure to support business operations. This includes state-of-the-art office spaces, reliable high-speed internet connectivity, and consistent power supply, which are crucial for the seamless functioning of the GCCs. Additionally, India's advanced transport systems and logistics networks facilitate the efficient movement of goods and personnel, ensuring that operations run smoothly and without interruption. For example, cities like Hyderabad, Bengaluru, and Pune have developed into major business hubs, offering world-class infrastructure that meets the demanding needs of global companies.

Integrating advanced technologies such as AI, machine learning, and big data analytics into the infrastructure framework supports innovation and enhances operational efficiency. Digital infrastructure initiatives such as the creation of smart cities and tech parks provide an ecosystem conducive to cutting-edge research and development.

Lilly's GCC in Bengaluru supports digital transformation and innovation by providing cloud automation, advanced analytics, AI, software engineering, and information security solutions. Leveraging expertise in data analytics and digital technologies, it enhances clinical trial processes and drives innovation in AI and machine learning for biopharmaceutical challenges.

Focus on Innovation and R&D

India is rapidly emerging as a global hub for pharmaceutical R&D, driven by a robust ecosystem that includes academic and research institutions, industry partnerships, and government support. This ecosystem fosters collaboration and innovation, making India an ideal location for GCCs in the pharmaceutical sector. These centres are at the forefront of cutting-edge research, clinical trials, and drug development, significantly contributing to the global R&D efforts of their parent companies.

Pfizer collaborated with the National Institute of Pharmaceutical Education & Research (NIPER), Ahmedabad to encourage startups in India and help early-stage innovators advance on their journey. This collaboration is an example of how healthcare startups are turning their innovative ideas into market-ready solutions. Sanofi's The Department of Scientific and Industrial Research (DSIR)-approved R&D centre in Goa has developed innovative products and technologies for the past 15 years, focusing on new product development, lifecycle management, new dosage forms, R&D support, technology transfer, site troubleshooting, product harmonisation, process improvements, and compliance.

Ferring India R&D works on technology platforms like FDG's, SmaRTgel, and LBOL-IR/XR, investing over 60 million Euros in Indian R&D, with 1-2 million Euros spent annually on capital expenditure. Lilly Capability Centre India (LCCI) in Bengaluru and Merck's new Healthcare R&D Excellence Centre in Bengaluru leverage India's strengths in drug development and technology, driving global healthcare innovation.

Growing Technological Infrastructure

The rapidly expanding technological infrastructure provides a significant competitive advantage, enabling global pharma companies to enhance their operations, drive innovation, and achieve cost efficiencies. The country's robust IT infrastructure supports various aspects of operations, including R&D, data management, and digital health initiatives. For instance, Roche is harnessing India's robust technology ecosystem to forge ahead in the digital landscape, crafting innovative solutions that resonate on a global scale. Roche Services and Solutions (RSS) adds expertise around the technological advancements happening in the healthcare space through the utilisation of AI/ML concepts contributing towards significant improvement in the lives of patients.

Similarly, AstraZeneca's Global Innovation & Technology Centre (GITC) in Chennai drives the company's digital journey and technology innovation, housing over 50 per cent of its global IT staff. GITC offers services in software engineering, cybersecurity, IT infrastructure, cloud, hyper-automation, AI/ML, extended reality, and IoT.

Way Forward

The future of these hubs in India's pharmaceutical sector appears promising. Factors such as continued investment and talent accessibility, contribute to their sustained growth. Additionally, a favourable regulatory environment and an expanding healthcare market attract global companies to establish their hubs, facilitating collaborations and technology-driven solutions. These hubs also have ample opportunities to explore emerging technologies and foster collaborations, leading to breakthrough discoveries. Furthermore, increasing government support for innovation and entrepreneurship through initiatives and policies enhances the growth potential of these hubs. As we move forward, it's crucial to leverage the opportunities these GCCs present and continue to solve the healthcare challenges of India. BS

Transformative role of Indian pathology market in healthcare

« **Aryaman Tandon,** Co-Founder and Managing Partner-Healthcare, Praxis Global Alliance

The Indian pathology market has emerged as a critical component of the country's healthcare ecosystem, driven by the increasing prevalence of chronic diseases, infections, and lifestyle-related health problems. As the demand for precise and prompt diagnosis rises, the importance of pathology services has never been more pronounced. Let's delve into the market landscape, segmentation, global and Indian test prices, types of tests, and pathology equipment base, painting a comprehensive picture of the Indian pathology market.

The Indian pathology market is valued at approximately $7.5 billion, as of FY23, with projections indicating growth to $14.4 billion by FY28 at a CAGR of around 14 per cent. This robust growth is fueled by several factors, including the rise in chronic diseases, an ageing population, and increased demand for preventive tests.

Pathology services encompass a wide range of disciplines such as clinical chemistry, haematology, immunology, molecular pathology, histopathology, and more.

The market is characterised by its fragmentation, with an estimated 132,000 labs spread across the country. Over 60 per cent of these are standalone labs, though they generate the lowest average revenue per lab per year at approximately $25,000. In contrast, labs within large private hospitals, which make up around 1 per cent of the total, exhibit the highest average revenue per lab per year at about $1,330,000.

Market Segmentation

Clinical chemistry, immunology, and haematology collectively dominate about 80 per cent of the pathology market. Clinical chemistry, holding the largest share at 35 per cent, involves the analysis of bodily fluids like blood and urine to assess health and diagnose diseases. Tests in this segment measure electrolytes, enzymes, lipids, proteins, and glucose levels, aiding in the evaluation of organ function and metabolic processes. These tests are crucial for detecting conditions such as diabetes, kidney disorders, liver diseases, and metabolic disorders.

Immunology, accounting for 23 per cent of the market, focuses on the study of the immune system. Immunology tests gauge the immune response to pathogens, allergens, and autoimmune disorders. Common tests include antibody tests, allergy tests, autoimmune tests, and infectious disease tests, which are essential for diagnosing conditions like HIV/AIDS, autoimmune diseases, allergies, and immunodeficiency disorders.

Haematology, making up 20 per cent of the market, assesses the cellular components of blood, including red blood cells, white blood cells, and platelets. Tests such as the complete blood count (CBC) measure red blood cell count, white blood cell count, haemoglobin level, platelet count, and hematocrit level, offering insights into various blood-related disorders. Beyond the major segments, the pathology market includes molecular biology, histopathology, urinalysis, and surgical pathology.

Global and Indian Test Prices

India's diagnostic test prices are significantly lower compared to those in developed countries. For instance, common tests such as liver function, thyroid assessment (TSH), Vitamin D screening, CBC, and urinalysis are much more affordable in India than in countries like the United States and the United Kingdom. This affordability is crucial in a country with diverse economic strata, ensuring that diagnostic services remain accessible to a broader population. However, there is potential for price realisation improvement as advancements in technology and healthcare infrastructure continue to progress. This evolution highlights the need for sustainable strategies to optimise healthcare delivery and outcomes while maintaining affordability.

Growth Drivers

Several factors are driving the growth of the Indian pathology market:

Rise in Chronic Diseases: The increasing prevalence of chronic diseases underscores the need for accurate diagnosis and treatment planning. Conditions such as diabetes, cardiovascular diseases, and cancer require regular monitoring through pathology tests.

Ageing Population: The expansion of the geriatric population, prone to age-related illnesses, necessitates routine diagnostics. Specialised pathology services and enhanced geriatric facilities are becoming indispensable for addressing the healthcare needs of older adults.

Preventive Healthcare: Growing awareness of preventive healthcare, coupled with government initiatives like Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), propels the demand for preventive tests. This proactive approach encourages regular health screenings for early detection and management of potential health issues.

Pathology Lab Landscape

The pathology lab landscape in India is highly fragmented, with standalone labs forming the majority at 63 per cent. Small and medium private hospital labs constitute 19 per cent, while national chain labs and large private hospital labs hold the smallest shares at 1 per cent and 0.5 per cent, respectively.

Tier 1 and 2 cities encompass around 67 per cent of India's total pathology network, indicating a significant concentration of laboratory facilities in urban areas. This urban-centric distribution highlights the disparity in access to diagnostic services across regions. To address this imbalance, the government is striving to expand laboratory presence in tier 3+ and rural areas, aiming to improve healthcare accessibility and affordability nationwide.

Specialised Testing

Specialised testing is experiencing significant growth, driven by the ageing population, the integration of personalised medicine practices, and technological advancements in diagnostics. Specialised tests are targeted investigations used for specific diagnoses, monitoring particular conditions, and assessing specific markers or functions within patients.

This segment positions diagnostics providers for accelerated growth and innovation. Investing in these capabilities will enhance overall service offerings, leading to improved patient outcomes and greater market differentiation.

Pathology Equipment Base

Automated Analysers: Used extensively in clinical chemistry and haematology, these devices perform multiple tests simultaneously, increasing efficiency and accuracy.

Flow Cytometers: Crucial for immunology and haematology, these devices analyse the physical and chemical characteristics of cells or particles.

PCR Machines: Widely used in molecular biology, these machines amplify DNA sequences, allowing for the detection of genetic material from pathogens.

Microscopes: Essential in histopathology and cytology, advanced microscopes enable detailed examination of tissues and cells.

Different Types of Pathology Tests

Molecular Biology: This field provides insights into genetic predispositions and personalised treatment approaches, playing a pivotal role in the era of precision medicine.

Histopathology: This involves examining tissue samples to diagnose diseases, particularly cancer, helping in understanding disease progression and guiding treatment decisions.

Urinalysis: This detects abnormalities indicative of various health conditions, offering a simple yet effective diagnostic tool.

Surgical Pathology: Analysing tissue specimens from surgeries, this field helps in guiding treatment decisions and understanding disease progression.

The Indian pathology market stands at the forefront of the healthcare sector's transformation, driven by the rising demand for accurate and prompt diagnostic services. As the market continues to grow and evolve, it is imperative for stakeholders to embrace technological advancements, invest in specialised testing capabilities, and expand accessibility to underserved regions.

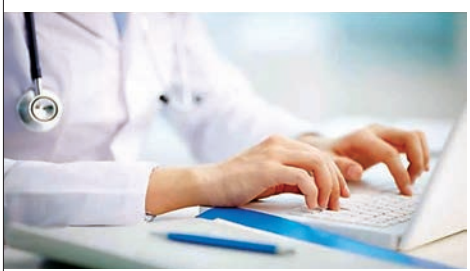
By doing so, the pathology sector will not only enhance healthcare delivery but also contribute significantly to improving health outcomes and quality of life across India. The future of the Indian pathology market is promising, with immense potential for growth, innovation, and improved patient care. BS

MSN Labs collaborates with BITS Pilani to elevate educational opportunities for young workforce

Hyderabad-based MSN Laboratories has signed a Memorandum of Understanding (MoU) with Birla Institute of Technology and Science (BITS) Pilani's Work Integrated Learning Programmes (WILP) division, in an endeavour to elevate educational opportunities for their Self-Directed Teams (SDTs) within the formulation units. This collaboration aims to help their professionals in keeping pace with the rapid global pharmaceutical industry evolution and in preparing them for their designated roles, which in turn will aid MSN Labs in addressing the ever-changing business requirements. As part of the collaboration, the professionals will also undergo training to operate machinery and fulfil roles within different production departments, by working closely with their senior staff members. As of now, sixty team members from MSN Laboratories' formulation division have been enrolled in the B.Sc. Pharmaceutical Science programme offered by BITS Pilani WILP.

International Institute of Health Management Research launches new PG certificate programmes

International Institute of Health Management Research (IIHMR), Delhi has announced the launch of All India Council for Technical Education (AICTE)-approved Online Postgraduate (PG) Certificate Programmes, designed to cater to the growing demand for specialised education in the healthcare sector. In alignment with the National Education Policy's mandate to enhance the quality and reach of higher education, IIHMR Delhi has introduced three courses- PG Certificate in Hospital Management; PG Certificate in Logistics & Supply Chain Management; and PG Certificate in Public Health Financial Management. These online programmes are specifically designed to provide flexibility and accessibility for working executives, enabling them to advance their careers without disrupting their professional commitments.

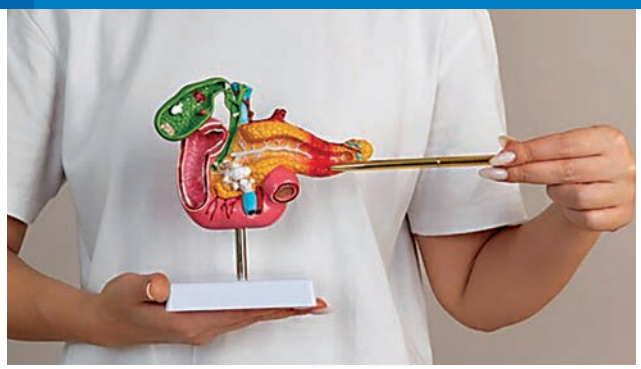


Aster Health Academy announces partnerships with premier hospitals across India

Aster Health Academy, part of Aster DM Healthcare, has announced its strategic collaborations with a distinguished array of hospitals across India. Currently, the academy has secured partnerships with 15 esteemed hospitals, furthering its mission to provide unparalleled practical training opportunities for its enrollees. These affiliations are integral to the Academy's curriculum, particularly for clinical programmes such as Fellowships in Emergency Medicine, Diabetes, and Critical Care. Enrolled doctors are placed in hospitals for Observership programmes, where they gain invaluable hands-on experience under the mentorship of departmental heads. This practical exposure is meticulously aligned with the educational objectives of their respective programmes. Prominent among the partnered institutions are KIMS Hospital, Telangana & Andhra Pradesh, Jaslok Hospital – Maharashtra, Metro Hospital – Delhi NCR, Accord Super speciality Hospital, Faridabad, Aster Whitefield Hospital - Karnataka, Charnock Hospital- West Bengal, Chandan Hospital – Lucknow, Spandana Hospital – Bengaluru.

IISc designs novel 3D hydrogel culture to study TB infection and treatment

Researchers from the Department of Bioengineering (BE), Indian Institute of Science (IISc), Bengaluru have designed a novel 3D hydrogel culture system that mimics the mammalian lung environment. It provides a powerful platform to track and study how tuberculosis (TB) bacteria (Mycobacterium tuberculosis or Mtb) infect lung cells and test the efficacy of therapeutics used to treat TB. Current culture models used to study Mtb infection have several limitations. They are typically culture plates that are monolayered and do not accurately mimic the 3D microenvironment inside the lungs. The microenvironment experienced by the cells in such 2D culture is vastly different from the actual extracellular matrix (ECM) surrounding lung tissue. The researchers have now designed a novel 3D hydrogel culture made of collagen, a key molecule present in the ECM of lung cells. Collagen is soluble in water at a slightly acidic pH. As the pH is increased, the collagen forms fibrils which cross-link to form a gel-like 3D structure. At the time of gelling, the researchers added human macrophages – immune cells involved in fighting infection – along with Mtb.

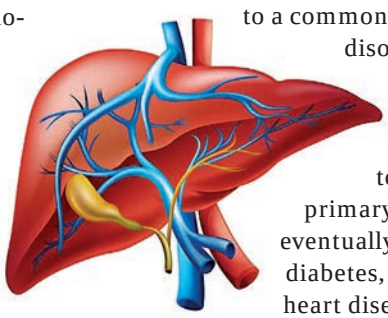


VEGFR1 enzyme holds key to medical solutions for colon and renal cancers

Researchers at the Indian Institute of Science Education and Research (IISER), Kolkata have decoded the molecular mechanism in which a cell surface receptor belonging to the family of enzymes that bind growth factors, regulate cell differentiation, proliferation, survival, metabolism, and migration, prevents cancers. This enzyme called VEGFR1 withholds self-expression (autoinhibited) in the absence of a ligand, for example hormones. The research can show the way for developing medical solutions for colon and renal cancers by using molecules that preferentially stabilises the inactive state of VEGFR1. This discovery may open new avenues for developing therapeutic interventions against pathological conditions due to the spontaneous activation of VEGFR signalling. The small molecules targeting the autoinhibited state will have a higher potential for treating cancers like human colorectal carcinoma and renal cancer, where VEGFR1 is overexpressed.

S & T Minister unveils Indo-French Liver and Metabolic Disease Network

The Union Minister of Science & Technology (S&T) Dr Jitendra Singh launched Indo-French Liver and Metabolic Disease Network (InFLiMeN), a virtual node to prevent and cure metabolic liver diseases at Institute of Liver and Biliary Sciences (ILBS) in New Delhi. Dr Jitendra Singh highlighted that the Indo-French Node, InFLiMeN, aims to address key issues related to a common metabolic liver disorder, non-alcoholic fatty liver disease (NAFLD), which can progress to cirrhosis and primary liver cancer eventually. It predates diabetes, hypertension, heart disease and many other diseases. Dr Jitendra Singh advised that a joint multi-disciplinary collaborative programme like InFLiMeN is urgently needed to understand the development, progression and possible management of liver diseases using a comprehensive omics approach for biomarker discovery. He also appreciated Prof. Abhay Karandikar, Secretary, Department of Science and Technology (DST) along with the department and Indo-French Centre for the Promotion of Advanced Research (CEFIPERA) for taking this novel approach proposed by ILBS.



Happiest Health appoints Dr Sreenivasan Narayana as President & CEO of Healthcare Services Division

Bengaluru-based organisation Happiest Health has announced the appointment of Dr Sreenivasan Narayana as President & Chief Executive Officer of the knowledge, health and wellness enterprise's new division— Healthcare Services. This will help Happiest Health to strengthen its offerings in the healthcare services sector. Dr Sreenivasan will be responsible for strategic planning, operations, and the development of new healthcare service centres. Dr Sreenivasan Narayana is an ENT surgeon who has worked in renowned healthcare organisations such as the Apollo Hospitals Group and Narayana Health. He also founded Doctree Health, a startup aimed at affordable treatments. Dr Sreenivasan completed his postgraduate programme in management at the Indian School of Business, Hyderabad, where he undertook a full semester exchange MBA programme at The Wharton School, USA.

Cloudphysician names Dr Mandar Vaidya as CEO-India

Bengaluru-based AI health startup Cloudphysician, a full-stack tech and operations company that partners with hospitals to manage patients in their ICU and Emergency departments, has announced the appointment of Dr Mandar Vaidya as CEO-India, effective June 2024. Dr Vaidya brings over two decades of experience driving global businesses and delivering transformative results. His experience as a former partner at McKinsey & Co., where he led the healthcare practice in Asia and developed strategies for hospitals and pharmaceutical companies, will help Cloudphysician serve partner hospitals effectively and drive growth across India. He was regional CEO at OYO for four years, where he led multiple geographies outside of India (Europe, SE Asia, Middle East, and Japan). He led profitable and transformative growth in these markets via a tech-enabled approach: building scale from India for the world. Additionally, Vaidya is an independent director on the board of Cipla Limited.

Raja Bhanu steps in as new Director General of Pharmexcil

K Raja Bhanu has been elevated from Executive Director to Director General of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), effective July 1, 2024. This announcement follows the retirement of Ravi Udaya Bhaskar on June 30, 2024. The appointment was confirmed by S.V. Veeramani, Chairman, and Namit Joshi, Vice Chairman of Pharmexcil. Raja Bhanu, a distinguished former official of the Drug Control Administration (DCA), has a robust background in drug control and regulation.

His previous role as Executive Director of Pharmexcil showcased his capability to lead and implement significant initiatives within the organisation. Bhanu's career with the DCA is notable for his numerous achievements in ensuring drug quality, safety, and regulatory compliance. During his tenure, he implemented key initiatives that improved the standards and enforcement of drug regulations in India. In his new role, Bhanu is expected to focus on expanding India's pharmaceutical exports, enhancing global competitiveness, and navigating complex regulatory landscapes in various countries. His deep understanding of both domestic and international pharmaceutical regulations is anticipated to benefit the industry and promote its growth.

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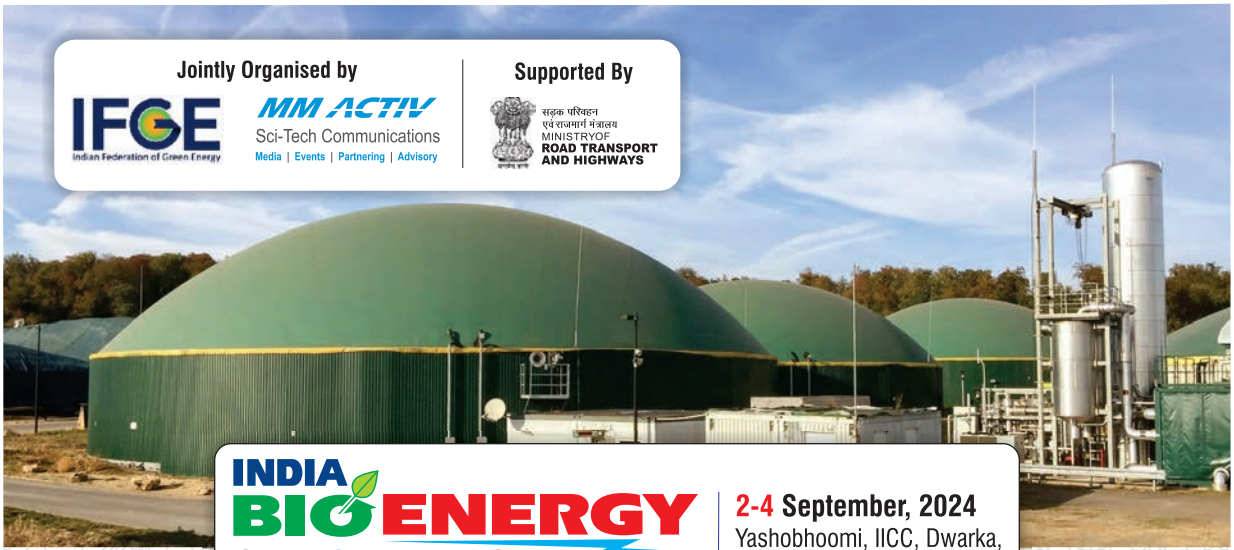

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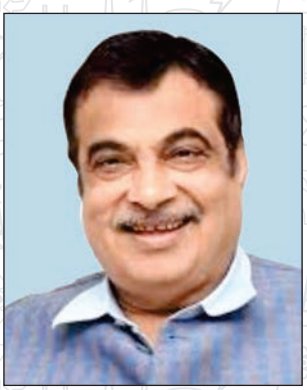

Shri Nitin Gadkari
Hon'ble Minister of Road Transport & Highways Government of India

Shri Hardeep Singh Puri
Hon'ble Minister of Petroleum and Natural Gas Government of India

EXHIBITORS PROFILE

Biofuel / Energy Companies
- CBG Producers
- Ethanol Producers and Distillers
- Biomass Pellets and Briquettes Processors and Suppliers
- Biofuel processors
- Waste to Energy Companies

Fertilizer Companies
- Fertilizer Marketing/Supplying Companies
- Organic Manure producers

Raw Material Suppliers
- Feed Stock suppliers/aggregators
- Industrial Enzyme/Biotechnology/ Microorganism Co.
- Sugar Cane/Grain Suppliers
- Biomass plantation Companies
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Ravindra Boratkar, Publisher, MM Activ Media, receives Exemplary Leadership Award of Exhibition Industry

Ravindra Boratkar receiving Exemplary Leadership Award from dignitaries at the Exhibition Excellence Award ceremony.

Jagdish Patankar, Executive Chairman, Ravindra Boratkar, Managing Director and the team of MM Activ Sci Tech Communications Pvt Ltd receiving the award presented to Bengaluru Tech Summit in Grand Conference category.

Ravindra Boratkar, Publisher & Managing Editor, BioSpectrum (India and Asia), NUFFOODS Spectrum (India and Asia) and AgroSpectrum (India and Asia) was presented the Exemplary Leadership Award in the Exhibition Excellence Awards in the Editor's Choice category in his capacity as the Managing Director of MM Activ Sci-Tech Communications Pvt Ltd., the parent company of all the media brands.

Exhibition Excellence Awards are presented annually for various events, exhibitions, conferences seminars, venues and personalities to recognise their contribution and felicitate the distinguished achievers of the sector. The awards are Asia's iconic, only recognition initiative for the exhibition and convention industry.

The awards are given by the Exhibition Showcase, Asia's most comprehensive media platform for exhibitions. This was the 8th edition of the Exhibition Excellence Awards and Summit 2024, held at the CIDCO exhibition and convention centre in Navi Mumbai.

The award citation said, "Boratkar's remarkable contributions and visionary leadership has left an indelible mark on the industry, shaping its trajectory for the better. Boratkar is a driving force in the organisational consulting, marketing, management and event organisation."

MM Activ gets awards for BTS 2023, Startup Mahakumbh

MM Activ Sci Tech Communications, received other three awards for two of its shows at the Exhibition Excellence Awards 2024. Bengaluru Tech Summit (BTS) 2023, encapsulating Bio Technology, bagged the award as the Grand Conference, while the Start Up Mahakumbh 2024, organised in Delhi received award as Top Start-Up India Promotion Show and 1st runner up in the category Top New Show (B2C). Jagdish Patankar, Executive Chairman and Ravindra Boratkar, Managing Director and the team of MM Activ Sci Tech Communications Pvt Ltd received the awards.

Boratkar also moderated the panel discussion on CEO's Forum titled "Future outlook for India's Exhibition Industry" prior to the award ceremony. Panellists in the discussion, were Sanjeev Bolia, Founder Afairs Exhibitions & Media Pvt Ltd, Phil Chung, CEO KINEXIN – IICC, Milind Dixit, Managing Director, KOELNMESSE Pvt Ltd, Nabjeet Ganguli, Chief Marketing Officer, Informa Markets, Pradeep Padekar, Chief Financial Officer, Messe Muenchen India, Vinay Mittal, Managing Director Deepali Design & Exhibits Pvt Ltd.

In his remarks during moderating the session, Boratkar said that the future of India's exhibition industry appears exceedingly bright. India's rapidly expanding economy and its strategic geographical location make it an attractive destination for global exhibitions. India's rich cultural heritage and diverse industrial base provide a fertile ground for specialised exhibitions across various sectors—from automotive and healthcare to information technology and agriculture. Each exhibition serves as a platform for knowledge-sharing, networking, and exploring new business opportunities.

MM Activ Sci-Tech Communications has won these awards consecutively for the third time. BS

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Thermo Fisher introduces biobased solutions to help reduce climate impact in manufacturing of therapies

US-based Thermo Fisher Scientific Inc. is contributing to the sustainability of biologics therapy manufacturing by leveraging plant-based materials, rather than fossil fuel materials, to deliver lower-carbon, biobased films for its single-use technology bioprocessing containers (BPCs). The biobased films build on Thermo Fisher's existing Aegis and CX film offerings that are widely used and validated by customers. As a result, customers can maintain consistency in their BPCs while also realising a reduction in greenhouse gas (GHG) emissions. By adopting biobased, sustainable films in their BPCs, Thermo Fisher customers can eliminate carbon emissions related to the plastic resin. The biobased films have earned an International Sustainability and Carbon Certification (ISCC) PLUS certification, a globally recognised certification for circular and biobased products. Biopharma manufacturers can pre-purchase the biobased films now to incorporate into their upstream or downstream system in early 2025. In addition, Thermo Fisher will support customers as they track their carbon reduction quantities and advance towards their sustainability objectives.

VFL Sciences launches GreatSpin range of centrifuges

VFL Sciences, based in Chennai, has announced the launch of the GreatSpin range of centrifuges. This is the first range of centrifuge from VFL Sciences and the company is planning to launch several other models in the next one year. GreatSpin is a 'better alternative' to the existing centrifuges in the market with best-in-class features and benefits. The new series features advanced centrifuges designed for a wide range of applications in research and clinical laboratories. These centrifuges offer precise control, high speed, and exceptional reliability, making them ideal for sample separation, cell culture, and more. With user-friendly interfaces and robust construction, Great Spin centrifuges provide consistent performance and longevity.

Nikon offers new imaging technology to accelerate biotech research

Nikon Instruments Inc., the US microscopy arm of Nikon Healthcare, is expanding its AX series lineup with the introduction of the AX R with NSPARC 2K software. This solution provides maximum resolution performance across four times the field of view. The expanded capabilities of the AX R with NSPARC Super-Resolution Confocal Microscope contribute to accelerated speed and efficiency of experiments across fundamental biology, disease research, and drug development. The Nikon Spatial Array Confocal (NSPARC) detector, combined with the AX R Confocal Microscope system, enables more precise observations with extremely low noise and exceptionally sharp image contrast. The newly updated software expands the observation range by about four times at the same magnification compared with previous products. In addition, the image acquisition speed at the same magnification is improved six-fold compared to a traditional galvano scanner. Equipped with the NSPARC detector, which provides high-speed, large field of view, high-resolution imaging capability, researchers can clearly observe even the smallest parts of cells and tissues. This enables higher-quality data analysis, deeper scientific understanding, and valuable insights into understanding the root causes of disease.

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TAVI: Advanced Heart Care for Complex Health Conditions

Sharad Chandra
Professor,
King George's Medical University, Lucknow

Transcatheter Aortic Valve Implantation (TAVI) has emerged as a revolutionary treatment for severe aortic stenosis (AS), particularly benefiting patients with comorbidities like diabetes and hypertension. These patients face heightened surgical risks and complications, making TAVI's minimally invasive nature a crucial alternative.

TAVI involves inserting a new aortic valve via a catheter, typically through the femoral artery (artery in the leg), thus avoiding the need for chest opening. This approach significantly reduces surgical trauma and accelerates recovery, making it an ideal choice for high-risk patients. For diabetic patients, TAVI's reduced infection risk and faster healing times are particularly beneficial, as their condition often impairs wound healing and increases susceptibility to infections. Hypertensive patients also benefit from TAVI due to the procedure's ability to minimize cardiovascular stress, resulting in fewer complications and a smoother recovery process.

The advantages of TAVI extend beyond the operating room. Patients who undergo TAVI typically experience shorter hospital stays and quicker recoveries. This is especially important for those with comorbidities, as prolonged recovery can aggravate existing health issues. Post-TAVI, many patients report significant improvements in cardiac function and overall quality of life, with minimal impact on their other health conditions.

India's high prevalence of diabetes and hypertension underscores the necessity for advanced medical solutions like TAVI. With approximately 77 million adults living with diabetes, India ranks second globally, trailing only China. Urbanization, changing lifestyles, and genetic predispositions further intensify this health crisis. Therefore, the demand for safer, more effective treatments like TAVI is increasing.

Dr Naveen Jamwal
Professor (JR),
RML Hospital, Lucknow

Dealing with heart surgery in obese patients can be tricky because of extra tissue and other risks like prolonged recovery, heightened infection risk, and added strain on the cardiovascular system. TAVI, a less invasive procedure, offers a great solution. It involves inserting a new heart valve through a catheter, a thin flexible tube, typically via the femoral artery in the leg, and guiding it to the heart, reducing risks and speeding up recovery and improves outcomes for obese patients with Aortic Stenosis (AS).

I recently encountered a particularly challenging case involving an obese patient with severe aortic stenosis (AS). Given the patient's condition, I chose Transcatheter Aortic Valve Implantation (TAVI) because of its minimally invasive nature, aiming to reduce the surgical risks significantly. This method allowed us to avoid large chest incisions, minimize the risk of infection, and reduce the stress on the heart. The patient's smooth recovery reaffirmed TAVI's effectiveness in such complex cases.

The benefits of TAVI for obese patients are significant. By avoiding large incisions, it lowers the risk of wound infections and speeds up healing, which is crucial for those prone to slow recovery. This procedure also reduces the risk of heart attacks or strokes.

For obese patients, TAVI ensures quicker recovery, facilitating early hospital discharge and faster return to normal activities. This approach is vital in managing conditions like diabetes and hypertension. TAVI's minimal invasiveness minimizes surgical risks, ensuring safer procedures and better outcomes in treating severe heart problems among high-risk individuals.

Preemptively Combating Chandipura Virus

An emerging pathogen that causes rapidly progressing influenza-like illness and acute encephalitis often leading to coma and death of the human host, Chandipura vesiculovirus (CHPV) is back again claiming lives in Gujarat and Rajasthan.

First identified during a 1965 outbreak in Chandipura village, Maharashtra, the virus has probably been endemic in this region for decades, and might have been responsible for several earlier outbreaks of encephalitis that have been recorded in India since 1954.

However, the first evidence for the Chandipura viral association with human epidemics was obtained during the monsoon season in 2003, when this virus was identified in patient samples during an outbreak in central India as a determinant of the acute encephalitis with a high fatality rate claiming more than 300 lives, mostly children, in Andhra Pradesh, Maharashtra and Gujarat. Later, cases have also been documented in Nagpur, Muzaffarpur and Warangal.

The medical examination of patients recorded high-grade fever, occasional vomiting, rigours, sensorium, drowsiness leading to coma and death within 48 hours. Subsequently, another outbreak of this infection with more than 75 per cent fatality rate was reported in the eastern region of Gujarat, in 2004.

The virus belongs to the rhabdovirus family, and has a single-stranded RNA and five genes. It travels through arthropod vectors like sand flies and mosquitoes. The virus reaches the salivary gland of the insect and is transferred to the mammalian host through bites. Animal studies showed that the virus affects only neurons and causes neurodegeneration.

The virus upon entering the neurons triggers cellular stress factors and release of reactive oxygen species (ROS). The granules produced in response to cellular stress have been implicated in viral replication and ROS generation, which stimulates neuronal death. Both these phenomena cohesively explain the neuropathogenesis and neurodegeneration following the viral infection.

However, the geographical distribution of the virus might extend well beyond India. It has also been detected in sand flies in Senegal and Nigeria. The viral detection in sand flies of the African continent indicates a high risk of its spread causing an epidemic in more parts of the globe. Given these forewarnings, it is of paramount importance to comprehensively understand viral biology and make efforts in the direction of developing antiviral measures.

Though CHPV was first isolated in 1965, it was considered as an orphan virus due to low pathogenicity to cause infections in man and domestic animals. No efforts were, therefore, made to develop diagnostics or prophylactics. However, post-2003 outbreak in central India, it garnered global attention as a human pathogen of public health importance.

For instance, researchers have demonstrated the application of sandfly and mosquito cell lines for early detection of the infection as the virus antigen could be detected within 2 hours of inoculation using immunofluorescent antibody technique. Also, according to studies, two candidate vaccines against this virus are under development, and awaiting trials.

Providing much needed hope, virologists at the Institute of Medical Sciences, Banaras Hindu University are studying the pathogenic processes of the virus and will be helpful in diagnosis and drug formulation in times to come. This study highlights the important role of microRNA-155 in restricting CHPV multiplication inside the host which can then be used in microRNA based therapy.

Recently, researchers at the National Institute of Virology (NIV) explored the repurposing of the antiviral drug Favipiravir against CHPV. Owing to its use during COVID-19, Favipiravir has emerged as a promising candidate, and its unique characteristics and clinical efficacy have garnered significant attention and demonstrated considerable potential in the fight against viral diseases. NIV has now gathered enough evidence of the antiviral activity of Favipiravir against CHPV infection, and further clinical evaluation may alleviate the associated mortality.

Combined efforts from all stakeholders including virologists, neurologists, paediatricians and the government are warranted to address this public health concern. BS

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