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Can Policy Reform And Investments Trigger **India's Medtech Makeover?**

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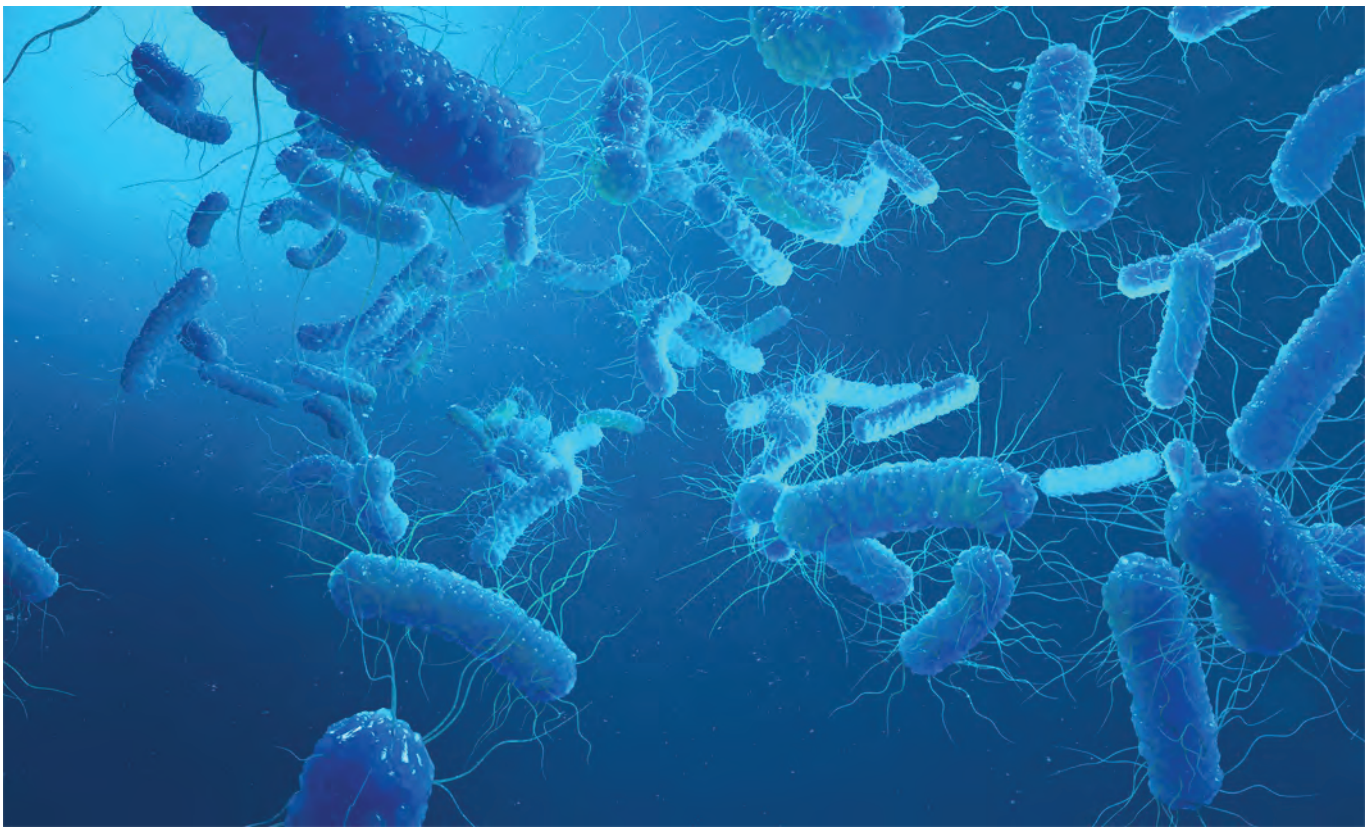

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Acknowledgement/Feedback

The article by Healthark Insights on Immune Cell and Gene Therapies in the BioSpectrum's July 2025 edition looks great. Thank you

-Miral Mehta, Ahmedabad

Thank you so much for publishing the write-up by Praxis Global on how genomic revolution is reshaping healthcare in emerging markets.

-Shivam Bajaj, Delhi

In my view the article on GLP-1 production is comprehensive & insightful. The aspect of whether these molecules are easy or difficult to synthesise/ manufacture could have been dealt with more.

-Girdhar Balwani, Ahmedabad

Honoured to share my thoughts in BioSpectrum India alongside industry colleagues, and kudos for the article highlighting US MFN Pricing cuts, an important shift.

-Dr Rashmi Chaturvedi Upadhyay, Bengaluru

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Letter from Publisher

Ravindra Boratkar
Publisher &
Managing Editor,
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Dear Readers,

The Indian market for medical devices is rapidly expanding, driven by a growing population, surging health issues, and active government efforts. Expected to grow from $12 billion in 2023-24 to $50 billion by 2030, the market offers significant growth prospects driven by rising disposable incomes, an ageing demographic, and the increasing incidence of chronic health conditions. This expansion will likewise be bolstered by enhanced healthcare infrastructure and increased health awareness, resulting in a higher demand for and availability of sophisticated medical technologies. Key market-driving segments include diagnostic imaging, cardiovascular equipment, orthopaedic implants, medical supplies, and in-vitro diagnostics.

To accelerate the patient-centric approach with a vision to lead in the manufacturing and innovation of medical devices, the Indian government has approved the Medical Devices Policy, which envisages a global share of 10–12 per cent in the next 25 years. To incentivise the manufacturing of medical devices within the country, the Production-Linked Incentive Scheme for medical devices was also launched, offering financial incentives on incremental sales, and opening up opportunities for both domestic and international players to set up and expand their production capabilities in India. The lead story explores how the country is making all out efforts to become self-sufficient in medical devices as India is largely dependent on imports which stood at nearly double its exports, at $8.1 billion.

A fire and explosion at a pharmaceutical factory in Pashamylaram, near Hyderabad, on June 30, 2025, resulted in at least 39 fatalities and 34 injuries. The incident occurred at Sigachi Industries, a pharmaceutical unit. It was also reported that the state of Telangana witnessed a whopping 102 major incidents of fire in pharma units over the last decade, resulting in losses exceeding Rs 100 crore. The Indian pharma industry with around 3000 drug companies and having over 10,500 manufacturing units, is a major contributor to the global pharmaceutical supply. Our team looked at what measures the industry should consider to avert such accidents in future.

The US National Institutes of Health (NIH), on April 29, unveiled a new initiative aimed at enhancing innovative, human-centred science while decreasing the use of animals in research. At the same time, the European Medicines Agency (EMA) has published a new draft document detailing non-animal replacement tests that producers can implement to eradicate animal usage in drug testing. Considering these advancements on a global scale, we examined India's position and discovered that Indian regulatory agencies are still exploring methods to enhance the implementation of non-animal testing techniques in laboratories nationwide, recognising that the total removal of animal models might not be a practical approach.

Recent technological progress in manipulating the realm of the ultra-small, achieved over the last few decades, has led to the emergence of a domain known as “Quantum Sensing.” Quantum sensors are extremely sensitive instruments, able to sense the weakest biological signals—whether they are magnetic, electric, thermal, or mechanical. They might facilitate transformative applications in real-time diagnostics by identifying or quantifying phenomena within individual cells that were previously unobservable. A specialist, in a piece, has emphasised that through mission-focused investment, integrated infrastructure, and a flourishing innovation ecosystem, quantum sensing could emerge as a transformative opportunity to fundamentally reshape diagnostics and treatment

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

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

Can Policy Reforms & Investments Trigger India's MedTech MAKEOVER?

India's MedTech sector has long been import-dependent. The Centre is now working to change this by positioning the country as an export-oriented manufacturing hub. A series of policies and investments have been introduced to support this shift. Have these made an impact? What steps are necessary to strengthen India's position in the global medical technology (MedTech) landscape? Let's find out.

Neeraj Nitin Jadhav,
Senior Industry Analyst & Team Lead, TechVision, Frost & Sullivan

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How to structure an academic programme to make Indian pharmacists reach global stage- a perspective by Dr Akram Ahmad, CEO & Founder, Academically Global.

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Pankaj Chandna, Co-Founder, Vaidam Health shares his views on the Top Destinations for Medical Tourism in 2025.

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Rising Threat of Substandard Chemo Drugs

A research study has uncovered alarming evidence of substandard chemotherapy drugs, putting cancer patients at risk of ineffective treatment in nearly 100 countries. The Bureau of Investigative Journalism (TBIJ) investigated the matter by speaking with doctors in several countries and reporting on testing the drug samples.

The findings of the study are deeply troubling. Many patients are not responding to treatment as expected. In some other cases the patients experienced severe side effects so toxic that they could no longer tolerate the medicine, doctors have observed. These drugs are the vital components of chemotherapy treatment plans for numerous types of cancers. They are used around the world.

A landmark study published in the Lancet Global Health last month examined the amount of active ingredient in seven common types of cancer drugs, which are classed as essential medicines by the World Health Organisation (WHO). The samples of the seven drugs were collected for the study covertly and overtly between April 2023 and February 2024 from 12 hospitals and 25 private or community pharmacies in African countries of Ethiopia, Kenya, Malawi, and Cameroon.

Examination of the samples revealed that out of 189 samples, about one-fifth, consisting of 20 brands of generic drugs made by 17 manufacturers, failed the quality test. Most of the sub-standard samples contained less than 88 per cent of the active ingredient stated on the label. In some cases, the opposite problem of over-concentration was observed with more than 112 per cent of the active ingredient. Both scenarios are dangerous in chemotherapy, where accurate dosing is critical. Less reduces effectiveness, and too much can lead to severe toxicity.

What's most alarming is the global distribution of these drugs. Over the past six years, they have been exported to more than 100 countries, ranging from low-income to high-income nations. Manufacturers often argue that poor storage conditions, particularly temperature sensitivity, might affect the quality. However, drug regulators in importing countries are responsible for testing and verifying product efficacy. Unfortunately, many low-income nations lack the infrastructure and resources to carry out such quality control effectively.

Cancer remains a major health burden, claiming around 10 million lives annually. In regions like Sub-Saharan Africa, the number of cancer cases has doubled over the past three decades. With high costs for branded medication, generic drugs are a crucial alternative. India is linked to this whole issue since the names of some Indian pharma companies have been revealed as producers of some of these drugs. This adds to growing concerns over the quality of Indian-made medicines.

Recently, Indian media reported that only 1,700 of the country's estimated 6,000 pharmaceutical companies submitted mandatory upgradation plans to meet global standards by the May 31, 2025, deadline. The majority of the firms that have not submitted plans are from the MSME sector. Going by the poor response, the government extended the deadline to December 31, 2025.

The government took a significant step to upgrade the technological capabilities of pharma companies to align with global standards. Recent incidents like cough syrups causing deaths among children or the one related to chemotherapy drugs underline the need for aligning with global standards. Hence, the Pharmaceutical department announced in March 2024 the revamped Pharmaceutical Technology Upgradation Assistance (RPTUAS) scheme. The pharma firms were to submit their plans for upgradation by May 31. Due to the very encouraging response, the deadline is extended.

The pharma producing firms will have to take the issues related to safe and effective drugs seriously and adopt GMPs to avoid any dent globally to their reputation. India is a hub for producing generic drugs, giving it the identity as the Pharmacy of the World. Generic drugs have a huge market potential due to their low price. Thus, Indian pharma companies have good market potential. But they will have to stick to globally accepted GMPs to tap and exploit that potential. BS

Dr Milind Kokje
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Cabinet approves Research Development and Innovation (RDI) scheme with corpus of Rs 1 lakh crore

In a transformative step to bolster India's research and innovation ecosystem, the Union Cabinet, chaired by Prime Minister Narendra Modi, has approved the Research Development and Innovation (RDI) Scheme with a corpus of Rs one lakh crore. Recognising the critical role that the private sector plays in driving innovation and commercialising research the RDI Scheme aims to provide long-term financing or refinancing with long tenors at low or nil interest rates to spur private sector investment in RDI.

The scheme has been designed to overcome the constraints and challenges in funding of the private sector and seeks to provide growth & risk capital to sunrise and strategic sectors to facilitate innovation, promote adoption of technology and enhance competitiveness. The Governing Board of Anusandhan National Research Foundation (ANRF), chaired by the Prime Minister, will provide overarching strategic direction to the RDI Scheme. The Executive Council (EC) of ANRF will approve the Scheme's guidelines, and recommend 2nd level fund managers and scope and type of projects in sunrise sectors.

Centre announces launch of Phenome India "National Biobank"

Union Minister of State (Independent Charge) for Science & Technology (S & T) and Vice President of CSIR, Dr Jitendra Singh, inaugurated the state-of-the-art Phenome India "National Biobank" at the CSIR-Institute of Genomics and Integrative Biology (IGIB), New Delhi. The newly launched facility marks a significant stride towards building India's own longitudinal health database and enabling personalised treatment regimens in future. The Biobank will serve as the backbone of a nationwide cohort study, collecting comprehensive genomic, lifestyle, and clinical data from 10,000 individuals across India. Drawing inspiration from the UK Biobank model, the Indian version is tailored to capture the country's unique diversity, across geography, ethnicity, and socio-economic backgrounds. Researchers believe the initiative will aid early diagnosis, improve therapeutic targeting, and bolster the fight against complex diseases such as diabetes, cancer, cardiovascular ailments, and rare genetic disorders. The Phenome India Project, under which the Biobank has been launched, is designed to be a long-term, data-rich study tracking the health trajectories of individuals over several years. It will help scientists uncover disease patterns, gene-environment interactions, and response to therapies, all within the Indian context.

Punjab launches Data Intelligence & Technical Support Unit to strengthen fight against drugs

In a decisive step towards combating drugs and substance abuse, the Government of Punjab has launched the Data Intelligence and Technical Support Unit (DITSU) - a pioneering initiative under its flagship campaign Yudh Nasheyan Virudh (War Against Drugs). This first-of-its-kind public-private collaboration is supported by the Ananya Birla Foundation (ABF) and is poised to drive systemic, data-driven reforms to create a drug-free Punjab. DITSU will serve as the state's central technical and data insights hub, enabling the development of evidence-based policies, strategic interventions, and improved coordination across enforcement agencies, healthcare systems, and community-based organisations. The unit will be headquartered at the Dr. B.R. Ambedkar State Institute of Medical Sciences, Mohali.

Torrent Pharma buys controlling stake in JB Pharma from KKR for Rs 25,689 Cr valuation

Ahmedabad-based Torrent Pharmaceuticals and global investment firm KKR have announced that Torrent has entered into definitive agreements to acquire controlling stake in Mumbai-based J. B. Chemicals and Pharmaceuticals (JB Pharma) from KKR at an Equity Valuation of Rs 25,689 crore (on fully diluted basis), followed by a merger of the two entities. The transaction marks a significant step in Torrent's ambition to create a future-ready, diversified healthcare platform combining a deep chronic segment heritage with emerging international contract development and manufacturing organisation (CDMO) capabilities. The transaction will be executed in 2 phases: (1) Acquisition of 46.39 per cent equity stake (on a fully diluted basis) through a Share Purchase Agreement (SPA) at a consideration of Rs 11,917 crore (Rs 1,600 per share) followed by a mandatory open offer to acquire up to 26 per cent of JB Pharma shares from public shareholders at an open offer price of Rs 1,639.18 per share; (2) Merger between Torrent and JB Pharma through a scheme of arrangement.

Piramal Pharma Solutions breaks ground on $90 M expansion plan in US

Piramal Pharma Solutions, a leading global Contract Development and Manufacturing Organisation (CDMO) and part of Mumbai-based Piramal Pharma Ltd., recently announced a $90 million investment plan to expand two of its US facilities, which are critical to its integrated offering. The two sites involved in the expansion are Riverview in Michigan and Lexington in Kentucky. The Riverview site provides comprehensive drug substance development and manufacturing services, including specialised solutions for high potency APIs (HPAPIs). This facility is a vital element of ADCelerate, supplying the payload-linkers essential to the overall safety, stability, and efficacy of ADC therapies. The expansion will add a commercial-scale suite specifically designed for the development and manufacturing of payload-linkers, which is expected to be operational by the end of 2025. While the Lexington site is Piramal Pharma's dedicated fill/finish facility, specialising in sterile compounding, liquid filling, and lyophilization for sterile injectable drug products.

Kashmik Formulation to expand capacity, eyes Rs 100 Cr revenue in FY26

Kashmik Formulation, a pharmaceutical manufacturing company headquartered in Ahmedabad, has announced significant expansion plans aimed at increasing production capacity, strengthening its presence in international markets, and enhancing operational efficiencies through automation. The company has also set an ambitious revenue target of Rs 100 crore for the financial year 2025–26, following a 100 per cent year-on-year growth from Rs 20 crore to Rs 40 crore in FY24–25. Currently operating at

full capacity with a daily output of 1 crore tablets, the company is planning to undertake a 50 per cent capacity enhancement to scale up production to 1.5 crore tablets per day. An investment of approximately Rs 20 crore will be allocated towards this expansion, with infrastructure development already underway to support the planned growth. The company is in the process of registering its products in several semi-regulated international markets, including Myanmar, Latin America, and select African countries. Further, the company is investing Rs 4–5 crore in the automation of its packaging operations, to enhance productivity and ensure compliance with evolving industry standards.

Rubicon Research completes acquisition of Alkem's Pithampur unit for Rs 149 Cr

Rubicon Research has completed the acquisition of Alkem Laboratories' formulations manufacturing facility in Pithampur, Madhya Pradesh in an all-cash deal for Rs 149 crore. The acquired facility, located in the Special Economic Zone at Pithampur, Madhya Pradesh, is equipped to manufacture steroids, hormones, and high-potency products, including immunosuppressants and oncology medications. The facility was inspected by the US Food and Drug Administration (US FDA) in 2022. With a built-up area of more than 16,000 sq. m. and total plot area of more than 1,25,000 sq. m., the site has potential for future expansion. Besides capacity expansion, the addition of a third formulation manufacturing location strengthens Rubicon's supply chain and adds new manufacturing capabilities for Rubicon in segments like steroids, hormones, and high-potency products.

Suraksha Diagnostics injects Rs 22 Cr to establish Eastern India's largest genomics lab

Suraksha Diagnostics, one of the leading diagnostics chains in Eastern India, has launched one of the largest and a state-of-the-art genomics lab in Eastern India. The company has invested Rs 22 crore in establishing its Genomics Lab. An additional Rs 46 crore investment is planned over the next 24 months to establish one of Asia's most advanced Genomics Laboratories. This initiative is a significant leap forward for West Bengal, Eastern & North-Eastern India, and India's future in precision diagnostics. This State-of-the-Art Genomics Lab is equipped with Cytogenetics, Microarray Technology, Sanger Sequencing, Multiple Next-Generation Sequencers (NGS). Together, these technologies enable the full spectrum of advanced genetic testing, offering predictive, preventive, and personalised care. Suraksha's Genomics Lab enables the detection of chromosomal abnormalities like Down syndrome, Edwards syndrome, & Patau syndrome, as well as sex chromosome aneuploidies & microdeletions.

AstraZeneca invests Rs 166 Cr to expand Global Hub in Bengaluru

AstraZeneca, a global, science-led biopharmaceutical company, has announced the expansion of its state-of-the-art Global Hub in Bengaluru, strengthening its presence in India. The new facility will house nearly 1300 employees, including 400 new jobs, supporting the company's capabilities in artificial intelligence (AI)-powered innovation across Research and Development, Global Business Services, IT, and Digital Health operations. This announcement represents AstraZeneca's second major investment in India within a year, following the expansion of its Global Innovation and Technology Centre (GITC) in Chennai. The combined workforce now at AstraZeneca India Private Limited (AZIPL) will reach close to 4,000 employees, strengthening the company's capability to deliver life-changing medicines to patients worldwide. The new facility will serve as a dynamic hub dedicated to advancing AstraZeneca's critical priorities: Advanced clinical research supporting AstraZeneca's global therapeutic areas; Development of AI-powered healthcare solutions and digital health technologies; Centralised data analytics to enhance clinical trial efficiency and patient outcomes; Specialised support for global regulatory compliance and pharmacovigilance.

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4. MedTech Centre by BIRAC under BioNEST
5. Branding/ Networking (Events & Workshops)
6. IP Facilitation
7. Mentorship

Incubatees

Inhouse Incubatees	111
Graduate Incubatees	55
Associate Incubatees	51
Idea2PoC Grantees	26
IP Facilitated	71
Employment Generated	3000
Products Launched	45

Infrastructure


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Bench space Incubation

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OMRON and Tricog Health launch KeeboHealth to combat India's cardiac crisis

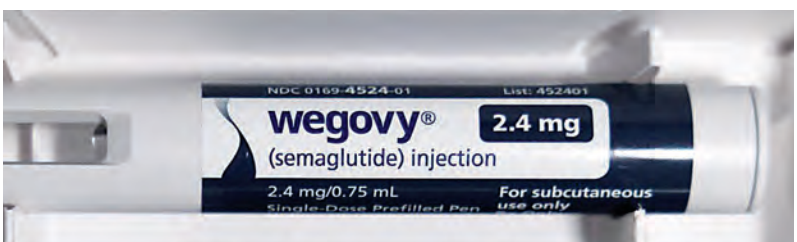
OMRON Healthcare, a global leader in innovative home health monitoring solutions, has expanded its collaboration with Tricog Health, an AI-driven cardiac care company, to launch KeeboHealth- an advanced connected health platform designed to transform remote cardiac care and accelerate progress toward OMRON's ambitious 'Going for Zero' vision - a world with zero cardiovascular events. OMRON's 'Going for Zero' vision represents its commitment to eliminating heart attacks and strokes through early detection, proactive monitoring, and patient-centric interventions. The integration of KeeboHealth into this vision is a significant milestone, combining Tricog's cutting-edge AI capabilities and clinical expertise with OMRON's trusted home health devices and global reach. OMRON and Tricog plan to expand KeeboHealth widely across India in 2025, marking a paradigm shift in remote cardiac care. The combined expertise of both organisations promises a scalable, cost-effective solution that brings proactive, personalised heart health management to patients worldwide, propelling OMRON's mission of Going for Zero.

Bharat Biotech to reduce cost of malaria vaccine RTS,S to less than $5

Hyderabad-based Bharat Biotech International Limited (BBIL) and GSK plc have announced their commitment to Gavi, the Vaccine Alliance (Gavi), in the continued roll out of the world's first malaria vaccine. Bharat Biotech will be reducing the price of RTS.S, developed by GSK, PATH and partners, by more than half, to less than $5 progressively by 2028. This price reduction is driven by process improvements, expanded production capacity, cost-effective manufacturing, and minimal profit margins. The announcement forms part of pledges to Gavi for its next replenishment phase (Gavi 6.0, 2026-2030) by both companies. RTS,S was the first malaria vaccine recommended by the World Health Organization (WHO) in 2021. Since then, GSK has made significant investments to enhance production capacity and efficiency, and to undertake the planned technology transfer to Bharat Biotech. In parallel, Bharat Biotech has invested over $200 million in new, higher- output manufacturing facilities, product development and technology transfers.

Novo Nordisk launches injectable Semaglutide for weight management in India

Novo Nordisk, a leading global healthcare company headquartered in Denmark with over a 100-year legacy of chronic disease care, has announced the launch of Wegovy (injectable Semaglutide) in India. Wegovy, a once-weekly glucagon-like peptide-1 receptor agonist (GLP-1 RA), is the first and only weight management medication in India indicated for both long-term chronic weight management and reduction in risk of major adverse cardiovascular events in people living with the condition. It is available in five dosing strengths with the convenience of an innovative easy-to-use pen device. It is a prescription-only medication that has the potential to improve the quality of life for millions of Indians living with obesity or being overweight. As per the INDIAB study, India has 254 million people with generalised obesity and 351 people with abdominal obesity. Semaglutide is the active ingredient in both Ozempic and Wegovy.



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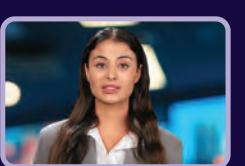

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GTT Data AI Accelerator Network to empower startups in healthcare and life sciences

GTT Data Solutions, a BSE-listed technology enabler known for its Dual Intelligence framework that blends human expertise with advanced artificial intelligence (AI), has launched GAIN (GTT Data AI Accelerator Network), a platform designed to support over 100 AI startups across industries, including a sharp focus on healthcare and life sciences. GAIN aims to fast-track innovation in AI-powered medical imaging, predictive diagnostics, hospital automation, and more, by providing selected startups with mentorship, go-to-market enablement, and potential funding support from partners such as Sangli Miraj Commercial Ventures. As part of the healthcare vertical, GTT Data is keen to help startups develop and scale AI tools that improve diagnosis accuracy, enhance clinical workflows, and support value-based care models.

LogicFlo AI gets $2.7 M to scale AI agent workforce across global life sciences enterprises

Chennai-based startup LogicFlo AI, an artificial intelligence (AI) platform designed specifically for the life sciences sector, has raised $2.7 million in a seed round led by Lightspeed, with participation from leading healthcare and enterprise AI investors. The funding will support LogicFlo AI's global expansion across pharmaceutical, biotech, and medtech organisations, and enable deeper deployment with global clients, including a Fortune 500 company already under contract. The company is redefining how regulated scientific work is done by replacing fragmented tools and repetitive processes with intelligent AI agents that work under human guidance. Across regulatory affairs, medical writing, quality assurance, and medical information teams, LogicFlo AI enables experts to complete high-compliance workflows in a fraction of the time, without sacrificing accuracy or oversight. With the new funding, LogicFlo AI will accelerate product development, expand integrations with life sciences systems like Veeva and IQVIA, and grow its go-to-market and technical teams to meet rising industry demand.

Lamark Biotech secures Rs 6.5 Cr to accelerate development of thermostable insulin

Lamark Biotech, an innovation-led biopharma startup, has raised Rs 6.5 crore in a Pre-Series A round led by IAN Group, including IAN Alpha Fund, powered by BioAngels, Dr Vinayender Tulla, Dr Nita Roy, and Venkataraman KNK, domain experts of IAN's angel investors led the round. The startup's proprietary ProteoStrong platform enables the stabilisation of fragile protein-based drugs, such as insulin, monoclonal antibodies, and enzymes, without altering their molecular structure.

Lamark addresses a critical gap in the biologics ecosystem, reducing the cold-chain dependency. The Ahmedabad-headquartered startup, leveraging R&D base of Venture Center, NCL-innovation park in Pune, is advancing a new class of temperature-resilient biologics that retain potency across extreme conditions, ideal for underserved regions where cold storage infrastructure is limited. With its lead programme, InsulinStrong, Lamark is targeting the Rs 4,000 crore worth Indian insulin market and intends to expand across Southeast Asia and the UAE, expanding its platform into diabetic eye disease and cancer immunotherapy.

WHO launches bold push to raise health taxes and save millions of lives

The World Health Organization (WHO) has launched a major new initiative urging countries to raise real prices on tobacco, alcohol, and sugary drinks by at least 50 per cent by 2035 through health taxes in a move designed to curb chronic diseases and generate critical public revenue. The "3 by 35" Initiative comes at a time when health systems are under enormous strain from rising noncommunicable diseases (NCDs), shrinking development aid and growing public debt. The consumption of tobacco, alcohol, and sugary drinks are fuelling the NCD epidemic. NCDs, including heart disease, cancer, and diabetes, account for over 75 per cent of all deaths worldwide. A recent report shows that a one-time 50 per cent price increase on these products could prevent 50 million premature deaths over the next 50 years. The Initiative has an ambitious but achievable goal of raising $1 trillion over the next 10 years. Between 2012 and 2022, nearly 140 countries raised tobacco taxes, which resulted in an increase of real prices by over 50 per cent on average, showing that large-scale change is possible. From Colombia to South Africa, governments that have introduced health taxes have seen reduced consumption and increased revenue.

WHO certifies Suriname malaria-free

Suriname became the first country in the Amazon region to receive malaria-free certification from the World Health Organization (WHO). This historic milestone follows nearly 70 years of commitment by the government and people of Suriname to eliminate the disease across its vast rainforests and diverse communities.

With this announcement, a total of 46 countries and 1 territory have been certified as malaria-free by WHO, including 12 countries in the Region of the Americas. Certification of malaria elimination is granted by WHO when a country has proven, beyond reasonable doubt, that the chain of indigenous transmission has been interrupted nationwide for at least the previous three consecutive years. Suriname's malaria control efforts began in the 1950s in the country's densely-populated coastal areas, relying heavily on indoor spraying with the pesticide DDT and antimalarial treatment. By the 1960s, the coastal areas had become malaria-free and attention turned towards the country's forested interior, home to diverse indigenous and tribal communities. The government of Suriname has shown strong commitment to malaria elimination, including through the National Malaria Elimination Taskforce, Malaria Program, Malaria Elimination Fund, and cross-border collaboration with Brazil, Guyana and French Guiana.

WHO highlights risks associated with use of semaglutide medicines

The World Health Organisation (WHO) is alerting healthcare professionals and regulatory authorities to the risk of non-arteritic anterior ischemic optic neuropathy (NAION) associated with the use of semaglutide medicines—Ozempic, Rybelsus, and Wegovy. The European Medicines Agency (EMA) has recommended updating the product information for these medicines to include NAION as a side effect, with a frequency classified as very rare. Semaglutide, a glucagon-like peptide-1 receptor agonist (GLP-1RA), is the active ingredient in medications used to treat type 2 diabetes and obesity. NAION is a leading cause of vision loss in adults and the second most common optic neuropathy after glaucoma. It typically presents as sudden, painless, monocular vision loss accompanied by optic disc edema. The vision loss is generally irreversible, and there is currently no effective treatment available. WHO is issuing this safety alert due to the widespread global use of semaglutide and the serious nature of NAION.

World-first AI system to warn of NHS patient safety concerns

Patients will receive better care owing to a world-first artificial intelligence (AI) early warning system being developed to automatically identify safety concerns across the National Health Service (NHS) in England, helping stop failures before they escalate. It follows a pledge by the Health and Social Care Secretary to overhaul health and care regulation, root out poor performance and guarantee patients safe, quality care. There have been growing concerns about safety in the NHS in recent years after a spate of scandals, including in mental health and maternity services. The new safety warning system, being developed as part of the government's 10 Year Health Plan, will rapidly analyse healthcare data and ring the alarm bell on emerging safety issues. Work on rolling out the system is already underway. A new maternity outcomes signal system will launch across NHS trusts from November, using near real-time data to flag higher than expected rates of stillbirth, neonatal death and brain injury.

World leaders recommit to immunisation amid global funding shortfall

At the recently held Global Summit: Health and Prosperity through Immunisation in Brussels, world leaders have pledged support for Gavi, the Vaccine Alliance, leading to a total of more than $9 billion secured against a targeted $11.9 billion budget for its next five-year strategic period from 2026 to 2030 (Gavi 6.0). Additional donor commitments are expected in the coming months. The Summit also resulted in $4.5 billion in complementary financing unlocked from development finance institutions, up to $200 million in cost savings for Gavi-supported programmes announced by vaccine manufacturers – alongside other innovation and supply commitments that will further boost equitable access to critical vaccines, and a range of private sector partnerships aimed at transforming immunisation systems in lower-income countries, including a $40 million anchor commitment towards a new Innovation Scale-Up Fund. These commitments bring Gavi a major step closer to securing the resources it needs for Gavi 6.0, in which it hopes to protect 500 million children from preventable disease, averting between 8-9 million future deaths, protecting the world from deadly outbreaks of diseases such as cholera, mpox and Ebola through its vaccine stockpiles and unlocking $100 billion in economic benefits for countries.

PAHO and SEGIB strengthen partnership for healthier Ibero-America

The Director of the Pan American Health Organisation (PAHO), Dr Jarbas Barbosa, and the Secretary-General of the Ibero-American General Secretariat (SEGIB), Andrés Allamand, have reaffirmed their joint commitment to advancing a more inclusive, equitable, and healthier Ibero-America. The two institutions signed a new Memorandum of Understanding (MoU) to strengthen and expand their collaboration in key areas, including the elimination of congenital Chagas transmission, road safety, care for persons with disabilities, mental health of adolescents and youth, and South-South cooperation. Both organisations have also expressed interest in including specific health issues as a way to strengthen collaboration among countries, address shared challenges, and promote sustainable development across the region.

Africa unites to take stock of Neglected Tropical Diseases burden

Fifty African Union Member States have endorsed a ground-breaking digital micro-planning portal co-created by Africa Centres for Disease Control and Prevention (Africa CDC) to accelerate the elimination of Neglected Tropical Diseases, a diverse group of infectious diseases that primarily affect impoverished communities in tropical and subtropical areas. This innovative platform developed with inputs from Member States, World Health Organization (WHO), END Fund, and other technical partners will track resource utilisation, advocate for sustainable financing and domestic resource mobilisation, and drive Africa-owned solutions to end these diseases of poverty by 2030. Each Member State shared a country-specific micro-plan for the top six high-burden NTDs guided by existing national Masterplans. This continental NTD microplanning workshop occurred in the context of the recent reduction in funding from key global partners, which has disrupted essential NTD programmes and exposed the vulnerabilities in current financing models.

US FDA determines safety and effectiveness of immunotherapies

The US Food and Drug Administration (FDA) has eliminated the Risk Evaluation and Mitigation Strategies (REMS) for currently approved BCMA- and CD19-directed autologous chimeric antigen receptor CAR T cell immunotherapies. These products are gene therapies that are currently approved to treat blood cancers, such as multiple myeloma and certain types of leukaemia and lymphoma. A REMS is a safety programme that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The FDA determined that the approved REMS for the following products should be eliminated because a REMS is no longer necessary to ensure that the benefits of the autologous CAR T cell immunotherapies outweigh their risks- Abecma (idecabtagene vicleucel); Breyanzi (lisocabtagene maraleucel); Carvykti (ciltacabtagene autoleucel); Kymriah (tisagenlecleucel); Tecartus (brexucabtagene autoleucel); and Yescarta (axicabtagene ciloleucel).

Pioneering research to develop all-in-one vaccine against deadly diseases

Scientists at Denmark's AdaptVac will lead the development of a new vaccine that could provide all-in-one protection against multiple deadly viruses including Ebolavirus Zaire, Sudan Ebolavirus and Marburg, all of which cause frequent unpredictable outbreaks in regions of Africa, with significant health and societal impacts and fatality rates of up to 90 per cent. Backed by $12.4 million of funding from Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) and the European Union's Horizon Europe programme, a global consortium led by AdaptVac aims to design and test a new vaccine that could offer broad protection against several filoviruses. Such a vaccine could be used to protect high risk populations, such as health workers, in areas where filovirus outbreaks are most prevalent, primarily in Central and East Africa.

Can Policy Reforms & Investments Trigger India's MedTech MAKEOVER?

India's MedTech sector has long been import-dependent. The Centre is now working to change this by positioning the country as an export-oriented manufacturing hub. A series of policies and investments have been introduced to support this shift. Have these made an impact? What steps are necessary to strengthen India's position in the global medical technology (MedTech) landscape? Let's find out.

India stands as the fourth-largest medical devices market in Asia, trailing only Japan, China, and South Korea, and is counted among the top 20 markets worldwide. The sector is broadly categorised into five key segments: electronic equipment (56 per cent), disposables and consumables (26.5 per cent), in-vitro diagnostics (8.1 per cent), implants (7.1 per cent), and surgical instruments (2.3 per cent). (Source: Invest India)

Most domestic manufacturers are concentrated in the disposables and consumables segment, primarily serving local demand. In contrast, high-end categories such as electronic equipment remain dominated by multinational companies. The domestic industry comprises around 800 manufacturers, with production still focused on a limited set of product areas.

In 2023–24, India's medical device exports crossed $4 billion, which is an impressive number on its own, but compared to imports which stood at nearly double, at $8.1 billion, it highlights the country's continued reliance on foreign medical technologies, with nearly 80 per cent of its medical device requirements still met through imports. To address this imbalance and expand domestic manufacturing capacity, the government has set a goal to reduce import dependence to below 50 per cent over the next five years and has announced a slew of initiatives, investments, and incentives.

Government Initiatives: Have they moved the needle?

The government is pushing to transform the MedTech sector through policy reforms and targeted financial incentives, aiming to build self-reliance, drive innovation, and boost global competitiveness. This shift gained momentum in 2023 with the launch of the National Medical Devices Policy, which aims to position India as a global manufacturing and innovation hub. The policy sets ambitious goals: expanding India's global market share in medical devices from less than 2 per cent to 10–12 per cent over the next 25 years, and growing the domestic market from $11 billion to $50 billion by 2030.

To complement manufacturing with innovation, the government launched the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme in August 2023. With a total budget of Rs 5,000 crore, Rs 4,250 crore of which is dedicated to building the R&D ecosystem. PRIP seeks to transform India into a global R&D hub for medical devices and pharmaceuticals. To guide implementation, an industry dialogue was held in Mumbai in March 2025, involving stakeholders such as the Indian Council of Medical Research (ICMR), the Council of Scientific & Industrial Research (CSIR), the National Institutes of Pharmaceutical Education and Research (NIPERs),

regulatory bodies, and industry associations. The Expression of Interest (EoI) portal opened shortly thereafter, accepting proposals until April 7, 2025.

In 2023, the government also launched MedTech Mitra, a strategic initiative designed to support MedTech startups and companies through clinical evaluation, regulatory facilitation, and new product adoption, providing end-to-end handholding from development to market entry.

To boost local manufacturing, the government launched the Production Linked Incentive (PLI) Scheme for Medical Devices in 2020–21, with a financial outlay of Rs 3,420 crore and a timeline extending to 2027–28. The scheme offers 5 per cent incentives on incremental sales of domestically manufactured devices across four high-value categories: radiotherapy and imaging equipment, anaesthesia devices, cardio-respiratory and critical care equipment, and implants. So far, 19 greenfield projects have been commissioned, leading to the local production of 44 devices—including MRI machines, CT scanners, mammography systems, C-arms, and ultrasound machines—that were previously imported. As of September 2024, cumulative sales by participating companies have reached Rs 8,039.63 crore, including exports worth Rs 3,844.01 crore.

In 2024, the Government of India has launched a Rs 500 crore scheme to boost domestic medical device manufacturing through five targeted sub-schemes: Rs 110 crore for common infrastructure like R&D labs and testing centres; Rs 180 crore for 10–20 per cent capital subsidies to support local production of components; Rs 100 crore for capacity building through Master's programmes and vocational training; Rs 100 crore for clinical studies including animal trials, human trials, and diagnostic evaluations; and Rs 10 crore to support industry associations in promoting MedTech innovation.

These efforts appear to be gaining traction. A key milestone was India's entry into the International Medical Device Regulators Forum (IMDRF), signalling the country's commitment to aligning with global quality and regulatory standards and paving the way for greater international collaboration. This growing credibility has been matched by rising investor interest. By August 2024, India's MedTech sector had attracted over $1.2 billion in private equity and venture capital, the highest in five years. Foreign direct investment has also gained momentum. In just the first half of FY 2023–24, FDI stood at $425 million, reflecting growing confidence in the sector's long-term potential.

But the question is, have these initiatives truly moved the needle? Experts believe that while these are welcome developments, the on-ground reality is more nuanced.

"India's push for a self-sufficient medical device industry, through initiatives like PLI and medical device parks, has shown promise but delivered limited ground-level results so far, especially for domestic manufacturers in low-margin sectors where we are usually not competitive with China. While the PLI has spurred investment in certain high-end areas, its overall impact remains narrow, with very few projects sanctioned and disbursed," said Rajiv Nath, Managing Director, Hindustan Syringes & Medical Devices Ltd & Forum Coordinator, Association of Indian Manufacturers of Medical Devices (AiMeD).

Similarly, the Marginal Investment Scheme, Clinical Performance Scheme, Common Infrastructure Scheme, and Skilling Scheme announced by the Department of Pharmaceuticals in November 2023 are yet to gain meaningful traction. "These schemes need faster implementation to improve manufacturers' competitiveness. While policy intent is strong and some progress has been made, India's MedTech sector needs more consistent execution, wider participation, and accelerated infrastructure development to truly unlock its global potential," added Nath.

According to a white paper by AiMeD and Consocia Advisory, developing high-end medical equipment requires substantial investment in R&D, testing, and clinical validation. At present, Indian manufacturers face both financial and bureaucratic hurdles in these areas. Government schemes like the PLI programme exist, but smaller companies often struggle to access the benefits due to complex application procedures and delays in disbursement. There are also limited targeted research grants or tax incentives specifically designed for critical care devices. Without strong policy support for innovation, such as grants for designing next-generation ventilators or funding to upgrade manufacturing capabilities, domestic firms risk falling behind global competitors. While initiatives like the India AI Mission have received Rs 10,000 crore in structured government support, the MedTech sector's PRIP scheme has been allocated only Rs 5,000 crore, which experts argue is disproportionately low given the sector's potential and its critical role in healthcare innovation and national preparedness.

Inside the MedTech Parks: Are they delivering?

India is steadily building a network of medical

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device parks to support domestic manufacturing, R&D, and innovation in the MedTech sector. Under the Rs 400 crore 'Promotion of Medical Devices Parks' scheme (2020–2025), four states—Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh have received approvals of Rs 100 crore each. Separately, the Department of Pharmaceuticals has also supported a superconducting magnet testing facility at AMTZ, Andhra Pradesh, under a common facility scheme.

The Andhra Pradesh MedTech Zone (AMTZ) in Visakhapatnam, launched in 2016, is fully operational and hosts over 100 companies focused on R&D and manufacturing. Hyderabad's Medical Devices Park, active since 2017, houses over 50 firms making devices ranging from imaging systems to ICU and home-use equipment. Other key parks are under development: Solan (Himachal Pradesh) is focusing on radiology and implants; Gautam Buddh Nagar (Uttar Pradesh) is attracting IVD and diagnostic manufacturers; and Kancheepuram (Tamil Nadu) has received 28 investment proposals to produce stents, implants, and diagnostics. Ujjain (Madhya Pradesh) is targeting high-risk devices, while MedSpark in Thiruvananthapuram (Kerala) is being developed as a hub for manufacturing, research, and training. New parks are also planned in Rajkot (Gujarat) and Panipat (Haryana), featuring proposed testing labs, centres of excellence, and R&D facilities.

Together, these parks are expected to enhance India's MedTech infrastructure, although several remain in various stages of development and await full operationalisation.

India's MedTech infrastructure

Development Status	District / City	State	Park Name / Focus Areas	Companies /Activity
Operational (2016)	Visakhapatnam	Andhra Pradesh	AMTZ (Andhra Pradesh MedTech Zone)	100+ companies in R&D and production
Operational (2017)	Hyderabad	Telangana	- Medical electronics: ultrasound, C-arm, X-ray, lab analysers - Home devices: glucometer, - OT/ICU equipment, implants thermometer, oximeter	50+ companies in production
Under Development	Solan	Himachal Pradesh	- Cancer care, radiology, anaesthetics - Imaging tech, cardio-respiratory equipment - Pacemaker devices, cochlear implants	
Under Development	Gautam Buddh Nagar (Noida)	Uttar Pradesh	- Preventive, diagnostic, therapeutic devices - Application software - IVD, reagents, artificial bio-devices	Plot allotments underway
Under Development	Kancheepuram	Tamil Nadu	- Stents, implants, diagnostic devices - Rs 430 Cr investment proposals from 28 companies (as of Apr 2024)	
Under Development	Ujjain	Madhya Pradesh	- High-risk medical devices - Implants, extracorporeal devices	
Under Development	Thiruvananthapuram (MedSpark)	Kerala	- R&D, testing, manufacturing, training, and incubation	Allotments to begin in July 2025
Under Development	Rajkot	Gujarat	- Proposed CoE, R&D centres, and testing labs	
Under Development	Panipat	Haryana	- Details yet to be specified; land earmarked	

(Source: EY India MedTech Report)

"The medical device parks model, exemplified by AMTZ's success in Visakhapatnam, offers shared infrastructure and reduced capital costs but faces operational delays and inconsistent implementation across other states due to restrictive criteria and underdeveloped facilities. Improved execution and stronger coordination

between central and state policies, using AMTZ as a benchmark, are needed," said Nath.

Global giants and local players fuel MedTech manufacturing

India's 'Make in India' initiative in the MedTech sector has begun to show visible traction, with both multinational corporations and Indian companies scaling up their local manufacturing, R&D, and innovation capabilities. Several global players have expanded their operations in India, recognising its growing role in the global medical devices supply chain.

Medtronic, for instance, operates its largest R&D facility outside the United States in Hyderabad. The company has recently invested around Rs 3,000 crore to expand this facility further. The India innovation centres are not only engaged in traditional medical device development but are also focusing on building software capabilities for global product platforms.

Similarly, Siemens Healthineers—one of the approved participants under India's PLI scheme—has invested Rs 91.9 crore to manufacture CT and MRI systems at its Bengaluru plant. The company has also introduced the Multix Impact E digital radiography systems from this facility. Siemens' mobile C-arm system, Cios Fit, is fully conceptualised, designed, and manufactured in India and is now exported to over 64 countries. Additionally, the company has received approval to manufacture RT-PCR kits for mpox detection at its Vadodara site.

Philips Healthcare has also ramped up its 'Make in India' efforts. Over the past few years, the company has cumulatively invested around Rs 750 crore, including Rs 350 crore recently allocated to a new 300,000 sq ft R&D facility in Pune. This facility will focus on imaging and image-guided therapy technologies for global markets. The Pune centre already serves as a global hub for mobile surgery, exporting devices like the Zenition Mobile C-arm series to over 100 countries. In Bengaluru, Philips has invested an additional Rs 500 crore to establish its largest global innovation hub. Philips has also launched the Affiniti ultrasound machines as part of its India-made portfolio.

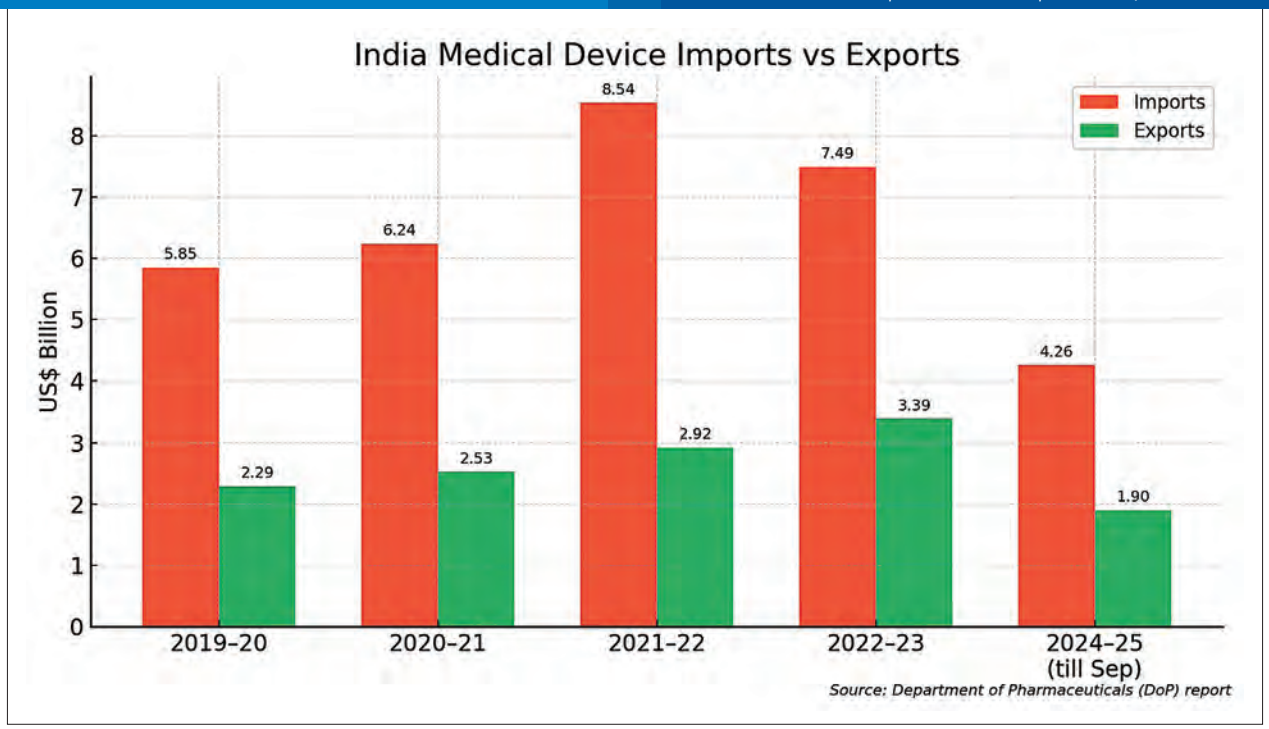
The India operation of Omron Healthcare, a japanese medtech company with $30 million in sales last year and growing at double digit has invested Rs 128 crore in its Chennai facility which is spread over 24000 square metres. The company will be rolling out about 1 million blood pressure monitors (BPM) per year from its Chennai facility with 'Made in India' log by December this year. The foundation for the facility was laid after signing the memorandum on the establishment of the factory on June 2, 2023 in the presence of M.K. Stalin, Chief Minister of the Tamil Nadu State Government.

Wipro GE Healthcare is another major player deepening its India footprint. The company recently announced a strategic investment of over Rs 8,000 crore over the next five years to enhance manufacturing capacity and R&D. This investment supports supply chain resilience and strengthens the company's role in both domestic and international markets. Products like the Made in India PET CT Discovery IQ are now exported to 15 countries. Other locally manufactured devices include the Revolution Aspire CT, Revolution ACT, and MR breast coils—all developed 'In India for the World.' The company currently operates four manufacturing plants in Bengaluru, all export-focused. The latest facility was set up in March 2022 with a Rs 100 crore investment under the PLI scheme.

Spellman, the global leader in X-ray generator production, is set to establish its first-ever manufacturing facility in India at the AMTZ, a

Innovative MedTech companies

- Agatsa has developed the world's smallest touch-based 12-lead ECG device, SanketLife
- Voxelgrids Innovations launched the country's first indigenously developed Magnetic Resonance Imaging (MRI) scanner.
- SS Innovations launched India's first mobile tele-robotic surgery unit, SSI Mantra, marking a breakthrough in the country's surgical capabilities.
- Panacea's EU and USFDA-approved Stereotactic Body Radiation Therapy (SBRT) enabled LINAC system, Siddharth II, with precise treatment delivery for multiple types of surgeries
- Piltover Technologies has developed the world's most functional mechanical prosthetic hand
- PlebC Innovations has developed a teleoperated robotic ultrasound system where radiologists can operate ultrasound from multiple centres without changing their location
- Qure.ai is leveraging deep learning algorithms to automate the interpretation of radiology exams
- Niramai is transforming breast cancer detection with its innovative, radiation-free screening method that uses AI-powered thermal imaging to enable early and precise diagnosis



significant step in enhancing the country's medical technology sector.

While multinational companies are deepening their footprint in India, local medical device manufacturers are also stepping up to reduce import dependence and drive indigenous innovation. Several Indian firms are now focusing on developing complex, high-end equipment that is traditionally imported.

In 2024, Meril inaugurated new manufacturing facilities under the PLI scheme and signed an MoU with the Gujarat government to invest Rs 910 crore. The company has already invested over Rs 1,400 crore in the MedTech sector. This expansion is expected to create 5,000 jobs and reduce imports of critical devices.

Efforts are also underway in the public sector and academia to accelerate the development of indigenous high-end technologies. The All India Institute of Medical Sciences (AIIMS), New Delhi, recently announced plans to install the country's first indigenously developed 1.5 Tesla MRI machine by October 2025. The project is being executed in partnership with the Society for Applied Microwave Electronic Engineering and Research (SAMEER), an autonomous institution under the Ministry of Electronics and Information Technology.

IIT Kanpur is developing Hridayantra, India's first indigenously designed left ventricular assist device (LVAD), aimed at helping patients with advanced heart failure. The implantable mechanical pump is expected to last 10–12 years and cost significantly less, Rs 10–15 lakh, compared to the global price of Rs 70–80 lakh.

Bengaluru-based Voxelgrids Innovations, India's first and only manufacturer of MRI scanners, has received regulatory approval and launched the country's first indigenously developed Magnetic Resonance Imaging (MRI) scanner.

SS Innovations, based in Gurugram, recently launched India's first mobile tele-robotic surgery unit, SSI Mantra, marking a breakthrough in the country's surgical capabilities.

Innovation is also being backed by institutional support. The Technology Development Board (TDB), under the Department of Science and Technology (DST), has extended financial support to Mysuru-based S3V Vascular Technologies for its project on manufacturing mechanical thrombectomy kits for acute ischemic stroke treatment. This initiative positions S3V as the first Indian company to design and manufacture a full suite of neuro-intervention devices—including microcatheters, aspiration catheters, guidewires, and stent retriever systems- in a fully integrated upstream facility.

Filling the gaps

All these initiatives and investments have propelled notable growth in India's MedTech sector. However, structural challenges and limited policy support in key strategic areas continue to constrain the country's global competitiveness.

"One challenge is the regulatory framework. Some stakeholders suggest the adoption of a separate decriminalised regulatory framework and an independent regulator for medical devices, like the Food Safety and Standards Authority of India (FSSAI) in the food sector. There are views that current regulations, which link medical devices

closely with pharmaceuticals under a common Drug Law, may inhibit the independent implementation of Medical Device Rules. International guidance from the WHO and regulatory frameworks in markets such as the UK (Medicines and Healthcare products Regulatory Agency (MHRA), Canada (Health Canada), Singapore (Health Sciences Authority (HSA), and Malaysia's Medical Devices Authority are often cited as references. The umbilical cord with pharma needs to be severed, as the bias of the drug rules at times overshadows the independent implementation of the Medical Device Rules. Medical devices, while classified as medical products, differ from medicines in that they are considered engineering goods. This distinction is like the way the Air Force, Navy, and Army each require unique treatment despite all being branches of the defence forces," said Nath.

R&D in the sector is another area where India's investment remains modest compared to global standards. While policies like the PRIP scheme and the creation of Centres of Excellence represent welcome positive developments, R&D activity tends to be fragmented and mainly led by the public sector.

"In comparison, countries such as China have promoted integrated ecosystems with significant private-sector involvement and incentives for advanced medical device manufacturing," said Nath.

Manufacturing output in India is largely focused on low-value consumables and in-vitro diagnostics, with less emphasis on high-technology electronic or implantable devices. This focus limits participation in high-tech international trade.

"Some manufacturers indicate that public procurement policies sometimes favour imported products by requiring overseas regulatory approvals, potentially limiting market access for Indian producers. The few units that bravely invested need nurturing but at times they face challenges in public procurement instead of getting preference and support in pruning the paradoxical enlargement of the GTE (Global Tender Exemption) list even for those medical equipment available since long and from more than one licensed manufacturer, but also in some public tenders continue to discriminate and disallow Indian manufacturers to participate in bidding process by seeking a mandatory qualifying criteria of overseas US FDA and CE approval instead of seeking a Central Drugs Standard Control Organisation (CDSCO) manufacturing license. Some Buyers' reasoning is to filter out low-priced but low-quality Indian goods, which, in many cases, are relabelled, repackaged, and shoddy Chinese goods. For this, some manufacturers seek an amendment of labelling requirements in the Indian MDR'17 for alignment with Department for Promotion of Industry and Internal Trade - Public Procurement Order (DPITT- PPO) and Department of Pharmaceuticals (DoP)'s guidance requirements and the label to clearly state if the Manufacturer is level 1, i.e. with over 50 per cent domestic content, or level 2, with over 20 per cent domestic content or simply a Repackaging or relabelling company. This distinction will help buyers give preference to higher value-added medical devices," said Nath.

There is also discussion about the alignment of Indian certification standards, such as BIS-based CDSCO certification, with international regulatory benchmarks. The introduction of the QCI's Indian Certification of Medical Devices (ICMED) 13485 Plus aims to provide Indian manufacturers with internationally recognised quality compliance credentials. Aligning these certifications with other international certifications, such as the MDSAP and CE, is considered a possible approach for enhancing market access via mutual recognition agreements in trade negotiations.

"Some industry participants highlight the importance of a predictable nominal tariff policy to provide balanced protection for both domestic and foreign manufacturers, addressing Niti Aayog stated 15 per cent disability factors that affect the sector's competitiveness," said Nath.

India currently holds a modest 1.5 per cent share of the global medical devices market. To claim a larger share, the country has laid out an ambitious vision backed by policies, incentives, and investments. But achieving the $50 billion target and becoming Atmanirbhar will depend on sustained execution, stronger ecosystem integration, and the ability to scale both innovation and manufacturing. BS

Ayesha Siddiqui

Next-generation surgical robotics stand poised for global revolution

« **Neeraj Nitin Jadhav,** Senior Industry Analyst & Team Lead, TechVision, Frost & Sullivan

The adoption of robot-assisted surgery has increased significantly in the past decade as opportunities for performing minimally invasive procedures have multiplied. Robotic-assisted interventions as a proportion of the total number of surgeries have witnessed strong uptake among hospitals, especially in both developed and developing countries such as the United States, Japan, South Korea, China and India. Surgical robotic platforms facilitate more precise surgeries and improve the repeatability of procedural movements. These benefits support faster recovery and better outcomes for patients, which has helped drive their adoption among healthcare providers.

In spite of the many advantages, surgical robotic platforms have drawbacks. Legacy surgical robots involve a large setup that consumes significant space in the operating room. The platforms are not mobile and cannot be transferred from one room to another after installation. Moreover, the instrument setup and positioning of conventional robotic surgical arms before the procedure require considerable effort, which subsequently increases the total operation time frame. The use of rigid instruments in these traditional surgical robotic platforms becomes extremely challenging in non-linear pathways and makes it difficult to reach anatomical areas such as the brain in a minimally invasive fashion. This has spurred the development of agile and state-of-the-art next-generation surgical robotic technology platforms, which have been built with unique designs, advanced instrumentation, analytics and visualisation technologies that address the limitations of conventional surgical robotic systems.

Small footprint: Next-generation surgical robotic technology platforms have a smaller footprint that makes them easily accommodated in operating rooms without taking up much space. Moreover, these mobile platforms can be rapidly deployed in various operating rooms to facilitate higher utilisation.

Shorter setup time: The unique configuration and minimal cable management of next-generation platforms ensure quick docking and setup, resulting in shorter operating room time frames for both surgeons and patients.

Ergonomic design: The robotic platforms' console allows surgeons to be situated in an ergonomically comfortable position throughout the procedure. This helps reduce physical strain and the procedure-related burnout commonly observed among surgeons.

Multi-articulating and flexible instruments: These instruments aid in achieving optimal triangulation and easily maneuver through non-linear pathways in a patient's body to reach the target site and effectively carry out a surgical procedure in hard-to-reach areas.

Motion control and anthropomorphic movements: The platforms provide high-precision motion control and anthropomorphic movements that are nearly identical to human hand movement while performing delicate surgeries.

Haptic sensing: The ability of robotic systems to provide haptic feedback to surgeons allows them to feel the pressure/force exerted on the tissues or organs during surgery, both in and outside the field of view. Alerts are provided to surgeons if the pressure threshold is reached to prevent damage to the anatomical structures.

Multi-quadrant surgeries: The robotic systems offer a unique column architecture that facilitates its placement in any position around the patient, providing four-quadrant anatomical access to the surgical site. This enables greater accessibility to the patients' anatomy for the surgeons without the need to frequently move the robotic platform.

Open platform architecture: The open-platform architecture of these systems enables seamless integration with existing technologies in the operating room ecosystem. This allows hospitals to maximise benefit from existing capital investments while providing surgeons access to devices and instruments of their preference.

Decreasing learning curve: The time required to train surgeons on the next-generation surgical robotic systems is significantly lower compared to

conventional robotic platforms. This helps shorten the learning curve, enabling surgeons to learn the robotic-assisted procedures within days instead of months, typically required for traditional ones. Depending on the type or route of incision, the next-generation surgical robotic systems have been classified into multi-port, single-port, and robotic natural orifice surgery systems.

Multi-Port Robotic Surgery Systems: These systems typically require multiple small ports or incisions to be carried out on the patients' body to insert long surgical instruments for performing the procedures. These platforms feature haptic feedback that provide alerts to the surgeons if the pressure threshold is reached to prevent damage to the anatomical structures and deploy artificial intelligence (AI) to offer insights to the surgeons based on the accumulated procedural data.

For instance, in January 2025, SS Innovations International, Inc launched its made-in-India, Central Drugs Standard Control Organization (CDSCO) certified SSi Mantra 3 surgical robotic system (SSi Mantra 3) at Pune's Noble Hospital in India. The SSi Mantra 3 is a modular, multi-robotic arm system featuring open-faced ergonomic surgeon command center, a large 3D 4K monitor and has 40 different types of robotic endo-surgical instruments to support various specialties, including cardiac surgery.

Single-Port Robotic Systems: The procedures carried out through single-port robotic systems require a single, small incisions in the patients' body to reach target anatomical structures. The platforms provide high precision motion control and anthropomorphic movements that facilitate controlled motion and movements. The single-port robotic systems offer a unique column architecture that facilitates its placement in any position around the patient providing four-quadrant anatomical access to the surgical site. This enables greater accessibility to the patients' anatomy for the surgeons without the need to frequently move the robotic platform.

For instance, Intuitive Surgical's da Vinci SP surgical system features high precision motion control and anthropomorphic movements that allow surgeons exceptional flexibility and deep, narrow access to internal tissues and organs for performing challenging surgical tasks while filtering out tremors during instrument movements. Besides receiving US Food and Drug Administration (FDA) clearance and Conformité Européenne (CE) mark, the system has been approved for use in Japan and Korea for surgical procedures such as general surgeries, thoracic surgeries, urologic surgeries, and gynecological surgeries.

Robotic Natural Orifice Surgery Systems: The robotic natural orifice surgery systems use the body's natural orifices including mouth, anus, or vagina to perform incisionless surgery on patients. Anthropomorphic movements of the robotic arms and the use of multi-articulating and flexible instruments in these platforms aid in optimal triangulation and also enable them to circumvent non-linear pathways in the patients' body to reach the target site and effectively carry out surgical procedure in hard-to-reach areas.

Israel-based Momentis Surgical Ltd has developed the Anovo robotic surgical platform, featuring miniature humanoid shaped robotic arms with anthropomorphic movements. This helps provide multi-planar flexibility, human-level dexterity and 360 degrees of articulation for performing challenging surgical tasks and avoiding obstacles in non-linear pathways within the body. The platform has received US FDA clearance for performing natural orifice transvaginal benign gynaecology procedures and single site, abdominal access ventral hernia repair.

The Way Forward

Developers of next-generation surgical robotic systems can focus on flexible payment models, shifting from the traditional upfront capital model to a managed service wherein the robot, all required instrumentation, and maintenance are bundled into an annual contract based on agreed procedure volumes, with the intent to reduce the lifetime cost of robotic surgery. This model will allow hospitals to tie costs to revenues, making robotic surgery viable for more healthcare facilities.

Next-generation surgical robotics companies need to create a customer-centred design process and work closely with surgeons and healthcare executives during their product development activities. Following a dynamic research loop - where client feedback is actively incorporated into refining the platforms' functionality, can go a long way in developing surgical robotics systems that are closely aligned with customer needs.

Currently, surgical robots are restricted to inpatient settings at hospitals. However, an increasing number of surgical procedures are being performed in outpatient settings and ambulatory surgical centres, which currently do not have access to surgical robots. Deployment of next-generation surgical robotic technology platforms in these settings can help companies capture lucrative growth opportunities offered by the shift toward outpatient procedures. BS

Deadly Silence: India's Negligent Pharma Manufacturing Units

Indian pharma manufacturing units are a ticking time bomb. Inflammable chemicals that require special handling are often callously used by ignorant workers leading to reactions, reactor blasts and deaths. Above it, ill-designed setups and less knowledge of hardware and software are taking a toll on the industry. Showing a lackadaisical attitude towards the way manufacturing sites are being operated, Indian pharma companies are at the receiving end of various domestic and global regulators. Overlooking safety issues will lead to more catastrophic events.

India's growing pharma industry has a sordid tale to say. Amidst the hype of 'Pharmacy of the World,' discussions about tariffs and patent expiry leading to an opportunity for Indian pharma companies, hardly any discussions are held on the killer pharma manufacturing facilities. Unless and until something fatal happens.

A majority of the pharma companies seem to turn a blind eye to the lurking danger at its manufacturing sites across the country. So much so that lives are lost due to these catastrophic events.

Pharma manufacturing plants store chemicals, sometimes inflammable that are always at high risk. Reports of manufacturing plants not complying with safety standards are nothing new. Not following safety and other protocols becomes a free ride for the US FDA to issue warning letters. The US watchdog is notoriously known for issuing warning letters and somewhere the feeling comes that the agency does it right on certain occasions.

The Indian pharma industry has a history of incidents leading to deaths at manufacturing facilities with fire breakouts the common one.

Multiple incidents

The industry is marred with fire safety issues. Reports of fatality in pharma plants due to fire, inhaling toxic gas etc. happen quite often.

The recent blast at the Sigachi Industries plant at Pashamylaram in Telangana points out a disaster that is being compared with the Bhopal Gas Tragedy that happened way back in 1984. The powerful blast led to more than 40 dead and scores injured.

The management of Sigachi Industries was booked for culpable homicide. A criminal investigation is being pursued where there are allegations of gross negligence by the company. It is also being claimed that repeated warnings of outdated and unsafe machinery were ignored.

This is the same company that has secured Terms of Reference (ToR) Approval from the State Environment Impact Assessment Authority (SEIAA), Andhra Pradesh for its upcoming API and Specialty Chemicals Manufacturing Facility in Orvakal, Andhra Pradesh.

The Sigachi incident is not an isolated case. In another tragic incident, in June 2025 two workers died while one was found critically injured due to toxic gas inhalation at Sai Sreyas Pharmaceuticals located at Jawaharlal Nehru Pharma City, Parawada of Anakapalle district, Andhra Pradesh. Here also repeated pleas to safety standards were ignored leading to a disaster.

On January 10, 2025, a fire incident was reported at Samarth Life Sciences at Manakpur in Baddi, Himachal Pradesh. Though no casualties were reported, the investigation revealed that the fire was caused by a short circuit.

In August 2024, Escientia Advanced Sciences in the Special Economic Zone at Atchutapuram in the Anakapalli district of Andhra Pradesh had a fire incident leading to 17 deaths and more than 35 injured. The investigation led to key design faults. There were reports of leakage of a highly inflammable solvent, Methyl Tert-Butyl Ether (MTBE) that is used in the pharmaceutical industry.

About 14 workers sustained injuries in a fire at a pharma company in Puducherry in November 2023. Solara Active Pharma Sciences at Kalapet reported the fire incident.

In another event seven workers suffered severe burns in a massive explosion that rocked Unit-1 of the Sahiti Pharma plant at Atchutapuram SEZ in Anakapalli district in June 2023. Reports suggest that the blast occurred while loading solvents into the solvent recovery plant.

Laurus Labs reported that four of its employees died following a flash fire in a room in a manufacturing block of its plant in

Visakhapatnam, Andhra Pradesh in December 2022. In January 2021, Pune-based Serum Institute of India reported a fire incident leading to five deaths at its Pune facility. The fire spread from a half-constructed building within the institute that was reportedly producing Covishield. And the list goes on.

What Industry Says...

A lot of manufacturing companies say they hold safety workshops; however, these programmes are usually rushed and don't work. This is what ***Vinay Kumar, Senior Pharmacovigilance Professional*** says, while expressing his views. He further states that this ecosystem is quite complete; however, enforcement is not always constant and only happens when something goes wrong.

"Safety rules exist more on paper than in practice in a lot of plants, especially those in rural or heavily industrialised areas. The most worrisome thing is not the lack of information or equipment, but the lack of responsibility," Kumar added.

He further said "A lot of places have regular inspection visits that are easy to schedule for. However, they usually miss the structural, ongoing problems that develop between audits. Regulatory groups also don't have a lot of digital connections, which means that reports are duplicated and can be changed. The laws aren't the problem; the challenge is following them, keeping an eye on them, and working together across agencies. Many units will still consider compliance as a formality unless enforcement happens more regularly and is based on more data."

During the Confederation of Indian Industry (CII) Telangana 'Pillars of Protection: Building a Fortress of Safety in Pharmaceutical and Chemical Manufacturing' event, it was mentioned that the state of Telangana witnessed a whopping 102 major fire incidents in pharma units over the last decade, resulting in losses exceeding Rs 100 crore.

Dr Vinay Kumar Gupta, Assistant Drugs Controller (India), CDSCO Zonal Office, Hyderabad, Ministry of Health & Family Welfare, Government of India, emphasised the critical importance of safety in pharmaceutical and chemical manufacturing. According to him, during inspections, identifying even one safety issue can trigger significant improvements in an organisation. He also pointed out specific risks like potential product contamination from colour mix-ups and the importance of proper sampling environments.

Chakravarthi AVPS, Convener, CII Telangana Pharma and Life Sciences Panel & Chairman & Managing Director, Ecobliss India noted, "It's our collective responsibility to ensure that every manufacturing facility becomes a beacon of protection where safety, sustainability and operational excellence go hand in hand."

He also mentioned the rolling of a dedicated workshop on mitigating human errors in pharmaceutical manufacturing and operations. A much-needed intervention, this workshop will address the core challenges that often get overlooked yet contribute significantly to quality deviations, regulatory observations, and workplace incidents.

According to ***Ranjit Barshikar, CEO – QbD International, United Nations Advisor, Member of Editorial Board of Journal of Generic Medicine UK,*** in the pharmaceutical industry, risk assessments are an ongoing and continuous process throughout the entire product lifecycle, as per ICH Q9. Safety programmes in the pharmaceutical industry are crucial for protecting workers, ensuring product quality, maintaining regulatory compliance, and in the interest of the company's credibility. These programmes are typically integrated into the overall quality management system. (ICH Q10).

Emergency Preparedness

Most businesses have the necessary documents, such as chemical spill SOPs, evacuation maps, and emergency response plans. But the way they really do them on the ground isn't necessarily the same or enough to deal with real-life crises like chemical leaks, fires, explosions, or broken equipment.

Experts point out that:

- When there are emergencies, different departments don't work together enough (EHS, maintenance, production, and HR usually only work in their areas).
- There are no official links to local hospitals, fire departments, or crisis response teams.
- There aren't any emergency simulation programmes that are made just for plants that take

into account how hazardous materials are carried and stored.

- Not enough training for junior personnel and contract workers who are likely to be affected in emergencies when it comes to language and literacy.
- It is even more disturbing since a few simple steps could save a lot of lives and avoid injuries:
- Installing gas leak detectors and alarms that go off by themselves.

Pharma companies need to migrate from static risk assessments to dynamic risk management systems that are connected to real-time plant data, updated after any changes, and assessed on a regular basis in order to expand. Not only do teams need to be taught how to obey the regulations, but they also need to understand and internalise how important hazard analysis and risk assessment are as a life-saving tool instead of a burden.

Sharing his thoughts on the issue, ***Namitesh Roy Choudhury, Vice Chairman and Managing Director, LANXESS India*** said, "A comprehensive safety management system sets out exactly how employees should approach safety-relevant processes at production plants. Staff training and regular reviews ensure that these regulations are systematically implemented. During compliance checks, experts conduct spot checks to assess whether all necessary measures are being taken to ensure the safe operation of facilities."

LANXESS operates about 48 production sites in 32 countries worldwide. Safety is also of paramount importance in acquisition projects. A technical due diligence audit designed to identify potential risks is always conducted alongside the standard economic review during the preliminary stages. LANXESS uses comprehensive gap analyses to determine how best to resolve any safety shortcomings and implement the company's demanding HSEQ standards in good time.

Will this scenario change?

Indian pharma companies especially the smaller ones adopt the so-called 'Juggad' attitude leading to these types of catastrophic events. Unlike the MNC pharma companies that are known to implement tough protocols at their manufacturing units, the Indian counterparts are callous when it comes to providing safety.

Risk evaluations for Indian pharmaceutical manufacturers are not common, are not done consistently, and are done in response to problems. There is no standard across the industry for dynamic or periodic reassessments, especially when the layout of the plant, the way processes are optimised, new chemicals, or equipment upgrades change. Risk registers are rarely updated in real-time, even when things change.

Lack of fire safety audits, and bribing officials to procure safety certificates are common. The pharma industry has failed while complying with regular fire safety audits. This apart from accountability, stricter management accountability is missing in a majority of the cases.

Indian pharma companies need to chalk down comprehensive multi-pronged strategies, organise rigorous training for workers, adopt digital safety tools and automation, strictly monitor any unusual occurrences in manufacturing sites etc. to overcome the crisis.

Risk assessments should be done every three months for high-risk areas, right after process changes or deviations, with teams from several departments working together, and they should lead to tracked and closed remedial actions.

As ***Suresh Pareek, Managing Director, Sukvi Ventures and Founder and Former Managing Director, Ideal Cures*** points out, "Despite existing legal frameworks for chemical accident prevention, serious incidents continue to occur, pointing to potential deficiencies in implementation or oversight. There is no direct evidence to suggest a deliberate intent to 'hush things up'; from the available information; however, the lack of adherence to safety standards, as seen in the Sigachi case, indicates a failure in robust preventative action and transparency in addressing known risks. Effective accident prevention requires strong leadership commitment, employee education, and transparent hazard management."

Key safety measures like the use of personal protective equipment, robust emergency response plans, proper storage of chemicals and proper handling etc. should be of paramount importance.

Human error is claimed to be the likely cause of accidents happening at manufacturing sites. Recruiting qualified professionals in a plant can avert any untoward incident in the long run. The current scenario is not going to change sooner as many companies try to hush up things and try to suppress facts. Stricter regulations and proper training of staff at manufacturing facilities will help to avert disaster in days to come. BS

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Accelerated Reliance on Digital Animal Replacement Tech

While Europe is talking about non-animal replacement tests to be used for drug development and research purposes, US FDA is acting upon it with a detailed roadmap aimed at rapidly reducing animal testing in preclinical safety assessments. These developments clearly provide huge opportunities for global companies that are developing alternative methods such as organoids, 3D bioprinting, digital animal replacement technology, computer simulation, to name a few. But where does India stand in this regard, and how skilled are we to make this shift?

On April 29, the National Institutes of Health (NIH) in the US announced the adoption of a new initiative to expand innovative, human-based science while reducing animal use in research. In particular, the NIH intends to establish the Office of Research Innovation, Validation, and Application (ORIVA) to develop, validate, and scale the use of non-animal approaches across the agency's biomedical research portfolio and serve as a hub for interagency coordination and regulatory translation for public health protection.

Developing and using cutting-edge non-animal research models very well aligns with the US Food and Drug Administration's (FDA) recent initiative to reduce testing in animals.

Simultaneously, the European Medicines Agency (EMA) has released a revised draft paper that outlines non-animal replacement tests manufacturers can use to eliminate the use of animals in pharmaceutical testing. Further, the European Commission has confirmed plans to finalise its 'Save Cruelty Free Cosmetics' roadmap by early 2026, setting the stage for a gradual transition toward non-animal testing in chemical safety assessments.

Where does India stand in this scenario? Although an amendment to the New Drugs and Clinical Trial Rules (2023), passed by the Government of India in 2023, aimed to replace the use of animals in research, especially in drug testing, not much progress has been made so far. Indian regulatory bodies are still working out ways to strengthen the use of non-animal testing methods in laboratories across the country, as they are aware that completely eliminating animal models may not be a feasible process.

"There are continuous challenges in drug development due to species specific limitations, inadequate mechanistic prediction of human adverse effects by animal models. The concerning high clinical attrition in Phase II & III brings to the demand of developing more human relevant New Approach Methodologies (NAMs) aiming to replace, reduce and refine (3Rs) the animals in research. With continued support from national programmes like Biotechnology Industry Research Assistance Council (BIRAC) and global collaborations, India stands poised to emerge as a leader in NAM-driven innovation, advancing the 3R agenda and reshaping the future of drug discovery and toxicology testing", said ***Dr Amit Khanna, Lead Scientist – Integrated Drug Discovery and Development, Yashraj Biotechnology.***

New technologies and challenges

The global non-animal alternatives market inclusive of organoids, spheroids, three-dimensional (3D) bioprinting, computer simulation, Digital Animal Replacement Technology, cell culture, is expected to reach $4.08 billion by 2029 at a compound annual growth rate of 12 per cent. As a result, we see a rise in new initiatives by a number of companies across the world including India.

Recently, Hyderabad-based biotech startup Transcell Biologics announced a strategic investment from award-winning AI-first engineers, Quantiphi Inc, based in Boston. This investment aims to support expanding the client base and implementation of Digital Animal Replacement Technology (DART) as an Enterprise Solution for the global bio and pharmaceutical industry.

DART embodies an innovative leap forward in animal-free testing methods, fusing human MicroPhysiological Systems (hMPS) technology with AI/ML embedded in silico platform configurations to streamline and automate the bioassay processes producing statistically compliant reports.

According to ***Dr Subhadra Dravida, Founder and Chief Executive Officer of Transcell Biologics,*** "The implementation of

DART has gained significant traction in the Indian market, with leading biopharmaceutical companies already adopting this Enterprise Solution in their high-impact programmes. DART represents a significant breakthrough in revolutionising drug and vaccine testing."

Focusing on another non-animal testing alternative, Visakhapatnam-based startup Oncoseek Bio, innovating organoid and spheroid-based in vitro models to expedite the drug discovery process, has organised international conference last year on 3Rs with global researchers from academia and industry communicating the research trends in non-animal alternatives.

Further, researchers of Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh have come up with a prototype for establishment and characterisation of novel self-organising neurovascular organoids/ embryoids (NVOEs) entirely from autologous blood without any genetic manoeuvring or morphogen supplementation.

These organoids that can help to reduce and replace animal testing in research, are being developed to understand the genetic basis of neurosensory hearing loss and auditory comprehension challenges.

"Emerging human-relevant models such as the organoids, organ-on-chips, 3D bioprinted tissues, and spheroids show promise by capturing snapshots of human physiology including personalised genetic variations. Often, they leverage patient-derived cells to offer an accurate understanding of diseases and drug responses. While there is a global effort to advance these technologies for translational research, in India, a major challenge is the scarcity of highly skilled professionals. There is a dire need for indigenous skill development programmes to train next-generation scientists, leaders, and entrepreneurs in human-relevant technologies", said ***Tejaswini Dhurde, Senior Science Communicator, Centre for Predictive Human Model Systems, Atal Incubation Centre-Centre for Cellular and Molecular Biology (AIC-CCMB).***

To further understand the challenges associated with the utilisation of non-animal testing alternatives, the Nanomedicine Research Group at the Institute of Chemical Technology (ICT), Mumbai organised a 3D cell culture workshop and conference in 2024. The four-day workshop covered emerging technologies such as organs-on-chip, and 3D bioprinting mimicking organ function. A similar workshop was held in March 2025 at the National Institute of Pharmaceutical Education and Research (NIPER) in Ahmedabad.

"Interaction with participants enabled us to understand the growing interest of the country's pharmaceutical sector and contract research organisations (CROs) to explore suitable non-animal models. Participants' interest in organ-on-chip, other 3D culture methods, and also their demand for continued skill development opportunities and networking platforms where Indian and international academicians, industries and regulators could regularly interact, is in line with the government's recent interest in this field", said ***Prajakta Dandekar, Assistant Professor, ICT Mumbai.***

Few other startups like Next Big Innovation Labs and Avay Biosciences are offering hands-on and foundational courses on 3D bioprinting. Leveraging the potential of this new technology as a non-animal testing alternative, researchers at the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), in Thiruvananthapuram, have built India's first patented indigenous bioink designed for advanced 3D bioprinting technology.

"From cellular based research to developing 3D printed tissues and disease models for regenerative medicine and drug testing, 3D bioprinting has emerged as a remarkable tool for a wide range of applications in the healthcare industry. Despite exponential growth, the industry players need to address challenges associated with it such as scalability, vascularisation, post printing edits etc.", said ***Satyajit Shinde, Consultant, Roots Analysis.***

All this may sound substantial, but we are merely scratching the surface. There is indeed a need to increase innovative training programmes to enable transdisciplinary research in human-relevant technologies, to reduce the dependence on animal testing within the life sciences sector. Human-relevant science in the country can emerge as the next superpower accelerating healthcare for all. BS

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How Are Indian Institutions Advancing Organoid Research?

For Indian businesses, the combination of robotics and artificial intelligence with organoid technology offers enormous potential for creating automated, scalable organoid production systems.

Dr Rishika Agarwal,
Advisor,
Nucleate,
Switzerland and India

India's organoid research ecosystem is rapidly developing, with key institutions leading groundbreaking studies across multiple therapeutic areas. The Indian Institute of Science (IISc) in Bengaluru has emerged as a prominent hub, with researchers like Ramray Bhat at the Molecular Reproduction, Development and Genetics (MRDG) department actively studying cancer organoids, particularly ovarian and breast cancer models using 3D cell culture systems. The Centre for Neuroscience at IISc has also leveraged existing expertise in engineering, mathematics, physics and biology to advance cerebral organoid research for modelling human brain development and microcephaly.

Post Graduate Institute of Medical Education & Research has made significant strides in developing patient-specific neurovascular organoids from autologous blood, targeting neurodegenerative diseases including autism, Attention Deficit Hyperactivity Disorder, Alzheimer's and Parkinson's disease. This cost-efficient approach requires only autologous plasma and blood cells, eliminating the need for specific differential media or growth factors.

The Centre for Cellular and Molecular Biology (CSIR-CCMB) in Hyderabad is conducting a major research initiative on "Organoid models for biomedical research applications" from 2020-2025, funded by the Council of Scientific and Industrial Research (CSIR), focusing on stem cell-based organoid development. Additionally, the Institute for Stem Cell Science and Regenerative Medicine (inStem) continues advancing human embryonic stem cell research and gastruloid development.

Key companies driving organoid-related research include Pandorum Technologies, a Bengaluru-based biotechnology company specialising in tissue engineering & regenerative medicine, which has developed proprietary platforms combining therapeutic exosomes with biomaterials for cornea, liver and lung tissue regeneration. The company has secured government grants (BIG, SBIRI) & private funding, positioning itself as India's first company to 3D-print human liver tissue for medical research in 2015.

Stellixir Biotech in Bengaluru provides specialised services in 3D spheroid culture and stem cell research, offering anti-cancer cell-based drug screening and predictive toxicology services. Meanwhile, companies like InSphero have established distribution partnerships with Indian suppliers like Bionova Supplies to accelerate spheroid and organoid culture development in India.

Recent international research, including work by Agarwal et al. on human epidermis organotypic cultures published in Experimental Dermatology, demonstrates reproducible systems for recapitulating human epidermis in vitro, offering valuable models for dermatological research and drug screening. Such methodologies present opportunities for Indian researchers to develop standardised organoid protocols for various tissue types.

While India's organoid research shows promise, significant gaps exist in clinical translation compared to global leaders. Internationally, organoids have successfully transitioned from bench to bedside through patient-derived organoid (PDO) clinical trials for personalised cancer treatment, with platforms predicting clinical efficacy and guiding therapeutic decisions. Companies like HUB Organoids globally have demonstrated the ability to reduce drug development timelines from 10-15 years to approximately 5 years through organoid-based screening. Indian research remains predominantly in preclinical stages, with PGIMER's neurovascular organoid prototype being filed for patent protection but not yet in clinical trials. However, this represents an opportunity for India to leverage its strong pharmaceutical manufacturing base and clinical trial capabilities to accelerate organoid-based therapeutic development.

India faces several challenges including limited regulatory frameworks for organoid-based therapies, insufficient standardisation protocols, and the need for enhanced public-private collaboration. However, the strong foundation in biotechnology research, growing investment climate, and government support through initiatives like the National Biotechnology Development Strategy position India well for future growth. BS

“India is setting a global benchmark with proactive adoption of AI in lab design”

« Swatasiddha Majumdar, Principal Strategy, Unispace

India’s life sciences industry is outpacing its global peers when it comes to designing and delivering future-ready lab environments, according to a new survey and report by Unispace, a global leader in strategy, design, and construction of workplace environments. The survey’s findings suggest that India’s life sciences sector is not only ready for rapid R&D evolution but is also shaping global trends in lab strategy. To find out how Indian life sciences companies can truly emerge as global frontrunners in building labs of the future, BioSpectrum India spoke to Swatasiddha Majumdar, Principal Strategy at Unispace. ***Edited excerpts:***

Why is Unispace betting big on India as a key player in global life sciences innovation? How do you see India's lab infrastructure evolving over the next five years, especially compared to mature markets like the US or UK?

At Unispace, we’re not simply betting on India; we are following what evidence says. Our latest research positions India as a frontrunner in designing and delivering future-ready lab environments. 66 per cent of Indian life sciences leaders consider their labs highly adaptable, well ahead of the global average of 56 per cent. Similarly, 65 per cent of Indian leaders say their labs are equipped to integrate new technologies, again outpacing countries like the UK, USA and Switzerland. This speaks to a level of preparedness and progressive thinking that’s rapidly shaping global trends. What’s particularly striking is how the perception of lab spaces in India has evolved and made room for fostering innovation, talent retention, and digital transformation.

We anticipate three major developments in India's lab infrastructure going forward: a surge in strategic alliances and co-development models, a focus on modular and collaborative design, and a quick uptake of digital and artificial intelligence (AI) technology.

The report notes wellness zones and human-centric design as important for talent retention. How is Unispace working with clients to bring these elements into labs that are traditionally focused solely on functionality?

Our approach is simple. We believe that you cannot achieve world-class science without taking care of the workforce behind it. Unispace is committed to transforming lab design from purely functional spaces into environments that are centred around human experience and well-being. This mindset is becoming increasingly important in India’s life sciences ecosystem, where talent retention and wellbeing are emerging as competitive differentiators. Our research also supports it as we found that 57 per cent of Indian leaders consider rest and recharge spaces essential, echoing a global trend where 52 per cent of leaders prioritise wellness zones and nearly half value inclusive, accessible design. In response, we’ve adopted an evidence-based approach. We are studying how scientists interact with their environment, how they move, focus, and work, and use these insights to create lab spaces that reduce fatigue, enhance focus, and improve overall workplace satisfaction. We are integrating natural light for better attentiveness, biophilic design, improved acoustics, and thoughtful zoning to promote comfort. We are also increasingly building in accessible, inclusive features and dedicated wellness amenities. It’s no more about creating great labs; it’s about creating environments where researchers can thrive, collaborate, and feel supported every day.

India leads in lab adaptability, according to your survey. What specific design elements or strategies are contributing to this high adaptability in Indian labs compared to their global counterparts?

One of the most compelling findings from our research shows how far ahead India is when it comes to lab adaptability. 66 per cent of Indian leaders rate their labs as highly adaptable, which reflects a mindset that prioritises flexibility as a core design principle. According to our survey,

flexible and modular design tops the list, with over 54 per cent of leaders emphasising reconfigurable lab infrastructure, such as mobile benches and movable workstations. These elements make it easy for workers to adapt quickly and set up their work station without major capital investment.

Indian labs are also designed with collaboration in mind, with 80 per cent of leaders saying their labs promote cross-functional teamwork. We're seeing more open-plan spaces and shared environments that break down silos between departments. Additionally, Indian labs are rapidly adopting digital technologies. Digital Twins, for example, is a technology that allows teams to simulate and plan lab layouts virtually, enhancing agility and efficiency. With these new approaches in place, Indian labs have gone through a sharp fundamental shift from being seen as a static space to a dynamic platform for continuous innovation.

Over half of Indian leaders are prioritising AI and digital tools in lab design. What are some standout tech innovations you're seeing being adopted?

India's proactive adoption of AI and digital technologies in lab design is another area where the country is setting a global benchmark. More than half of Indian leaders, 56 per cent, are actively prioritising smart, AI-driven tools in their lab environments. This goes beyond automation. AI is being used to analyse large datasets and even predict experimental outcomes, which can significantly reduce research cycles. Additionally, IoT sensors are embedded into lab infrastructure to monitor equipment, air quality, and other operational metrics in real time. We're also seeing increased adoption of digital twins, virtual replicas that allow for layout simulations, safety planning, and immersive training via VR and AR. Cloud-based platforms are further enabling seamless data management and collaboration across locations.

What are some of the most effective sustainability strategies being adopted in Indian labs right now?

Sustainability is no longer a 'nice-to-have'; it's a strategic priority, and Indian leaders are taking it very seriously. Our report shows that 46 per cent of global leaders rank sustainability as a top-three factor in their design decisions. It is a huge priority in India right now. We're seeing growing adoption of smart energy systems, from motion-sensor lighting to highly efficient HVAC setups. Solar power is also gaining ground, not just for its sustainability credentials, but as a reliable energy source in regions where the grid can be unstable. Water conservation and recycling technologies are increasingly built into new lab projects, which is especially important in the pharmaceutical sector. And finally, there's a clear shift toward using eco-friendly, locally sourced materials that reduce the environmental impact from construction onward. What's encouraging is that sustainability isn't being treated as a checkbox; it's being integrated into core business and design strategies.

India's proactive adoption of AI and digital technologies in lab design is another area where the country is setting a global benchmark. More than half of Indian leaders, 56 per cent, are actively prioritising smart, AI-driven tools in their lab environments. This goes beyond automation. AI is being used to analyse large datasets and even predict experimental outcomes, which can significantly reduce research cycles. Additionally, IoT sensors are embedded into lab infrastructure to monitor equipment, air quality, and other operational metrics in real time.

What does Unispace's India roadmap look like for 2025–2027 in the life sciences space?

India's life sciences sector is growing at an incredible pace, and our roadmap for 2025–2027 is focused on scaling with it through strategic partnerships, innovation, and a strong emphasis on people-centric, sustainable design. We aim to be the partner of choice for organisations looking to co-develop next-generation lab infrastructure, bringing global expertise tailored to local needs.

A big part of our approach is designing labs that are not just functional, but built for talent retention and long-term adaptability. We're also helping clients integrate cutting-edge technologies like AI and digital twins into their spaces to create smart, agile labs that can evolve with scientific demands.

However, implementing such bold and ambitious plans comes with its own set of challenges. There's a need to bridge collaboration gaps across dispersed teams and to manage budgets without compromising innovation. But with the right design thinking, we're confident these are solvable. BS

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Can Algae Transform Tomorrow's Science & Medicine?

« **Dr Sougata Roy,** Assistant Professor of Biology, Ashoka University

More than two-thirds of our planet is covered by water, encompassing vast oceans, lakes, and rivers, yet much of this underwater world remains a mystery, with large regions still unexplored and ecosystems waiting to be discovered. Among the most vital yet overlooked inhabitants of these waters are phytoplankton, microscopic organisms invisible to the naked eye, drifting silently through aquatic environments. These microscopic photosynthetic organisms not only serve as the foundation of aquatic food webs and generate oxygen to sustain aerobic life, but also are rapidly emerging as one of the most powerful and versatile resources in modern science.

As primary producers, microscopic photosynthetic organisms play a crucial role in capturing carbon dioxide and synthesising high-value organic compounds, which are increasingly being recognised for their significant commercial potential. While phytoplanktons continue to shed light on fascinating questions in basic science, they're also proving to be a rising star in applied science, fuelling innovations that could transform how we power our world, grow our food, and care for our health.

From combating climate change to inspiring new therapeutics, these unassuming microbes are increasingly gaining the long-overdue recognition for their significance, and their potential is only beginning to be revealed.

Like all other organisms on Earth, phytoplankton must adapt to the daily cycle of light and darkness, a fundamental rhythm driven by Earth's rotation on its axis. Despite being unicellular, they exhibit a remarkable ability to temporally organise their metabolic processes, partitioning various metabolic tasks according to the time of day. This rhythmic regulation allows them to optimise energy production, nutrient assimilation, and growth in synchrony with environmental cues.

A key research aspect is to understand how this temporal partitioning is regulated at the molecular level, with the long-term goal of fine-tuning these processes to optimise cellular efficiency and adaptability, to enhance algal productivity for sustainable biotechnological applications. To fully accomplish this, we must first identify the key molecular players and understand how their interactions drive the time-of-day-dependent outputs of metabolism.

It has been recognised that enzymes, a subclass of proteins that catalyse biochemical reactions within the cellular metabolic framework, are likely to play a major role in determining the time-of-day dependency of metabolism. To explore how these tiny organisms manage their internal schedules, the levels of key enzymes have been tracked in a common species of phytoplankton over a full day.

Since enzymes help carry out the cell's chemical reactions, we reasoned that higher levels at certain times would mean greater activity, shaping when and how important biomolecules and metabolites are produced throughout the day. In the process, researchers have not only uncovered several metabolic pathways previously not known to exhibit time-of-day regulation, but also identified the molecular players involved in well-established metabolic rhythms.

Studies have opened up exciting new possibilities for understanding how microscopic organisms like phytoplankton manage their daily routines at the molecular level, shedding light on the hidden rhythms that drive life in our oceans. What makes this even more exciting is that these primary rhythmic metabolic pathways are essential for survival across all forms of life, from algae to plants and even humans. We believe that these findings offer important insights into how different organisms, from tiny algae to humans, partition metabolism over the daily cycle at the molecular level.

By comparing these processes across species, we can uncover shared patterns and unique differences,

paving the way for real-world applications in areas like farming, clean energy, and even healthcare. Unlike land plants, phytoplankton don't require arable soil to grow. These microscopic, plant-like organisms thrive in water, occupying nearly 70 per cent of Earth's surface, including oceans, lakes, and even brackish or salty waters that are otherwise unusable for agriculture. Their ability to flourish in such vast and varied environments makes them an incredibly sustainable resource.

Recent research has begun to uncover just how vital phytoplankton could be for humanity. They are already showing promise in a wide range of fields, from pharmaceuticals and therapeutics to regenerative medicine, agriculture, and industrial biotechnology. They are even being explored as natural biosensors and tools for diagnostics. And this is just the tip of the iceberg.

As we continue to unlock their secrets, the full potential of phytoplankton is only beginning to emerge, offering exciting possibilities for innovation, sustainability, and global well-being. One such exciting example from the world of medicine is the discovery of bioactive compounds in certain marine phytoplankton that show strong anti-inflammatory, antiviral, and even anticancer properties.

Take fucoxanthin, for example, a natural pigment in some microalgae that plays a key role in capturing light for photosynthesis. While it helps algae capture sunlight to survive, this remarkable compound has also drawn interest for its potential health benefits, ranging from fighting obesity and diabetes to supporting treatments for cancer, liver problems, and even brain-related disorders.

It is worthwhile to explore how these naturally derived molecules could pave the way for developing new, safer, and more effective drugs. In the field of clean energy, phytoplankton are also making waves. Some species of microalgae can produce large amounts of lipids and starch, which can be converted into biofuels—an eco-friendly alternative to fossil fuels, one of the main drivers of global warming and air pollution.

As the world searches for sustainable energy solutions, algae-based biofuels offer a promising path toward reducing our carbon footprint and combating climate change. These algal biofuels burn cleaner, can be produced sustainably, and don't compete with food crops for land or water.

Several pilot projects around the world are already demonstrating how algae-based fuels could one day power vehicles, aeroplanes, and industries with significantly reduced greenhouse gas emissions, which has far less environmental impact. To truly unlock the potential of algae as a sustainable solution for climate and societal challenges, we need more than breakthroughs at the laboratory bench.

Fucoxanthin, a natural pigment in some microalgae plays a key role in capturing light for photosynthesis. While it helps algae capture sunlight to survive, this remarkable compound has also drawn interest for its potential health benefits, ranging from fighting obesity and diabetes to supporting treatments for cancer, liver problems, and even brain-related disorders. It is worthwhile to explore how these naturally derived molecules could pave the way for developing new, safer, and more effective drugs.

While laboratory research provides critical insights into how these microscopic organisms grow, metabolise, and produce meaningful and important compounds, real-world impact requires a multidisciplinary effort, bringing together scientists, engineers, economists, industry partners, and policymakers.

This kind of collaboration ensures that algae-based innovations can move from petri dishes to large-scale applications that benefit both people and the planet. There are several compelling examples of this kind of cross-sector collaboration. One notable case is Algenol, a US-based biotech company that developed an innovative method to produce ethanol using blue-green algae. BS

Quantum Sensing and Healthcare: Charting India's Next Frontier

« **Ravi Puvvala,** MD, Quantum Biosciences Private Limited, India

Quantum sensing can revolutionise healthcare by enabling early disease detection, precise diagnostics, and customized treatment plans. It detects subtle changes in fields, improving diagnoses for various diseases.

Technological advances in controlling the world of the ultra-small, made over the past few decades, have brought to fruition a field called "Quantum Sensing." While it has applicability in a wide variety of problems, medical-diagnostics and healthcare-innovation would be revolutionised. Quantum sensors are ultra-sensitive devices, capable of detecting the faintest of biological signals—be they magnetic, electric, thermal or even mechanical. They could enable game-changing applications in real-time diagnostics by detecting or measuring phenomena within single cells that were previously undetectable.

With a strategic investment in research, infrastructure, and translational pathways, India is today presented with a golden opportunity to play a leading role in this emerging domain, radically improving healthcare outcomes and building a global leadership in healthcare technologies.

National Quantum Mission: Catalysing Quantum Healthcare

India's National Quantum Mission (NQM), anchored in T-hubs like Indian Institute of Science (IISc) Bengaluru, Indian Institute of Technology (IIT) Madras, IIT Mumbai, IIT Delhi, has laid the groundwork for innovation across several domains in the field of Quantum Technology. To unlock the full potential for a revolutionary impact on healthcare, the NQM ought to give a high priority to the utilisation of quantum sensing for the bio-medical field. A few example applications might include NV center-based subcellular imaging, optically pumped magnetometer (OPM)-driven brain scans, and quantum sensors for tissue oxygenation and metabolism etc. A clearly developed roadmap involving partnerships between the specialised academic establishment with leading clinics, regulatory integration, and funding for translational research could easily position India at the forefront of international players in this field.

Elevate Karnataka: Accelerating Deep-Tech Startups

Programmes like Elevate Karnataka demonstrate the power of state-led innovation. By providing seed funding, lab access, and mentorship, startups like Quantum Biosciences have advanced prototypes such as quantum-enhanced MRI systems for low-radiation, high-resolution diagnostics. Such collaborative models must be scaled at a national level to unlock the full role startups can play in India's quantum healthcare.

Quantum Valley, Amaravati (Andhra): Infrastructure for the Future

The Amaravati Quantum Valley initiative represents a leap toward setting up a national quantum infrastructure. Its centerpiece, the QChipIN, is a state-supported open testbed with access to IBM quantum systems, SPAD detectors, and deployable OPM platforms. With Rs1,000 crore in funding and with full backing of both the IIT Madras and of the TCS, this initiative offers healthcare startups a full and vibrant ecosystem for clinical testing, validation, and commercialisation—making Amaravati a potential hub for quantum-enabled healthcare.

Bridging Infrastructure Gaps & Launching Quantum Biology

To sustain innovation in quantum healthcare, India must address the deep structural gaps in its R&D ecosystem. Steps to be taken currently would perhaps include:

- Setting up of dedicated Quantum–Healthcare Innovation Zones – perhaps in Amaravati, Bengaluru, and in Hyderabad.
- Setting up Clinical testbeds in hospitals—for example in All India Institute of Medical Sciences (AIIMS), Narayana, Apollo.
- Setting up National standards for quantum

sensor validation and calibration – Working with National Physical Laboratory team.

• Setting up an industry for scalable device manufacturing of NV sensors and OPMs

Equally important is the establishment of a world-class research facility focused on quantum biology. This centre would study quantum effects in living systems, for example ranging from enzyme tunneling to neural coherence. Its mission would include discovery-driven diagnostics, development of next-generation quantum biosensors, creating a foundation and curriculum for the absolutely required interdisciplinary training, and structuring global collaboration with internationally renowned institutions outside India.

Building Talent and Global Research Alliances

India's academic network—including from the IISc, IITs, International Centre for Theoretical Sciences (ICTS), National Centre for Biological Sciences (NCBS), Tata Institute of Fundamental Research (TIFR) and Raman Research Institute (RRI) and—must be mobilised into these interdisciplinary platforms. These should combine providing a solid educational structure for quantum sensing, data science, AI and biomedical engineering. International fellowships, jointly structured labs with US institutions like the Elevate Colorado, Quantum Chicago Hub, and the development of standards will boost India's capabilities of innovating in this upcoming field.

Translational Use Cases: Quantum Sensing in Healthcare

Quantum sensing has tangible applications in diagnostics and monitoring. Key opportunities include:

• **Biophoton Detection:** Label-free cancer detection.

• **Brain Imaging (OPM-MEG):** Non-invasive mapping for neurological conditions.

• **Fetal Imaging:** Safe prenatal diagnostics using wearable quantum sensors.

• **Microbiome Monitoring:** Real-time gut diagnostics via breath/stool sensing.

• **NV-based Subcellular Sensing:** Usage of fluorescent nanodiamonds to detect free radicals, these are tiny stress signals inside your cells. When hit with a laser, they glow based on oxidative stress levels. This glow is turned into real-time data with T1 curves, offering non-destructive, subcellular insights. This yields into single-cell resolution analytics, and advanced predictive toxicology.

• **Quantum MRI:** High-resolution imaging with reduced radiation.

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Create a Startup Ecosystem and Industry Translation

India must foster its ecosystem for startups in quantum-healthcare with incubation support Biotechnology Industry Research Assistance Council (BIRAC), Centre for Cellular And Molecular Platforms (C-CAMP), I-Hub Quantum Sensing), providing targeted R&D funding, and preparing for viable commercialisation pathways. Academic–industry consortiums should be encouraged to fast-track translation from lab to clinic.

Positioning India as a Global Quantum Health Leader

With its strengths in quality science on a large population scale, India can lead the Global South in the field of quantum health. Hosting global challenges, publishing clinical validations, and shaping global standards will help build the Brand India in the field of quantum-enabled healthcare.

Conclusion

Quantum sensing is a generational opportunity to critically redefine both diagnostics as well as treatment. With a mission-driven investment, coordinated infrastructure, and a thriving innovation ecosystem, India can not only provide radically improved health care to its own citizens, but can also lead the future of healthcare at the international level.

The time to start on India's quantum-health revolution in now! BS

Digital Personal Data Protection Act (DPDPA) – A Wake-Up Call for IVF Clinics

With the introduction of the Digital Personal Data Protection Act, 2023 (DPDPA), questions are being raised about how India's earlier medical laws handle patient data and privacy. While certain medical laws do talk about concepts such as confidentiality of medical records, they have remained silent on several key compliance requirements from a data protection standpoint. This article explores how DPDPA compares with existing medical laws from a data protection perspective for clinical establishments carrying out the procedures related to assisted reproductive technology.

Today, In vitro fertilisation (IVF) clinics are mushrooming across Indian cities and towns. Unlike multi-specialty hospitals, these clinics often operate with small, tight-knit teams: a medical director, a gynaecologist, an embryologist, and perhaps a visiting anaesthesiologist. Rarely do they have an in-house IT officer, let alone a Chief Information Security Officer. This lean structure may be efficient for treatment delivery but it poses a serious compliance risk under India's Digital Personal Data Protection Act (DPDPA), 2023.

What makes this risk more acute is that IVF clinics handle what can only be described as hypersensitive personal data like fertility status, sperm donor identities, embryo development details, hormonal profiles, and more. If such data were to leak, it wouldn't just violate privacy; it could lead to social stigma, reputational harm, breakdown of marriages, and even inheritance disputes. Under the DPDPA, this isn't just a theoretical risk- it's a regulatory trigger which can result in the imposition of fines of up to Rs 250 crore (approximately $30 million) on such IVF clinics. To put this in perspective, even a 1per cent imposition of the highest penalty of Rs 250 crore is still Rs 2.5 crore, which is a substantial amount for an IVF clinic.

From a regulatory standpoint, these clinics operate in a cross-regulated environment governed by a patchwork of sectoral laws including the Assisted Reproductive Technology (Regulation) Act, 2021 (ART Act), the Surrogacy (Regulation) Act, 2021 (Surrogacy Act), the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (PCPNDT Act). Each of these laws addresses a specific aspect of clinical or ethical regulation such as consent for treatment, donor registration, sex selection prohibition, and pregnancy termination. However, none of them are focused on digital data governance.

It is also important to clarify that while terms like IVF clinic, fertility centre, test tube baby clinic, or surrogacy centre are used interchangeably in popular and commercial usage, the legal terms under the ART and Surrogacy Acts are more narrowly defined. These statutes define entities as ART Clinics, ART Banks and Surrogacy Clinics, each with specific functions and regulatory obligations. However, in practical terms, it is common to find a single clinic marketing itself as an IVF clinic while simultaneously offering services that legally fall within the remit of multiple categories. For instance, one setup may function both as an ART Clinic and a Surrogacy Clinic, and sometimes even as a bank storing gametes or embryos. This article uses IVF clinic as an umbrella term for such entities, but it is critical to note that their compliance obligations under DPDPA will vary based on the actual functions they perform, not what they choose to call themselves.

Comparative Analysis:

The following comparative analysis between medical laws such as the ART Act, Surrogacy Act and the DPDPA, 2023

Medical Laws	DPDPA, 2023
Consent under medical laws is different than that of DPDPA	
Consent for medicolegal perspective such as – • Procedures, treatment, risk disclosure. • No mention of how personal data should be processed, stored and shared etc.	Consent for protecting personal data- • Consent is obtained for the governance of data lifecycle. The consent should be free, fair, unconditional, informed for the specific purpose and it shall signify an agreement to the processing of patients personal data. • Consent is obtained for a specific duration of time period with withdrawal rights.

Security measures	
ART Laws mandate digital recordkeeping, but no security baseline for the records which are to be maintained.	DPDPA requires an IVF clinic to adopt reasonable security safeguards to protect data. It also requires implementation of technical and organizational measures such as ISO 27001 or ISO 27701.
Data retention and erasure	
The ART laws and Surrogacy laws require the clinics and banks to: • Retain the data for ten and twenty-five years respectively. • In case of any dispute before court of law the data needs to be retained during the pendency of court proceedings.	Under DPDPA, the data needs to be deleted upon the expiry of the retention period, as per a documented 'data retention policy'. If you are keeping it after that period, it is a breach of DPDPA.
Grievance redressal	
No legal requirement to implement grievance redressal from the data protection point of view.	Under the DPDPA, implementation of grievance redressal mechanism is mandatory, to entertain grievances related to exercise of rights granted under the DPDPA.
Data breach reporting	
Under any of the medical laws there is no requirement to report data breach to any authority.	Immediate reporting to the Data Protection Board of India and impacted data principals in case of any personal data breach is mandatory under the DPDPA.
Personal data access requests	
Upon the request of a patient, medical records must be shared within seventy- two hours as per the Indian Medical Council (Professional Ethics and Etiquette) Rules, 2002 and under the Electronic Health Guidelines, 2016, within thirty days such medical data has to be shared with the patient.	Upon the request from the data principal, the data fiduciary must share a summary of all data being processed, a list of third parties with whom data is being shared. In this case, the data includes not only the medical records but also all the personal data being processed by the data fiduciary.

* The Indian Government is yet to define the 'Significant data fiduciary' (SDF). By the prescribed

standards under Section 10 of the DPDPA, any institution handling sensitive data may fall under this category. Since IVF clinics deal with sensitive data such as fertility status of couples, details of surrogate mother, details of reproductive deficiencies and like, the IVF in all likelihood will fall under this category. Therefore, these clinics will likely be required to adopt the additional obligations of SDF.

Conclusion

To sum up, while laws such as the Assisted Reproductive Technology (Regulation) Act, 2021 (ART Act), the Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 (PCPNDT Act), and the Surrogacy (Regulation) Act, 2021 have long regulated IVF clinics in India, they do not comprehensively address the evolving concerns surrounding patient data and privacy. This is where the DPDPA 2023 assumes particular significance. It introduces a more holistic, people-centric framework for the governance of personal and sensitive health information. For IVF clinics, compliance with DPDPA is not merely a statutory requirement; it is an opportunity to foster patient trust by demonstrating that their data is managed with care, transparency, and respect in the digital age. BS

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Nanozymes: The Next Generation of Artificial Enzymes

« **Vijeta Sah,**
Senior Consultant,
Ingenious e-Brain

Since their discovery in the early 2000s, nanozymes have gained attention for their durability under extreme conditions and versatility in applications ranging from medicine to industry. Made from materials like metal oxides, noble metals, and carbon nanostructures, nanozymes are redefining the future of catalysis and biochemistry.

The nanozyme market is set to soar, with its value estimated at $5.13 billion in 2024. Forecasts predict a remarkable climb from $6.54 billion in 2025 to an impressive $57.95 billion by 2034, driven by a robust CAGR of around 27.4 per cent during this period. This explosive growth underscores the transformative potential of nanozymes across diverse industries.

The healthcare sector is anticipated to dominate, driven by applications in diagnostics, drug delivery, and personalised medicine. Environmental and agricultural sectors are also witnessing increased adoption, with nanozymes being utilised for pollutant degradation and crop protection.

Regionally, North America currently leads the market, accounting for over 42 per cent of the revenue share in 2023, due to robust research and development activities and a well-established healthcare infrastructure. Asia-Pacific is projected to exhibit the fastest growth, fueled by increasing healthcare expenditure and the prevalence of chronic diseases in countries like China and India.

Key players in the nanozyme market include Novozymes A/S, Creative Enzymes, Cenyx Biotech Inc., Geno Technology Inc., Profacgen, and NanoComposix. These companies are focusing on developing innovative products with improved functionality and cost-effectiveness. Recent advancements involve the creation of hybrid and multifunctional nanozymes with enhanced catalytic properties, as well as smart nanozymes with responsive behaviour for real-time applications.

A New Frontier in Addressing Disease Burdens

Professor Yan Xiyun, a nanozyme trailblazer at the Chinese Academy of Sciences, is pioneering cancer therapies with antibodies targeting CD146. Meanwhile, a dynamic team from Nanjing University clinched the 2023 Dalton Horizon Prize for crafting powerful nanozymes that shine in cancer treatment, inflammation therapy, and wearable biosensors, pushing the frontiers of medicine and tech!

Researchers are advancing cancer treatment using carbon-based nanozymes (CNs) that precisely target tumours, enhancing therapy effectiveness. CNs have tunable electronic properties that boost catalytic efficiency and stability, outperforming traditional metal nanozymes in physiological conditions. For instance, graphene-based nanozymes maintain strong peroxidase-like activity under mild conditions, making them ideal for managing oxidative stress in tumour environments.

Carbon quantum dots (CQDs) outperform cerium oxide nanozymes in biosensing cancer biomarkers due to their superior sensitivity, stability, photoluminescence, and antioxidant properties. Their multifunctional oxidase and peroxidase-like activities make them especially effective in complex biological settings.

Ligands like antibodies or peptides attached to carbon nanozymes (CNs) enable precise targeting of cancer cells, reducing toxicity. CNs' enzyme-like actions trigger reactions in tumours that produce cytotoxic agents to kill cancer cells, promising safer and more effective cancer treatments ahead.

Metabolic disorders like obesity, diabetes, and cardiovascular diseases disrupt key bodily processes and are linked to oxidative stress from excess free radicals. Current treatments often lack safety and effectiveness. Nanozymes, advanced nanomaterials that manage reactive oxygen species (ROS), show promise in improving treatment outcomes for these conditions.

Future Outlook

Nanozymes are a transformative and promising advancement in biochemistry and nanotechnology. They are revolutionising various fields, especially cancer treatment and metabolic diseases. However, nanozymes face key challenges such as selectivity, biocompatibility, and precise control over activity. Unlike natural enzymes that are exquisitely specific, nanozymes may catalyse unwanted side reactions. As the field advances, the capabilities of nanozymes continue to evolve. BS

How Can Labs Reduce Their Energy Consumption?

« **Atul Bhardwaj,**
Business Head,
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Research labs can concentrate on innovation by collaborating with infrastructure providers, leaving waste, water, and energy management to professionals.

India's advancements in life sciences R&D are making a mark on the global stage, positioning the nation as a hub for innovation, drug discovery, and biotech development. At the heart of this transformation are cutting-edge research laboratories, indispensable engines of innovation that drive breakthroughs in the life sciences and beyond. These facilities, distinct from manufacturing plants, focus on developing new processes and products in controlled, small-scale environments.

Yet these vital hubs often rank among the most resource-intensive buildings, consuming 3 to 6 times more energy per square meter than standard office spaces. As India's demand for advanced research infrastructure grows, companies are leading the charge to design sustainable laboratories that reduce environmental impact while maintaining high performance and innovation standards through energy-efficient systems, smart resource management, and eco-conscious designs.

Environmental toll of traditional facilities

India's research laboratories, adhering to Good Laboratory Practices (GLP) to ensure reliability and integrity, require significant energy and resources to maintain stringent environmental controls for experiments. Unlike manufacturing facilities, these labs typically operate intermittently, focusing instead on innovation and process development.

Studies show that HVAC systems account for up to two-thirds of energy consumption in such facilities due to strict air quality requirements. Additionally, water usage for cooling and cleaning generates substantial wastewater, while biological waste demands careful processing to prevent environmental harm. Although India's energy mix includes significant renewable sources like hydroelectric power, the high energy intensity of labs underscores the need for sustainable infrastructure. The Energy Conservation Building Code (ECBC), adopted by 23 of 28 states, including major life sciences hubs like Telangana and Maharashtra, promotes energy efficiency, but further advancements in lab design are needed to balance operational demands with environmental responsibility. Neovantage, as an infrastructure provider, plays a critical role in addressing these challenges by offering facilities that integrate sustainable systems, relieving labs of building management burdens.

Transition to green laboratories

The transition to sustainable laboratories in India, supported by the National Action Plan on Climate Change, is accelerating through innovative infrastructure designs. These labs prioritise energy efficiency and resource conservation, leveraging renewable sources like solar power and closed-loop waste systems to minimise environmental impact. For instance, advanced HVAC systems and smart water recycling reduce energy and water consumption, while eco-conscious building materials enhance sustainability. Economically, these facilities lower operational costs and offer a strong return on investment, with payback periods as short as 3-5 years, while enhancing asset value. With current technology, labs can reduce energy consumption by 30 to 50 per cent, demonstrating a substantial potential for efficiency improvements. Scientifically, they boost researcher productivity and well-being through improved indoor environments, fostering innovation and educating future scientists in sustainability. By leasing facilities from providers, labs can focus on research while infrastructure experts manage energy, water, and waste systems, ensuring environmental, financial, and scientific progress.

Way forward

India stands at a pivotal moment where scientific progress and sustainability can converge. As the life sciences R&D sector aims for global leadership, Neovantage Innovation Park's sustainable laboratory infrastructure, featuring innovative designs, ECBC compliance, and green certifications, reduces environmental impact while fostering cutting-edge discoveries. By partnering with infrastructure providers, research labs can focus on innovation, leaving energy, water, and waste management to experts. BS

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INSA Women Associates names Dr Prajakta Dandekar Jain as Founding Member

The Institute of Chemical Technology (ICT), Mumbai, has announced the selection of Dr Prajakta Dandekar Jain, UGC Assistant Professor at the Department of Pharmaceutical Sciences and Technology, as a Founding Member of the newly constituted INSA Women Associates (IWA) by the Indian National Science Academy (INSA), New Delhi. Dr Prajakta joins a formidable list of Indian scientific and technological pioneers shaping the national innovation landscape. Through this role, she will collaborate with other IWA members and the Governing Board comprising eminent leaders like Dr Soumya Swaminathan, Dr Renu Swarup, Dr Chandrima Shaha, and Kiran Mazumdar-Shaw, among others, to build dynamic platforms for leadership, policy development, and next-generation mentorship. Dr Prajakta's work spans cutting-edge areas including 3D cell culture, nanomedicine, tissue engineering, and pharmaceutical biotechnology, and she is a group leader of ICT's Nanomedicine Research Group.

Asia Healthcare Holdings names Arvind N Sivaramakrishnan as CTO

Asia Healthcare Holdings (AHH), a leading operating platform for single specialty healthcare in India & South Asia, has announced the appointment of Arvind N Sivaramakrishnan as its Chief Technology Officer (CTO). With a proven track record in driving enterprise-scale digital health transformation, Sivaramakrishnan will lead AHH's digital technology strategy, overseeing digital infrastructure, AI integration, cybersecurity, telehealth platforms and electronic health record (EHR) optimisation across its verticals. This appointment comes at a time when AHH has taken a leadership position in driving the growth of multiple single speciality healthcare enterprises on its platform and is moving towards rapid tech evolution and shift towards intelligent, patient-centric systems. Before joining AHH, Sivaramakrishnan held leadership roles across some of the most respected names in global and Indian healthcare. He began his journey with Ramco Systems and later served as Principal Leader at DXC Technology (formerly Computer Sciences Corporation), where he led the Clinical Applications Portfolio for Henry Ford Health Systems in Detroit, Michigan.

Quadria Group appoints Rahul Agarwal as Partner at HealthQuad

Quadria Group, Asia's leading healthcare-focused private equity platform, has announced the appointment of Rahul Agarwal as Partner at HealthQuad, India's leading healthcare-focused growth venture capital platform. Agarwal joins HealthQuad following a long and successful tenure at Quadria Capital, where he most recently served as Managing Director. As part of Quadria since its inception, he has spent over 13 years playing a pivotal role in investments, scaling portfolio companies, fundraising, and, most importantly, delivering successful exits. In his new role, Agarwal will help shape and drive the future fund strategy of HealthQuad and will step in to lead the investment team and committee, majority of who have been instrumental in driving the success of HealthQuad Fund I and Fund II. With over 18 years of experience in healthcare investing and fund management, Agarwal brings a rare combination of institutional investment discipline, operational insight, and deep healthcare expertise across healthcare delivery, pharma and digital health. He has executed investment and exit transactions of over $1.5 billion across India, Southeast Asia and US during his stint at Quadria prior to that at Religare Global Asset Management and Evolvence India Fund.

CeNS designs pocket-sized sensor to detect health threats in air

Scientists from Centre for Nano and Soft Matter Sciences (CeNS), Bengaluru, an autonomous institute of Department of Science and Technology (DST), have fabricated a sensor by combining two metal oxides- nickel oxide (NiO) and neodymium nickelate (NdNiO3), through a simple synthesis process. While NiO acts as the receptor for the gas, NdNiO3 serves as the transducer that efficiently transmits the signal, enabling detection at concentrations as low as 320 ppb, far surpassing the sensitivity of many commercial sensors. The new low-cost sensor can help detect toxic sulfur dioxide (SO2) gas responsible for respiratory irritation, asthma attacks, and long-term lung damage, at extremely low concentrations. With its high sensitivity, portability, and user-friendly operation, this sensor system offers a practical solution to monitor and manage SO2 pollution, supporting public health and environmental safety. This work demonstrates the potential of material science to create accessible technologies for real-world challenges.

IISc develops simple sensor for liver cancer detection

Researchers at the Indian Institute of Science (IISc), Bengaluru have developed a unique luminescent probe that uses terbium, a rare earth metal, to sense the presence of an enzyme called β-glucuronidase, which can potentially aid in the detection of liver cancer. The roots of the project trace back nearly a decade, beginning with the team's experiments on metal ions and their gel-forming properties. The team found that terbium ions couched in a gel matrix derived from bile salts can emit green fluorescence. Within the same gel matrix, the team added an organic molecule called 2,3-DHN (2,3-Dihydroxynaphthalene) masked with glucuronic acid. When β-glucuronidase slices this modified molecule, 2,3-DHN gets released. The researchers then shined UV light on the sample. For ease of application, the team designed this assay as a simple paper-based sensor by anchoring the gel matrix onto a paper disc. When β-glucuronidase pre-treated with modified 2,3-DHN is added, the disc exhibits a much stronger green glow under UV light. The researchers say that clinical studies will still need to be carried out to validate the assay. But they are hopeful that such sensors can bring down the cost of detecting clinically significant biomarkers.

Scientists in Guwahati reveal hidden healing power of poisonous plants

Researchers at the Institute of Advanced Study in Science and Technology (IASST), Guwahati, an autonomous institute of the Department of Science and Technology (DST), are tracing the secrets held in the leaves, roots, and sap of the natural world, having comprehensively investigated various poisonous plant species and their phytochemical constituents. The researchers emphasised that plants produce phytochemicals, natural compounds used for their own survival, which can also affect human biology. While some of these are toxic, others, when isolated and modified, hold immense medicinal promise.

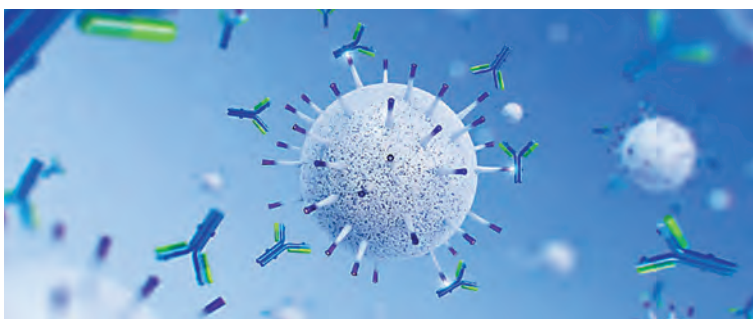
The team has reviewed existing literature and identified 70 poisonous plant species which are used traditionally to treat a wide array of illnesses, from fevers and colds to skin diseases and oedema. The findings draw upon ethnopharmacology, how indigenous cultures use plants for healing. From treating snakebites to managing jaundice, these traditional remedies are now being re-evaluated through the lens of modern science. The implications are vast.

Xcell Biosciences collaborates with Thermo Fisher to advance next generation of cell therapies

Xcell Biosciences, a US-based instrumentation company focused on cell and gene therapy applications, has announced a strategic collaboration with Thermo Fisher Scientific Inc., the world leader in serving science, to advance research in regulatory T cells (Tregs) and tumour-infiltrating lymphocytes (TILs). While significant progress has been made in the cell therapy space leveraging Chimeric Antigen Receptor T (CAR T) cells, this collaboration aims to advance Treg and TIL cell therapies that specialise in combating autoimmune and solid tumour diseases. With solid tumours representing approximately 90 per cent of adult cancers and instances of autoimmune diseases on the rise worldwide, this collaboration looks to target a crucial area for improving global health. Leveraging the strengths of both companies, the joint research will focus on developing new methodologies to enhance the efficacy of Tregs and TILs in therapeutic applications. The collaboration also seeks to streamline workflows while improving scalability and reproducibility in cell therapy manufacturing to help make these critical treatments more accessible to patients.

Illumina buys SomaLogic for $425 M to accelerate proteomics business

Illumina, Inc. has entered into a definitive agreement with Standard BioTools under which Illumina will acquire SomaLogic, a leader in data-driven proteomics technology, and other specified assets for $350 million in cash payable at closing, subject to customary adjustments, plus up to $75 million in near-term performance-based milestones and performance-based royalties. This transaction builds on a co-development agreement Illumina established with SomaLogic in December 2021 to bring the SomaScan Proteomics Assay onto Illumina's high-throughput next-generation-sequencing (NGS) platforms. Illumina Protein Prep is currently in use with nearly 40 early-access customers globally and will become available to all customers starting in the third quarter of 2025. Combining SomaLogic's proteomics technology with Illumina's scalable NGS ecosystem, DRAGEN software, and Illumina Connected Multiomics will accelerate the technology development roadmap for proteomics and reduce time and cost of proteomic research.



Ecolab Life Sciences unveils new bioprocessing purification resin

US-based Ecolab Life Sciences has launched an innovative new resin to help achieve cost savings and optimise operations throughout the antibody manufacturing process. Purolite AP+50 is an affinity chromatography resin with a 50-micron bead size offering the highest dynamic binding capacity of the AP resin platform while providing excellent durability for monoclonal antibody capture.

It also leverages Ecolab's patented Jetted resin bead manufacturing technology, an innovative approach that enables lot-to-lot consistency and shorter lead times.
It is the latest addition to Ecolab's robust Purolite Resin affinity toolbox which helps biopharmaceutical companies and Contract Development and Manufacturing Organisations solve complex purification challenges.

Waters launches Xevo TQ Absolute XR Mass Spectrometer

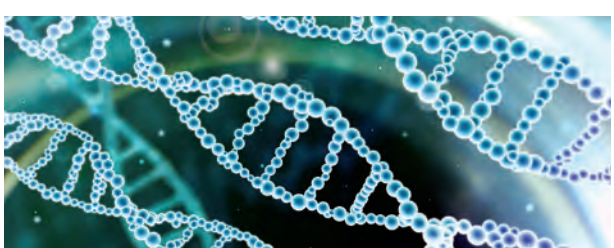
Waters Corporation has announced the launch of the Xevo TQ Absolute XR Mass Spectrometer, the company's most sensitive, robust, and reliable benchtop tandem quadrupole. Notably, the product exceeds the performance capabilities of the Xevo TQ Absolute, which itself set the benchmark in the industry for tandem quadrupole sensitivity, particularly in areas such as pharmaceutical quantitation and PFAS detection. Tailored for high-throughput applications in pharmaceutical companies, contract testing organisations, and government laboratories, the new system is designed to deliver exceptional performance for the most sensitive trace-level analyses in complex matrices, while maximising system uptime and efficiency. Built on the trusted, intuitive design of the Xevo TQ Absolute Mass Spectrometer, the Xevo TQ Absolute XR Mass Spectrometer offers significant operational efficiencies. It uses up to 50 per cent less power and nitrogen gas, produces 50 per cent less heat than any other high-performing tandem or triple quadrupole on the market, and takes up to 50 per cent less bench space, making it the ideal system for laboratories striving to reduce their environmental footprint without compromising throughput or performance.

Bionova Scientific expands capacity and enters advanced therapies market

Bionova Scientific, a contract development and manufacturing organisation (CDMO), is entering the advanced therapy manufacturing space. The company is installing its third FlexFactory manufacturing platform from Cytiva, a Danaher company and a leader in the life sciences industry, to help meet the surging demand for advanced therapies, while maintaining their core monoclonal antibody (mAb) business. Bionova will also use Cytiva's Fast Trak process development services to help advance their entry into genomic medicines. The FlexFactory platform for advanced therapies offers substantial benefits that reduce business risks, increase operational speed, faster product ramp-up, and enhance flexibility. Its built-in compliance features and robust quality controls helps improve regulatory adherence and minimise production issues, while its modular setup allows rapid adaptation to market shifts. Cytiva's Fast Trak process development services will help Bionova accelerate their molecule through clinical development.

Revvity introduces new IVD reference standards for oncology testing

Revvity, Inc. has announced the launch of three Mimix reference standards for IVD use, designed for monitoring of next-generation sequencing (NGS) or droplet digital polymerase chain reacting (ddPCR) assays designed to detect somatic mutations in genomic DNA (gDNA) from human samples for IVD use. These cell line-derived reference standards have undergone appropriate design controls to meet US Food and Drug Administration (FDA) regulatory requirements, which helps laboratories integrate them into existing workflows to support monitoring test performance, assay variation, and to help identify increases in random or systemic errors. Offering the Mimix reference standards for IVD indicates the products have been developed and manufactured in accordance with applicable quality system requirements allowing for improved reliability and precision of these reference standards.



Transformative 'Quantum' Leap in Healthcare

With the healthcare sector facing complex challenges that call for innovative solutions to improve diagnostic accuracy, treatment efficacy, and data management, we see quantum technology, with its unique capabilities, holding the potential to revolutionise various aspects of healthcare. For instance, quantum algorithms can accelerate the identification of genetic markers associated with diseases, facilitate the analysis of medical images, and optimise treatment plans based on individual genetic profiles. Further, quantum cryptography can offer a robust security solution for safeguarding sensitive patient data, a critical need as healthcare increasingly relies on digital platforms.

Moreover, as the explosion of data within the healthcare sector, especially from genomic sequencing and electronic health records, poses unique challenges in data management and analysis, quantum computing offers transformative solutions for big data analytics in healthcare by leveraging its inherent ability to handle vast datasets more efficiently than classical computers. As a result, we are observing numerous initiatives taking place by countries across the world to strengthen their expertise in quantum technology. For example, India and South Korea have recently launched a transformative initiative to industrialise artificial intelligence (AI)-quantum medical devices and diagnostics. Researchers from Yeungnam University Hospital in South Korea have projected a future where Korea's AI-quantum systems can integrate with India's traditional natural medicine.

With a vibrant IT, biotechnology, nanotechnology, and startup ecosystem flourishing in Bengaluru, the Karnataka state government is embarking on its next venture, i.e. establishing a quantum ecosystem in its capital. This is in close harmony with the recent initiative that the Government of India undertook to promote Quantum Technologies by launching the National Quantum Mission. This Mission was approved back in 2023 at a total cost of Rs 6003.65 crore from 2023-24 to 2030-31, aiming to seed, nurture and scale up scientific and industrial R&D in Quantum Technology.

These developments have in turn led the Karnataka Science and Technology Promotion Society (KSTePS), Department of Science & Technology, Government of Karnataka, in association with the Indian Institute of Science (IISc) Quantum Technology Initiative (IQTI), to host India's first large-scale summit - Quantum India Bengaluru Summit (QIB 2025) from July 31 to August 1, 2025.

Reports have also revealed that India is set to establish its first Quantum Computing Valley in Amaravati by January 2026, a visionary initiative led by the Andhra Pradesh government in alignment with the National Quantum Mission, with special focus on healthcare. On the global front, the European Commission launched a new strategy on July 2, 2025, aiming to secure European leadership in quantum technology. According to projections of the Commission's Joint Research Centre (JRC), thousands of highly skilled jobs in the quantum area will open up by 2040, while the sector's estimated value is expected to grow to over €155 billion in value by 2040.

However, in this regard, the United States (US) has been the leader. Much earlier in 2023, the Cleveland Clinic and IBM officially unveiled the first deployment of an on-site private sector IBM-managed quantum computer in the US. The IBM Quantum System One installed at the Cleveland Clinic became the first quantum computer in the world to be uniquely dedicated to healthcare research, with an aim to help the Cleveland Clinic accelerate biomedical discoveries.

In 2024, China set up the country's first quantum computing and data medicine research institute, which is expected to pioneer the application of quantum computing power in the medical field.

While many other countries, such as Singapore, Japan, etc, are ramping up their investments in this technology, collaborative efforts involving researchers, healthcare providers, and technology developers will be crucial to overcoming hurdles and realising the full potential of quantum computing in transforming healthcare. The delicate nature of quantum hardware, the need for error correction, and the scalability of quantum systems pose huge barriers to the widespread adoption of this technology in the long run. BS

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