

BioSpectrum

the business of Bio & Health Sciences

PUNE ■ Volume 22 ■ Issue 11 ■ November 2024

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₹150

Total pages including cover 52

Will Boosting Biofoundries Transform India's Biomanufacturing Landscape?

"To achieve our 'Skilled India' vision, we'll train a large number of individuals quickly and to high standards"

- Jayant Singh Chaudhary, Union Minister of State
(Independent Charge), Skill Development and Entrepreneurship,
Government of India - 26





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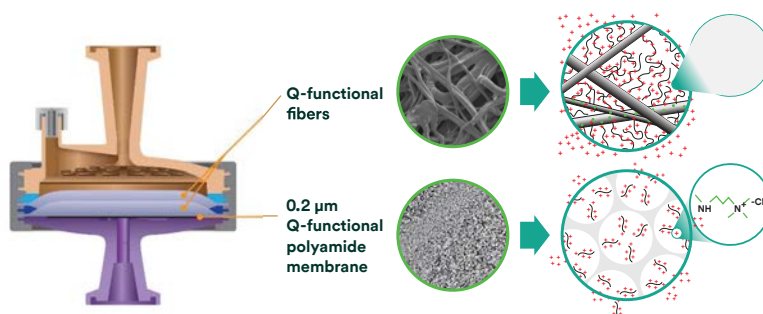
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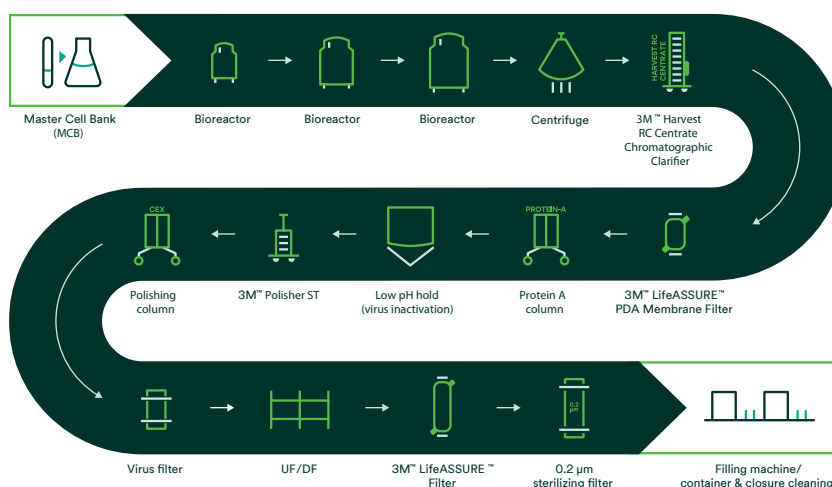
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Vol 22; Issue 10; October 2024

Acknowledgement/ Feedback

Thank you very much for sharing HiMedia Labs' inputs on the BioE3 policy through your esteemed forum of BioSpectrum. We sincerely appreciate your and your team's effort to help the government of India spread the flavour of such approved policies and bring awareness to the professional community.

Dr Girish Mahajan, Mumbai

Thank you BioSpectrum for the feature on Pratima Reddy, Country Speaker for Merck India & MD, Merck Specialties, in your October edition.

Saritha Hajare, Mumbai

Appreciate the opportunity to feature Siemens Healthineers, and for the lovely story on

Kalavathi GV, Head of Development Centre (DC) and Executive Director at Siemens Healthineers India.

Archana Sebastian, Bengaluru

It is lovely working with BioSpectrum. We truly appreciate your time, effort, and support, for featuring the inputs by the India Brazil Chamber of Commerce, in the BioE3 policy related story.

Pronshu Arora, New Delhi



Vol 22; Issue 11; November 2024

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

Website: www.biospectrumindia.com

Reprinted for private Circulation

Letter from Publisher



Ravindra Boratkar
Publisher &
Managing Editor,
MD, MM Activ Sci-Tech
Communications Pvt. Ltd.

Dear Readers,

India's prowess in the pharmaceutical industry has been acknowledged for quite a long time, especially in creating vaccines and generic medications. In recent years, the nation has broadened its focus to encompass biomanufacturing, which entails large-scale manufacturing of items generated from biological sources. Additionally, India is entering the field of gene and cell therapy. As India looks to strengthen its place in the global biotech supply chain, governmental initiatives for biotech infrastructure demonstrate the country's dedication to becoming a global leader in biomanufacturing through biofoundries that are particularly positioned to speed up these efforts. By lowering the time and expense involved in biomanufacturing, biofoundries' automation can give Indian businesses a competitive edge when expanding their output.

India has come up with multiple initiatives to support and set up biofoundries, including the BioE3 Policy, the Bio-RIDE scheme, and the Vigyan Dhara scheme. With the new BioE3 Policy in place, the coming years will provide insight into how biofoundries will play a role in boosting innovation, scaling up and commercialisation of bio-based products. Our lead story talks about how India is positioning in this rapidly evolving space, and the role of biofoundries in India's biomanufacturing initiatives.

With one of the youngest populations in the world, India can realise its demographic dividend through a workforce that is trained in 'employable' skills and is industry-ready. As India continues its journey towards becoming the skill capital of the world, various ambitious programmes and policies are steering the nation towards a skilled, employable, and future-ready workforce. We had an opportunity to speak with Jayant Singh Chaudhary, Union Minister of State (Independent Charge), Skill Development and Entrepreneurship in Hyderabad where he exudes confidence that the new BioE3 Policy will give a new direction to the Indian industry, further grounding its roots and boosting its manufacturing prowess to meet the domestic needs and global demands in key areas of pharma, biotechnology and other sectors.

On September 9, 2024, the House of Representatives in the US passed the BIOSECURE Act, which restricts US Federal agencies from contracting with or procuring services and equipment from Chinese "biotechnology companies of concern", and will extend to companies that source or utilise equipment or services from five Chinese companies. We have an article that explores its implications on the Indian CRDMO sector.

India has the second largest population of diabetics in the world and without periodic tracking, diabetes will lead to renal and cardiovascular mortalities. There is a rising need for initiatives and interventions to reduce or reverse the impact of non-communicable diseases such as obesity, hypertension, and diabetes. We have an expert article that addresses this, as we observe November 14 as World Diabetes Day, elaborating the public and private initiatives, coupled with rapid technology advancements that will drastically help reduce the rising diabetes prevalence in the Indian subcontinent.

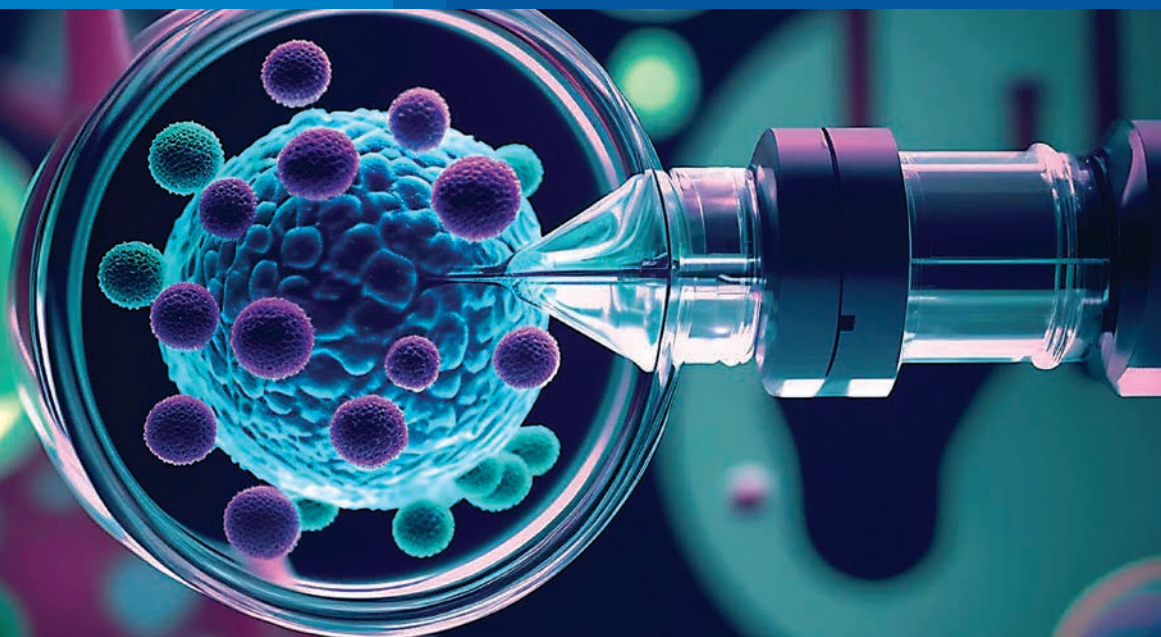
I am sure you will find this edition a great read.

Thanks & Regards,

A handwritten signature in blue ink, appearing to read 'Ravindra Boratkar'.

Ravindra Boratkar,
Publisher & Managing Editor

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Will Boosting Biofoundries Transform India's Biomanufacturing Landscape?

Biofoundries hold the potential to emerge as the backbone of biomanufacturing and synthetic biology, offering integrated infrastructure to streamline the design, construction, and testing of genetically engineered organisms. Biofoundry is a place where biomanufacturing meets automation. The highly modular structure of a biofoundry helps accelerate the design-build-test-learn (DBTL) workflow to deliver products fast and in a streamlined fashion. Advanced platforms to enable rapid, high-throughput experimentation, and automating processes that were once labour-intensive and time-consuming is a central theme. India has come up with multiple initiatives to support and set up biofoundries, including the BioE3 (Biotechnology for Economy, Environment and Employment) Policy, the Bio-RIDE scheme, and the Vigyan Dhara scheme. The BioE3 Policy lays out plans for accelerating the transition to biomanufacturing by promoting integrated use of Artificial Intelligence (AI), digitalisation with 'omics', and upstream biotechnology innovations through bio-AI hubs, biofoundries, and biomanufacturing hubs across the country. With the new BioE3 Policy in place, coming years will provide insight into how biofoundries will play a role in boosting innovation, scale-up and commercialisation of bio-based products. In addition, with a Global Biofoundry Alliance now established to coordinate biofoundry activities and innovations worldwide, the question arises: how is India positioned in this rapidly evolving field, and what role do biofoundries play in India's biomanufacturing initiatives? Let's explore.



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"To achieve our 'Skilled India' vision, we'll train a large number of individuals quickly and to high standards"



Jayant Singh Chaudhary,

Union Minister of State (Independent Charge), Skill Development and Entrepreneurship, Government of India

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"A network of Biofoundries, will boost ecosystem's value creation status as 'Innovator'"



Dr Manish Diwan,

Mission Director – Make in India for Biotech Sector, BIRAC and Head – Biofoundry, NCR Biotech Cluster & IVCOL

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Neha Sinha, Dementia Specialist, Co-Founder & CEO of Epoch Elder Care shares her thoughts on how to address the growing burden of Alzheimer's and related disorders.



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Kamal D Shah, Co-founder, NephroPlus talks about the challenges facing the dialysis devices market in the country.



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Red-flagging Sub-standard Chinese APIs

While India had been previously battling the crucial issue of overdependence on Chinese Active Pharmaceutical Ingredients (APIs), now the country has to swiftly address the mounting problem of substandard materials, specifically, Isopropyl Alcohol (IPA), an important ingredient in drug-making. Naturally, Indian pharmaceutical companies have raised a Red Flag over this dangerous trend, as the image of Indian pharma is at stake, yet again, in the global market.

India's dependence on imports of such types of pharma ingredients from China is well-known and has been discussed several times. This overdependence hit the Indian pharma industry severely particularly during the initial phase of COVID-19 as the Chinese authorities imposed a lockdown after the initial reports of a 'Lab leak in Wuhan' province. The closure of industrial activities affected imports of APIs from China. Since then, the issue of our over-dependence on API imports from China has been discussed at length.

To help reduce this dependence the government introduced production-linked incentive (PLI) schemes for API production in India. As a result, 32 projects, with a total installed capacity of 56,680 MT per annum of APIs have been completed. Though it is a significant achievement, considering our imports of 3 lakh MT (in 2022-23), there is still a long way to go. Imports being unavoidable, will have to continue, though they may be reduced to a large degree.

China supplies 64 per cent of our IPA requirement, which had grown from 57 per cent in 2020. Import of sub-standard and non-pharmacopoeia grade IPA from China poses a risk to India in two ways as its usage in our drug production may affect the quality and safety of the drugs produced here. As a result, the first risk is to the public health of the people here. The second risk to the image of Indian pharma companies, exporting drugs. India's export of generic drugs is so high that it is widely known as 'pharmacy to the world'. India's reputation itself is at stake, said Vikas

Biyani, an expert in Food and Drug Administration (FDA) matters, who has recently raised this issue through a statement about sub-standard IPA imports and its effect on the pharma industry.

Before that, even the Director General of Trade Remedies (DGTR) investigated this issue following the issue being referred to by Deepak Fertilisers in September 2023. Following the regular procedure of investigation, the DGTR gave its recommendations in a report released in August 2024. Its investigation showed that China has undercut the prices by 20 to 30 per cent straining the domestic industry and leading to an increase in dependence on China. Pharma companies buy cheaper imported IPA to have price competitiveness in the global market. DGTR recommended imposing anti-dumping duties on Chinese IPA imports. It will help stabilise prices and ensure the supply of standard IPA, experts feel.

Experts point out one more problem related to sub-standard material is about the storage facility at ports when the IPAs reach there. IPA is transported in bulk chemical tankers and then stored in tanks at the ports till picked up from there. But these tanks store various other chemicals and liquids imported from different countries. Hence, different products get mixed leading to contamination.

The main problem is that China is dumping sub-standard and non-pharmacopoeia grade IPA which is used in some other industries. Dumping of sub-standard IPA at low cost will affect the domestic IPA industry. Experts recall a similar feature in the case of Penicillin-G around 2010. The scene has started repeating, they feel.

Non-pharmacopoeia grade IPA may affect the efficacy and safety of life-saving drugs badly impacting the image of the pharmaceutical companies as well as the exports which the industry would not afford to happen. Going by experience, early action is required from authorities before the problem aggravates. Fortunately, warning red flags have been raised early by the experts. **BS**

Dr Milind Kokje

Chief Editor

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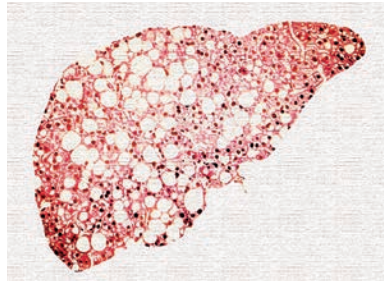


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Health Ministry releases revised operational guidelines for Non-Alcoholic Fatty Liver disease

The Union Health Ministry has released the revised Operational Guidelines and Training Module of Non-Alcoholic Fatty Liver Disease (NAFLD). These documents are designed to improve patient care and outcomes related to NAFLD through informed, evidence-based practices. NAFLD is rapidly emerging as a major public health concern, closely linked with metabolic disorders such as obesity, diabetes and cardiovascular diseases. These



guidelines need to reach the grassroot level workers so that the disease is detected early and the burden of NAFLD is reduced. The release of the training module is

a significant addition to India's efforts to build capacities amongst healthcare professionals to tackle the rising burden of NCDs in India. The guidelines focus on health promotion and early detection which are important for ensuring that patients with NAFLD receive timely and appropriate care. It also advocates for a multidisciplinary approach, integrating the efforts of healthcare providers from various disciplines to offer holistic care to individuals affected by NAFLD.

Karnataka launches draft for India's first dedicated policy for Global Capability Centres

The Draft Global Capability Centre (GCC) Policy 2024-2029 has been launched by the Karnataka government. Key highlights include the creation of Global Innovation Districts with three new tech parks in Bengaluru and Beyond Bengaluru, and the establishment of a Centre of Excellence for artificial intelligence (AI) to boost AI R&D and talent development. The policy also introduces the Beyond Bengaluru Package, offering recruitment assistance and rental support, while creating 3.5 lakh jobs. The government aims to attract establishment of 500 new GCCs achieving a total number of 1,000 GCCs in Karnataka by 2029; To support creation of 3.5 lakh new jobs in Karnataka by 2029; and to generate economic output of \$50 billion in Karnataka through the GCCs being established by 2029. The government is also announcing an Innovation Fund with an allocation of Rs 100 crore, to support joint research between GCCs and academia, and innovation challenges. The government will set up a dedicated unit within the Department of Electronics, IT, Bt, and S&T to offer dedicated support for GCCs establishing operations in Karnataka.

CDSCO becomes Affiliate Member of International Medical Device Regulators Forum

To achieve global alignment in its medical device regulatory system, enhance the competitiveness of the domestic industry, and boost transnational prominence, the Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, applied for Affiliate Membership in the International Medical Device Regulators Forum



(IMDRF) in 2024. IMDRF members include national regulatory authorities from the United States, Australia, Canada, the European Union, Japan, the United Kingdom, Brazil, Russia, China, South Korea, Singapore, and the World Health Organization (WHO). Achieving Affiliate Membership in the IMDRF

will provide significant opportunities for reliance and collaboration with regulatory authorities around the world. The membership helps to harmonise regulatory requirements across the globe, which reduces the complexity for manufacturers and helps in safeguarding public health by promoting collaboration, harmonising regulations, and promoting convergence.

Meghalaya signs MoU with Bill & Melinda Gates Foundation to improve health outcomes

The Government of Meghalaya and the Bill & Melinda Gates Foundation (BMGF) made a major stride in the area of health when they entered into a Memorandum of Understanding (MoU) to work together towards improving population health outcomes of the state, particularly related to maternal and newborn health, family planning, nursing education. Meghalaya is only the third state in India in area of both health and agriculture, after Uttar Pradesh and Bihar, with whom the Gates Foundation

is establishing a partnership. The MoU signed called for the realisation of efficient and effective healthcare solutions in Meghalaya, and the parties also pledged to undertake numerous activities in the achievement of the United Nations Sustainable Development Goals, especially the health-related goal for the year 2030. The MoU will last for four years where both stakeholders shall facilitate successful delivery of the set objectives in the paper with efficiency checkups, monitoring, and evaluation.

Cabinet approves 'Bio-RIDE' scheme to support cutting edge biotech R&D

The Union Cabinet, chaired by the Prime Minister (PM) Narendra Modi, has approved continuation of the two umbrella schemes of Department of Biotechnology (DBT), merged as one scheme- 'Biotechnology Research Innovation and Entrepreneurship Development (Bio-RIDE)' with a new component namely Biomanufacturing and Biofoundry. The scheme has three broad components: Biotechnology Research and Development (R&D); Industrial & Entrepreneurship Development (I&ED); Biomanufacturing and Biofoundry. The proposed outlay for the implementation of the unified scheme 'Bio-RIDE' is Rs 9197 crore during the 15th finance Commission period from 2021-22 to

2025-26. Bio-RIDE scheme is designed to foster innovation, promote bio-entrepreneurship, and strengthen India's position as a global leader in biomanufacturing and biotechnology. It aims to accelerate research, enhance product development, and bridge the gap between academic research and industrial applications.



PMBI and Coal India ink MoU to provide high-quality generic medicines

In a significant milestone under the mission to provide quality generic medicines and surgical equipment at affordable prices to the masses, the Pharmaceuticals and Medical Devices Bureau of India (PMBI) and Coal India Limited (under the administrative control of the Ministry of Coal, Government of India) have signed a Memorandum of Understanding (MoU) for opening of Jan Aushadhi Kendras in the premises of every coal field, selected hospitals or any suitable location specified or decided by Coal India Limited. These facilities include Coal India Limited in Kolkata, West Bengal; Eastern Coalfields Limited in Sanctoria, West Bengal; Bharat Coking Coal Limited in Dhanbad, Jharkhand; Central Coalfields Limited in Ranchi, Jharkhand; South Eastern Coalfields Limited in Bilaspur, Chhattisgarh; Western Coalfields Limited in Nagpur, Maharashtra; Northern Coalfields Limited in Singrauli, M.P.; Mahanadi Coalfields Limited in Sambalpur, Orissa; North Eastern Coalfields in Assam; and Central Mining Planning & Design in Ranchi, Jharkhand.

Aster DM Healthcare to invest Rs 220 Cr to build largest exclusive women & children's hospital in Hyderabad

Aster DM Healthcare, one of the largest integrated healthcare providers in India, will be launching the largest Women & Children Hospital in Hyderabad. This 300-bed state-of-the-art facility will cater to the unique healthcare needs of children and women of all ages. Aster DM Healthcare will be making an investment of around Rs 220 crore in this facility spreading over 3 lakh sq ft. Phase 1 of the project is expected to be completed and fully functional by mid - FY26. The Aster Women & Children Hospital will offer specialised medical services such as obstetrics, gynecology, pediatrics, neonatal care, and reproductive health. It will feature 100 critical care beds and 10 modular operating theatres, along with luxury birthing suites. The company plans to add ~2000 beds by FY27 taking the total bed tally in India to 6800+ through the organic route and will further look for expansion through the inorganic route as well to achieve its aim of becoming the top 3 integrated healthcare providers in India along with a strong presence of labs and pharmacies in the geographies that Aster has a presence in. The plan encompasses a mix of brownfield and greenfield projects, including the upcoming Aster Capital in Trivandrum, and Aster MIMS Kasargod and adding bed capacity to the existing hospitals. The company will also be eyeing potential markets such as Maharashtra and Uttar Pradesh. The capital allocation for this expansion is in the range of Rs 1200 crore.

Piramal Pharma Solutions announces \$80 M expansion plan for sterile injectables facility in US

Mumbai-based Piramal Pharma Solutions (PPS), a leading global Contract Development and Manufacturing Organisation (CDMO) and part of Piramal Pharma, has unveiled an \$80 million investment plan to expand its Lexington, Kentucky facility in



the US. The site specialises in sterile compounding, liquid filling, and lyophilisation for sterile injectable drug products, playing a vital role in Piramal Pharma Solutions integrated antibody-drug conjugate development and manufacturing programme, ADCelerate. The investment, financed by bank loans and internal accruals, aims to enhance the site's existing

capacity and capabilities to meet the demands of a rapidly growing market. With this expansion, Piramal Pharma will strengthen its position as an efficient and reliable global partner for biologic manufacturing, leveraging deep scientific expertise and extensive experience managing complex technical projects. The expansion will create over 40 full-time jobs, contributing to the area's economic development and fostering a diverse, vibrant workforce.

Neovantage Innovation Parks secures Rs 300 Cr for life sciences real estate portfolio

Neovantage Innovation Parks, South Asia's largest private owner and operator of life sciences-focused real estate, has secured its inaugural green loan of Rs 300 crore from HSBC India. This is HSBC's first green loan facility in the life sciences real estate sector in India. Neovantage Innovation Parks, located



in Genome Valley in Hyderabad, is home to leading Pharma and Life Sciences Research and Development (R&D) companies and is South Asia's leading privately operated life sciences real estate portfolio. The portfolio is set up as a joint venture (JV) between Ivanhoe Cambridge, the real estate group of CDPQ, and Lighthouse Canton, a global investment institution. The portfolio consists of buildings which have been additionally awarded the

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Pfizer launches first ever dedicated commercial analytics centre in India

US-based pharmaceutical company Pfizer Inc. has launched the company's first ever dedicated commercial analytics centre in India called, 'the Analytics Gateway'. The Analytics Gateway represents a significant milestone in Pfizer's international commercial strategy and is positioned to be a global capability centre serving all of Pfizer's international (ex-US) markets to bring analytics, and insight breakthroughs that will benefit patients. The Analytics Gateway comprises a talented and experienced pool of data and analytics experts. The centre that is set up in Mumbai, is expected to accelerate data science and artificial intelligence (AI) solutions to meet Pfizer's ambitions in modernising marketing and creating an agile salesforce. It will also drive continuous commercial effectiveness, enabling Pfizer to bring more of its medicines to more patients in India and around the world.

Lupin partners with Celnova to commercialise orphan drug NaMuscla in Argentina and Colombia

Mumbai-based global pharma major Lupin has announced that its subsidiary Lupin Atlantis Holdings SA has entered into a distribution agreement with Celnova Pharma for Lupin's orphan drug NaMuscla (mexiletine). Celnova will commercialise NaMuscla in Argentina and Colombia, for the symptomatic treatment of myotonia in adults with non-dystrophic myotonic (NDM) disorders. NaMuscla is the first and only licensed product in Europe for this indication. NDM disorders are a group of rare, inherited neuromuscular disorders, characterised by the inability to relax muscles due to voluntary contraction resulting in myotonia or muscle stiffness. NaMuscla reduces myotonia symptoms in people with NDM, resulting in a significant improvement in quality of life and other functional and clinical outcomes for patients. NaMuscla, which has been designated orphan drug status in Europe and US, received EU marketing authorisation in December 2018. As per the agreement, Celnova will be the exclusive distributor of NaMuscla in Argentina and Colombia, and drive the registration, importation, storage, and sales.



Twist Bioscience teams up with MedGenome to diagnose rare diseases

To address the rare disease burden in India, Bengaluru-based MedGenome is partnering with Twist Bioscience, a leading and rapidly growing synthetic biology and genomics company based in the US, to establish the HOPE for Rare Diseases Programme in India. Within the programme, discounted whole



exome sequencing is provided to the patients from economically disadvantaged families (with necessary documentation) and is a time limited programme. This collaboration coincides with MedGenome's commemoration of a decade of pioneering genomics advancements in India. With this partnership, MedGenome reaffirms its commitment to

democratise access to quality and affordable genetic solutions for all sections of society. MedGenome will continue to be guided by its vision to enhance healthcare affordability and accessibility and focus on its mission to leverage genomics to address the huge unmet need across emerging markets. Twist Bioscience is deploying the Twist Exome 2.0 to support this mission.

IIM Bangalore releases report on Startup Incubation Ecosystem

Nadathur S Raghavan Centre for Entrepreneurial Learning (NSRCEL), the startup incubator at the Indian Institute of Management (IIM) Bangalore, and the Centre for Research on Startups and Risk Financing (CREST), Indian Institute of Technology (IIT) Madras, have announced the release of their joint research report, 'India Incubator Kaleidoscope 2024'. The report reveals that the number of incubators in the Indian ecosystem has grown steadily, with more than 1,100 active incubators dotting the Indian startup ecosystem.

The Southern region leads the pack, housing 45 per cent of all incubators and having the highest density of incubators. Tier I cities house almost half of all incubators (48 per cent). However, the mix of incubators, namely, those hosted by academic institutions, industry and public sector, show significant variation across cities. Chennai has a high proportion of academic incubators (82 per cent), whereas Bengaluru and Gurugram have a high proportion of industry incubators at 71 per cent and 84 per cent respectively.



Qure.ai completes \$65 M Series D funding round

Mumbai-based startup Qure.ai, a global healthcare artificial intelligence (AI) innovator, has announced the completion of a \$65 million Series D funding round. The investment will expedite expansion into the US market and other geographies, increase investment into foundational AI models and enable complementary medtech company acquisitions. The Series D round saw the participation of new strategic and financial investors led by Lightspeed and 360 ONE Asset, joined by Merck Global Health Innovation Fund and Kae Capital. Existing investors also participated in the round, including Novo Holdings, Health Quad, and TeamFund. Qure.ai is on a mission to make healthcare more accessible and equitable globally. This has driven its AI solution development, positioning the company as the world's most deployed healthcare AI. Qure.ai solutions are deployed in over 90 countries across 3000+ sites, powering the efficient identification and management of critical diseases. The company has 18 US FDA-cleared indications, and its products are Class IIb certified per EU MDR regulations.

Venture Center partners with UNIDO and BEE to strengthen technology transfer offices in India

Pune-based Venture Center, a leading technology business incubator for science-driven enterprises in India, has announced a partnership with the United Nations Industrial Development Organization (UNIDO) and the Bureau of Energy Efficiency (BEE) to support capacity-building efforts aimed at strengthening technology transfer offices in Indian institutions, to increase commercialisation of innovations. It is envisaged that this will improve industry-academia collaborations in research, development, and deployment, leading to co-design and co-development of innovative products and solutions. Venture Centre's engagement comes in the backdrop of UNIDO and BEE's ongoing project in India, 'Facility for Low Carbon Technology Deployment (FLCTD)'. This project has supported early-stage and late-stage climate-tech startups to provide innovative solutions for industrial and commercial sectors. The unique approach evolved in the FLCTD project to 'de-risk' innovations has helped over 30 climate tech startups in commercialising their products and solutions.



Lissun raises \$2.5 M in Pre-Series A funding round

Gurugram-based mental healthcare startup Lissun has announced a successful Pre-Series A funding round, raising \$2.5 million, marking a significant milestone in Lissun's continued growth and success. Round led by RPSG Capital Ventures, also saw new investors such as Multiply ventures and Atrium Angels joining in, along with continued support from existing investors such as Ivycap Ventures, Rainmatter and SucSEED Ventures. The latest



funding brings the company's total capital raised to ~\$5 million. With its innovative

phygital approach, Lissun collaborates with healthcare, corporate, and educational institutions, delivering integrated solutions to address high-stress challenges like chronic illnesses, exam anxiety, and workplace pressure. Through a division called Sunshine by Lissun, the company offers world-class child development services in neurodevelopmental and behavioural disorders, such as Autism Spectrum Disorder, ADHD, Learning Disorders etc.

BizDateUp leads \$1 M Pre-IPO funding round in pharma packaging startup Sorich

BizDateUp, amongst the largest ecosystem enablers for startups that provide comprehensive support services, has taken a significant step in the health and wellness sector by announcing a \$1 million investment in the pre-IPO funding round for Gujarat-based Sorich, an innovative company committed to revolutionising

pharmaceutical packaging. The funds raised will be utilised to optimise production capacity and enhance working capital, facilitating the development of patented products and necessary certifications. A considerable portion of the investment will also focus on upgrading existing machinery to

produce high-margin products, including the recently introduced Heat Transfer Labels (HTL). Recent performance metrics highlight Sorich's rapid growth trajectory, reporting a turnover of \$2.4 million in 2023-24 with a target of reaching \$7.2 million in the current fiscal year. The company's planned expansion into Sikkim is expected to generate an additional \$1.8 to 2.4 million in revenue, showcasing its strategic approach to market penetration.



Ahammune Biosciences raises \$5 M in series A funding led by pi Ventures

Pune-based Ahammune Biosciences, a clinical stage therapeutics company working towards creating new ways to treat and cure skin diseases, has raised a Series A funding round of \$5 million led by pi Ventures. Others participating in the round include Capital2B, Colossa Ventures, Bipin Agarwal, Unicornus Maximus LLP, and existing investors Ideaspring Capital, Kotak Alternate Assets, Legacy Assets LLP and IAN. The recently raised funding will assist the company in conducting Phase II human clinical trials for its promising drug candidate for vitiligo. Additionally, the funds will be utilised to expand the patent portfolio, and advance Ahammune's R&D efforts for other immune-mediated skin diseases. Since its inception, Ahammune has been working on its vision to advance innovative solutions for chronic skin diseases which are unmet medical needs. The company is also guided by a distinguished advisory board with extensive experience in drug discovery and development. Ahammune's initial programme is focused on developing a new drug candidate for vitiligo, a skin depigmenting disorder that currently has no cure. In addition to vitiligo, Ahammune is developing a strong pipeline of patented molecules to treat other dermatological and autoimmune diseases.



WHO and multilateral development banks kick off \$1.5 B primary health financing platform

Execution is starting under the new Health Impact Investment Platform on the first country health investment plans turning original commitment into operational reality. The landmark partnership between Multilateral Development Banks (MDBs), the World Health Organisation (WHO) and low- and middle-income countries (LMICs) is addressing the critical need for coordinated efforts to strengthen primary healthcare (PHC) in vulnerable and underserved communities to build resilience against pandemic threats like mpox and the climate crisis. At a high-level roundtable meeting in New York on the margins of the UN Summit of the Future in New York recently, new funding was signed, and it was agreed that the partners will sit down and start identifying needs and planning health care improvements in 15 countries- Burundi, Central African Republic, Comoros, Djibouti, Egypt, Ethiopia, Gambia, Guinea Bissau, Jordan, Maldives, Morocco, Senegal, South Sudan, Tunisia and Zambia. The platform is a key part of an effort to unlock \$1.5 billion in concessional loans and grants to expand and improve primary healthcare services in LMICs, especially in the most vulnerable communities.

WHO launches global strategic plan to fight rising dengue and other Aedes-borne arboviral diseases

The World Health Organisation (WHO) has launched the Global Strategic Preparedness, Readiness and Response Plan (SPRP) to tackle dengue and other Aedes-borne arboviruses. The Plan aims at reducing the burden of disease, suffering and deaths from dengue and other Aedes-borne arboviral diseases such as Zika and chikungunya, by fostering a global coordinated response. The Plan outlines priority actions to control transmission and offers recommendations to affected countries across various sectors, including disease surveillance, laboratory activities, vector control, community engagement, clinical management, and research and development, through a whole-of-society and regional approach. The Plan will be implemented over one year until September 2025, and requires \$55 million to support health preparedness, readiness and response efforts. It is aligned with the Global Vector Control Response 2017-2030, a global strategy to strengthen vector control worldwide, and the Global Arbovirus Initiative, launched in 2022, which focuses on tackling mosquito-borne arboviruses with epidemic potential.

WHO adds HPV vaccine, Cecolin for single-dose use

The World Health Organisation (WHO) has announced that a fourth WHO-prequalified human papillomavirus (HPV) vaccine product, Cecolin (developed by Xiamen Innovax Biotech) has been confirmed for use in a single-dose schedule. The decision is made based on new data on the product that fulfilled the criteria set out in the WHO's 2022 recommendations for alternative, off-label use of HPV vaccines in single-dose schedules. A growing number of vaccine



products initially prequalified for use in a 2-dose schedule can now be used in a single-dose schedule. The single-dose use indication for

this additional vaccine, Cecolin, is incorporated into the second edition of WHO's technical document on considerations for HPV vaccine product choice. A further piece of news is the WHO prequalification on August 2, 2024, of an additional HPV vaccine, Walrinvax (manufactured by Yuxi Zerun), making it the fifth product available on the global market. This will contribute to a more sustainable supply of HPV vaccines, enabling more girls to receive the vaccine.

Gavi harnesses innovation to mitigate effects of climate change on global health

Four global health innovators, from a pool of over 100 applicants, have been chosen as the 2024 Gavi Innovation for Uptake, Scale and Equity in Immunisation (INFUSE) Pacesetters. The winners – Atlas AI from the USA, Causal Foundry from Spain, Figorr from Nigeria and Signalytic from Uganda – were selected from a shortlist of ten finalists by a panel of global health, technology and private sector experts after a two-day workshop funded by the Rockefeller Foundation in Nairobi, Kenya. Through the use of innovative solutions, the selected 2024 Pacesetters will address a number of critical gaps in immunisation efforts. Atlas AI (US) has developed an advanced geospatial platform that leverages artificial intelligence (AI) and big data analytics to identify and geotarget in the last mile in order to find 'zero-dose' children and missed communities; and predict how

shocks will affect them. Causal Foundry (Spain) engages health workers with adaptive tools such as personalised recommendations, an AI-based resource allocation system and tailored weather insights, enabling more precise and effective immunisation activities to prevent climate-related outbreaks and issues of access. Figorr's (Nigeria) solution offers end-to-end and real-time temperature tracking for vaccines and cold chain infrastructure; and Signalytic (Uganda) provides a solar-powered, high-speed digital experience for related software in any health centre, making it possible to generate, store and share health data within and across remote health clinics.



PAHO and OTCA to promote health in the Amazon region

The Pan American Health Organization (PAHO) and the Amazon Cooperation Treaty Organization (OTCA) have signed an agreement to continue to collaborate in strengthening the health of Indigenous Peoples in the Amazon. The agreement follows seven years of cooperation between the two organisations and will focus on three main areas: indigenous health, health and climate change, and access to health in remote areas, including through the development of situation analysis, epidemiological surveillance, and technology for health interventions. Cooperation between the organisations will also focus on training indigenous community health workers in order to strengthen the capacity and retain human resources for health, particularly in border areas.

UK to scale up production of mRNA vaccines

Scientists at the University of Sheffield, in the United Kingdom (UK), will receive up to £3.7 million (\$4.8 million) from Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) to establish proof-of-concept for RNABox, a specialised process designed to scale up production of messenger RNA (mRNA) vaccines at regional vaccine manufacturing sites. The easily adaptable and automated process aims to improve the world's pandemic readiness by helping to increase equitable access to future doses of different mRNA vaccines as and when



needed. It also has the potential to speed up our response to future emerging outbreaks, containing them before they spread to epidemic or pandemic proportions. Rather than the typical approach where vaccines are made in batches, the RNABox process will run continuously

which could create 7-10x more mRNA at a time and enable more efficient use of raw materials. This fast, optimised vaccine production is critical to the 100 Days Mission, a goal spearheaded by CEPI and embraced by the G7 and G20 to accelerate the development of vaccines and other countermeasures to as little as 100 days from identification of a future virus. CEPI's investment will explore using the technology to develop vaccines against CEPI priority pathogens, including the viruses causing deadly diseases like Ebola, Lassa fever, MERS and Nipah.

Rwanda strengthens Marburg virus disease response

US-based pharmaceutical firm Gilead Sciences, Inc., in collaboration with Africa CDC (Centres for Disease Control and Prevention) and Rwanda's Ministry of Health, has donated 5,100 vials of remdesivir to support Rwanda's response to the Marburg Virus Disease (MVD). This emergency donation aims to provide treatment to those affected by the virus following negotiations led by Africa CDC. Upon declaration of the outbreak on September 27, 2024, by the Ministry of Health of Rwanda, Africa CDC deployed senior response leaders to Kigali to assist with surveillance, lab testing, and research. While there is no approved cure for MVD, remdesivir is being supplied for emergency use as global vaccine and therapeutic trials, led by WHO, are underway. Gilead is now coordinating directly with the Ministry of Health of Rwanda to enable getting treatment courses of remdesivir to patients in need across the affected regions.



Brazil eliminates lymphatic filariasis as a public health problem

The World Health Organization (WHO) has announced that Brazil has eliminated lymphatic filariasis as a public health problem. Lymphatic filariasis, commonly known as elephantiasis, is a debilitating parasitic disease spread by mosquitoes. For centuries, this disease has afflicted millions worldwide, causing pain, chronic, severe swelling, serious disability, and social stigmatisation. Over the past few decades, Brazil has implemented integrated actions to eliminate lymphatic filariasis, including the development of a national plan to fight this disease in 1997, the mass distribution of antiparasitic drugs, vector control activities, and strong surveillance, particularly in the most affected areas. With these efforts, the country achieved the end of disease transmission in 2017. The elimination of lymphatic filariasis was also one of the goals of the Brasil Saudável programme, a multisectoral initiative aimed at ending socially determined diseases with a whole-of-government approach and civil society participation, including the involvement of affected people in the implementation of disease control efforts.

World Bank approves new financing for Nigeria to improve health outcomes

The World Bank has approved three operations for a total of \$1.57 billion to support the government of Nigeria in strengthening human capital through better health for women, children and adolescents and building resilience to the effects of climate change such as floods and droughts through improving dam safety and irrigation. The new financing includes \$500 million for addressing governance issues that constrain the delivery of education and health (HOPE-

GOV), \$570 million for the Primary Healthcare Provision Strengthening Programme (HOPE-PHC) and \$500 million for the Sustainable Power and Irrigation for Nigeria Project (SPIN). The HOPE-GOV and HOPE-PHC programmes combined will support the Government of Nigeria to improve service delivery in the basic education and primary healthcare sectors which are critical towards improving Nigeria's human capital outcomes.



Will Boosting Biofoundries Transform India's Biomanufacturing Landscape?



Biofoundries hold the potential to emerge as the backbone of biomanufacturing and synthetic biology, offering integrated infrastructure to streamline the design, construction, and testing of genetically engineered organisms. Biofoundry is a place where biomanufacturing meets automation. The highly modular structure of a biofoundry helps accelerate the design-build-test-learn (DBTL) workflow to deliver products fast and in a streamlined fashion. Advanced platforms to enable rapid, high-throughput experimentation, and automating processes that were once labour-intensive and time-consuming is a central theme. India has come up with multiple initiatives to support and set up biofoundries, including the BioE3 (Biotechnology for Economy, Environment and Employment) Policy, the Bio-RIDE scheme, and the Vigyan Dhara scheme. The BioE3 Policy lays out plans for accelerating the transition to biomanufacturing by promoting integrated use of Artificial Intelligence (AI), digitalisation with 'omics', and upstream biotechnology innovations through bio-AI hubs, biofoundries, and biomanufacturing hubs across the country. With the new BioE3 Policy in place, coming years will provide insight into how biofoundries will play a role in boosting innovation, scale-up and commercialisation of bio-based products. In addition, with a Global Biofoundry Alliance now established to coordinate biofoundry activities and innovations worldwide, the question arises: how is India positioned in this rapidly evolving field, and what role do biofoundries play in India's biomanufacturing initiatives? Let's explore.

Why do we need biofoundries?

Biofoundries represent a new paradigm in biotechnology research, focusing on efficiency, scalability, and innovation. At their core, these facilities bring together automation, artificial intelligence, high-throughput screening, and advanced analytics to accelerate biological research and product development. The ability to genetically reprogram organisms for various applications—from

producing sustainable biofuels and pharmaceuticals to biodegradable plastics and agricultural enhancements—gives biofoundries a pivotal role in shaping the future of biotech industries. The emergence and evolution of engineering biology, and its potential to address multiple global challenges is associated with the rise of biofoundries.

Biofoundries are changing how laboratories approach engineering biology. For example,



synthetic biology combines biological, engineering, and computational principles to create complex biosystems. To do this, scientists relied until recently on bibliographic research and previous knowledge to design and build constructs, essentially one by one. This process is time-consuming and expensive and can be compared with the early mechanical engineering steps where the production chain was almost completely manual.

Biofoundries aim to accelerate academic and translational research, especially in engineering/synthetic biology, by enabling researchers/companies access to automation and high-throughput equipment including process scale-up, computer-aided design software, and other new workflows and tools. Iterative Design-Build-Test-Learn (DBTL) biological engineering cycles allow researchers to test large-scale genetic designs and apply Artificial Intelligence (AI)/Machine Learning (ML) to enhance the design process. Other goals include building a robust engineering/synthetic biology industry and accelerating the commercialisation of engineering/synthetic biology and biomanufacturing process engineering.

Innovation in biomanufacturing, to develop new biologics, vaccines, gene therapies, and diagnostics, is underway across the globe. Biofoundries are proving to be instrumental in revolutionising

biotechnology for healthcare, agriculture, and environmental sustainability - from personalised therapies and advanced biologics in healthcare to synthetic fertilisers and sustainable bio-based materials in agriculture.

In terms of throughput, current exemplars, as highlighted in 'Building a global alliance of Biofoundries' published in *Nature Communications*, 2019, include the Edinburgh Genome Foundry, which for example can process over 2000 DNA assembly reactions per week, twenty times the throughput of a single person without automation. At the University of Illinois at Urbana-Champaign, iBioFAB can build up to 1000 TALEN constructs per day at <\$3 each, 0.3 per cent of what it might otherwise cost. Moreover, iBioFAB can perform multiplex genome-scale engineering of *Saccharomyces cerevisiae* in a fully automated manner, greater than ten times the throughput of a single person without automation. Working with small companies, the London DNA Foundry, Singapore SynCTI Foundry, and US DOE Agile BioFoundry now provide cost-effective access to expensive equipment and the necessary expertise for product prototyping and commercial process validation, which are often required to secure additional capital investment.

India's Growing Biomanufacturing Landscape

India has long been recognised for its strengths in pharmaceutical manufacturing, particularly in the production of generic drugs and vaccines. In recent years, the country has expanded its focus to include biomanufacturing, the large-scale production of biologically derived products. India is also expanding into the cell and gene therapy space. The BioE3 policy also highlights precision biotherapeutics as a thematic area of focus. Government initiatives for biotech infrastructure reflect India's commitment to becoming a global leader in biomanufacturing through biofoundries.

Biofoundries are uniquely positioned to accelerate these efforts, as India seeks to enhance its position in the global biotech supply chain. The automation provided by biofoundries can reduce the time and cost associated with biomanufacturing, giving Indian companies a competitive edge in scaling up production. India's biotechnology ecosystem is growing rapidly, with strong support from both the government and private sectors. The Department of Biotechnology (DBT) has been instrumental in fostering innovation through grants, research centres, and collaborations. Biofoundries would fit naturally into this ecosystem

by complementing existing research facilities and biomanufacturing plants.

For India, this level of automation could enhance the efficiency and scalability of biomanufacturing processes. While a relatively unexplored concept in the country yet, how India's promising biotechnology landscape and favourable policy framework can enable growth of advanced biofoundries is yet to be seen.

Dr Pawan K Dhar, Executive Director, CVJ Centre for Synthetic Biology & Biomanufacturing said, "India's rich and diverse bio-economy—focusing on areas like sustainable agriculture, renewable energy, and environmental biotechnology—will fuel the growth of localised biofoundry applications. These applications will address key national and global challenges such as food security, pollution, biomaterials, and efficient bioresource management. What's exciting is that the rise of low-cost, high-throughput screening technologies will make these advancements accessible to smaller institutions and startups. This democratisation of bioengineering resources will spur innovation across sectors, placing India at the cutting edge of bio-based manufacturing on the global stage."

The Government of India has introduced several Production Linked Incentive (PLI) Schemes aimed at enhancing domestic manufacturing and attracting significant investments in the life sciences-related sectors. Additionally, initiatives like 'Make-in-India', the National Biopharma Mission (NBM), as well as new provisions from the Anusandhan National Research Foundation (ANRF), to name a few, are set to boost innovation and technological prowess.

Recent significant developments include the approval of the BioE3 Policy for biomanufacturing and the approval of the BioRIDE scheme. These initiatives highlight establishment of biofoundries, in boosting bio-innovation and high-performance biomanufacturing. By providing a platform for rapid prototyping and scaling biomanufacturing processes, biofoundries can support the growth of Indian biotech startups, enhance the country's production capabilities, and drive innovation in bio-based industries.

Sharing his views Dr Premnath Venugopalan, Director, Venture Center said, "I think the Biofoundry facilities and capabilities will be especially important for startups looking at emerging opportunities in biopharma (cell and gene therapies, biosimilars, living therapeutics etc), agriculture and nutrition (agrobiologics, climate resilient agriculture), energy and environment (biorenewable chemicals and fuels, sustainable

ingredients), blue economy (marine chemicals and materials, aquaculture etc) and other such areas."

By integrating biofoundries into India's biotechnology infrastructure, the country can accelerate the development of cost-effective, and sustainable solutions for healthcare, agriculture, and environmental challenges.

Dr Dhar further said "The growing availability of funding to establish biofoundry infrastructures in India opens up tremendous possibilities, as the country is on its way to becoming a global leader in biotechnology and biomanufacturing. Over the next 5 to 10 years, we can expect to see a rise in biofoundries that bring together academic research, industry collaboration, and government support. These hubs of innovation will likely focus on automating synthetic biology processes, speeding up the development of new biological systems, and leveraging AI to drive breakthroughs in biomanufacturing using sophisticated computational models."

Global scenario: The Global Biofoundry Alliance (GBA)

The Global Biofoundry Alliance (GBA) was formally launched on May 9, 2019 in Kobe, Japan to enable the sharing of experiences and resources and for working together to overcome shared challenges and unmet scientific and engineering needs. The GBA is a community collective of publicly funded Biofoundries across the world. The members of the GBA are a test-bed for new technologies and the development of skills. The advanced infrastructure allows researchers to adopt cutting-edge high-throughput workflows and enable accessibility for startups, SMEs, and academic researchers alike. Signing members of the GBA include research institutions, research funding agencies, or other entities that operate non-commercial biofoundries, as well as other organisations that actively support public-funded biofoundries. The parties have non-overlapping missions with for-profit entities.

The Alliance includes member countries like the USA, Singapore, China, Australia, Canada, Germany, Denmark, Finland, Japan, Mexico, South Korea, and the United Kingdom biofoundry destinations like Edinburgh, London, and Manchester, and India. Out of the prominent member countries of the GBA, India perhaps stands as a relative newcomer, with 'Biofoundry India' from Delhi representing the country at the GBA.

The objectives of the GBA include

1. Develop, promote, and support non-commercial biofoundries established around the world,
2. Intensify collaboration and communication

among biofoundries,

3. Collectively develop responses to technological, operational, and other types of common challenges,

4. Enhance visibility, impact, and sustainability of non-commercial biofoundries, and

5. Explore globally relevant and societally impactful grand challenge collaborative projects.

GBA: What It Means for India

The establishment of the GBA marks an important milestone in the coordination of biofoundry activities across the world, promoting collaborations among biofoundries in different countries. For India, participation in this alliance could be beneficial, in terms of an enhanced access to cutting-edge technologies, expertise, and international partnerships. By being a part of the GBA, Indian biofoundries can tap into a global network of innovation, accelerating the country's ability to meet both domestic and international demands for biotech products. This also could also position India as a strategic player in the global biotech supply chain, especially as the need for sustainable, scalable solutions in healthcare and agriculture continues to grow.

Challenges and way forward

While biofoundries hold incredible promise, academic researchers may face several hurdles in fully tapping into their potential. Researchers coming purely from a biological background adapting to automation and advanced technologies on one end, to managing the massive amounts of data generated by Biofoundries on the other, will find it difficult to work at biofoundries.

Explaining challenges working at biofoundries, Dr Dhar said, "One of the biggest challenges is a mental disengagement with the traditional slow and steady model of performing cellular edits and waiting for the response that can take weeks together. Moving to a biofoundry approach would call for a new way of thinking and designing experiments. In addition, the high cost of establishing biofoundry infrastructure can be difficult for smaller labs with limited budgets. One way to overcome this is through by establishing hub and spoke model across the nation and enhancing collaborative efforts between universities, industries, creation of shared, open-access resources that empower researchers at an affordable cost. For those coming from a purely biological background, adapting to automation, robotics, and AI might feel overwhelming. To bridge this gap, academic institutions will need to invest in cross-disciplinary

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- Dr Pawan K Dhar,
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"Indian startups need to leverage biofoundries to quickly test out and scale new ideas in emerging areas of market opportunity. Biofoundries can play a useful role after the Proof-of-Concept stage in moving ideas to market faster and in helping generate evidence for feasibility and data for Proof-of-Value. This can be crucial for fund raising for startups."

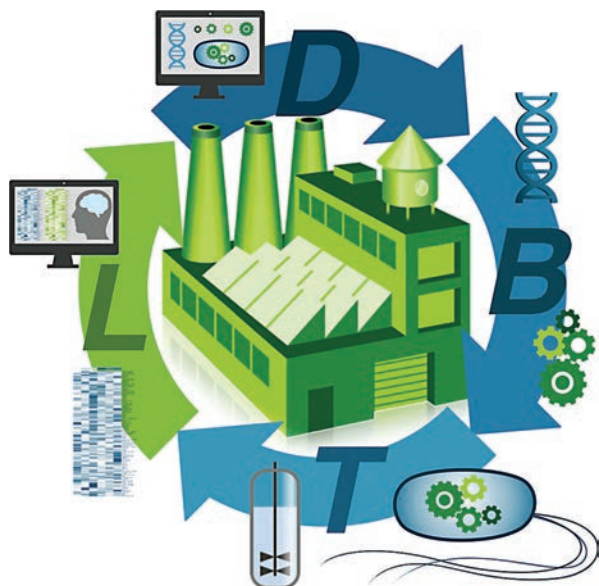


- Dr Premnath Venugopalan,
Director, Venture Center

"The regulatory framework is still evolving around novel synthetic biology techniques, which can slow down DBTL-driven innovations. In terms of data infrastructure, the lack of a centralised data repository and bioinformatics platforms makes the learning phase of the DBTL cycle less efficient. Addressing these challenges through PPP and targeted government interventions can significantly accelerate the establishment of biofoundries and the adoption of DBTL.



- Dr Gaurav Singh,
CEO, Blockchain for Impact (BFI)



The Design-Build-Test-Learn (DBTL) approach

The Design-Build-Test-Learn (DBTL) biological engineering cycle. In simple terms the DBTL framework aims to fulfill particular design criteria for a synthetic biology application, which might for example be the production of a specific product at an optimal titer or the detection of a specific clinical biomarker using an engineered gut microbiome. The cycle begins with D (Design), which defines the desired target function/specifications and involves the computational design of genetic parts, circuits, regulatory and metabolic pathways to whole genomes; B (Build) involves the physical assembly of those designed genetic components; T (Test) involves the prototyping and testing of the assembled genetic designs in living cells (also called "chassis") at different scales, which also includes comprehensive analytical measurements ("omics") of specific cellular components. This can also include testing components in cell-free extract systems; L (Learn) is the application of modeling and computational learning tools, which uses the data obtained in T to inform the design process. Iterations of the DBTL cycle results in genetic designs that aim to fulfill the design specifications established in D. In the figure the DBTL cycle is depicted around an imagined biofactory or biorefinery where many products will be produced using more sustainable and circular economic processes forming the future infrastructure for a global bioeconomy. (Credit: Christopher Johnson, DOE Agile BioFoundry, Golden, CO, USA)

Source: Building a global alliance of biofoundries, Nature Communications, 2019

programmes that teach both technical and computational skills, ensuring researchers are well-equipped to navigate the biofoundry landscape."

He also added that managing the massive amounts of data generated by biofoundries presents its challenges, in that establishing clear guidelines around data sharing, ownership, and intellectual property will be crucial factors. "By developing transparent frameworks for handling these aspects, researchers can collaborate more freely and make the most of the breakthroughs biofoundries offer", he said.

Dr Gaurav Singh, CEO of Blockchain for Impact (BFI) highlighted some other challenges that will be encountered in establishing biofoundry infrastructures and promoting the Design-Build-Test-Learn (DBTL) approach in India. He said, "High capital investment in building state-of-the-art biofoundries requires significant upfront capital investment in cutting-edge equipment and technologies like synthetic biology, automated screening, and genetic engineering. In addition, a limited expertise and talent pool, the biotechnology workforce often lacks specialised skills in areas like bioinformatics, AI-based modelling, and advanced bioprocess engineering, which are crucial for DBTL."

He also added that the gaps in collaborations between academia, startups, and industry are currently fragmented in the Indian biotech sector and that effective DBTL workflows require strong coordination between these elements. "The regulatory framework is still evolving around novel synthetic biology techniques, which can slow down DBTL-driven innovations. In terms of data infrastructure, the lack of a centralised data repository and bioinformatics platforms makes the learning phase of the DBTL cycle less efficient. Addressing these challenges through public-private partnerships and targeted government interventions can significantly accelerate the establishment of biofoundries and the adoption of DBTL," he added.

Meanwhile, sharing his views on how biofoundry infrastructure will strengthen the DBTL approach, to drive biotech innovation and high-performance biomanufacturing Dr Dhar said "Biotechnology is often a game of trial and error, relying on a mix of educated guesses and probability. Driven by hypothesis, scientists design a plan of editing cellular traffic, based on past experience, and hope to get predicted results. Even today, genetic engineering is still largely probability-driven. But with the pressure to deliver faster results, there's a need for a more precise, engineering-focused approach to turn ideas into outcomes more quickly. This is where DBTL

cycle within a biofoundry comes in.”

Dr Dhar pointed out that the biofoundries are revolutionising how we innovate in biotech. With automation, AI, and robotics at the forefront, they enable researchers to test a wide range of ideas at an accelerated pace. This not only improves the Design phase, where new biological systems are imagined and refined, but also brings precision and speed to the entire process. By allowing for high-throughput experiments and rapid prototyping, biofoundries drastically reduce the time it takes to turn an idea into a real-world product. “The most profound shift happens in the Learn phase. Biofoundries use machine learning to analyse vast amounts of data from experiments, uncovering insights that would be impossible to see manually. This powerful feedback loop doesn’t just speed up the DBTL process—it also leads to more efficient, sustainable, and scalable manufacturing, ultimately transforming the way we approach biotechnology,” he added.

On these lines, initiatives like the BioE3 Policy lay heavy focus on collaborations for bioinnovation and entrepreneurship. Dr Premnath said that the Venture Center brought together stakeholders including industry, academia, startups and suppliers to meet in the run-up to the BioE3 Policy announcement. “These have led to some collaborations and joint programmes to contribute to the goals of the BioE3 Policy. Besides a collaboration between Venture Center and National Chemical Laboratory (NCL), Pune in Biopharma Manufacturing, several industry led and academia partnered initiatives are being planned in the Pune region. The Venture Center also plans to expand its ability to support startups in emerging areas of climate resilient agriculture, food and feed, and industrial biotechnology”, he said.

Startup ecosystem will play an important role in these networks. The country’s total biotech startup base has expanded to 8,531 companies. The base grew from 3,397 companies in 2019. How this vast startup ecosystem can strategise to leverage biofoundries to innovate in areas like synthetic biology, biopharmaceuticals, and industrial biotechnology can be crucial factors.

Dr Premnath added, “Indian startups need to leverage biofoundries to quickly test out and scale new ideas in emerging areas of market opportunity. Biofoundries can play a useful role after the Proof-of-Concept stage in moving ideas to market faster and in helping generate evidence for feasibility and data for Proof-of-Value. This can be crucial for fund raising for startups. For example, in the biopharma sector, startups will need to have access to platform technologies enabling cell and gene therapy as well

as facilities that help companies generate samples for human clinical studies. Pilot scale facilities to scale up synthetic biology-based ideas in producing sustainable ingredients for the FMCG industry will be important.”

Establishing and running a biofoundry in India may require more than just financial and technical resources; it could necessitate integrating both physical and digital infrastructures while addressing organisational and operational challenges.

An article titled 'Building Biofoundry India: challenges and path forward' published in Synthetic Biology in 2021, talks about the challenges in the path of building 'Biofoundry India', among other factors. The article highlights that adopting a large resource base in a biofoundry will require re-educating the science administrators, granting agencies, institutions and individual scientists, to embrace shared facilities. The facility must balance providing cost-effective services with offering hard-to-find technical expertise to attract users. BI (Biofoundry India) plans to create several models for client engagement while maintaining equipment access for internal stakeholders. Additionally, BI aims to work with the Global Biofoundry Alliance to become a leader in software maintenance, support, and data analysis platforms, while addressing long-term challenges like securing and retaining personnel through collaborative projects and career development within the facility.

Catalysts for India's Biotech Future

India is at a crucial juncture in its biotech journey, and biofoundries offer the technological infrastructure needed to take biomanufacturing to the next level. By embracing biofoundry technology and automation, India can strengthen its position as a global leader in biotechnology. “We hope that the biofoundry facilities proposed in the BioE3 Policy will expand the translation capabilities of incubators in the country across multiple sectors”, said Dr Premnath.

Participation in the Global Biofoundry Alliance, combined with national initiatives supporting biotech growth, will enable the country to leverage biofoundries to drive innovation, create sustainable biomanufacturing solutions, and meet growing global demand for biotech products.

On this path, biofoundries will not only enhance India’s biomanufacturing capabilities but also contribute significantly to the country’s broader goals of becoming a biotech powerhouse and a key player in the global bioeconomy. **BS**

Shivani Thakar

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“To achieve our ‘Skilled India’ vision, we’ll train a large number of individuals quickly and to high standards”



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Jayant Singh Chaudhary,
Union Minister of State
(Independent Charge),
Skill Development
and Entrepreneurship,
Government of India

Jayant Singh Chaudhary, Union Minister of State (Independent Charge), Skill Development and Entrepreneurship, Government of India, in an interaction with BioSpectrum in Hyderabad, shares his insights on the various initiatives taken up by the Centre for skill development programmes, boosting self-employment. He exudes confidence that the new BioE3 Policy will give a new direction to the Indian industry, further grounding its roots and boosting its manufacturing prowess to meet the domestic needs and global demands in key areas of pharma, biotechnology and other sectors. ***Edited excerpts:***

What according to you are the key objectives of the BioE3 policy and how is it going to boost the industrial sector in the country?

The BioE3 (Biotechnology for Economy, Environment, and Employment) Policy aims to position India as a leader in bio-manufacturing and address critical challenges like climate change and resource sustainability. Its main objectives include increasing Research and Innovation, Strengthening Domestic Bio-manufacturing, Promoting AI and Digital Tools, Establishing Facilities and most importantly developing a skilled workforce.

I am quite confident that by increasing research and innovation, the industry can focus on solutions to tackle climate change and reduce carbon emissions. Enhancing collaborations among science, technology, engineering and manufacturing sectors will strengthen domestic Bio-manufacturing. I believe this new BioE3 policy is going to put more stress on encouraging the use of advanced technologies alongside biotechnology innovations and this will promote India in Artificial Intelligence and Digital Tools. This policy will also enable the creation of Bio-manufacturing Hubs and Biofoundries to support scalable production. Above all nurturing a skilled workforce is very important. This

policy stresses developing a talented workforce which is needed to drive innovation and boost the next level of the Industrial Revolution in the country.

What specific initiatives is the government implementing to foster a skill development ecosystem for startups involved in Active Pharmaceutical Ingredients (APIs), Key Starting Materials (KSMs), and bio-pharma sectors, especially in terms of adhering to sustainable environmental norms?

The government is committed to fostering a robust skill development ecosystem for startups in APIs, KSMs, and bio-pharma sectors. To achieve this goal, we are implementing several specific initiatives.

We are launching targeted skill development programmes that focus on the technical skills required for the production of APIs and KSMs. These programmes will incorporate best practices in sustainability and environmental management. In addition, we are partnering with industry leaders to design curricula that meet current market demands, ensuring that startups are equipped with the necessary skills to thrive in a competitive environment. To encourage environmentally friendly practices, the government is providing financial incentives for startups that adopt sustainable methods. This includes grants and subsidies for technologies that reduce waste and enhance energy efficiency. Furthermore, we are establishing mentorship programmes and incubators specifically for bio-pharma startups, offering guidance on regulatory compliance, sustainable production methods, and innovation in product development.

We are also allocating funds for research and development in sustainable technologies within the bio-pharma sector, encouraging startups to innovate while adhering to environmental norms. Through these initiatives, we aim to create a dynamic and skilled workforce that not only meets industry needs but also prioritises sustainable development in the pharmaceutical and bio-pharma sectors.

How does the BioE3 policy initiative help existing pharmaceutical and biotechnology companies in India boost domestic production and reduce reliance on imports, particularly from countries like China?

The BioE3 policy initiative significantly supports pharmaceutical and biotechnology companies in India by enhancing domestic production and

decreasing reliance on imports. As I said earlier, it encourages the establishment of Bulk drug and Bio-manufacturing Hubs and Biofoundries, providing essential infrastructure for scaling up local production. Additionally, the policy increases funding for research and development, motivating companies to innovate and develop homegrown solutions, particularly for APIs and KSMs.

By promoting the integration of advanced technologies, such as artificial intelligence, the initiative helps improve production efficiency and reduce costs, making domestic manufacturing more competitive. Furthermore, the policy focuses on developing a skilled workforce tailored to the industry's needs, ensuring access to high-quality talent. Most importantly, the policy emphasising sustainable practices also aligns Indian companies with global standards, enhancing their reputation and attractiveness in international markets, and ultimately enabling them to compete effectively and minimise import dependency.

How does the BioE3 policy specifically encourage new startups?

The BioE3 policy encourages new startups by empowering concerned institutions, universities, and industries to collaborate on transformative innovations. By increasing research funding, establishing bio-manufacturing facilities, and promoting the use of advanced technologies, the policy creates an environment that supports the growth of startups in the pharmaceutical and biotechnology sectors. This approach helps foster innovation and enables startups to efficiently address market needs while contributing to sustainable practices.

How is the government addressing the shortcomings in skill development in pharma, biotechnology, and life sciences?

The government recognises the critical need to enhance workforce skill development across all sectors, especially in key areas like pharma, biotechnology, and life sciences. India has already made its mark in the global generic market, but we require deep research skills to succeed in innovation and new drug development. Creating an environment that fosters this kind of expertise is essential, and we are actively working in that direction.

Our approach to enhancing skill development focuses on comprehensive coordination of efforts nationwide. The Ministry is committed to bridging the gap between the demand and supply of skilled manpower by establishing a strong vocational and technical training framework and facilitating skill up-gradation. This includes fostering innovative

thinking for both current and future job roles. To achieve our vision of a 'Skilled India', we aim to train a large number of individuals quickly and to high standards. Our efforts are supported by several functional arms, including the Directorate General of Training (DGT), the National Council for Vocational Education and Training (NCVET), and the National Skill Development Corporation (NSDC). We also operate 33 National Skill Training Institutes (NSTIs) and around 15,000 Industrial Training Institutes (ITIs), alongside 187 registered training partners.

Collaboration is essential, and we work with skill development centres, universities, Central Ministries, State governments, international organisations, and NGOs for impactful implementation of our initiatives.

Could you highlight an initiative from your ministry that makes a difference to an individual?

I'm pleased to share that the Indian School of Business (ISB), Hyderabad, has introduced innovative entrepreneur development courses. Interestingly, candidates are not required to have specific higher education qualifications; instead, we prioritise commitment and determination, especially for those with strong business concepts, like Aryan, who has a 12th-grade pass certificate and yet enrolled in the high-profile ISB to seek a career as an entrepreneur. Every individual has innovative ideas, and it's crucial to provide an environment that nurtures these thoughts and helps scale them up. The government is also focusing on sectors like Green Hydrogen, semiconductors, and the Make in India initiative to create more job opportunities.

What about support to entrepreneurs & MSMEs?

We have established two divisions to cater to the needs of aspiring entrepreneurs and MSMEs: the National Centre for Small Businesses in Haryana and the Indian Institute of Entrepreneurship (IIE) in Gujarat. Under the PM Vishwakarma Yojana, we have trained 900,000 people, helping them gain self-employment through skill development. Over the next three years, our target is to train an additional 1.3 million youth across various sectors.

What initiatives are being taken to inspire innovation among students?

To foster skill development and encourage innovative thinking, we are training over 250 million students in 10,000 schools across India. By investing in our youth today, we are preparing them to tackle tomorrow's challenges. **BS**

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"A network of Biofoundries, will boost ecosystem's value creation status as 'Innovator'"



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Dr Manish Diwan,
Mission Director –
Make in India for Biotech
Sector, BIRAC and
Head – Biofoundry, NCR
Biotech Cluster & IVCOL

After a policy shift under Narendra Modi's regime, biotechnology research and Bio StartUps are prioritised and have taken centre stage. Now the centre has announced a BioE3 Policy aimed at 'Fostering High Performance Biomanufacturing'. The policy lays out plans for accelerating the transition to biomanufacturing by promoting integrated use of AI, digitalisation with 'omics', and upstream biotechnology innovations through bio-AI hubs, biofoundries, and biomanufacturing hubs across the country. In an interaction with BioSpectrum, Dr Manish Diwan, Mission Director, Make in India for Biotech Sector, Biotechnology Industry Research Assistance Council (BIRAC) and Head, Biofoundry, NCR Biotech Cluster & IVCOL shared some insights about new BioE3 policy and plans for upcoming iBRIC Biosciences Innovation Park and goals of this pioneering facility. ***Edited excerpts;***

Could you give us an insight into the iBRIC Biosciences Innovation Park's upcoming plans for biotech innovations, especially in the precision therapeutics space?

The iBRIC+ Biosciences Innovation Park, a 200-acre campus in the serene Aravali hills on Faridabad-Gurgaon highway, would be India's first model Biocluster powered by the Department of Biotechnology (DBT) and BIRAC. It will address a large infrastructural gap that currently exists in the innovation ecosystem by setting up a pilot and pre-product development facilities for startups, and SMEs. The biocluster would nucleate the best talent, industry and investments to create a world-class ecosystem.

The campus already has a presence of 800+ researchers, top-of-the-line research institutions

- Translational Health Science and Technology Institute (THSTI) & Regional Centre for Biotechnology (RCB), BioNEST incubation centre, BSL3 facility, India's largest vivarium, India's only Ferret facility, a primate centre and Indian Biological Data Centre. The cluster will integrate complementary strengths of engineering, medical and business schools, international capacity centres and capability centres of national and international R&D companies. Lifesciences deep-tech startups, SMEs would be able to lease out space to set up their independent R&D, and early-stage manufacturing facilities. The translational research leads from startups, SMEs, and DBT's research institutes particularly National Institute of Immunology (NII), International Centre for Genetic Engineering and Biotechnology (ICGEB), National Brain Research Centre (NBRC) and National Institute of Plant Genome Research (NIPGR) that are located in NCR and others which are spread out across the country, would become accessible for development through this Innovation Park. A new i3C-RCB PhD programme initiated in August this year would create a pipeline of industry ready skilled PhD scholars who could be locally employable. Enabling stakeholders of the innovation ecosystem like IP, legal, regulatory, financial service providers, Funders, Angels, VCs, Knowledge Process Outsourcing (KPOs), industry associations, etc. would have local offices. On the lines of MassBio in the US, and Biopolis in Singapore, the NCR biotech cluster would emerge as a vibrant bio-innovation hub and draw in private investments and Public-Private Partnerships (PPP).

Under the guidance of the recently approved BioE3 policy priorities, the lifesciences deep tech innovations and pre-product development would take the central stage at this cluster. The primary strength would include biologics, precision medicine, cell and gene therapy, live biotherapeutics, in vitro diagnostics, biological data and sample repository for pre-clinical development. The Medical Research Centre at the iBRIC+ Bioscience Innovation Park which is likely to be functional in Q1 2025, is preparing to offer capacities for first-in-human clinical studies, controlled human infection and challenge studies, metabolomics, genomics, biomarkers and clinical pharmacology studies.

Are iBRIC's goals aligned with the framework of the new BioE3 policy for

biomanufacturing? In the coming years, how would iBRIC strategise to capitalise on the momentum the BioE3 policy is set to provide?

The BioE3 policy would pave the way for India to become a \$100 billion Bio-manufacturing Hub. It has identified Bio-innovation and Bio-manufacturing as the two key drivers for promoting India's BioEconomy for the 'Viksit Bharat'. The iBRIC+ Bioscience Innovation Park at NCR biotech cluster would have capacities to promote the progression of life sciences innovations up to pre-product development which is currently a rate-limiting stage in the innovation ecosystem. DBT/ BIRAC have successfully nurtured a biotech startup ecosystem in the country that has reached 95 bio-incubation centres and 8500+ biotech startups from less than 6 bio-incubators and 50 biotech startups in 2012. For the progression of innovations, from ideation to Proof of Concept level, the infrastructure of bio-incubation centres is adequate. But to progress to the pilot and validation stage, the startups struggle and perish. They have to depend on industry-scale service providers to prepare pilot and validation batches, avail development expertise, regulated facilities and infrastructure which are highly unaffordable and not easy to access. This has become a valley of death for most life sciences startups.

BioE3 policy recognising this gap, has envisaged the setting up of domain-centric Biofoundry and Bio-manufacturing facilities that would provide pilot and validation level infrastructural and expertise access. iBRIC+ Biosciences Innovation Park at NCR biotech cluster would plug this gap. Research leads from NCR and across the country in the biological sciences domain would be able to access all this in the biocluster. Thus, preparing a pipeline of projects for bio-manufacturing. The Department of Biotechnology would set up additional bioclusters in the country under the scope of the BioE3 policy.

iBRIC's biofoundry infrastructure presents a unique PPP model. Can you tell us more about the implementation that goes behind establishing a sustainable PPP model, especially in the context of fostering product innovations and scale-up for intricate precision therapeutics space?

Public Private Partnerships is the central thesis of the iBRIC biofoundry and the cluster model. For an innovation to evolve into a commercial product and used by a target customer, it takes expertise, resources, and support of several stakeholders. Government as a central enabler, through DBT/ BIRAC in this case, is creating the grounds for


different actors to come together with their expertise to partner and perform.

Let's understand this with an example, a vaccine candidate is tested by THSTI scientists in laboratory and animal models to establish the Proof of Concept. This 'research lead' would need pre-clinical and clinical development before going to market. Then there is manufacturing, sales of millions of doses and post-market surveillance. This is the forte of the biotech industry and has a limited in-house 'research lead' pipeline, therefore, bringing the two together. Funders and Investors join to support the two parties' commitment increasing the overall probability of success in such partnerships. We all remember the convergence of several such PPP for COVID-19 vaccines at the NCR biotech campus.

Likewise, value chains for CAR-T/NK cell therapies, monoclonal antibodies, diagnostics and therapeutics solutions are to be created with the engagement of relevant stakeholders from India and overseas. Biofoundry would be run in a PPP model to provide scientists access to professional expertise and high-end infrastructure on a pay-per-use basis. Participation of the supporting industry i.e., equipment and reagent with latest products, is encouraged.

In general, how are Biofoundry infrastructures and a robust 'Design-Build-Test-Learn' approach positioned to drive biotech innovation, and what strategies can be undertaken to make Biofoundries more accessible to researchers and industries that are at varying levels of expertise/ business scale?

Co-localisation of Biofoundry with research institutions, startups & SMEs would enable the fertilisation of high-level innovative ideas. The translation of existing ideas into Proof of Concept and demonstration of pilot-level success. Biofoundry setups would be affordable, scientists would be able to avail the common access facilities and take operational & intellectual assistance from professional experts running the operations. This enabling module would enhance turnaround time (TAT) and the probability of translational success of research leads from academia and startups.

A network of such Biofoundries, will boost the ecosystem's value creation status as 'Innovator'. With the success of each such proposition, the number of startups growing in the industry would go up. This would transform India's growth journey in 'Amrit Kaal'. 

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Can India Leverage US Biosecure Act to Strengthen CRDMOs?

The United States of America (USA) is set to implement an Act that will impact the global biotechnology and pharmaceutical industries, potentially opening opportunities for India to dominate the landscape – the Biosecure Act. On September 9, 2024, the House of Representatives passed the BIOSECURE Act. The US BIOSECURE Act restricts US Federal agencies from contracting with or procuring services and equipment from Chinese “biotechnology companies of concern”, and will extend to companies that source or utilise equipment or services from five Chinese companies, namely WuXi Apptec, MGI, BGI, Complete Genomics, and WuXi Biologics. With China as a leading destination for the USA for outsourcing contract manufacturing and research services in the biotech and pharmaceutical sectors, this Act can affect supply chain dynamics in these sectors and countries like India are positioned to be alternative destinations for the US for Contract Development and Manufacturing Organisations (CDMO)/ Contract Research Organisations (CRO) services and capitalise on this. Let's take a look at what its implications would be on the Indian CRDMO sector.

The US Biosecure Act aims to decouple its supply chains from China, presenting a huge opportunity for India's pharma industry. Experts predict that the US Biosecure Act is set to make a strong impact on the entire pharma and biotech sectors globally. The Act restricts US pharmaceutical and biotech companies from outsourcing their services to China-origin Contract Research Development and Manufacturing Organisations (CRDMOs). The Act aims to encourage US pharmaceutical companies to diversify their supply chains, and to shift their partnerships from China to neighbouring countries like India. This move will further boost the already global approach of the China + 1 strategy and help grow India-based CRDMOs who can offer competitive cost advantages along with a skilled labour force for the global pharmaceutical markets. With new developments happening around the US Biosecure Act, India with its strengths in CRDMOs space has been in the driver seat and can look up to capitalise on the opportunities that this Act will open up in the coming period.

The Biosecure Act, which mandates a phased reduction of dependency on China by 2032, underscores the need for global pharma companies to recalibrate their global supply chain strategies. “Over the past few quarters, we have seen a steady shift, presenting significant opportunities for Indian CRDMOs to leverage the evolving pharma ecosystem and the large skilled workforce to attract global pharma companies,” said Sibaji Biswas, Chief Financial Officer and Executive Director, Syngene International Ltd.

What India brings to the table

The Indian pharmaceutical sector, particularly the CDMO/CROs is experiencing a significant transformation driven by strategic investments and evolving market trends. According to a recent industry report by Mordor Intelligence, the pharmaceutical CDMO Market revenue in India was valued at \$15.63 billion in 2023, and is expected to reach \$26.73 billion by 2028, growing at a CAGR of 11.34 per cent during the forecast period of 2023-28. The report also highlights that the market is witnessing growth in clinical trials, driving the demand. For instance, according to ClinicalTrials.gov, the total number of registered clinical studies was 437.513 million in 2022, reaching 477.237 million in 2023.

Looking at the increase in novel biomolecules and biopharmaceuticals taking up a niche in India's burgeoning pharma market, the services sector, through advanced technology and specialised expertise, could be the highlight of the biopharma industry in the coming years. Owing to opportunities stemming from various novel biomolecules and biopharmaceuticals meeting with their patent expirations, multiple industry experts have estimated a significant growth of the Indian services market by the CDMO/CRO companies leveraging these.

Over the years, Indian CDMOs have invested in building state-of-the-art infrastructure. Reports and industry analysts are seeing the sector moving towards embracing advanced technologies, such as continuous manufacturing, and biomanufacturing capabilities, and also a focus on high-potency active pharmaceutical ingredients (HPAPIs) for instance.

Experts state that India's ability to offer high-quality services at a lower cost compared to Western countries remains one of its biggest advantages. This cost-effective proposition has the potential to further attract more multinational pharmaceutical companies looking to outsource their R&D and manufacturing needs.

Even in terms of skilled workforce and expertise, India is host to strong scientific capabilities in terms of academia, and Indian CROs and CDMOs have also developed certain expertise in areas like analytical services, process development, etc. In addition, favourable government policies to support the pharmaceutical sector through initiatives like "Make in India" and Production-Linked Incentives (PLI) schemes for the biopharmaceutical sector further strengthen the competitive position of Indian CDMOs/CROs in the global market. The introduction of new forward-looking policies like the BioE3 policy for biomanufacturing, which aims to pave the way for India to become a leading global biomanufacturing hub, would potentially be another feather in the cap of India's able CDMO/CRO sector.

Expressing his thoughts on India's strengths Sanjay Vyas, President and Managing Director, Parexel India said, "Strategically, Indian CROs possess several advantages, including cost-effectiveness, a skilled workforce, and existing infrastructure capable of supporting increased production and research activities. Therefore, analysts predict that this shift will lead to a notable increase in demand for Indian CROs and CDMOs, which are well-positioned to fill the gap left by Chinese suppliers. This will simulate increased business opportunities for India, which in turn will project a doubling in market growth in the next three years."

In the context of India positioning itself as an able competing market for the Chinese market, Sibaji Biswas said "India is becoming the preferred choice in the supply chain realignment due to its robust talent pool, infrastructure, and comprehensive capabilities. As clients seek to diversify and mitigate risks in their supply chains, the move towards India is further driven by the solutions and capabilities we offer. This is significant not only for our company but also reflects a wider industry movement. The "China plus one" strategy has been in discussion for some time and with the development around the Biosecure Act we are now seeing action on the ground and a definitive momentum to diversify away from China. Syngene is strategically poised to take advantage of this trend. We are experiencing a surge in activity, client engagement, and numerous pilot projects".

Sharing his thoughts Dr Mahesh Bhalgat, Group CEO and Managing Director of Veeda Clinical

"To fully seize this opportunity, India must prioritise effective strategic planning and execution. This involves not only investing in physical infrastructure but also developing a robust regulatory framework, nurturing a skilled workforce, and fostering an environment that promotes innovation and quality. India needs to improve to be competitive to Chinese output i.e. speed and efficiency of delivery."



- Dr Mahesh Bhalgat,
Group CEO and Managing Director,
Veeda Clinical Research

"With the passage of the Act, more CROs in India will need to elevate their service offerings to meet the regulatory and quality expectations of US clients. To achieve this, they will likely invest in cutting-edge technologies and processes to enhance efficiency and ensure compliance with international standards."



- Sanjay Vyas,
President and Managing Director,
Parexel India

"Following the enactment of the Biosecure Act, regulatory standards for biosimilars are anticipated to tighten as existing supply chains are disrupted and new ones emerge. To effectively navigate these changes and instil confidence in regulatory bodies, companies must equip themselves with advanced technologies and streamlined processes that ensure operational transparency and uphold quality standards."



- Chandrachur Datta,
Senior Partner,
Vector Consulting Group

"India is becoming the preferred choice in the supply chain realignment due to its robust talent pool, infrastructure, and comprehensive capabilities. As clients seek to diversify and mitigate risks in their supply chains, the move towards India is further driven by the solutions and capabilities we offer."



- Sibaji Biswas,
Chief Financial Officer and Executive Director,
Syngene International

"The USA Biosecure Act is expected to further boost the growth of the Indian pharmaceutical and biotechnology manufacturing sector."



- Dr Satinder Singh,
Associate Director DMPK, Aragen Life Sciences

Research Limited said "India offers advantages coming from strong scientific capabilities with graduates from world-renowned institutions IITs and IISc, NIPER including others. Government interventions through incentives schemes such as Promotion of Research and Innovation in Pharma-MedTech sector (PRIPs) and PLI, help in building more capacity and skillsets."

Implications of the US Biosecure Act

The Biosecure Act, indeed, has the potential to transform India's CDMO sector. By fostering a more robust regulatory and operational framework, it can attract substantial investment in infrastructure and talent. This, in turn, positions India to manage a growing influx of global collaborations and; partnerships and enhance its standing in the global pharmaceutical industry.

Welcoming the move, Dr Satinder Singh, Associate Director DMPK, Aragen Life Sciences, India opined, "The USA Biosecure Act is expected to further boost the growth of the Indian pharmaceutical and biotechnology manufacturing sector. Additionally, this Act which prohibits US origin firms to source the services or equipment from prominent Chinese CDMOs and CROs like Complete Genomics, WuXi AppTec, or WuXi

Biologics may fuel the growth and expansion of Indian preclinical CROs."

Sharing his thoughts on the US Biosecure Act, Dr Bhalgat said "The US Biosecure Act is likely to have a cascading impact in two directions. First, other countries would look to reduce dependency on the Chinese supply chain and second, is the reduction in Chinese sourcing of raw materials and manufacturing components. As we are seeing, the transition is easiest to be done for developmental programmes, such as those in phase II and phase III clinical trials, as the starting point for moving activities out of China. The other area of opportunity that we see is in preclinical research. Currently, there is a significant amount of preclinical research conducted in the Chinese CRO space and revaluating these programmes is an expected outcome. Notable increase in opportunities, particularly for products in phases II and III, driven by the passage of the US Biosecure Act has also been observed in recent times during our dialogues with clients. With strategic planning and execution, India will be able to capitalise on this opportunity and become a major player in the global pharmaceutical landscape."

"With the passage of this Act, more CROs in India will need to elevate their service offerings to meet the regulatory and quality expectations of US clients. To achieve this, they will likely invest in cutting-edge technologies and processes to enhance efficiency and ensure compliance with international standards. Consequently, the Act is expected to drive a significant increase in R&D investments among Indian CROs. There is also an anticipated increase in focus on biologics, biosimilars, Active Pharmaceutical Ingredients (APIs) and specialty drugs, areas where Indian firms can leverage their existing expertise. The demand for clinical trials in India is set to rise as US firms seek its diverse patient base and cost-effective services, leading to more trials by Indian CROs. Increased regulatory complexities will also boost the need for consulting services, giving Indian CROs with expertise a significant advantage," said Sanjay Vyas.

Echoing similar views, Chandrachur Datta, Senior Partner with Vector Consulting Group said, "Manufacturing expansion in biosimilars is both time- and investment-intensive. Once the decision is made to expand capacities, the actual augmentation may take anywhere from 2 to 3 years, depending on the availability of supplies, equipment, and process validation capacities. This situation creates a challenge in determining the lead indicator: whether to capture market share first or to augment capacities first. Regardless, any company making expansion decisions should prioritise adopting the latest technology in this

constantly evolving space. Following the enactment of the Biosecure Act, regulatory standards for biosimilars are anticipated to tighten as existing supply chains are disrupted and new ones emerge. To effectively navigate these changes and instil confidence in regulatory bodies, companies must equip themselves with advanced technologies and streamlined processes that ensure operational transparency and uphold quality standards.”

He further added, “When pursuing long-term growth through expansion, companies often concentrate solely on acquiring manufacturing equipment, overlooking essential areas like raw material storage, quality control (QC), and quality assurance (QA) capacities. If these aspects are not scaled alongside manufacturing capacity, they may create bottlenecks that restrict overall capacity increases and diminish the effectiveness of the investment.”

Challenges

As the USA will aim to reorganise supply chains for pharma/biopharma outsourcing services, experts predict that shifting productions to other countries will involve challenges like high costs and higher capacities that will need to be built. According to a recent report, around 120 US biopharmaceutical drugs are currently being developed in partnership with Chinese CDMOs. Implications of the US Biosecure Act could mean extended development cycles and higher drug prices in the short term. Despite these challenges, analysts and industry experts predict that it could open up opportunities for Indian CDMOs that could offer competitive cost advantages along with a skilled labour force for the global pharmaceutical markets.

Analysts suggest that increased focus of Indian CRDMOs on compliance and regulatory frameworks, to optimise safety and efficacy of their products according to global standards, effective strategic planning along with investing in infrastructure comprising advanced technologies, expansion of facilities with specialised capabilities etc. could position India as a leading destination for US biotech companies in the coming years.

Talking about the strategies that will need to be implemented by Indian companies to stay globally competitive in this evolving landscape, Chandrachur Datta said, “To make significant leaps in the biosimilar space, the most important factor is technical know-how. For existing CDMOs that already possess a decent level of technical expertise for these molecules and have USFDA-approved facilities, scaling up is relatively straightforward. In contrast, CROs face significantly higher challenges

related to technical know-how and clinical trials as they take on more projects. Improved technical expertise will enable firms to gain the confidence of innovators and regulatory authorities. For the long-term sustainability of this business, Indian CROs and CDMOs must prioritise investment in research and development. This commitment will enhance their expertise in biosimilar development and foster innovation, enabling them to create cutting-edge solutions. Additionally, forming strategic partnerships—an approach some companies have already adopted—with global biotech firms can provide access to advanced technologies, market insights, and collaborative research opportunities.”

He further said that this implementation must go hand in hand with establishing robust quality assurance processes and strict adherence to Good Manufacturing Practices (GMP), as these are essential factors for building trust with both innovators and regulatory authorities, to ultimately position Indian companies as reliable players in the global biosimilars market.

Raising concern about India's established supply chain relationships with Chinese API manufacturers, Chandrachur Datta said, “As the new Act prevents involvement with the banned companies from China, even in the supply chain, steps must be taken immediately including Existing contracts should be evaluated and potentially terminated based on the likelihood of the firms being designated as “of concern.” The associated risk of losing business is significantly higher than the risk of premature contract termination. As soon as possible, substitutes for the equipment or services provided by these companies should be explored to avoid disruptions in business.”

“To fully seize this opportunity, India must prioritise effective strategic planning and execution. This involves not only investing in physical infrastructure but also developing a robust regulatory framework, nurturing a skilled workforce, and fostering an environment that promotes innovation and quality. India needs to improve to be competitive to Chinese output i.e. speed and efficiency of delivery. Indian CROs and CDMOs need to partner with US counterparts to bring in efficiency and delivery of output. Indian firms do have other hurdles to clear like having advanced technology compared to their Chinese counterparts. Although the initial response has sparked greater investor interest in the U.S., it's important not to underestimate the resilience and adaptability of the Chinese biotech sector,” concludes Dr Mahesh Bhalgat. 

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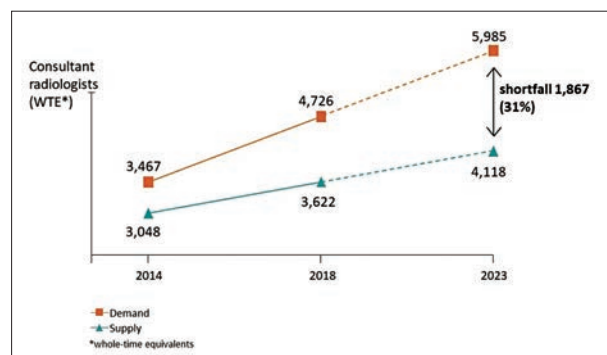
How AI is Propelling Radiology & Medical Imaging Capabilities



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Suraj Nair,
Lead,
TechSprouts,
Ankur Capital

Medical imaging has been used extensively for early diagnosis of various diseases. Be it computed tomography (CT), mammography, ultrasonography, magnetic resonance imaging (MRI), and nuclear medicine tests, radiologists and pathologists have relied on these images to analyse the condition of patients. However, most of the analysis has been manual, heavily depending on the skill sets of the radiologists or pathologists to identify anomalies in the images. The challenge has been the enormous volumes of patient samples to be analysed and the limited number of radiologists or pathologists. Let's take an in-depth look at the impact and possibilities of AI and new applications in the Indian context.

In India, there is only one radiologist for every one lakh patients, which translates to one radiologist for every 100 scans performed each day. There is a severe shortage of radiologists in tier 2 and 3 cities as well. As the number of scans keeps rising and new high-resolution imaging technologies enter the market, it has become highly imperative to develop



Demand- Supply mismatch for radiologists

faster analytical techniques to assist pathologists and radiologists.

Enter AI, ML

Artificial intelligence (AI), using machine learning (ML) and deep learning (DL) algorithms has provided interventions in this direction. Machine learning and deep learning algorithms have been used for the past decade to interpret and analyse medical images and aid radiologists and pathologists in screening and diagnosis. Today AI has extended its capability to the entire radiology world, which includes digitising the devices, aiding in diagnosis and finally collating all the data and information into a digital assistant. Image analysis can be broken down into computer-aided detection, diagnosis, and image segmentation. Computer-aided detection and diagnosis involves the use of AI algorithms to analyse medical images and detect abnormalities and diseases.

On the other hand, image segmentation uses AI algorithms to identify and label various parts of a medical image as organs, blood vessels, or tumours. This can help radiologists locate abnormalities and design surgeries more accurately. For example, around 3.5 billion chest X-rays are performed annually worldwide, which require timely and accurate interpretation. AI solutions categorise X-rays based on suspicions of diseases which can be prioritised by radiologists for faster diagnoses boosting efficiency by 30-50 per cent.

On the digital assistant front, traditional Picture Archiving and Communication Systems (PACS) are used for managing the medical images. However, the growing volume of these images is a huge challenge. Novel AI platforms are aiding PACS by optimising radiology workflows. These platforms use cutting-edge AI and enhance reporting and overall productivity. Some of these platforms act as a virtual assistant, intelligently prioritising worklists and efficiently sorting the scans. They highlight important cases and catch hold of abnormalities with precision by carefully scrutinising each image. Further, they also offer click-generated reports, saving radiologists' time, and fostering seamless collaboration between technicians, radiologists, and referring physicians.

Major Pros & Cons

Machine learning has in many cases, been shown to perform on par with medical experts. However, despite the high promise and comparisons with benchmark data, conversion into clinical data and problem-solving has been lacking. A recent review of 62 AI models developed to detect COVID-19 using X-ray and CT images showed that none could be translated into clinical use due to methodological flaws. The “non-explainability”, or the inability of the algorithm to explain the diagnosis through evidence, discourages and deters clinicians from adopting AI systems.

Secondly, there are challenges in data availability and collection. Medical datasets are typically small in size, on the order of hundreds or thousands. These datasets come with inherent biases, around various demographics, spectrum of patients and symptoms, which also feed into the algorithms. The test data must be an actual representation of the actual population, rather than being a subset of the training dataset, the latter being the prevailing practice. In medical imaging, dataset bias has been demonstrated in chest X-rays, retinal imaging, brain imaging, histopathology, or dermatology. Sometimes images capture medical interventions as well, which create unnecessary errors during the analysis. Finally, labelling-related errors also exist which need to be avoided. Generating high-quality data sets for very specific use cases and collecting these data sets without any biases will go a long way in improving the clinical outcomes of the use of machine learning in medical diagnosis.

In March 2024, Google partnered with Apollo Radiology International to advance the use of AI in healthcare. The Google Health AI team has been working on various disease conditions such as tuberculosis, and breast and lung cancer and through this partnership, Apollo Radiology will provide them access to high-quality medical data.

Startup Pioneers and Future Prospects

In India, startups such as Niramai, Qure.ai, and Sigtuple were the first set of companies focused on using machine learning for disease diagnosis and reporting. These startups have deployed their solutions pan-India, and they collect more real-world unbiased data and constantly improve their algorithms. Sigtuple has raised more than \$40 million during its journey in digitising the pathology and radiology labs and claims to have a portfolio of 21 granted patents. Qure.ai raised a \$40 million round in 2022 to



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scale its medical imaging diagnostics AI services globally. Niramai received the US FDA approval for its breast cancer screening system SMILE-100 in 2022 and boasts a portfolio of more than 25 patents. Some new-generation startups are also using Gen AI to generate synthetic medical images that resemble real patient data, to aid the training and validation of machine-learning models. Gen AI solutions are also automating the radiology report generation, thereby reducing the burden on radiologists and creating a fast and seamless experience for patients.

The advancements in Gen AI and machine learning to understand complex medical images and provide precise diagnoses in the fastest time possible will shape the future of radiology across the world. **BS**

Targeted Transformation of Diabetes Care in India



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Vandana Iyer,
Research Director,
TechVision,
Frost & Sullivan

According to the International Diabetes Federation (IDF) about 63 per cent of people with diabetes say that the fear of developing diabetes-related complications affects their well-being. And around 28 per cent of people with diabetes find it hard to remain positive in relation to their condition. Hence the theme for this year's World Diabetes Day (WDD) 2024-26 observed on November 14, the world's largest diabetes awareness campaign reaching a global audience of over 1 billion people in over 160 countries, is Diabetes and well-being. Let's look at ways to reduce or reverse diabetes in India.

The Indian Council of Medical Research–India Diabetes (ICMR-INDIAB) study published in 2023 reported that the overall weighted prevalence of diabetes in India was 11.4 per cent, accounting for 101 million people. The study findings also reported an alarming increase in non-communicable diseases (NCDs) such as prediabetes, hypertension, and obesity. Hence, there is a rising need to holistically manage the rising diabetes prevalence by improving awareness, diet, lifestyle, screening, treatment and monitoring practices in India.

Public and Private Campaigns for Improving Awareness

A study of the National Family Health Survey of India (NFHS), 2019–2021 reported that diabetes awareness varied from 14.4 per cent to 54.4 per cent. Not surprisingly, the less educated and poorer sections of the society had lower diabetes awareness. Thus, considering the rising prevalence of the disease, there is a need to improve diabetes awareness in India. Several public and private initiatives are looking to address this concern.

However, it is important to ensure that the awareness campaigns have wider outreach.

For instance, mDiabetes, launched in collaboration with the Ministry of Health and Family Welfare, India and the World Health Organization (WHO) aims to provide basic diabetes information to users who dial a missed call to a number. This is likely to ensure a wide outreach as even rural Indian sectors have good mobile connectivity in India. In 2021, the Research Society for the Study of Diabetes in India (RSSDI) launched the Defeat Diabetes Campaign to reach out to over 100 million people in 100 days to 'test, track and treat' diabetes. The campaign was successful and managed to screen over 106 million people in over 10,000 locations in India. There is a need to continue such targeted campaigns with well-defined outcomes and timelines.

Private initiatives such as the Novartis Indian Metabolics team launched 'Prayaas' and currently this programme collaborates with healthcare professionals (HCPs) across 100 camps for diabetes diagnosis of more than 2,000 people every month. The awareness campaigns have demonstrated promising outcomes, but there is still a rising need for increased collaboration between the public and private sectors. Such initiatives can help create wider awareness outreach, especially across remote regions within the Indian landscape. Multichannel outreach, across physical, print, digital and radio campaigns can amplify the awareness impact for improved diabetes management.

Targeted Diet and Lifestyle Changes

Diet and lifestyle changes are crucial for the holistic management of diabetes, especially in emerging economies like India where rising urbanisation has grown proportionately with sedentary lifestyles and unhealthy diets. Fortunately, technological advances, like connected diabetes care devices have enabled improved diet and lifestyle habits of diabetics. For instance, Humrahi is an ISO/IEC 27001:2013 certified digital diabetes patient support programme that provides customised counselling, blood sugar test recommendations, medication adherence, and diet and lifestyle changes to improve health outcomes.

Joyhealth, an AI-powered diabetes management tool, can predict the impact of different foods on sugar levels and offers personalised coaching on how to reduce their adverse health impact. Exercise-based

apps like 7 Minute Workout curate a personalised 7-minute workout routine for effective diabetes management. Smart and connected continuous glucose monitors (CGMs) and associated apps have been crucial for providing real-time feedback for blood glucose spikes and managing diabetes. Leading medical device companies such as Abbott and Medtronic offer clinically approved CGMs in India, allowing for improved diabetes care. However, the cost of a 14-day CGM sensor can range from Rs 5,000 to Rs 10,000, which may hinder access to rural diabetes care, especially for children with type 1 diabetes. Hence, public healthcare support for improving access to continuous diabetes care can positively impact health outcomes across India.

Recent Tech Advances

In 2023, the Ministry of Health and Family Welfare, India, launched a roadmap to scale primary healthcare services for people with hypertension and diabetes. Under this initiative, the Indian government plans to screen and provide standard care to 75 million people with diabetes or hypertension by 2025.

Technological advances in diabetes management have enabled the development of smart glucometers, CGMs, connected insulin pumps and closed-loop insulin delivery systems or artificial pancreas. Clinically approved CGMs such as FreeStyle Libre Pro, advanced insulin pumps such as Tandem T: Slim X2, Omnipod and Medtronic Minimed 640G are currently available in India. Even closed loop insulin delivery systems such as MiniMed 780G and MiniMed 770G are available for diabetes management in India. However, they are not easily accessible to the larger population due to high pricing, which can range from Rs 3 to 5 lakh for an automated closed-loop insulin pump.

While insulin is a mainstay for treating type 1 diabetes, it is now also being used for the treatment of people with type 2 diabetes. Insulin treatment most often needs to be self-administered through daily injections. There are several connected insulin pens available in India that enable convenient administration and tracking via mobile apps. Novo Nordisk's Insulin Icodec, a once-weekly dose, may be approved in India shortly enabling much needed respite from daily insulin injections. Weekly dosing may also improve patient adherence and diabetes care for diabetics on insulin therapy. While oral (Oral-Recosulin) and inhalable (Afrezza) are also available in India they are not as effective as injectable insulin formulations for diabetes management.

The Indian landscape has witnessed new drug

approvals for management of obesity and diabetes. Drugs such as Cadila Pharmaceuticals' Jankey M and Glemark's SITAZIT M were launched in 2022. The blockbuster injectable drugs, GLP-1 agonists, for diabetes and obesity treatment, have also been launched in India. Novo's tirzepatide formulations, Zepbound and Mounjaro, function as dual GIP/GLP-1 agonists and are approved for obesity and diabetes treatment respectively. Novo's oral semaglutide, Rybelsus, is also garnering rising popularity in India and has reported rising sales growth since 2023. However, there is growing concern regarding the overuse, off-label use or misuse of GLP-1 agonists as they are often associated with severe gastrointestinal side effects. Indian doctors are urging the government to regulate GLP-1 use amidst the surging demand for this class of drugs.

Outlook

Diabetes care must be a holistic combination of awareness, diet, lifestyle, continuous tracking and timely interventions. India has the second largest population of diabetics in the world and without periodic tracking, diabetes will lead to renal and cardiovascular mortalities. There is a rising need for initiatives and interventions to reduce or reverse the impact of non-communicable diseases such as obesity, hypertension, and diabetes.

The IMPACT India initiative helps address this need. This programme was launched in 2018 and uses a new approach for optimising diabetes care in India. The initiative intends to impact HCPs, diabetes and the Indian society by using the India Diabetes Care Index (iDCI) tool. The iDCI is a quarterly aggregate index of glycated haemoglobin, fasting plasma glucose (FPG), and postprandial plasma glucose (PPG) which is evaluated regularly, and the insights are related to HCPs to optimise diabetes care through timely diet, lifestyle and medical interventions. The initiative is also promoted on social media awareness through periodic iDCI reports.

The goal of the IMPACT India programme is to reduce glycated haemoglobin in Indian diabetics by one per cent within 1000 days. Private sector initiatives, like the Fortis C-DOC (Centre for Diabetes, Obesity and Cholesterol) Foundation and Apollo's Diabetes Management Program will also help improve awareness and timely diabetes care. The rising integration of technology to enable connected and remote care will greatly improve the outlook for diabetes management in India. The public and private initiatives, coupled with rapid technology advancements will drastically help reduce the rising diabetes prevalence in the Indian subcontinent. **BS**

How Seed Funding is Driving Indian Pharma Startups



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Dr Jay Doshi,
Chief Business Officer,
1Pharmacy

For pharmaceutical businesses in India, seed capital is more than just a financial boost; it is an essential component of long-term success. In order to draw in future investors, it assists businesses in innovating, scaling up, and overcoming regulatory obstacles. This has a beneficial knock-on impact and helps to create a healthier and more inventive future for India's health industry. Let's explore further.

Pharmaceutical startups looking for seed funding to turn their ideas into reality and develop solutions that improve patients' lives benefit greatly from early-stage capital. Such capital would be spent on innovation, breakthroughs in drug discovery, AI-related health technologies, and personalised medicine. For example, the majority of India's healthcare startups are focused on creating tech solutions that drive efficiency in the supply chain or improve patient outcomes. These startups have utilised seed funding to enhance their offerings, streamline operations, and deliver better healthcare solutions.

Seed funding plays a pivotal role in this growth trajectory, serving as the essential capital that ignites innovation and propels startups forward. For many emerging companies, access to early-stage capital is crucial for developing their proof of concept (POC) and attracting top talent. In a highly competitive market, having the right resources enables startups to innovate rapidly and respond to the evolving needs of the healthcare sector. As artificial intelligence (AI) and other advanced technologies reshape the healthcare industry, startups face constant pressure to adapt and enhance their offerings. This necessity for continuous innovation underscores the

importance of securing seed funding, as it allows companies to invest in research and development (R&D), refine their technologies, and launch new products or services without the immediate burden of achieving profitability.

Beginning of Innovation

Seed funding acts as a catalyst, especially for pharmaceutical companies stepping into new, uncharted territories. This initial capital allows them to invest in R&D, which is crucial for creating innovative drugs or medical devices. Whether the focus is on biotechnology or personalised medicine, pharma startups often lead the way, exploring areas where bigger, more established companies may take longer to innovate. Early-stage funding frees startups to try out some radical ideas, or at least the ability to come up with high-risk, high-reward projects, be it a life-saving drug or an AI-based diagnostic tool. Therefore, seed funding is critical for enabling long-term R&D. It also helps startups to adjust quickly, trying out new approaches, without stressing over immediate profits. This kind of support fosters innovation in India's pharmaceutical companies.

A Strong Business Foundation

For pharma startups, building a strong foundation is both challenging and costly. Seed funding helps in setting up the basics such as manufacturing, meeting regulations and hiring staff. Navigating the rules and regulations, especially for pharmaceutical products, demands a huge amount of money as startups must meet many compliance requirements before their products can be launched.

Startups need to create a strong supply chain and distribution network to get their products to market quickly. Securing early-stage funds is also important as it helps them attract talented people and build key partnerships. This is extremely crucial in competitive industries like pharma, where working with top researchers, scientists, and business experts can speed up their growth.

Technology Bridging

One of the critical areas for modern pharma startups is a cutting-edge reliance on technology. Seed funding allows startups to invest in tech-driven solutions that empower them with an ERP

system, telemedicine platforms, and automation tools. All these would help streamline operations, making processes much more efficient, and even could give them that competitive edge in a crowded marketplace.

It optimises the supply chains and manages inventories better while accelerating timelines of production by implementing automation and data analytics. Since digital health has now become the new dimension required for success in the pharma sector, seed funding at these startups gets them to assimilate a modern solution by excluding the traditional players, thereby positioning them well for long-term success.

Removing Regulatory Hurdles

Regulatory hurdles in the pharmaceutical industry are generally the principal concern for pharmaceutical firms wanting to enter the market. Testing, clinical trials, and certifications by authorities such as the US Food and Drug Administration (FDA) or the Central Drugs Standard Control Organisation (CDSCO) to new entrants are very cost-intensive.

The seed funding helps the new companies get rid of these regulations by covering the costs for such important processes. The financial aid frees the companies' emphasis on innovations and producing their products, minus the extra cost of complying with a measure. It thereby allows the startups to dodge the complexity of regulation with relative ease, like speed dating, where a product is placed in the market overnight.

Scaling the Market

The seed fund does more than launch a startup; it scales up business fast. In the pharmaceutical industry, this scaling up only means producing more to meet higher market demands. With seed capital, the startup can invest in additional manufacturing capabilities and establish another production line, ensuring that it keeps meeting the growing consumer needs. These early-stage funds can be used for the start of market research, marketing campaigns, and the beginning of the customer acquisition strategy. At a time when the global demand for Indian pharmaceutical products is increasing, seed funding can act as an important stepping stone for such startups keen on entering international markets. It helps in positioning their products abroad, thereby enhancing the global spread of India's pharma sector.

Strategic Partnerships

Seed funding is instrumental in strategic partnerships that multiply the effects of growth



in a startup's trajectory. Whether it is research institutions, hospitals, or technology companies, these linkages help startups gain access to sources of expertise and resources. It also makes co-developing or licensing agreements with big pharma companies. Such will speed up the scaling of the startup faster. Such partnerships are crucial for shared growth because they allow them to leverage existing networks, accelerate innovation, and enhance their reach in the healthcare ecosystem.

Roping-in Future Investors

If used strategically, seed funding becomes a potboiler to attract more investments in the form of venture capitalists, private equity houses, or institutional investors. Here, startups can boast of their efficient use of capital at the early stage, thereby increasing their credibility among later-phase investors.

Seed funding can be a further step for some companies to reach some kind of critical milestone that puts them in an eligibility situation for series-A or B funding rounds. Funding at these rounds is used to scale operations, enter new markets, or see improvement in the development of a product. Early success with seed capital brings a lot of confidence on the side of investors, which then forms a positive cycle of growth and investment.

For Long-Run Growth

Seed funding, as such, is more than a financial booster and crucial enabler of long-term growth for India's pharmaceutical startups. It helps companies innovate, work on overcoming regulatory hurdles, and scale-up their business in order to attract future investors, thereby causing a positive ripple effect and creating a healthier and more innovative future for India's health sector. The growth of the Indian pharma ecosystem will be supported by much more responsive mechanisms of seed funding to bring along further breakthrough pharmaceutical innovations. **BS**

Impact of Digital Transformation on Lab Efficiency



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TrioTree Technologies

The rapid advancement of technology has triggered a wave of digital transformation across various industries, and laboratories are no exception. Laboratories, especially those involved in research, clinical diagnostics, and development, have seen significant shifts in the way they operate due to the integration of advanced digital tools. From optimising workflows to improving accuracy, digital transformation is revolutionising lab operations, making them faster, more efficient, and capable of handling larger data volumes. This shift is not just a technological upgrade but a complete rethinking of how laboratories function to deliver more value while meeting increasingly stringent compliance and operational standards. Let's find out more.

Digital transformation in laboratories is fundamentally reshaping workflows. Historically, lab operations have depended heavily on manual processes—data entry, analysis, and report generation—which were time-intensive and prone to errors. However, the introduction of Laboratory Information Management Systems (LIMS) has been a game-changer. LIMS enables laboratories to standardise their workflows, ensuring consistency and minimising human error. With automation at the core, tasks that once required several hours or even days can now be completed in minutes, allowing lab technicians to focus on higher-value activities.

This reconfiguration of workflows is critical for labs handling large volumes of data. Automation allows them to manage the influx without compromising on quality or compliance. For instance, LIMS can efficiently process data, generate reports, and offer real-time insights, expediting decision-making and improving the accuracy of lab results. The adoption of these systems ensures that labs maintain high standards while reducing operational inefficiencies.

Additionally, digital transformation allows for the seamless integration of various laboratory functions, creating an interconnected and smooth flow of information. This reduces the occurrence of bottlenecks, eliminates redundant tasks, and optimises resource allocation, resulting in an efficient, error-free operational environment.

Ensuring Data Integrity and Accuracy

Laboratory results are only as good as the accuracy and integrity of the data they produce. The digital age offers several tools that can significantly enhance both. Modern laboratories now rely on advanced data analytics, machine learning (ML), and artificial intelligence (AI) to analyse data sets with greater precision and uncover patterns that manual analysis might overlook. These technologies enable predictive modelling, which helps labs forecast trends and outcomes, thereby minimising the need for repeated testing and validation.

AI and ML, when applied in experimental settings, enable laboratories to streamline their processes. By analysing data more accurately, these technologies can predict outcomes and highlight areas that need further investigation, reducing time and resource wastage. Moreover, automated systems continuously monitor experiments and data, alerting lab personnel to any anomalies or deviations in real time.

The importance of data integrity cannot be overstated, particularly in industries where accurate results directly impact human health, such as in clinical laboratories. Digital transformation ensures that the collected data remains unaltered through encryption and robust security protocols. With cloud-based solutions, labs can now store vast amounts of data securely, ensuring it is easily accessible for future analysis. This accessibility facilitates cross-team collaboration, ensuring all stakeholders can review and share insights efficiently.

Cloud technology further enhances reproducibility—a vital element in scientific research. Researchers and scientists can easily access shared data from any location, review past experiments, and reproduce studies with the same parameters, all while minimising human error. The ability to securely store and retrieve data reduces discrepancies in results, ensuring accuracy and reliability in the findings.

Accelerating Turnaround Times

One of the most direct and tangible benefits of digital transformation is the significant reduction in turnaround times. The ability to process samples

and analyse data at a much faster rate enables laboratories to produce results quicker than ever. Digital tools such as AI-driven analytics optimise experimental designs by running simulations, predicting potential outcomes, and identifying the most promising research avenues. This approach allows laboratories to focus on what matters most, eliminating unnecessary trial and error.

In clinical settings, this fast turnaround is particularly valuable. Laboratories responsible for diagnostic testing can provide results much faster, impacting patient care positively. For example, automated systems can process blood tests and other diagnostics in a fraction of the time required by manual methods, offering life-saving results sooner.

Another major aspect is the streamlining of communication. In traditional labs, delays often stem from the need to coordinate between teams. Digital tools now provide enhanced communication platforms where team members can share real-time updates, coordinate tasks, and resolve issues without unnecessary delays. This collaborative approach reduces downtime and ensures that every team member is aligned, leading to better resource management and faster project completion. In fast-paced industries, such as pharmaceuticals and clinical research, this can be the difference between meeting critical deadlines or falling behind.

Boosting Operational Efficiency

Digital transformation boosts operational efficiency by optimising the use of resources, both human and material. Automation reduces the need for human intervention in routine tasks, freeing up personnel to engage in more complex and critical activities. This not only boosts overall productivity but also enhances employee satisfaction, as lab technicians can now focus on higher-value tasks rather than manual, repetitive processes.

Additionally, the implementation of digital tools facilitates data-driven decision-making. Advanced analytics enable labs to make real-time adjustments to their processes, helping them optimise their resources and minimise waste. For example, predictive analytics can forecast supply needs, ensuring that materials are ordered just-in-time, thereby reducing both excess inventory and stockouts. This data-driven approach also improves compliance, ensuring that laboratories meet regulatory standards without sacrificing operational efficiency.

Moreover, digital platforms ensure that all laboratory systems are interconnected. The elimination of operational silos allows for smoother transitions between different stages of the workflow, further enhancing operational efficiency. This

cohesive system approach also improves the scalability of laboratory operations, ensuring that labs can expand their capabilities or scale down as required without major disruptions.

Overcoming Challenges

Despite the numerous benefits, digital transformation in laboratories is not without its challenges. The transition to a fully digitalised environment requires significant investments, both in terms of technology and personnel training. Laboratory staff must be adequately trained to utilise new systems effectively, ensuring that the full potential of digital tools is realised. Additionally, the integration of legacy systems with new digital platforms can be complex, necessitating careful planning and execution.

Change management is another critical factor in ensuring the success of digital transformation initiatives. Laboratories must foster a culture of innovation, encouraging staff to embrace new tools and approaches while ensuring that everyone remains aligned with the organisation's goals.

Moreover, the sheer volume of data generated by digital systems can present a challenge in terms of data management. Laboratories must ensure that they have the infrastructure and expertise required to manage and analyse this data efficiently. This includes investing in secure, scalable data storage solutions and ensuring that their data analytics capabilities are robust enough to handle the increasing demands of modern scientific research.

Future Prospects in Labs

The potential for further advancements in laboratory efficiency is immense. Emerging technologies such as AI, ML, and the Internet of Things (IoT) are poised to drive even greater levels of accuracy, speed, and collaboration in the future. These technologies can be used to monitor equipment, predict maintenance needs, and optimise resource allocation, further improving laboratory efficiency.

In a nutshell, digital transformation is not just a passing trend but a necessity for laboratories looking to remain competitive in today's fast-paced scientific environment. By reshaping workflows, enhancing data integrity, reducing turnaround times, and boosting operational efficiency, digital transformation is revolutionising laboratory operations. As laboratories continue to embrace these changes, they will be better positioned to meet the growing demands of modern science and healthcare, ultimately leading to better outcomes for both researchers and patients. The future of laboratory operations is digital, and the journey has only just begun. **BS**

Metropolis Healthcare launches Institute of Laboratory Education and Skilling

Metropolis Healthcare has announced the launch of its new initiative, the 'Metropolis Institute of Laboratory Education and Skilling (MiLES).' This initiative aims to bridge the gap between academic education and practical skills in healthcare. Through MiLES, Metropolis Healthcare has established a strategic partnership with DY Patil (Deemed-to-be) University in Navi Mumbai to offer fellowships courses. This collaboration with a prestigious academic institution marks a significant step towards equipping healthcare professionals with cutting-edge knowledge and expertise. In partnership with DY Patil (Deemed-to-be) University, Metropolis is introducing a one-year Fellowship Course in Advanced Clinical Chemistry, Advanced Hematopathology, Advanced Surgical Pathology, Quality Assurance in Laboratory Medicine, and Molecular Pathology & Cytogenomics. Designed for Post-MD and DNB students, these courses integrate theoretical knowledge with practical training, focusing on the latest advancements in diagnostic technologies.



IIM Lucknow, IIT Kanpur partner to offer joint PG programme in healthcare management

The Indian Institute of Management (IIM) Lucknow has signed a Memorandum of Understanding (MoU) with Indian Institute of Technology (IIT) Kanpur to launch a joint postgraduate (PG) programme in Healthcare Management. This collaboration aims to address the growing need for leadership in the healthcare industry by integrating management principles with advanced medical technology. The Postgraduate Programme in Healthcare Management will serve professionals from various fields, including healthcare workers and doctors in public hospitals. The course is designed to blend expertise in medical technology with business administration, empowering participants to spearhead advancements in healthcare delivery and innovation. The joint programme will collaborate closely with IIT Kanpur's Centre of Excellence in Digital Health, working with international institutions critical to India's healthcare landscape. The initiative seeks to produce leaders equipped to tackle the evolving challenges of healthcare management and foster the integration of cutting-edge technology into medical practice.

IIIT Hyderabad offers AI-based online courses for medical professionals

International Institute of Information Technology Hyderabad (IIIT-H) has launched an online course on 'AI for Medical Professionals', in collaboration with National Academy of Medical Sciences (NAMS), an autonomous organisation under the Ministry of Health & Family Welfare, Government of India, and IHub-Data. The 12-week online orientation course on artificial intelligence (AI) will equip medical professionals with the requisite skills needed



to understand, evaluate, and apply AI technologies in clinical settings, improving patient care and operational efficiency. It covers both theory and tutorials

covering the basics of AI, machine learning, deep learning, and case studies on clinical applications involving screening, diagnosis, prognosis, and patient management. Participants will also explore ethical and governance issues in the use of AI tools and techniques.

Delivered through video lectures, weekly contact sessions, and case studies, the course includes quizzes, assignments, and assessments, leading to certification upon completion.

Integris appoints medtech veteran Probir Das as new CEO

Integris Healthcare, a global diversified medical technology company, has announced the appointment of Probir Das as Chief Executive Officer (CEO). He will join effective November 2024 and will be based in New Delhi. With over three decades of global medtech experience, he will lead the next phase of growth and innovation for the



company. Das joins Integris from Terumo Asia Pacific, where he has served as Chairman & Managing Director since 2019. Das was earlier working as Director-

Diagnosics Systems at BD, where he had the complete P&L & strategic responsibility for BD's microbiology and women's health / cancer business vertical. His role involved creating a long-term strategic plan, driving investment, leading marketing, sales & issue- based advocacy, building an organisation and kick starting locally relevant product development.

Bhushan Akshikar steps in as OPPI President

The Organisation of Pharmaceutical Producers of India (OPPI), which represents the global research-based pharmaceutical companies in India, has appointed Bhushan Akshikar as its President for a term of two years effective September 26, 2024. Akshikar is a seasoned business leader and has an experience of over 13 years in key leadership roles in GSK across India, Middle East, Russia CIS & Africa region. Before joining GSK, Akshikar spent 15 years with Janssen, Johnson & Johnson, in local and regional positions in India, South Korea and Belgium. Akshikar joined GSK India in September 2011 to lead the specialty business and commercial excellence function. In 2014, he was appointed Head of the Mass Markets business. He was subsequently elevated as the Managing Director of the publicly listed entity of GSK in Nigeria, Africa in end- 2016. Apart from a strong business turn-around, he also built a high performing, resilient team. He then moved to Turkey in 2019 as the VML to drive strategic initiatives and launches in both private and tender segments in the Middle East, Russia CIS & Africa region. In December 2020 he returned to India as the Commercial Head of the General Medicines business and has led a cultural transformation journey delivering strong results reflected in the competitive performance of all flagship brands.



Victor Ambros and Gary Ruvkun win 2024 Nobel Prize in Physiology or Medicine for discovery of microRNA

The Nobel Assembly at Karolinska Institutet has decided to award the 2024 Nobel Prize in Physiology or Medicine jointly to Victor Ambros and Gary Ruvkun for the discovery of microRNA and its role in post-transcriptional gene regulation. This year's Nobel Prize honours two scientists for their discovery of a fundamental principle governing how gene activity is regulated. Victor Ambros received his PhD from Massachusetts Institute of Technology (MIT), US



Victor Ambros

Gary Ruvkun

where he also did postdoctoral research 1979-1985. He became a Principal Investigator at Harvard University, Cambridge. He was Professor at Dartmouth Medical

School from 1992-2007 and he is now Silverman Professor of Natural Science at the University of Massachusetts Medical School, Worcester. Gary Ruvkun received his PhD from Harvard University. He was a postdoctoral fellow at Massachusetts Institute of Technology (MIT), Cambridge. He became a Principal Investigator at Massachusetts General Hospital and Harvard Medical School in 1985, where he is now Professor of Genetics.

QR678 brings medtech leader Sridhar Ranganathan to advisory board

QR678, a pioneering company dedicated to revolutionising hair and skin science through groundbreaking research and innovative solutions, has announced the appointment of Sridhar Ranganathan to its Board of Advisors.



Ranganathan, former Managing Director at Allergan, brings a wealth of expertise in biotechnology, healthcare, and aesthetics, which is expected to significantly bolster QR678's strategic direction and market penetration. During his tenure as Managing Director at Allergan India and South Asia, Ranganathan played a pivotal

role in scaling up Botox over several years, significantly expanding its market presence and transforming it into a leading product in the aesthetics industry. His leadership and strategic vision were instrumental in elevating Botox's prominence, contributing to Allergan's strong foothold in the market. Ranganathan is a distinguished figure in the medtech industry, currently being part of the IIT Madras incubated enterprises including HELYXON.

Dr R N Gupta steps in as National President of Indian Pharmaceutical Association

Dr R N Gupta has been elected as the National President of the Indian Pharmaceutical Association (IPA), the oldest and largest association of pharmaceutical professionals in the country, for the term 2024 - 2026 (October 1, 2024 - September 30, 2026). Dr Gupta is a senior professional, with almost five decades of experience in the pharmaceutical industry, academia and research. Currently, an Adjunct Professor with the National Institute of Pharmaceutical Education and Research (NIPER) – Kolkata, Dr Gupta has earlier worked with Smith Stanistreet Pharmaceuticals, Kolkata, Bihar State Pharma & Chemical Development Corporation, Patna, Eastern Chemical Industries, Cuttack and Birla Institute of Technology, Ranchi. With over 100 research publications in peer-reviewed journals and 2 authored books on 'Pharmaceutical Marketing Management' and 'GPP in Hospital Pharmacy' respectively, he has successfully guided 8 Doctorate students. Dr Gupta has raised numerous issues concerning various facets of the profession through over 350 'Letters to the Editor' and has succeeded in resolving many of these in favour of the profession, through his sustained advocacy initiatives.



Practo strengthens Board with appointment of TVG Krishnamurthy and Dr Alexander Kuruvilla

Practo has appointed two new directors to its board: TVG Krishnamurthy and Dr Alexander Kuruvilla. These strategic additions come as the company continues to scale its business and deepens its commitment to leveraging AI for improved health outcomes. TVG Krishnamurthy brings over 40 years of board-level experience, having served in both multinational corporations and domestic enterprises. A mentor to entrepreneurs in India and



the US, particularly in early-stage technology ventures, he is deeply involved in philanthropic activities focused on women's empowerment and children's

education. Dr Alexander Kuruvilla, Practo's former Chief Healthcare Strategy Officer, has a distinguished 35-year career in healthcare administration, marked by his CEO & entrepreneurial journey in the Medica Synergie. He has been pivotal in planning, establishing, and managing hospitals across India, including prominent institutions such as Narayana Hrudayalaya, Apollo Hospitals Ahmedabad, and the Medica Group of Hospitals.

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ICMR signs agreements with industry and academic partners to advance first-in-human Ph 1 clinical trials

In a significant stride towards strengthening India's clinical research ecosystem, the Indian Council of Medical Research (ICMR) has formalised Memorandum of Agreements (MoAs) with multiple sponsors under its network of Phase 1 clinical trials. The agreements mark a ground-breaking entry into first-in-human clinical trials for four promising molecules. These include collaborative research over a small molecule for multiple myeloma with Aurigene Oncology, partnering for Zika vaccine development with Indian Immunologicals, coordinating seasonal influenza virus vaccine trial with Mynvax, and CAR-T cell therapy advancement study for a new indication of chronic lymphocytic leukemia with ImmunoACT. This initiative is a crucial step towards establishing India as a leader in the clinical development of pharmaceutical agents.



IIT Madras develops indigenous POCUS scanner for sports injury diagnosis

A team of researchers at the Indian Institute of Technology Madras (IIT-M) has developed an indigenous portable Point-of-Care-Ultrasound (POCUS) Scanner for sports injury diagnosis and management. They have already been granted several patents for technologies that went into this device and are working towards productisation. This research from the Center of Excellence in Sports Science and Analytics (CESSA) at IIT Madras could potentially allow for on-field diagnosis of injuries, immediate assessment of the extent of injury that will allow for medical professionals to take a call on whether to permit the sportsperson to continue playing. This Artificial Intelligence-powered POCUS scanner has a wide range of applications in sports medicine, and it has the benefits of safety (no radiation) and sufficient resolution compared to other modalities. A working POCUS prototype for Musculoskeletal (MSK) imaging, developed at the Biomedical Ultrasound Imaging Lab (BUSi) is currently ready. The researchers are targeting to complete the product prototype development by 2024.

IIT Madras identifies enhanced drug delivery method for eye treatments

Researchers at the Indian Institute of Technology Madras (IIT-M) have demonstrated how drugs injected in the human eye can be better delivered to the target region through 'convection caused by mild laser heating'. They used simulation and modelling studies to analyse the efficacy of various types of treatments on the human eye, focusing on heat and mass transfer. With nearly 11 million individuals afflicted by retinal disorders in India, indigenous original research of



this nature holds promise for the development and advancement of laser-based treatments for various eye diseases. Laser-based retinal treatments are increasingly being used to treat diseases like retinal tears, diabetic

retinopathy, macular oedema and retinal vein occlusion. Since the retina is the region of the eye that contains blood vessels and nerves, such treatments must be performed carefully and with precision. This research was taken up nearly a decade ago by Prof. Arunn Narasimhan, Department of Mechanical Engineering, IIT Madras, who collaborated with Dr Lingam Gopal of Shankar Nethralaya and initiated biothermal research into the effects of laser irradiation on the retina for the first time in India.

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UPS opens innovative temperature-controlled facility for pharma industry in Hyderabad

UPS has launched its specialised healthcare-focused cross-docking facility in Hyderabad. Designed to keep the Indian pharma customers and their needs at the core, this pharma-grade facility comes with global freight forwarding capabilities. It is equipped with advanced temperature control capabilities, ensuring that sensitive products are always stored and transported within their required temperature ranges, preserving their efficacy and safety. Providing an additional layer of security for temperature-controlled pharmaceutical shipments, it has a capacity to hold or sort 15 pallets in +15°C to +25°C, 7 Pallets in +2 to +8°C and 50 pallets under uncontrolled ambient conditions. This enables pharma companies to distribute their products more efficiently, eliminating the need for prolonged warehouse storage. The facility also serves as a safety net for critical shipments. It ensures that even in contingency situations, these vital shipments remain protected.

Singleron, Bioscreen to enhance access to single cell multi-omics solutions for Indian researchers

Singleron Biotechnologies, a leading innovator in single cell multi-omics solutions, has announced a strategic partnership with Bioscreen, a renowned distributor of advanced life science products in India. Under this agreement, Bioscreen will become the exclusive distributor of Singleron's cutting-edge single cell multi-omics solutions in the Indian market. Chennai-based Bioscreen will distribute Singleron's comprehensive suite of single cell multi-omics solutions, which cover the entire single cell analysis workflow, including tissue dissociation, library preparation, and bioinformatics analysis. The comprehensive support provides a smooth experience for researchers regardless of their prior experience in single cell analysis. The collaboration highlights the growing demand in the Asia-Pacific (APAC) region for innovative single cell analysis solutions.



Thermo Fisher introduces iCAP MX Series ICP-MS to simplify trace elemental analysis

Thermo Fisher Scientific Inc. has launched the Thermo Scientific iCAP MX Series ICP-MS to simplify trace element analysis with inductively coupled plasma mass spectrometry (ICP-MS). The launch includes a new single quadrupole Thermo Scientific iCAP MSX ICP-MS and triple quadrupole Thermo Scientific iCAP MTX ICP-MS designed for environmental, food, industrial and

research labs to analyse routine and challenging trace elements to detect and mitigate harmful substances. Laboratories that face challenges in analysing trace elements in complex and diverse matrix samples require sensitive and flexible instruments to deliver consistent results that support analytical research and quality testing. The single quadrupole iCAP MSX ICP-MS delivers a high level of



analytical performance without the usual compromise between matrix load and sensitivity, enabling users in applied analytical labs to consistently analyse various elemental samples. Building on this performance, the triple quadrupole iCAP MTX ICP-MS offers interference-free analysis for heightened confidence when analysing more complex samples.

Qiagen launches QIAcuityDx digital PCR system for clinical testing in oncology

Qiagen N.V. has announced the launch of the QIAcuityDx Digital PCR System, a pivotal addition to its digital PCR portfolio now expanding into clinical diagnostics. The instrument and accessories are 510(k) exempt in the US and IVDR-certified for diagnostic use in Europe. QIAcuityDx streamlines clinical testing by providing highly precise, absolute quantitation of target DNA and RNA, supporting applications with less invasive



liquid biopsies. These capabilities make it an ideal tool for monitoring cancer progression,

complementing routine cancer diagnoses, which are typically performed using Next Generation Sequencing (NGS). Qiagen is rapidly expanding the application menu available on QIAcuityDx-System, with a new BCR::ABL assay for oncohematology planned for US FDA submission in 2025. The platform also provides immediate access to Qiagen's full portfolio of research-use products and applications via its GeneGlobe platform.

Promega unveils GloMax Galaxy Bioluminescence Imager for illuminating protein dynamics in real time

US-based Promega Corporation, a life-sciences research partner dedicated to providing intuitive tools that empower scientists to innovate, has unveiled the new GloMax Galaxy Bioluminescence Imager. The GloMax Galaxy Bioluminescence Imager provides researchers the opportunity to observe the dynamics and cellular physiology of low expression protein targets in real time. This advanced microscope is developed for the visualisation of Promega NanoLuc luciferase chemistries, eliminating the complex process of translating bioluminescent reporter assays into fluorescence. GloMax Galaxy Bioluminescence Imager is a benchtop instrument developed for the visualisation of all NanoLuc technologies, including HiBiT, NanoBiT and NanoBRET. The technology allows researchers to use the same bioluminescent reporter used in other parts of their workflow.



Revvity's EUROIMMUN launches solution for specific typing of Alzheimer's Disease associated APOE gene

Revvity, Inc. has announced the launch of the in-vitro diagnostic EURORealTime APOE assay in European countries that accept the CE mark, which will enable accurate genotyping of the APOE gene. APOE genotyping is valuable to assess a patient's risk for side effects prior to the start of an anti-amyloid (beta) therapy in Alzheimer's disease. The real-time EURORealTime APOE PCR test allows simultaneous detection of the three most frequent APOE forms, designated E2, E3 and E4. Carriers of exclusively E4 exhibit the highest risk for ARIA under therapy. With the new test now available from Revvity's EUROIMMUN, only one reaction is required using genomic DNA isolated from a single blood sample to determine the patient's APOE genotype. The assay processing can be automated to scalable degrees on Revvity instruments, including the EUROIMMUN PreNAT II TM and the chemagic 360 platforms. Results are evaluated, documented and archived using the EURORealTime analysis software.



Early Diabetic Retinopathy Detection Remains a Challenge

The Vitreo Retinal Society of India (VRSI) and the Research Society for the Study of Diabetes in India (RSSDI) have formulated a first-of-its-kind diabetic retinopathy (DR) screening guideline to help physicians and diabetologists in India educate their patients about DR.

With a national prevalence of 12.5 per cent of DR & 4 per cent of vision-threatening DR, approximately 3 million Indians are at risk of vision loss. This highlights the critical need for timely screening of every patient with diabetes to prevent an irreversible loss of vision, which goes undetected in its early stage & is thus aptly known as a 'silent thief of sight.'

Despite the increasing prevalence of DR, limited awareness and the often-asymptomatic nature of the condition result in a disappointingly low number of individuals with diabetes seeking eye screenings. This makes raising awareness about vision loss due to DR and the need for timely screening and management imperative.

On the global front, earlier this year, the International Agency for the Prevention of Blindness (IAPB) and the International Diabetes Federation (IDF) came up with a policy brief to target advocates, healthcare professionals and policymakers in diabetes and eye health. According to their recommendation, there is a need to promote and fund a global research agenda for diabetes and DR that includes health systems, technological innovation and research to maximise the impact of the research into practice.

As a result, technology developers across India, and the globe, are exploring this need as an opportunity to develop innovative devices. Reports have revealed that manufacturers in the DR sector globally, are primed to capitalise on this rising demand, anticipating a substantial revenue boost, with a forecasted target of \$15.5 billion by 2033.

For instance, Remidio, a Bengaluru headquartered company, received the Central Drugs Standard Control Organisation (CDSCO) approval, a few weeks ago, for its product- Medios DR AI. It is the country's first ophthalmic artificial intelligence (AI) software that automatically detects referable DR in retinal images.

On the global front, US-based AEYE Health has recently the first-ever portable, fully autonomous DR

screening solution, that enables screening patients anywhere-whether at home or in clinics- providing instant diagnostic results without the need for human interpretation. It is the first US FDA-cleared solution of its kind, requiring just one image per eye and providing instant results directly on the camera screen for patients, along with diagnostic reports for healthcare providers.

University of Liverpool AI diagnostic technology spin-out, AI-Sight, has successfully concluded its seven-figure equity funding round from healthcare industry investors, for its first commercial product. The AI software device is designed to support training and diagnostic decision-making by human graders of DR in retinal scans.

While AI is demonstrating promising results in accurately detecting DR, whether the implementation of these algorithms is cost-effective in comparison with human graders can pose a challenge.

Besides AI, next-generation sequencing technology is emerging as a new tool to detect the genetic variations associated with DR, thereby pushing the development of personalised medicines to treat this condition. Further, technologies like single-cell RNA sequencing are offering a role in identifying unique retinal microglia types in early diabetic retinopathy. Studies have revealed that to prevent blindness in patients, it is important to identify early diabetic retinopathy more precisely based on the understanding of the pathological & molecular mechanisms in retinal microglia-induced inflammation.

However, just like AI, these new technologies also pose numerous challenges that might restrict their application at the clinical level for diagnosing DR on a large scale. Restricted by the acquisition of retinal samples from patients with DR, the majority of single-cell detection samples currently are derived from animal models, with only a few reports on human samples. A proper framework, cost-effectiveness, accessibility, and head-to-head validation are important factors to be considered to address the growing burden of DR worldwide. **BS**

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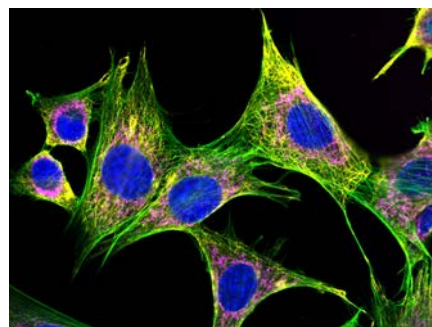
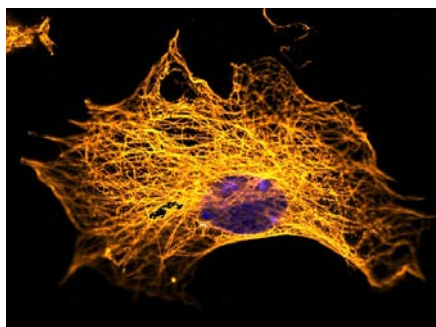
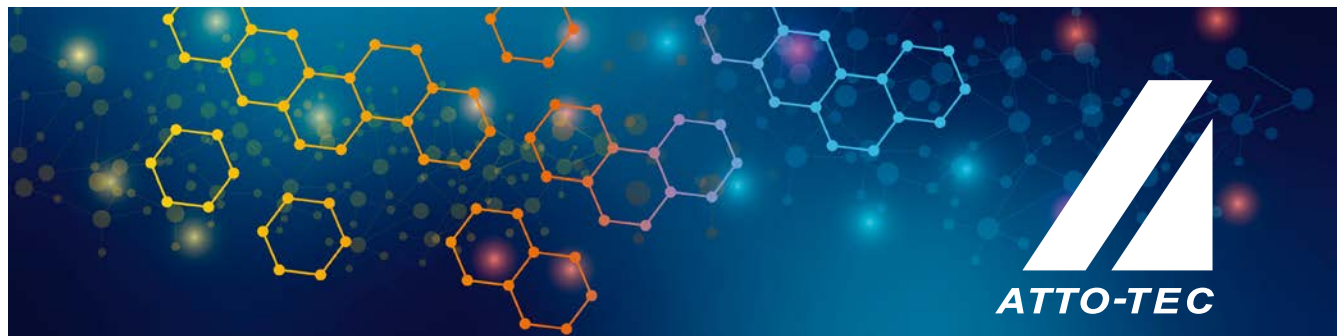
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