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Total pages including cover 52

BHARAT EYES GLOBAL BIOMANUFACTURING DOMINANCE:

Boosting Innovation, Collaboration & Entrepreneurship with BioE3 Policy

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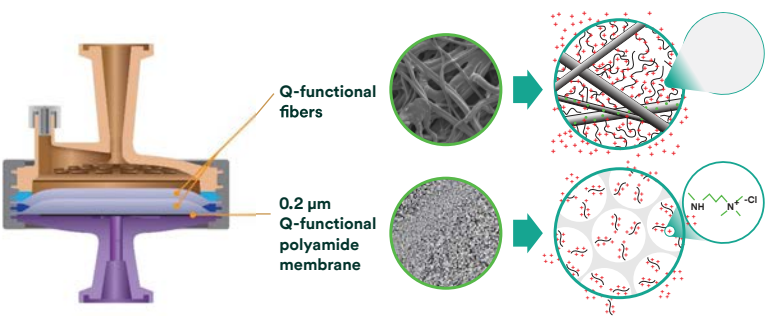

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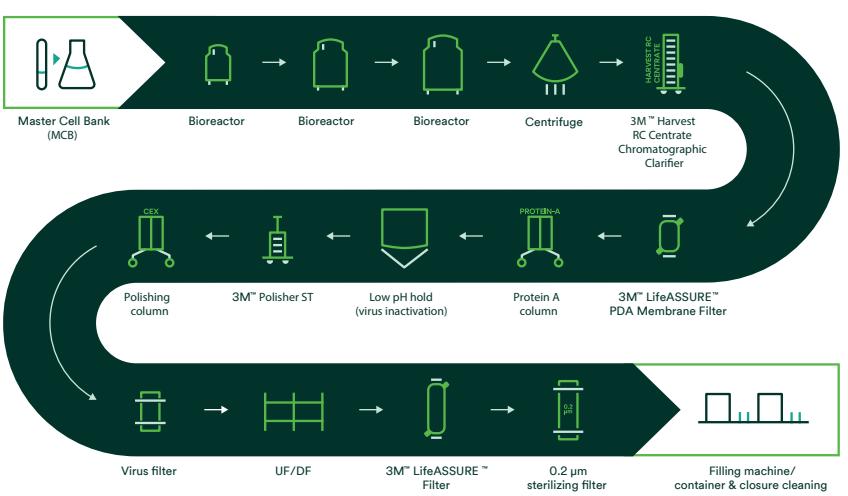

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Acknowledgement/ Feedback

Pharmexcil is actively involved in overcoming industry challenges by organising awareness campaigns, providing industry training, and facilitating dialogue between regulatory bodies and pharmaceutical companies. Our goal is to ensure that Indian pharmaceutical products meet the highest standards globally.

- K Raja Bhanu, Hyderabad

Thank you BioSpectrum for organising an exclusive event for the BioSupplier sector. All the panel discussions were very engaging and fruitful. Looking forward to more such events from your side.

- V Sankaranarayanan, Chennai

The Biotech Innovations & Suppliers Conclave 2024 was very well organised in Navi Mumbai on 23 August. Congratulations.

- Raghavendra Goud, Hyderabad

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Letter from Publisher

Ravindra Boratkar
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Dear Readers,

Bharat's bioeconomy is estimated to be valued around $300 billion by 2030, making it the third largest biotech destination in Asia Pacific and one of the top biotech destinations globally. With COVID-19 providing the industry with a much-needed boost, the country's bioeconomy reached $151 billion in 2023 and witnessed an exponential increase in valuation over the previous 11 years. As one of the top hubs for bioinnovation and biomanufacturing today, Bharat is recognised as a rising sector and a crucial component of the country's economic growth plan, which aims to see its GDP grow to $5 trillion by 2027.

To set the country at the forefront of a more sustainable future, and remain responsive to global challenges by accelerating and harnessing biomanufacturing solutions, the government introduced the BioE3 (Biotechnology for Economy, Environment, and Employment) Policy—a strategic framework designed to propel India into the next era of industrialisation. The BioE3 Policy was approved on August 24, 2024, by the Union Cabinet for "Fostering High-Performance Biomanufacturing". The policy chalks a strategic roadmap to turn India into a global biomanufacturing hub through innovation, for the development of bio-based products and building an infrastructure that enables scale-up and commercialisation. With inputs from the industry captains, we have put together an elaborate story as to how the BioE3 Policy is set to transform the biomanufacturing landscape in India.

The pharma representatives of the Laghu Udyog Bharati (LUB), a not-for-profit Pan India Organisation with an aim to empower MSMEs met with officials from the Department of Pharmaceuticals, and discussed key issues such as Trade Margin Rationalisation (TMR), Schedule-M extension, Revised PTUS Hurdles, and the Drug Tribunal Board formation. The LUB Pharma proposed the innovative "One Nation-One Molecule-One MRP" strategy and advocated that the top 100 companies sell their generic brands at molecule name and affordable Maximum Retail Price (MRP) for the benefit of patients. We are covering a story with recommendations from industry associations to make TMR more effective, balanced, and supportive of all stakeholders in the pharmaceutical supply chain.

India has already established itself as a global hub for pharmaceutical manufacturing, earning the nickname the "Pharmacy of the world." However, while the country excels in generics and large-scale production, its contribution to cutting-edge biomedical research and innovation still lags. We have an expert article that addresses how collaboration between academia, which can provide fundamental research and innovation, and industry, which can offer resources, funding, and practical implementation, will help bridge this gap.

Global Bio-India (GBI) 2024, organised by the Biotechnology Industry Research Assistance Council (BIRAC), from September 12-14, witnessed the launch of BioE3 Policy, and was a much bigger event compared to GBI 2023. Our team has covered the highlights of the event, which will surely be informative.

I believe you will find this edition a great read, as always.

Thanks & Regards,

Ravindra Boratkar,
Publisher & Managing Editor

COVER 18

BHARAT EYES GLOBAL BIOMANUFACTURING DOMINANCE: Boosting Innovation, Collaboration & Entrepreneurship with BioE3 Policy

Bharat has demonstrated a strong economic growth in the past decade and is poised to be amongst the global leaders in the next industrial revolution by leveraging emerging technologies and new innovative solutions. Bharat is competitively positioned to be amongst the global leaders in futuristic manufacturing that leverages living systems. Biomanufacturing can fundamentally transform the global economy from today's consumptive manufacturing paradigm to the one based on regenerative principles. Biomanufacturing refers to the use of engineered microbial, plant, and animal (including human) cells with increasing precision and control to produce commercially important products on scale. These are versatile processes that have the potential to create bio-based products allowing efficient utilisation of resources, in a scalable and cost-effective manner with reduced environmental impact. Keeping in view the national priority of steering Bharat on the path of accelerated 'Green Growth', an integrated BioE3 (Biotechnology for Economy, Environment and Employment) Policy for "Fostering High-Performance Biomanufacturing" with an aim to make a green, clean, prosperous, and self-reliant Bharat was released on September 12 at Global Bio-India (GBI) 2024. Let's take a look at how the BioE3 Policy for biomanufacturing is set to transform this landscape.

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Top Video

Nitin Stephen Abel, Senior Director, Terumo Interventional Systems, Terumo India responds to the question on how minimally invasive treatment has the potential to transform India's healthcare ecosystem.

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Dr Sanjay Sharma, Co-founder of FootSecure discusses the rising importance of podiatry and foot health in India.

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Event Report

Regulars

US Biotechnology Endgame

With the passing of the Biosecurity Act 2024 by the US House of Representatives, Indian pharma could capitalise on more export avenues on US shores. However, one more hurdle remains, as the Bill will now be discussed, before it's passed by the senate. The huge margin of 306 for and 81 opposed to the Bill in question, is an indication of the strong sentiments of the US over the issue. It is highly unlikely that the Bill would not be passed in the senate.

The Bill is kind of a seal over the tense relationship between the US and China in the biotechnology turf. The conflict had been lingering for quite some time. The Bill has black-listed Chinese biotech companies and their US subsidiaries. It specifically names five such companies to be black-listed.

The rationale behind the Biosecurity Act is very clear. The US feels that China has become too much of a monopolistic source of raw materials for pharma products. It is now alarmed over the entire dependence on China for the biotech supply chain. Two other pinching points are the US's failure to compete with China in the biotech field and also possession of the US people's genomic data with Chinese companies. As a result, the US lawmakers initiated the legislative steps to protect national security as well as commercial interests from the Chinese companies. The Bill passed in the house is the result and It is expected to deter the US pharma companies from outsourcing to China.

The US Senate's homeland security committee gave approval in March to forward a Bill restricting business with Chinese biotech companies on national security grounds. Prior to that, a similar Bill was moved in the US Congress in January seeking to ban federally funded medical providers from using the services of any Chinese biotech company, particularly BGI group, MGI and WuXi App Tech from accessing genetic information of American people. The Bill has been moved by two leading members of the Congressional select committee on Chinese Communist Party (CCP).

The legislation passed in the house was also passed 40-1 by the House Oversight Committee in May. Hence, the likelihood of its passing in the senate too is very high. The main idea of all the legislative efforts is to develop an alternate vendor ecosystem in event that China tries to weaponise its capabilities on the pharmaceutical raw materials side. Having an alternate vendor that can support you is so important that it needs to be developed even if at higher prices or higher cost appears to be the general feeling among the US policy makers.

Experts say, currently, an estimated over 100 biopharma drugs are being developed by the US companies in partnership with Contract Development and Manufacturing Organisations (CDMOs). The new Act is expected to delay the development cycle of the new drugs and disrupt the supply chains of the US life sciences companies. This is where Indian pharma players, particularly CDMOs, come into the picture.

In light of the impending snowball effect of the Biosecurity Act, the Indian Ratings and Research has projected a hike in orders for Indian CDMO and Contract Research Organisations (CROs) segments from the US pharma companies. The Indian CDMO market is expected to grow from over Rs 18,000 crore in 2024 to almost Rs 38,000 crore by 2029. In Active Pharmaceuticals Ingredient (API) exports, India is still lagging far behind China with India exporting APIs worth $4 billion while China exports $40 billion. Some Indian companies have already initiated steps to exploit this crucial opportunity.

While there is expected to be a scope for immense growth for the Indian companies due to the Biosecurity Act, there are some challenges too to overcome. Notwithstanding the usual hurdles, experts opine that the Indian companies should leverage the opportunity as it presents itself. BS

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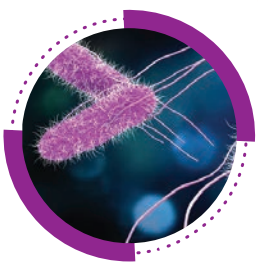
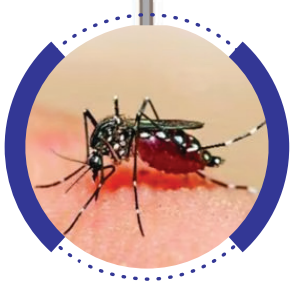


Salmonella



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Cabinet approves 'Vigyan Dhara' scheme of Department of Science and Technology

The Union Cabinet, chaired by Prime Minister Narendra Modi, has approved continuation of the three umbrella schemes, merged into a unified central sector scheme namely 'Vigyan Dhara' of Department of Science and Technology (DST). The scheme has three broad components: Science and Technology (S&T) Institutional and Human Capacity Building; Research and Development and Innovation, Technology Development and Deployment. The proposed outlay for the implementation of the unified scheme 'Vigyan Dhara' is Rs 10,579.84 crore during the 15th finance Commission period from 2021-22 to 2025-26. The merger of the schemes into a single scheme would enhance efficiency in fund utilisation and establish synchronisation among the sub-schemes/programmes.

Health Ministry approves introduction of shorter treatment regimen for drug-resistant TB in India

Union Ministry of Health & Family Welfare has approved introduction of the BPaLM regimen, a novel treatment for Multi-Drug-Resistant Tuberculosis (MDR-TB) under its National TB Elimination Programme (NTEP) as a highly effective and shorter treatment option. This regimen includes a new anti-TB drug namely Pretomanid in combination with Bedaquiline & Linezolid (with/ without Moxifloxacin). Pretomanid has earlier been approved and licensed for use in India by Central Drugs Standard Control Organisation (CDSCO). The BPaLM regimen, which consists of a four-drug combination – Bedaquiline, Pretomanid, Linezolid and Moxifloxacin, has been proven to be safe, more effective and a quicker treatment option than the previous MDR-TB treatment procedure. The Department of Health & Family Welfare, in consultation with the Department of Health Research ensured validation of this new TB treatment regimen that witnessed a thorough review of evidence by in-country subject experts. The Department of Health & Family Welfare has also got a Health Technology Assessment done through the Department of Health Research to ensure that this MDR-TB treatment option is safe and cost effective.

Centre launches National Strategy For Prevention of Unintentional Injury

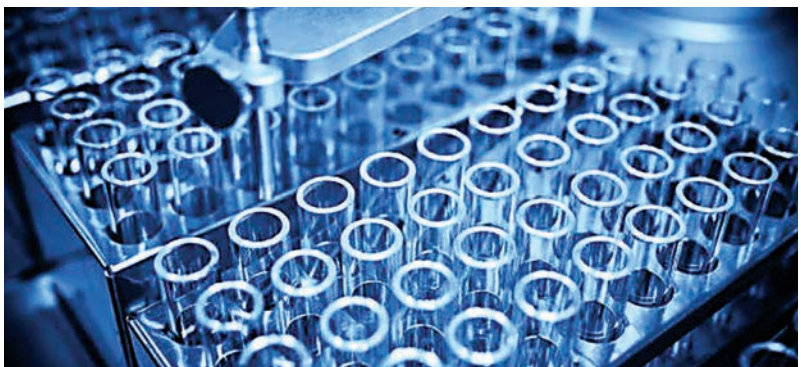
The Ministry of Health and Family Welfare, Government of India and World Health Organization (WHO) released India's National Strategy For Prevention of Unintentional Injury at #Safety2024: 15th World Conference on Injury Prevention and Safety Promotion on September 2 in New Delhi. The comprehensive roadmap, developed in collaboration with The George Institute for Global Health, aims to reduce the burden of injuries in India. It calls for a review and strengthening of India's injury prevention laws, prioritising enforcement and enacting new legislation, as needed. It also calls for allocation of dedicated and sustainable funding for injury prevention initiatives across various levels. The strategy prioritises four key injury mechanisms- road traffic injuries, drowning, burns, and falls from heights, and focuses on three vulnerable population groups- workers, children, and older people.

Karnataka to unveil Global Capability Centres Policy at BTS 2024 in November

"Karnataka, home to over 400 Global Capability Centres (GCCs) is ready with draft a policy on GCCs and will be sharing with all stakeholders soon so that it will be unveiled at the Bengaluru Tech Summit 2024 (BTS 2024) set to take place from November 19 to November 21, 2024" said Priyank Kharge, Minister for IT, Bt, Government of Karnataka. Speaking at the Global Innovation Alliance (GIA) Partners meet at BTS 2024, Kharge said "Bengaluru is not just the tech capital of India; it's a globally recognised hub for innovation, research, and technology-driven growth. The state's dynamic ecosystem has attracted over $45 billion in foreign direct investment, with global giants establishing significant R&D centres here. With over 15,000 startups and a startup valuation of $180 billion, Karnataka is at the forefront of global innovation. It is also the leading destination for GCCs, with more than 400 centres already established in Bengaluru, making up over 40 per cent of all GCCs in India."

Cabinet approves BioE3 Policy for fostering high performance biomanufacturing

The Union Cabinet, chaired by the Prime Minister Narendra Modi, has approved the proposal 'BioE3 (Biotechnology for Economy, Environment and Employment) Policy for Fostering High Performance Biomanufacturing' of the Department of Biotechnology. The salient features of BioE3 policy include innovation-driven support to R&D and entrepreneurship across thematic sectors. This will accelerate technology development and commercialisation by establishing Biomanufacturing & Bio-AI hubs and Biofoundry. Along with prioritising regenerative bioeconomy models of green growth, this policy will facilitate expansion of India's skilled workforce and provide a surge in job creation. To address the national priorities, the BioE3 Policy would broadly focus on the following strategic/thematic sectors: high value bio-based chemicals, biopolymers & enzymes; smart proteins & functional foods; precision biotherapeutics; climate resilient agriculture; carbon capture & its utilisation; marine and space research.



Health Minister introduces National Medical Register Portal of National Medical Commission

Union Minister for Health & Family Welfare, Jagat Prakash Nadda recently inaugurated the National Medical Register (NMR) Portal of the National Medical Commission (NMC) for registration of all the MBBS doctors who are eligible for registration in India, in presence of Union Minister of State (MoS) for Health & Family Welfare, Anupriya Patel and virtual presence of Union MoS for Health & Family Welfare, Prataprao Jadhav. The NMR is mandated under Section 31 of the NMC Act, 2019 which states that the Ethics & Medical Registration Board (EMRB) of NMC shall maintain a National Register in electronic form containing the name, address, and all recognised qualifications possessed by a licensed medical practitioner. NMR will be a comprehensive and dynamic database for all allopathic (MBBS) registered doctors in India. The uniqueness of the NMR is that it is linked with the Aadhaar ID of the doctors which ensures the individual's authenticity. The NMR will be upgraded and augmented with continuous improvements in the registration process on the portal.

Centre For Sight collaborates with Laxmi Eye Hospital to extend presence in Maharashtra

Centre For Sight, a leading network in ophthalmology nationwide, renowned for its cutting-edge technology, and trusted medical expertise, has announced a strategic collaboration with Laxmi Eye Hospital, a distinguished eye care provider with a legacy of over three decades. This partnership marks a significant milestone in Centre For Sight's expansion strategy, enhancing its presence in Maharashtra to 9 centres. Centre For Sight is looking to invest Rs 300-500 crore over the next few years to support its expansion plans. Over the past 12 months, Centre For Sight has added 10 brownfield centres with strategic collaborations, such as Srinagar (Fazili Eyecare), Sikar (I Max Eye Care Hospital), Warangal (Kakathiya Eye Hospital), Badlapur (Drishti Eye Hospital), Chembur (Rushabh Eye Hospital & Laser Centre) and the latest one in Mumbai (Laxmi Eye Hospital). On the other hand, Centre For Sight has also launched six greenfield centres - Bhiwani, Palwal, Jammu, Gorakhpur, Prayagraj, and Gurugram; further strengthening presence in Northern India. Centre For Sight will continue to look for more collaboration opportunities in the region, which is a key focus area of expansion, to deepen its presence in Western India. Further, it aims to add 15-20 centres annually, targeting to reach 150 centres in the next 4 years with its commitment to the 'Go Deep and Go Wide' strategy.

35North India Discovery Fund-II invests $3 M in Global Care

Non-hospital medical tourism startup Global Care, a unit of Gurugram-based Lavanya Medicare Solutions, has announced a funding of $3 million as a strategic investment by 35North India Discovery Fund -II (IDF-II) and its affiliates. This is the first-ever partnership of its kind in this domain. Rajeev Taneja, MD & Founder and a first-gen entrepreneur, founded Global Care with a strategic vision to become a multi-country company catering to medical patients from multiple countries. The company is focused on Eastern Africa, Francophone Africa, the Middle East, Central Asia, SAARC nations, and South-East Asia, as well as the Middle East, North Africa. With this investment, 35North IDF-II will support Global Care's aim to bridge healthcare divides worldwide, building clinical excellence through strategic consulting and facilitating convenient access to world-class patient care.

Hearzap acquires Speech and Hearing Care, eyes Rs 100 Cr revenue milestone

Hyderabad-based startup Hearzap, a leading hearing care provider funded by 360 ONE, has announced the acquisition of a majority stake in Speech and Hearing Care, a renowned player in the Bihar and Jharkhand regions. Funded entirely through internal cash flows, the deal underscores Hearzap's solid financial health and strategic capital management. This acquisition will boost Hearzap's revenue past Rs 100 crore this fiscal year, securing a 30 per cent market share in key regions. This expansion ensures access to top-quality hearing care provided by professionally trained audiologists and supports the company's target of expanding to 250 stores by 2026, doubling its growth by exploring more partnerships. By integrating Speech and Hearing Care into its operations, Hearzap extends its reach to every region of India, offering comprehensive speech and hearing solutions under one roof. With over two decades of experience in audiology, Speech and Hearing Care has a stronghold in cities like Patna, Ranchi, and Dhanbad.

Cambrian Bioworks raises $1.45 M to transform molecular diagnostics in India

Bengaluru-based biotechnology startup Cambrian Bioworks has secured $1.45 million in seed funding. The company builds cutting-edge solutions for the rapidly expanding next-generation sequencing (NGS) and molecular diagnostic markets. The round was spearheaded by the Irani family office, which has invested in several private ventures across the globe. The round also saw participation from the company's CEO and co-founder, Vaibhav Hegde. The funding will accelerate the development of Cambrian's automated molecular diagnostics platforms, bolster R&D efforts, expand the team, and support forays into international markets. The news follows the recent launch of Cambrian's nucleic acid extraction platform, Manta. A purpose-built automation, Manta provides high-quality DNA/RNA for genomics and PCR testing in hospitals and laboratories. Building on this, Cambrian aims to enable widespread access to automated devices for liquid biopsy testing and targeted sequencing. Cambrian's products find applications in oncology, genomics, rare disease testing, and anti-microbial resistance (AMR) detection.

Sunfox secures additional Rs 15 Cr to scale global cardiac innovations

Dehradun-based startup Sunfox Technologies has raised an additional Rs 15 crore in a pre-series funding round. The round was led by existing investor Venture Catalyst, alongside new investors such as Finvolve through the IA Growth Opportunities Fund I and Brew Opportunities Fund, as well as Universal Group, KP Singhvi Group, and several high-net-worth individuals (HNIs). This funding builds on a previous Rs 5 crore investment from USAID through SAMRIDH Health and LetsVenture, bringing the total raised in this round to Rs 20 crore. With this new capital, Sunfox is set for rapid expansion in India and globally, focusing on scaling its flagship innovation, Spandan- a smartphone-based portable ECG device that provides clinically accurate 12-lead ECG readings, empowering users to detect heart attacks and monitor cardiac health in real time. Used by over 30,000 individuals across 20 countries, Spandan has already saved more than 10,000 lives through early detection of heart conditions. This technology is proving critical as India confronts a surge in heart attacks post-COVID-19.

Serigen Mediproducts raises Rs 10 Cr funding led by IAN Alpha Fund & others

Pune-based Serigen Mediproducts, a biomedical products manufacturing startup, has raised Rs 10 crore from IAN Alpha Fund & Colossa Ventures, along with existing and new angel investors. This significant financial boost will be instrumental in furthering the company's mission to revolutionise regenerative medicine. Serigen Mediproducts is also a part of BioAngels' portfolio company, which aligns with their vision of advancing biotechnology innovations. Serigen is at the forefront of developing tissue regeneration products using silk proteins. With a focus on innovation, the company aims to revolutionise regenerative medicine through cutting-edge research and development. The company has developed three innovative products: Serioss, an osteoconductive bone void filler; Seriderm, an absorbent wound dressing designed using silk protein to accelerate wound healing; and Serimat, a silk protein mesh used in reconstruction surgeries of various organs, including breast reconstruction, abdominal wall reconstruction, and dural repair.

Amneal, Shilpa Medicare announce US FDA approval of RTU oncology product

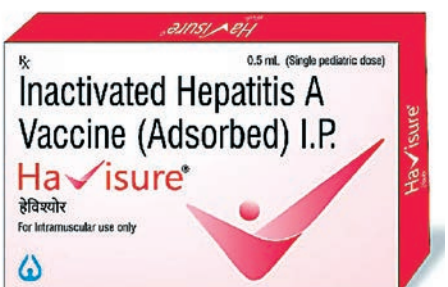
US-based Amneal Pharmaceuticals, Inc. and Karnataka-based Shilpa Medicare announced the US Food and Drug Administration (FDA) approval of BORUZU, a new presentation of bortezomib for ready-to-use (RTU) subcutaneous administration or intravenous (IV) administration. This new RTU oncology product reduces the compounding preparation steps typically required with administration. BORUZU (bortezomib injection), a proteasome inhibitor, is used for the treatment of multiple myeloma and mantle cell lymphoma. This product references the branded product Velcade, a lyophilised powder requiring reconstitution before use. Shilpa developed the molecule and Amneal will manufacture and commercialise the product. BORUZU is expected to launch with a unique J-code in the second quarter of 2025.

Illumina to establish GCC in Bengaluru to expand technology workforce

US-based Illumina Inc., a global leader in DNA sequencing and array-based technologies, has announced that it will establish a Global Capability Centre (GCC) in Bengaluru, India, as an investment to expand its technology workforce in support of a global customer base. Bengaluru joins Singapore; Cambridge, England; Eindhoven, the Netherlands; Shanghai; Madison, Wisconsin; Hayward, California; and San Diego as Illumina Global Capability Centres. As part of this, Illumina aims to hire 100 technology professionals in India, including software engineers, IT hardware and network engineers, and system analysts in 2024 and 200 more by the end of 2025. Last year, Illumina opened a new office and state-of-the-art genomics lab – known as an Illumina Solutions Centre in Bengaluru. The facility features a fully equipped laboratory with the latest next-generation sequencing technologies.

Indian Immunologicals unveils paediatric dose of indigenous hepatitis A vaccine

Hyderabad-based Indian Immunologicals Limited (IIL) has announced the launch of its latest breakthrough- the paediatric dose of India's first indigenous Hepatitis A vaccine, Havisure (0.5 ml). This launch marks a significant milestone in IIL's ongoing commitment to providing affordable and effective vaccines for all, especially for the most vulnerable sections of society, particularly children. Hepatitis A is a highly contagious liver infection caused by the Hepatitis A virus, which predominantly affects children and can lead to severe health complications. Vaccination is the most cost effective yet efficient method to prevent the disease. In line with its commitment to public health and social responsibility, IIL marked this significant launch with a series of community-focused activities. IIL organised free Hepatitis A vaccination drives for children in two orphanages in Hyderabad to start with, which includes one specifically for blind children. IIL also conducted a health awareness session at an old age home, and these are continuous efforts towards creating awareness and better health for the community at large.



Dr. Reddy's, Aurigene and Kainomyx to jointly develop affordable anti-malaria drug

Dr. Reddy's Laboratories, along with its subsidiaries, and its CRDMO arm Aurigene Pharmaceutical Services have signed a non-binding Memorandum of Understanding (MoU) with Kainomyx, Inc., a US-based company with a proprietary platform that helps target cytoskeletal proteins of parasites, a novel mechanism of action, for the development and commercialisation of affordable anti-malaria drug in the US, Europe, and in low and middle-income countries. Under the MoU, Kainomyx has agreed to lead the technical strategy and associated aspects for drug discovery and clinical phases, Aurigene has agreed to focus on developing cost-effective and scalable drug chemistry, and while the programme evolves, Dr. Reddy's will bring in its regulatory and market access expertise. As per WHO, an alarming number of 249 million malaria cases and 608,000 cases of malaria deaths were reported in the year 2022. It has been widely reported that climate change will increase the incidences of such vector-borne diseases.

Bharat Biotech launches next-gen Oral Cholera Vaccine 'HILLCHOL'

Hyderabad-based Bharat Biotech International Limited (BBIL) has announced the launch of HILLCHOL (BBV131), a novel single-strain Oral Cholera Vaccine (OCV). HILLCHOL was developed by Bharat Biotech under license from Hilleman Laboratories (funded by Merck, USA and Wellcome Trust, UK), to combat cholera, a significant advancement in global health. Currently, only one manufacturer supplies OCVs worldwide, resulting in a yearly deficit of ~40 million doses. To mitigate this global shortage of OCVs, Bharat Biotech has established large-scale manufacturing facilities in Hyderabad and Bhubaneswar with a capacity to produce up to 200 million doses of HILLCHOL. HILLCHOL vaccine is administered orally on day 0 and day 14 and is suitable for individuals older than one year. It is presented as a single-dose respule and should be stored between +2°C and +8°C. HILLCHOL is presented in a mono-multidose format, one of the first such presentations for vaccines.

Vipragen, Zumutor form strategic alliance in biologics CRO sector

Bengaluru-based companies Vipragen Biosciences and Zumutor Biologics have announced a strategic partnership to set up an end-to-end Biologics Contract Research Organisation (CRO) platform to support discovery, clone to pre-clinical development of biologics/biosimilars. This partnership will address 'all things biology' from biologics discovery and development to Investigational New Drug Application (IND) submissions. This will address the needs of research programmes from institutions and emerging to mid-size biotech companies. These programmes focus on biologics for cancer biology, metabolic diseases, pain and inflammation, and neuroscience. Through this collaboration, Vipragen and Zumutor aim to expedite R&D progression, ensure high-quality data, and reduce costs by bringing global research programmes to progress into a quicker commercialisation stage. This strategic alliance is expected to enhance the capabilities of both organisations and significantly contribute to the innovators to take their programmes to the next level.

Pristyn Care partners with CureMyKnee to establish CoE for joint replacement surgeries

Gurugram-based startup Pristyn Care, a leading healthcare provider specialising in advanced secondary care surgeries, is establishing a Centre for Excellence (CoE) in Joint Replacement Surgeries with Cure My Knee. This integration marks a significant milestone in delivering top-notch orthopaedic care, starting from Delhi NCR and extending across India. The Centre for Excellence will be dedicated to providing the highest quality services for patients

requiring joint replacement surgeries. It will leverage the combined clinical expertise of Pristyn Care and Dr Das (Founder of Cure My Knee). The initiative aims to enhance patient outcomes through advanced surgical techniques, state-of-the-art technology, and a patient-centric approach. As per recent market surveys, the rate of joint replacement surgeries in India has steadily increased each year. For instance, knee arthroplasty procedures were estimated to be about 2,00,000 in 2020 whereas hip arthroplasties are projected to grow at the fastest pace globally.

IIM Lucknow introduces Centre of Excellence in blockchain technology to nurture startups

Indian Institute of Management Lucknow's Enterprise Incubation Centre (IIML-EIC) has announced the establishment of a Centre of Excellence in Blockchain Technology (CoE-BT), an initiative supported by the Government of Uttar Pradesh (UP) under its StartInUP Policy. This significant development aims to create and nurture 100 startups in the blockchain domain over the next five years, fostering innovation and entrepreneurship throughout the state of Uttar Pradesh. The CoE-BT will serve as a technology enabler, offering stakeholders access to shared learning experiences, resources, and a dedicated blockchain platform. IIML EIC will lead the training and onboarding of startups, providing comprehensive support that includes mentorship from over 50 industry and academic experts, industry connections, VC funding, and specialised training programmes for students and aspiring entrepreneurs across various sectors with blockchain based applications such as healthcare, real estate, retail etc.

IIM Bangalore and DailyRounds join hands for healthcare incubation programme

NSRCEL, the leading incubation centre for startups, emerging business and women entrepreneurs at the Indian Institute of Management (IIM) Bangalore, in collaboration with DailyRounds, has announced the launch of their Healthcare Incubation Programme. This partnership, part of DailyRounds' CSR initiative, aims to support early-stage startups. It focuses on bringing to life innovations that solve unique problems in the field of healthcare. The programme will help healthcare innovators and entrepreneurs go from lab-tested to market-ready products. It takes the founders through a journey where they will receive complete support, including design thinking, mentorship by industry experts, business development guidance, building out their go-to market strategy, teach them how to run B2B and D2C sales, provide networking opportunities, access to potential funding sources, and even access to hospitals and labs for clinical trials and pilot projects.

IIM Bangalore to have India's first Global Centre of Excellence on PE & Venture Capital

Professor U Dinesh Kumar, Dean, Faculty, at the Indian Institute of Management (IIM) Bangalore has signed a Memorandum of Understanding (MoU), with Mathew Cyriac, Executive Chairman, Florintree Advisors and alumnus of the PGP Class of 1994, to pave the way to the setting up of a global Centre of Excellence, the Tony James Centre for Private Equity (PE) and Venture Capital (VC), at IIM Bangalore. Tony James – former President, Chief Operating Officer and Executive Vice Chairman of New York-based global asset management firm Blackstone – is one of the most well-known investment bankers on Wall Street. Through strategic investments and collaborative partnerships, the PE/VC industry can play a pivotal role in realising the vision of Atmanirbhar Bharat, and fostering entrepreneurship. The first-of-its-kind Centre will serve as a hub for cutting-edge research, education and industry collaboration in the field of PE/VC, where students will connect with industry leaders, gain hands-on insights, and explore the latest trends in PE/VC.

Sciverse opens new engineering R&D centre in Pune

Sciverse has announced the opening of its new Engineering R&D Centre in Pune. This new facility marks an important step in its growth and reinforces its commitment to advancing healthcare technology. The centre is dedicated to strengthening its capabilities in the design and development of medical devices, enabling the company to deliver even more innovative solutions to the healthcare industry. This new centre is Sciverse's third major facility, following the successful launch of its Biosensor R&D Centre in Pune last year. The addition of the engineering R&D Centre will help the company expand its team and bring in new expertise, allowing it to accelerate product development and broaden its range of medical technologies. The new Engineering R&D Centre will allow the startup to design and develop a new generation of portable, point-of-care diagnostic devices. These devices will be optimised for its biosensor technologies and are intended not just for the Indian market but also for export to international markets. By combining the strengths of the biosensor and engineering teams, the company intends to create integrated diagnostic solutions that meet the evolving needs of healthcare providers and patients worldwide.

Skye Air Mobility partners with CARiTAS Hospital for drone-based medical deliveries in Kottayam

New Delhi-based startup Skye Air Mobility, a leading drone technology-based logistics firm, has announced a collaboration with CARiTAS Hospital & Institute of Health Sciences, Kottayam, Kerala, to revolutionise medical deliveries through drone technology. This partnership aims to enhance healthcare accessibility and efficiency in the region by leveraging unmanned aerial vehicles for the transportation of essential

medical supplies and diagnostic samples. The Caritas Drone Medical Supply Delivery Unit is fist of its kind in South Kerala. The initiative will see drones carrying payloads of up to 3 kilograms over distances of 10-15 kilometres, connecting CARiTAS Hospital with various other satellite healthcare facilities of CARiTAS and remote areas in the region. The drone delivery programme is set to undergo a series of trial runs over the coming weeks, with plans for a full-scale rollout across Kottayam district in the near future.

BHARAT EYES GLOBAL BIOMANUFACTURING DOMINANCE: Boosting Innovation, Collaboration & Entrepreneurship with BioE3 Policy

Bharat has demonstrated a strong economic growth in the past decade and is poised to be amongst the global leaders in the next industrial revolution by leveraging emerging technologies and new innovative solutions. Bharat is competitively positioned to be amongst the global leaders in futuristic manufacturing that leverages living systems. Biomanufacturing can fundamentally transform the global economy from today's consumptive manufacturing paradigm to the one based on regenerative principles. Biomanufacturing refers to the use of engineered microbial, plant, and animal (including human) cells with increasing precision and control to produce commercially important products on scale. These are versatile processes that have the potential to create bio-based products allowing efficient utilisation of resources, in a scalable and cost-effective manner with reduced environmental impact. Keeping in view the national priority of steering Bharat on the path of accelerated 'Green Growth', an integrated BioE3 (Biotechnology for Economy, Environment and Employment) Policy for "Fostering High-Performance Biomanufacturing" with an aim to make a green, clean, prosperous, and self-reliant Bharat was released on September 12 at Global Bio-India (GBI) 2024. Let's take a look at how the BioE3 Policy for biomanufacturing is set to transform this landscape.

Bharat's bioeconomy is estimated to be valued around $300 billion by 2030, making it the third largest biotech destination in Asia Pacific and one of the top biotech destinations globally. With COVID-19 providing the industry with a much-needed boost, the country's bioeconomy reached $151 billion in 2023 and witnessed an exponential increase in valuation over the previous 11 years. As one of the top hubs for bioinnovation and biomanufacturing today, Bharat is recognised as a rising sector and a crucial component of the country's economic growth plan, which aims to see its GDP grow to $5 trillion by 2027.

The government introduced the BioE3 (Biotechnology for Economy, Environment, and Employment) Policy—a strategic framework designed to propel India into the next era of industrialisation through high-performance biomanufacturing. The BioE3 Policy was approved on August 24, 2024, by the Union Cabinet for "Fostering High-Performance Biomanufacturing". The policy chalks a strategic roadmap to making India a global biomanufacturing hub by promoting high-performance biomanufacturing through innovation for the development of bio-based products and building an infrastructure that enables scale-up and commercialisation.

The policy aims to empower Indian institutions, universities, startups, and industries to engage in transformative innovations by boosting domestic biomanufacturing capabilities by enabling synergy between science, technology, engineering, and manufacturing. 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.

The six thematic areas of focus highlighted in the BioE3 Policy include bio-based chemicals and enzymes, functional foods and smart proteins, climate-resistant agriculture, carbon capture and utilisation, futuristic marine and space research, and precision biotherapeutics. Out of these six, the area of focus relevant to life sciences industries that BioSpectrum will aim to explore is Precision Biotherapeutics.

'Precision Biotherapeutics' is of special focus and interest to the healthcare and biopharma sectors. The policy draws attention to biologics/biotherapies like Cell and Gene therapy, mRNA therapeutics, monoclonal antibodies, immunotherapy, as well as next-generation vaccines.

"To successfully implement the BioE3 Policy, various ministries and departments are collaborating and sharing resources. For instance, the Ministry of Electronics and Information Technology will support AI-based biomanufacturing, while the Indian Council of Agricultural Research will focus on developing agribiologicals. Other ministries like New and Renewable Energy, Space, Health, Pharmaceuticals, and Earth Sciences will play critical roles in ensuring the policy's success," said ***Dr Jitendra Singh, Union Minister of State (Independent Charge) for Science and Technology.***

The minister further said "Powered by the visionary BioE3 policy, I strongly believe that Bharat would emerge as a global biotechnology powerhouse with significant contribution of Bioeconomy to our shared vision of 'Viksit Bharat' by 2047".

BioE3 for Biomanufacturing

Biomanufacturing involves the use of biological systems to produce commercially relevant products. The world is at the cusp of a new industrial revolution driven by bio-innovation, and biotechnology will strongly influence future bio-based manufacturing. Many nations like the United States of America, Japan, Australia, Finland, and other European countries, have put forward their policies, strategies, and roadmaps to set up a robust framework for biomanufacturing. An efficient and sustainable biomanufacturing ecosystem can form the backbone for biotechnology innovation and an infrastructure that truly enables the translation of innovations to society at large. Fostering these aspects will be necessary for a holistic and sustainable infrastructure that is well-positioned to achieve key milestones in high-performance biomanufacturing and robust commercialisation of such innovative biotechnology products.

"The BioE3 Policy positions biomanufacturing as a crucial solution for sustainable growth", remarked ***Dr Rajesh Gokhale, Secretary to the Government of India, Department of Biotechnology (DBT), Director General, Biotechnology Research and Innovation Council (BRIC)***

and Chairman, Biotechnology Industry Research Assistance Council (BIRAC). "This BioE3 policy is about scaling up – Scaling up of the ambitions of startups to become successful entrepreneurs, scaling up of their programmes to become successful products, and scaling up of capabilities so that we can change the ecosystem in the world", he said.

Emerging technologies, like synthetic biology and artificial intelligence, present opportunities to accelerate the growth of bioeconomies. For instance, applying AI algorithms and machine learning tools to biological applications has been changing the outcomes biology can provide. If established models from countries leading the bioeconomy game are to be drawn inference from, fuelling biotech innovations brewing at the interface of advanced technology, biology, and bioprocess engineering could drastically speed up the development of commercial outcomes for healthcare. In that sense, generative biology presents limitless improvements and has already started delivering game-changing outcomes.

Dr Jitendra Kumar, Managing Director, BIRAC said, "Strategic reforms, harmonised with regulatory reforms and global standards, need to be defined for facilitating production

and commercialisation of novel bio-based products. The convergent and multi-disciplinary research for biomanufacturing at scale entails multiple elements of regulatory interface and approvals. Proactively engaging with all stakeholders to identify such challenges and facilitating stakeholder interactions to pursue potential solutions will be crucial – to create a convergence between biotechnology, engineering, and digitalisation. Implementation of this biomanufacturing initiative will be through a public-private co-creation model that combines expertise in academia, startups, and industry through inter-ministerial coordination. The BioE3 policy aims to achieve this through collaborations with international partners, research institutions, universities, government agencies, and public-private partnerships with startups and Indian industries, further enabling the growth of an economically and environmentally sustainable bioeconomy and contribute for making Bharat self-reliant."

The introduction of the BioE3 Policy comes at an interesting time for India's biotechnology sector, for focused industrialisation of 'bio-based products'.

Deeming the policy as a pivotal moment in India's biotechnology landscape, ***Prof. K VijayRaghavan, former Principal Scientific Adviser to the Government of India,*** spoke primarily about the policy's implications for successfully scaling up biotech innovations and its importance in helping the country move towards domestically developed products. He further said "India has already showcased its capacity to innovate in biotechnology, especially in vaccine development and agricultural biotech. However, scaling these innovations to meet both domestic and global demands requires a robust biomanufacturing ecosystem. The BioE3 policy addresses this need by fostering indigenous biomanufacturing capabilities. By building cutting-edge infrastructure, promoting skill development, and encouraging collaboration between research institutions, startups, and industry, this policy sets the stage for India to become a biomanufacturing powerhouse."

Remarking on the prospect of India becoming a global biotechnology leader by leveraging this policy, ***G S Krishnan, President of the Association of Biotechnology Led Enterprises (ABLE)*** stated, "The national Bioeconomy's growth with get further momentum with the newly unveiled BioE3 policy of the Department of Biotechnology. It is just the right catalyst to push our BioEconomy to a higher orbit by harnessing the power of biomanufacturing. The COVID-19 response demonstrated India's vaccine manufacturing prowess and BioE3 has the potential to replicate this success in many other sectors of our industry, particularly in the emerging areas of alternate proteins, biofuels, cell and gene therapy and so on."

By India, for India

Precision medicine and personalised healthcare are rapidly gaining traction globally. Broadly, precision medicine comprises detailed molecular characterisation of disease states using the biologic omics platforms to better individualise diagnostics, prognostics, and therapeutics, utilising individuals' factors like genetic, environmental, and lifestyle data to improve the prevention, diagnosis, and treatment of disease. Alongside concerns of data-sharing and patient privacy, equitable access to treatments is a major contemporary hurdle in truly manifesting large-scale effective precision medicine provision in India.

Unmet medical needs and inefficiencies drive healthcare innovation with the goal of protecting and promoting health for individuals and society at large. Non-communicable diseases are on the rise in the Indian population. The prevalence of deadly infectious diseases, along with the potential of numerous epidemic or pandemic-causing pathogens is a challenge. The prevalence of genetic disorders, and rare diseases such as sickle cell anaemia, muscular dystrophy, thalassemia, and haemophilia also poses a challenge for our society and healthcare system. The scenario not only presents opportunities but also necessitates, diving deep to act on the untapped potential for high-degree innovation and building a robust infrastructure for effectively translating health innovations to society at large.

India's biotech sector is poised to achieve new heights. India's biotechnology prowess, coupled with its leadership position in the biopharma sector, positions India to be a frontrunner in leading the 'Fourth Industrial Revolution' of bio innovation.

"Over the next decade, a lot of diseases that are currently incurable will start becoming treatable due to the advent of cell and gene therapy. It will be imperative for every country to create an indigenous platform from which a large ecosystem of companies and academia can do research to bring therapies to people in need," said ***Dr Jogin Desai, Founder and CEO, of Eyestem Research*** while talking about how high-performance,

innovation-driven biomanufacturing collectively set to boost the precision biotherapeutics space in India, particularly cell therapy.

"Biomanufacturing is a critical bottleneck in development of cell and gene therapies and I am delighted that the policy is targeting it as one of the key initiatives. Several such initiatives exist in the UK (Catapult networks), and Canada (Centre for Commercialisation of Regenerative Medicine) besides state-level networks in the US which have led to the flourishing of such therapies in those countries. I hope India will soon see a similar cohort of innovation-driven companies", he added.

Highlighting some prominent challenges India's biotech sector is facing in developing and achieving a successful transition of innovative cell therapies from lab-to-market and pre-commercialisation, Dr Desai said, "Two main challenges for such therapies hobble the sector. The first is the ability to productise the science i.e. the transition from research-led protocols to predictable GMP scale protocols. Second is the absence of a large ecosystem of knowledgeable funders from the VC community."

While ***Dr Rahul Purwar, Founder and CEO, ImmunoAct*** remarked on the fact that extremely high costs of such therapies is a hurdle we need to overcome. He stressed that innovation in India and indigenous production through solid public-private partnerships (PPP) across Indian academia and industry would be important to bring down costs. "If biomanufacturing can be done in a PPP format, it will make these therapies more affordable. We need to accelerate examples of such collaborations multifold now, and this is where the BioE3 policy will help", he said.

"Another important aspect to consider when talking about cell and gene therapy is the accessibility of the therapies. Only 10 per cent of our population can afford these therapies. Including (our) cell and gene therapies in Government healthcare access programmes, such as Ayushman Bharat and reduction in the high GST on oncology therapies, can also make cell and gene therapies affordable", he added.

Large-scale biomanufacturing and the successful scale-up and commercialisation of innovations are critical to making biotherapeutic therapies more affordable. By optimising production processes and achieving economies of scale, manufacturers can reduce the cost per unit of complex biologics, biosimilars, and advanced therapies. This, in turn, could lower the overall price of therapies, making cutting-edge treatments accessible to a broader

BioE3 policy opens up avenues for Brazil to import high-quality at competitive prices

« **Bruna Magnago,** Senior Fellow, India Brazil Chamber of Commerce (IBCC)

From a broader perspective, the policy presents several key impacts for Brazil-India business relations in the pharmaceutical sector. With India's focus on bio-based APIs, there are growing opportunities for Brazilian pharmaceutical companies to collaborate with Indian manufacturers. Brazil, with its strong pharmaceutical market and focus on innovation, can benefit from India's advanced capabilities in bio-based API production, fostering partnerships that ensure a sustainable supply chain for both countries.

The BioE3 policy will likely attract global investments into India's bio-based API sector, and Brazilian companies could capitalise on these opportunities by investing in joint ventures or technology transfer initiatives. This would deepen bilateral trade ties, as Brazil continues to seek reliable sources of APIs, especially in the post-pandemic context where supply chain resilience is paramount.

As India strengthens its bio-based pharmaceutical industry, both India and Brazil are increasingly focusing on regulatory convergence and reliance initiatives. By aligning regulatory frameworks, particularly for bio-based APIs, businesses in both countries could benefit from streamlined market entry and faster regulatory approval processes, paving the way for smoother cross-border transactions.

India's shift towards bio-based APIs under the BioE3 policy is expected to enhance the global competitiveness of Indian pharmaceutical exports. For Brazil, this opens up avenues to import high-quality, bio-based APIs at competitive prices, reducing dependency on traditional synthetic APIs and contributing to cost-effective, sustainable healthcare solutions. BS

Need for BioE3 Policy

- Strengthen and align science, technology innovation ecosystem by fostering public-private partnerships, inter-ministerial collaborations, and international cooperation
- Accelerate technology development and commercialization by setting up Bio-Enabler Hubs with access to technology platforms and infrastructure
- Foster surge in employment and intensify entrepreneurial momentum
- Harmonise regulatory reforms with global standards
- Effective and transparent patent system for use of genetic resources
- Promote sustainability in diverse ecosystems utilising valuable knowledge of local communities
- Harness regenerative bioeconomy with ethical and biosafety considerations

Strategies to promote biomanufacturing

1. Partnerships and Collaborations
2. Public-private co-creation model
3. International Collaborations
4. Inter-Ministerial Coordination
5. Skilling and Human Resources

New strategies for scaling-up biomanufacturing processes

- Discovery & Application-oriented Integrated Network Research
- Bridging the gaps for scale-up, between lab and market
- Reducing costs, time, and complexity in the biomanufacturing innovation ecosystem
- Setting up ' (Cross-cutting) Bio-Enabler Hubs'
- Addressing regulatory roadblocks
- Creating a large skill-set pool of trained manpower

population and addressing healthcare affordability on a global scale.

Technological advances in biotechnology have empowered companies to stay competitive by enabling efficient, cost-effective, and scalable production processes. A seamless integration of these approaches could stand as a crucial factor for our Biotech landscape. Strengthening supply chain efficiencies while driving innovation in biotherapeutics and other life sciences sectors would benefit from an infrastructure provisioning for technology-driven high-performance biomanufacturing.

Emphasising the policy's focus on self-reliance in biopharmaceuticals, vaccines, and biologics, Prof. Raghavan said, "The pandemic underscored the need for nations to secure their supply chains, especially in health-related manufacturing. Biomanufacturing will enhance India's ability to respond to future pandemics and reduce dependence on imports for critical products, fostering economic resilience."

India is an established leader in vaccine manufacturing and supply to the world. But, encouraging innovation, providing more financial initiatives and streamlining regulatory processes will benefit Indian companies engaged in the development and production of biological products, opined ***Dr K Anand Kumar, Managing Director of Indian Immunologicals Limited (IIL),*** while lauding the BioE3 policy for its comprehensive approach to enhancing the biomanufacturing ecosystem in India. Dr Kumar also highlighted the policy's alignment with IIL's objectives and a broader mission of advancing healthcare solutions while achieving self-sufficiency. "The BioE3 policy complements IIL's vision of advancing public health through indigenous vaccine development and biomanufacturing. It supports our efforts to scale up production capabilities and enhance our research initiatives," he stated.

In the context of biomanufacturing 'by India for India', factors in addition to innovation could be significant contributors to shaping a forward-looking biotechnology landscape. ***Krishna Mohan Puvvada, Regional President – MEIA, Novonesis*** said, "The BioE3 policy envisages the path for India towards becoming a global leader, adopting and expanding the biomanufacturing ecosystem. The policy also aims to effectively steer the transition to a circular economy. Biomanufacturing will enable high-

skilled job creation and intensify entrepreneurial momentum towards a knowledge-based industry sector. This initiative will accelerate India's ambition towards de-carbonisation targets by encouraging the Indian industry to shift towards more sustainable production processes."

Sharing his views ***Aditya Sharma, Head of Process Solutions, India Region, Merck Life Science*** said, "The BioE3 policy's focus on advancing biomanufacturing will not only benefit life sciences but also bolster the related sectors, contributing to a more sustainable and prosperous economy. Advancements in some strategic segments such as cell and gene therapy will be amplified with suitable interventions aligning with global scientific research. We truly believe that with key drivers such as public-private-partnerships; appropriate FDI incentivisation; skill development with global practices, learnings, industry-ready curriculums; identifying and supporting key projects with less-paper more-trust approach, and constant industry/stakeholder consultation will amplify the potential of BioE3 policy across all the players in India."

By India, for the world

India is set to emerge as a global leader in biomanufacturing. Recognised for its vast capabilities in producing biopharmaceuticals, biologics, and biotherapeutics at scale, and as one of the largest suppliers of vaccines and biosimilars, India's biomanufacturing prowess would be underpinned by a robust infrastructure, skilled workforce, and competitive cost advantages. With a growing emphasis on innovation, the country continues to strengthen its position as a key player in the global supply chain, driving advancements in precision therapeutics and biologics. India's role in biopharma is critical to ensuring global healthcare access, particularly in emerging markets.

Sharing views on impact of BioE3 policy on Contract Development and Manufacturing Organisations (CDMO) sector ***Alex Del Priore, SVP Manufacturing Services, Syngene,*** opined, "Over the next few years, the competitive landscape for Indian CDMOs is expected to undergo significant evolution, primarily propelled by the increasing emphasis on biologics and advanced manufacturing technologies. Indian manufacturers are producing biologics approved by US FDA and EMA which underscores adherence to international quality standards and fosters confidence in the sector. The burgeoning demand for biologics will serve as a pivotal growth catalyst, with Indian CDMOs such as Syngene, equipped with comprehensive capabilities in this domain, poised to seize a larger market share. Technological advancements like perfusion, continuous processing and automation will play a critical role in enhancing production efficiency and CDMOs in India investing in these areas are well-positioned to lead the market and capitalise on emerging opportunities. Further, the capabilities to produce peptides, oligonucleotides, plasmid DNA, mRNA enable the CDMOs to stay at the cutting edge of therapies. Continued government support through initiatives like the BioE3 policy, PRIP (Promotion of Research & Innovation in Pharma-MedTech sector) scheme and PLI (Production Linked Incentive) scheme will further bolster the capabilities of Indian CDMOs, enhancing their competitiveness globally."

Expressing his thoughts on the policy ***Dr Vishal Warke, Director- R & D (Cell Biology & Hydroponics), HiMedia Laboratories*** said, "To become a global manufacturing hub as well as a supplier, we need to have excellent quality at affordable prices. That can only come with economies of scale. Our national intent is not just about boosting our biotech sector, it's about making India a global hub for import substitution to furthering Atmanirbhar Bharat to Bharat Nirbhar Vishwa."

Dr Warke further said that with this policy, India is taking a giant leap forward in transforming the nation's biomanufacturing landscape. "The policy focuses on fostering innovation in critical areas like precision biotherapeutics (among others). The policy aims accelerated technology development and commercialisation to biomanufacturing hubs, bio-AI centres, and biofoundries. We need to set up a foundation for a massive scale-up, which is now provisioned for in the BioE3 policy. The policy is a game-changer for India, positioning us at the forefront of the global biotechnology revolution and paving the way for a prosperous self-reliant future," said Dr Warke.

Hailing the BioE3 policy as the Government's bold initiative to establish India as a global leader in biomanufacturing, ***Chakravarthi AVPS, Advisor International Affairs, Federation of Asian Biotech Associations (FABA) and Chairman, Federation of***

Pharmaceutical Entrepreneurs (FOPE) stressed upon factors that will give impetus to make this initiative a success. “While the policy lays out an ambitious and promising vision, its success will hinge on addressing several existing challenges. These include overcoming regulatory delays, ensuring infrastructure readiness, and bridging the skill gap within the biotech sector. Effective implementation of these measures will be crucial for the policy to achieve its full potential. If executed successfully, the BioE3 policy could significantly transform India’s bio-economy and propel the country to the forefront of global biotechnology and healthcare innovation, establishing it as a major player in these critical sectors”, he added.

With the BioE3 policy for high-performance biomanufacturing, India is aiming to step into the ‘next phase’ to become one of the top global hubs for biomanufacturing. With the momentum the policy is set to provide, how Indian players in large-scale commercial production of therapeutics, next-gen vaccines, biosimilars and novel biologics will capitalise on the opportunity to be a global leading supplier will be an interesting journey.

Biosuppliers Boosting Biomanufacturing

Biosuppliers play a critical role in enhancing biomanufacturing by providing essential raw materials, equipment, and technologies that enable efficient and scalable production of biologics, biosimilars, vaccines, and other biotherapeutics. Their contributions span across upstream and downstream processes, offering innovations in areas like single-use technologies, bioreactors, filtration systems, and advanced analytical tools that ensure quality and regulatory compliance.

In the context of the growing demand for biologics and emerging therapies such as cell and gene therapies, biosuppliers are crucial in accelerating production timelines while reducing costs. By fostering collaborations with biopharma companies, investing in R&D, and improving supply chain resilience, they can help streamline production processes, minimise contamination risks, and maintain high safety and efficacy standards. As the biotech industry evolves, biosuppliers are positioned as key partners in driving technological advancements, ensuring consistent manufacturing capacity, and supporting the global expansion of biomanufacturing capabilities.

V Sankaranarayanan, Managing Director, VFL Sciences opined, “The BioE3 policy is a welcome move by the government, and it is the need of the hour for India. This policy will attract more biosupplier companies to invest in India. This will also kindle entrepreneurship among the youth, and we can expect more startups to come into the biosupplier area. Biosuppliers are a very important part of this policy as equipment, consumables and reagents will be needed in large quantities to support the programme. Currently, India is depending more on imported products in this space, and the funds from the government for such programmes are very limited. In order for the programme to be a grand success, the government should support the biosuppliers from India.”

Sharing views about the primary obstacles biosuppliers face when scaling up innovative bioprocesses for large-scale production, commercialisation of precision biotherapeutics and biologics, Sankaranarayanan said, "The biosupplier industry is evolving, however, the market is currently very small. Due to the smaller market, we are not able to attract the best talent. Engineers with better experience in developing innovative products are very limited in India. As the market evolves and more players come into the market, I feel this will develop automatically. India currently lacks any government research lab which supports the biosupplier industries. We don’t have labs that are working on novel instruments. There is very little happening on the instrumentation part for life sciences."

Elaborating on how biosuppliers can capitalise on the momentum the policy is set to provide to drive high-performance biomanufacturing and large-scale production capabilities, he further said, " It is a good time for Indian companies engaged in the production of such instruments to upgrade the quality of the product as well as the support infrastructure to grow the business. I also expect more people with global experience to join Indian companies to support them with the knowledge and process. I also hope more global companies come forward and work with Indian manufacturers to develop the industry further. With the scale improving it is possible for global companies to set up their own manufacturing facilities in India. Overall it is going to be a very interesting time for Indian biosuppliers."

Sharing his perspective about the challenges biosuppliers face in scaling up innovative bioprocesses for large-scale production of precision biotherapeutics and biologics, ***Dr Girish Mahajan, Senior Vice President - Microbiology Department, HiMedia Laboratories*** said, “While some industrial R&D facilities can begin optimising from the

start using highly automated, synchronised mini-bioreactor systems, the cost is prohibitive for many new developers. As the scale increases by factors of 5x or 10x, nearly every parameter contributing to the complexity of the molecules must be carefully optimised. Scaling up cell cultures presents significant challenges due to variations in growth and performance at larger volumes, often leading to inconsistent yields and product quality. Additional technical hurdles include modifying bioreactor designs and mitigating contamination risks."

He further said, "High-end analytical tools are required to measure key variables in (production of) therapeutic molecules, and the cost of equipment or outsourcing these analyses further adds to the expense. Logistical issues also arise, including the high costs of purifying biologics to meet stringent quality and regulatory standards. Even if these hurdles are overcome, the feasibility of the project is often questioned based on the yield. For instance, achieving an optimised yield of 3.5 g/L may not be commercially viable if the minimum required yield is 5 g/L. For academic research institutions, such projects are feasible only with full funding support for the necessary advanced infrastructure."

With regards to how the BioE3 policy framework can strengthen the link between biotechnology research, scale-up, and commercialisation, he said, "The policy, promotes the development of advanced biomanufacturing technologies such as single-use bioreactors, perfusion systems, and wave bioreactors, which are critical for cost-effective and scalable production. The policy ensures collaboration between academia, industry, and regulatory bodies, increasing the likelihood of bringing new biotherapeutics from the research stage to market. By streamlining regulatory processes and offering subsidies for infrastructure development, BioE3 aims to accelerate the scaling and commercialisation of biologics, particularly in areas like precision medicine and biotherapeutics."

No time like present

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', 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. The country's total biotech startup base has expanded to 8,531 companies in 2023. The base grew from 3,397 companies in 2019. India is also witnessing an increase in the number of incubators and knowledge parks in the biotechnology landscape.

As highlighted by DBT BIRAC's India BioEconomy Report (IBER) 2024, MSMEs remain the backbone of India's BioEconomy, despite certain challenges. Their contributions are vital for the sector's growth and resilience, and with continued support and development, they are well-positioned to sustain their crucial role in the industry's future.

The IBER 2024 also highlights that Indian BioEconomy's drivers are rooted in diverse segments like BioPharma, BioIndustrial, and BioServices. This adaptability positions the India BioEconomy for continued success. Some of the key upcoming trends include global biosimilars market, therapeutics innovation and sustainable bio-industrial practices. Tech integration in the bio IT/research services will also be a major driver in the coming years.

Expanding global acceptance of Indian-made biosimilars presents a lucrative opportunity for the BioPharma sector to capture a larger market share in developed countries. Continued advancements in BioPharmaceuticals, personalised medicine, and precision treatments are expected to propel the therapeutics segment forward. Integration of advanced technologies like bioinformatics, data analytics, and artificial intelligence in bioresearch services is poised to accelerate, enhancing research capabilities and driving growth in BioIT/Research Services.

The picture this paints certainly points to the notion that it is going to be an interesting, perhaps revolutionising time for Indian biotechnology, albeit challenges and hurdles that will need to be overcome. How the BioE3 Policy for biomanufacturing will lead this revolution, time will tell. BS

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Can phased trade margin rationalisation boost pharma growth?

The pharma representatives of the Laghu Udyog Bharati (LUB), an RSS affiliate and a not-for-profit Pan India Organisation with the aim of empowering Micro and Small enterprises in the country since its formation in 1994, on July 24, had a meeting with officials from the Department of Pharmaceuticals, and discussed key issues such as Trade Margin Rationalisation (TMR), Schedule-M extension, Revised PTUS Hurdles, and the Drug Tribunal Board formation. LUB Pharma proposed the innovative "One Nation-One Molecule-One MRP" and advocated for the top 100 companies to sell their generic brands at molecule name and affordable Maximum Retail Price (MRP) for patient benefits. Here we are looking at a series of recommendations from industry associations to make TMR more effective, balanced, and supportive of all stakeholders in the pharmaceutical supply chain.

The pharmaceutical industry has called for a careful and phased implementation of Trade Margin Rationalisation (TMR), urging the government to ensure that the Drug Price Control Order (DPCO) is equipped to meet future challenges while fostering industry growth. Leading industry associations have put forward a series of recommendations to make TMR more effective, balanced, and supportive of all stakeholders in the pharmaceutical supply chain.

However, the industry is cautious about expanding TMR across the pharmaceutical sector, recognising the complexities involved. Industry associations have noted that while TMR is a promising tool for ensuring fair pricing, it must be applied in a manner that avoids unintended consequences such as supply chain disruptions, reduced market access, or the undermining of small and medium-sized enterprises (MSMEs).

Recognising the importance of a robust and future-ready DPCO, industry leaders have outlined key recommendations for how TMR should be implemented to achieve the desired balance between affordability and industry growth. These recommendations focus on maintaining a healthy supply chain while protecting the interests of consumers and MSMEs alike.

Industry stakeholders have called for TMR to be implemented in phases, with a focus on high-value, non-scheduled formulations as a starting point. The roll-out should be prospective, applying only to batches manufactured after the notification is issued, and stakeholders should be informed of TMR guidelines 3 to 6 months in advance. This phased approach would allow companies to adjust to the new regulations without major disruptions.

Exemptions for Key Sectors: The industry has recommended that certain areas of the pharmaceutical market be exempt from TMR. Specifically, Para 19 drugs (those critical to public health), government tender businesses, and patient assistance programs should not be included in the scope of TMR. These sectors often operate under different financial models and regulatory frameworks, making them unsuitable for margin rationalisation measures.

Simplification of Compliance via IPDMS: To streamline the regulatory process, the industry has requested that Form V price lists, which track the revised prices of drugs, be submitted exclusively through the Integrated Pharmaceutical Database Management System (IPDMS). This would eliminate the need for multiple submissions and reduce the administrative burden on manufacturers.

Price Revision Based on Para 20 Guidelines: The industry proposes that price revisions under TMR should adhere to Para 20 of the DPCO, which requires revisions to be based on the average of the preceding 12 months. This approach will help ensure that price adjustments are reflective of market conditions and are not overly disruptive to manufacturers and wholesalers.

Industry associations have also underscored the importance of protecting MSMEs, which play a significant role in the pharmaceutical sector. TMR should be applied in a manner that considers the unique challenges faced by these smaller companies, which may lack the financial resources to absorb sudden margin changes.

TMR in Practice

TMR, if implemented effectively, could lead to a significant restructuring of the pharmaceutical market. The pilot phase with cancer drugs has demonstrated that margin rationalisation can lead to lower prices for consumers, but the broader implications of extending it to other drugs remain a matter of debate.

The pharmaceutical industry is undergoing significant transformation as different retail models, including traditional retail, organised retail, and e-pharmacies, compete for market share. A recent analysis comparing the trade margins across these channels has highlighted the discrepancies in pricing and profitability at various stages of the pharmaceutical supply chain.

Branded Generics Rx: Traditional Retail Model

The traditional retail model for branded generic drugs is structured with multiple layers in the supply chain. The cost-and-freight (C&F) agent typically charges Rs 70, with a 3 per cent margin passed on to the wholesaler, who then charges Rs 72, taking a 10 per cent margin. Finally, the retailer charges Rs 80, with a 20 per cent margin. This results in a maximum retail price (MRP) for the customer of Rs 100.

Trade Generics: A disruptive force in the market

Trade generics, which are off-patent drugs sold under their chemical names rather than brand names, present a drastically different picture in terms of pricing and trade margins. In this model, the C&F margin is much lower at Rs 15, with a 2 per cent margin. The generic stockist takes Rs 15.30 with an 11 per cent margin, while the retailer charges Rs 17, reflecting a significant 500 per cent. The organised retail model offers a more structured pricing system, with slightly different trade margins than traditional retail. Here, the C&F agent again takes Rs 70 with a 3 per cent margin, and the modern trade wholesaler charges Rs 72 with a 10 per cent margin. However, modern trade retailers charge Rs 80 with a lower margin of 12.5 per cent, leading to a customer price of Rs 90, offering a more competitive price than traditional retail.

Industry stakeholders have called for TMR to be implemented in phases, with a focus on high-value, non-scheduled formulations as a starting point. The roll-out should be prospective, applying only to batches manufactured after the notification is issued, and stakeholders should be informed of TMR guidelines 3 to 6 months in advance. This phased approach would allow companies to adjust to the new regulations without major disruptions.

E-Pharmacies as digital disruptor

E-pharmacies have emerged as a major disruptor in the pharmaceutical industry, offering consumers greater convenience and competitive pricing. In this model, the C&F agent again charges Rs 70 with a 3 per cent margin, while the wholesaler takes Rs 72 with a 10 per cent margin. However, e-pharmacies take Rs 80 with a lower margin of 16.5 per cent, leading to a final customer price of Rs 85. This model offers some of the lowest prices for consumers, thanks to reduced overhead costs and streamlined distribution.

As the industry shifts towards more organised and digital models, consumers stand to benefit from lower drug prices, though this also poses challenges for traditional retailers who must adapt to these new competitive pressures. Ensuring that TMR is future-ready means protecting the interests of consumers, encouraging innovation, and safeguarding the livelihood of small businesses. BS

Bhagwati Prasad

TELANGANA WAGES WAR AGAINST COUNTERFEIT DRUGS

Telangana contributes nearly one-third to India's production and one-fifth to its exports in the pharmaceutical sector. Hyderabad is a home to 800 pharma companies and life sciences capital of the country. To make the state free of spurious drugs, the Drugs Control Administration (DCA), Telangana is working relentlessly to detect spurious drugs movement in the market. In 2023 the DCA has carried out 26,133 inspections and taken action in 4984 cases with 4991 cases of violations. In the first four months of this year till April 2024 DCA has carried out 8495 inspections and found out that 50 drugs are 'Not of Standard Quality' (NSQ). Let's look at how DCA is continuing its crusade against the spurious drugs issue and keep the public health of the state in order.

From the beginning of 2024, the DCA of Telangana, under the leadership of Director General (DG) V B Kamalasan Reddy, (who took charge as DG in July 2023) has intensified its efforts to combat the menace of spurious, fake and NSQ in the state. In the past few months, the DCA has targeted nearly 100 facilities across the state, resulting in the confiscation of 4000 to 5000 kgs of counterfeit medications worth Rs 50-60 crore. These recent raids have uncovered a widespread network of spurious drugs, highlighting the ongoing battle against counterfeit medications that pose a severe threat to public health.

Highlighting the efforts taken by the DCA of Telangana, Kamalasan Reddy said that he is committed to ensuring that quality, efficacy, and safety of medicines being supplied to the people in the state. "As part of this objective, we at the DCA have set our goals and accordingly devised plans for inspecting pharmaceutical companies, medical shops, medical device manufacturing companies, and blood banks across the state," said Kamalasan Reddy.

Emerging pharmaceutical hub

As Telangana state is regarded as a hub for bulk drugs in India, contributing 30 per cent of the nation's bulk drugs production, the DCA is entrusted with inspecting, supervising, and issuing licenses to pharmaceutical companies, medical shops, and medical device companies. In Telangana, there are over 800 pharmaceutical manufacturing companies and over 45,000 medical shops and pharmacies respectively involved in manufacturing and distribution of medicines to the people in the state.

"With the Genome Valley, the medical device park and the well-established bulk drug and formulation industry, Hyderabad is the fast-emerging pharmacy hub of India. In view of this, the DCA has the responsibility to not just providing a conducive atmosphere for the existing pharma companies and for those who are coming to invest in the state, but at the same time we are authorised to strictly implement the Drugs and Cosmetic Act 1940 and Rules 1945," said Kamalasan Reddy.

Human resource challenge

Being an IPS officer, he has taken some time to study his role as the DG, DCA's functioning and identified various shortcomings. Plugging them all, he had to face a big challenge of shortage of drug inspectors. As per the rules, for every 100 medical shops there should be one drug inspector and for

every 25 pharmaceutical companies there should be one inspector to monitor their activity and conduct inspections on a regular basis. However, with just 70-75 officers at the DCA, it is a daunting task to inspect more than 45,000 medical shops and over 800 pharmaceutical manufacturing companies in the state.

"We are having very limited human resource personnel at Telangana DCA. Despite limited resources, I selected a few officials to form a special vigilance wing. I gained the confidence of all drug control inspectors and officials through extensive brainstorming and motivation, emphasising their roles and responsibilities. I encouraged them to sincerely perform their duties for the betterment of healthcare in society," says Kamalasan Reddy, whose efforts are successfully delivering results as the DCA officials are cracking the whip against all those who are violating the rules and regulations on a regular basis.

With the full support from all department officials, though the DG faced some headwinds initially, with the vigilance cell functioning properly and with information of spurious drugs coming flooding in, the DCA authorities prepared an action plan and conducted regular raids.

Crack down

Citing some of the examples, the DG highlighted how the DCA authorities had successfully dismantled a spurious drug manufacturing racket operating in Kukatpally in Hyderabad. "We have arrested many gangs involved in the distribution of fake and substandard drugs in the state. We have busted interstate fake distribution networks and informed the enforcing agencies of other respective states to take action against them. Many of them are absconding and we have booked cases and sent non-bailable warrants against individuals responsible for the circulation of spurious drugs into the state," informed Reddy.

The DG noted that except for one or two majority pharmaceutical manufacturing companies in Telangana all are strictly abiding by the Drugs and Cosmetic Act and Rules. However, the DCA authorities are constantly are keeping a regular eye on their operations and attending regular plant inspections. In fact, Telangana DCA has become the 4th drug regulation enforcing body after Gujarat, Karnataka and Goa, in the country to have attained the status of observing the inspections of USFDA approved units in the state.

Curb on habit forming narcotic drugs

The government of Telangana led by Chief Minister, Revanth Reddy, has also extended its full support to the DCA to curb the supply and distribution of habit-forming medicines to unauthorised consumers. The state government has taken a policy decision to ban all narcotic drugs and is taking steps to curb the menace. The DCA is focusing on curbing on distribution and supply of habit-forming medicines to unauthorised persons. Usually some of the medicines like morphine, pentazocine, and some cough syrups, if consumed in higher doses without a prescription, can lead to severe health issues and have an adverse impact on the nervous system and can even lead to death. In view this, the DCA is also monitoring the sale and distribution of such habit forming drugs and it is also not hesitating to act on consumers who are violating the regulatory norms.

"The DCA has the responsibility to not just providing a conducive atmosphere for the existing pharma companies and for those who are coming to invest in the state, but at the same time we are authorised to strictly implement the Drugs and Cosmetic Act 1940 and Rules 1945."

V B Kamalasan Reddy,
DG, DCA, Telangana

Reacting to the DCA's action against counterfeit drugs Dr Appaji, former Director General of Pharmexcil said "We are glad that DCA is doing their job right to curb the fake and spurious medicines flooding the market. These fake companies are in fact causing grave damage to the reputation of good people in the industry."

Ravi Uday Bhaskar, who is also a former Director at the DCA and former DG of Pharmexcil, opined that it is a good scenario being observed in Telangana with regard to constant inspections being conducted on drug manufacturing firms, pharmacies and clinics to check the quality of medicines being manufactured and supplied to the patients. Post the cough syrup episode that had had a very negative reputation for Indian pharma exports at a point, these actions by regional regulatory bodies clearly indicate that India is serious with regard to the quality of medicines and its regulatory machinery are well equipped and capable of rooting out the menace of spurious medicines in the country and will not tolerate it at any level. BS

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"Netravaad is for stroke patients and also those who've very severe speech issues or lost their speech"

« **Dr Rajesh Kannan Megalingam,** Founder, T2H Innovations

T2HInnovations, a Kerala-based startup established under the AI and Robotics research center, HuT Labs of Amrita University, specialises in biomedical and healthcare robotics is set to commence production of Netravaad, an innovative device designed to revolutionise patient care for individuals with speech impairments. In an interaction with BioSpectrum Dr Rajesh Kannan Megalingam, Founder, T2H Innovations and Director, HuT Labs, Amrita Vishwa Vidyapeetham shared more details about the future plans of the company. ***Edited excerpts:***

What are the USPs of Netravaad?

Netravaad is a device developed and tested rigorously at Amrita Hospital in Kochi. It utilises innovative eye gesture-based technology to enable patients to communicate their needs effectively. The device consists of a camera, display, speaker, controller and a rechargeable battery that lasts for six hours on a single charge. The camera detects the eye sign of the user, which is converted into alphabet, word or a sentence by a customised AI algorithm called Sharani. The detected words and sentences are displayed on the screen. In addition, the voice through speakers helps the external world understand the patient's feelings, and the patient also gets a feel of speaking to others. Besides English, Netravaad is available in regional languages such as Malayalam and Hindi. Additionally, the user interface will be highly interactive, ensuring a comfortable experience for stroke patients.

How many trials have you done before entering the market?

We have already tried on 65 patients at our Department of Physical Medicine & Rehabilitation at Amrita Hospital with 95 per cent efficacy. We are trying to improve this further.

How do you wish to take this unique medical device to the masses?

Besides testing at Amrita Hospital, we have an opportunity to visit the National Institute for Physical Medicine and Rehabilitation (NIPMR) at Thrissur and also showcase this device at the International Conclave on AI & Robotics for Enabling Healthcare Singularity in Thiruvananthapuram. We will be signing an agreement with NIPMR to conduct more tests. We are also working to showcase the device to biomedical experts, NGOs and various rehabilitation centres across the country.

How do you plan to use the seed funds that you raised recently?

We have raised seed funding of about Rs 8 crore through the Nidhi Prayas Scheme of the Department of Science and Technology from Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)- TIMED, Thiruvananthapuram. We will use 60 per cent of the fund on growth, 20 per cent in operations, 10 per cent in product development and remaining 10 per cent in team building. At present we have a team of 16 and we are looking at increasing the staff by 60 by this December so that more people in need of this device will be benefitted.

What is the sales target for this year and for the next?

We have already set up the manufacturing facility in Chennai. We are confident of touching 100 units during this financial year and 500 units for the next financial year.

How do you see the market potential for this device in India?

There is no other similar product available in the market. That is the advantage we have right now. We are looking at anybody, not just stroke patients, who are bedridden and not able to speak for various reasons. In that sense, the market is huge. Even if we get our target initially, we'll easily cross the 100 mark we had set for this year. But that is not our target. We wish to have at least 5 per cent of the market share soon. And our target for Netravaad is not only stroke patients but also those who have very severe speech issues and have lost their speech. BS

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"ICMR has committed to funding all aspects of Phase I trials of Zika vaccine"

Hyderabad-based Indian Immunologicals Ltd (IIL) has signed an agreement with the Indian Council of Medical Research (ICMR) on September 12 for clinical development of India's first codon de-optimised live attenuated Zika vaccine. According to the Ministry of Health, as on July 22, 2024, 537 Zika cases were registered. Since no vaccine exists for Zika, this collaboration represents a crucial step in safeguarding public health against this emerging threat. In an interaction with BioSpectrum, Dr K Anand Kumar, Managing Director of IIL shares the latest developments and future goals of the company related to their vaccine portfolio. ***Edited excerpts:***

« **Dr K Anand Kumar,** Managing Director, Indian Immunologicals Limited

IIL launched India's first codon de-optimised live attenuated Zika vaccine in collaboration with ICMR. How significant is this for the Indian public health landscape?

The rise of emerging infectious diseases, particularly Zika, which poses serious risks to pregnant women, has been a growing concern. Zika can lead to severe birth defects like microcephaly, and in some cases, it causes neurological disorders such as Guillain-Barré syndrome. While no vaccine exists globally to prevent Zika, we recognised the need to take proactive measures in India. Our partnership with ICMR is a key milestone in addressing this challenge. The codon de-optimised live attenuated Zika vaccine we've developed has undergone extensive pre-clinical trials, and with ICMR's support, we are now moving into Phase I clinical trials. This vaccine marks a major step in strengthening India's defence against potential epidemics and pandemics.

Could you elaborate on the role of Griffith University and ICMR in the Zika vaccine's development and how the partnership accelerates clinical trials?

Our collaboration with Griffith University in Australia laid the groundwork for developing the vaccine, particularly in leveraging the codon de-optimisation technology, which enhances the safety profile of the virus. On the Indian front, ICMR's involvement is crucial. Their extensive trial network across India allows us to conduct first-in-human safety studies domestically, which accelerates the process and reduces dependency on international trials. This aligns perfectly with the vision of 'Atmanirbhar Bharat' by ensuring that innovations are trialled and developed here in India. ICMR has also committed to funding all aspects of Phase I trials, which is a great boost to this mission.

IIL being the first to develop an indigenous Hepatitis A vaccine, 'Havisure,' how do you envision its impact on India's immunisation efforts, especially for paediatric care?

The launch of Havisure is a proud achievement for IIL and for India. Until now, Hepatitis A vaccines were mostly imported, which made them less accessible to the masses. Havisure is the first indigenous vaccine for Hepatitis A, and it's available in both paediatric and adult doses. This is a significant step in enhancing immunisation coverage, particularly for children, who are most vulnerable to the disease. The paediatric dose ensures early protection, and we're working closely with healthcare professionals and government agencies to raise awareness about its benefits. This launch supports our mission to make vaccines affordable and accessible for everyone.

What are your future goals for expanding your vaccine portfolio?

Through our innovations, we aim to tackle the challenges head-on. Looking forward, we are continuously expanding our vaccine portfolio, not only for human health but also for animal and aquaculture sectors. Our goal is to remain a global leader in vaccine production, supporting both India and the world. BS

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“To truly transform cancer care in India, we need to focus on improving training for healthcare professionals”

« **Pratima Reddy,** Country Speaker, Merck India & MD, Merck Specialties

After the Centre announced the removal of customs duty on three cancer drugs in July 2024, the GST Council has now significantly reduced the Goods and Services Tax (GST) rate on those cancer drugs from 12 per cent to 5 per cent, marking a crucial step in making life-saving treatments more affordable for patients battling cancer. With a 12.8 per cent increase projected for 2025 in annual cancer cases , there is an urgent need to build a robust ecosystem to fight the inflating cancer load. To gain more insights on how the industry is planning to improve cancer treatments in India, BioSpectrum spoke to Pratima Reddy, Country Speaker for Merck India & MD, Merck Specialties. ***Edited excerpt:-***

What is Merck Healthcare's ‘Vision 2025’ for India?

Merck Healthcare's 2025 vision for the Indian market centres on expanding access, growing our cardiometabolic segment, accelerating the introduction of innovative therapies, and shaping the fertility market. Our focus remains on oncology, neurology, and immunology, while also driving growth in cardiometabolic care. We're committed to deepening and broadening our reach, ensuring more people benefit from our treatments. In fields like neurology, where unmet needs are significant, we are advancing our innovative portfolio with effective go-to-market strategies.

As global leaders in IVF, we're actively shaping the market through awareness, access initiatives, and policy advocacy, including supporting our women employees with IVF benefits. Despite India's population, the declining fertility rate is a concern we aim to address.

What are your views on improving cancer treatment in India, in line with the government’s recent announcement of exemption of three additional cancer drugs from customs duties?

The government’s decision is a commendable step towards making advanced treatments more accessible and affordable for patients in India. This initiative aligns with the country's growing focus on improving cancer care, especially as the disease burden continues to rise. However, there are still significant challenges, including late diagnosis, limited access to specialised treatment centres, and disparities in care across urban and rural areas.

To truly transform cancer care, we need to focus on strengthening healthcare infrastructure, increasing early screening and diagnostic programmes, and improving training for healthcare professionals. Public-private partnerships can also play a key role in expanding access to innovative therapies and ensuring that treatment reaches underserved populations. The disease burden in India demands a comprehensive, multi-faceted approach, and while these recent measures are a strong start, there is much more that can be done to alleviate the impact of cancer on patients and society.

As per the recent notification by the Central Drugs Standard Control Organisation (CDSCO), breakthrough drugs might be launched in India without local clinical trials. How does Merck plan to leverage this development?

The CDSCO’s decision to waive local clinical trials for breakthrough drugs is a significant step forward, allowing Indian patients to have faster access to advanced therapies. We welcome this move, as it aligns with our commitment to accelerating access to innovative treatments. This development enables us to prioritise India as a

key market for launching breakthrough therapies, ensuring faster availability of our high-quality medications to a broader patient population. We are actively exploring opportunities to leverage this regulatory change and expect to introduce more advanced treatments in India in the near future.

Speaking of improvement in cancer diagnostics, what initiatives are being taken by Merck in this space, especially with the advent of newer technologies?

Merck's oncology division is focused on addressing critical unmet medical needs, including in India, by advancing innovation in cancer diagnostics and treatments. We are prioritising cutting-edge technologies like targeted therapies, precision medicine, and immuno-oncology to not only extend survival but also enhance the quality of life for cancer patients.

In India, we've been delivering precision-led treatments for several cancers, including head and neck, colorectal, bladder, renal, and lung cancers. A key breakthrough is our immuno-oncology therapy, avelumab, which harnesses the immune system to fight cancer, offering new hope for patients with metastatic bladder, renal, and Merkel cell carcinoma.

Are there new partnerships with academias/ industry in the pipeline to strengthen healthcare delivery?

Aligning with the government's vision of universal healthcare, we pioneered the National Payers Partnership programme on cancer care. This groundbreaking initiative collaborates with national payers like the Employees State Insurance Corporation (ESIC) and the Ministry of Railways to facilitate access pathways for cancer therapies.

We also work closely with state governments and other stakeholders to implement innovative and sustainable solutions for addressing access needs tailored to specific populations and regional diversity and dynamics.

To advance personalised medicine in oncology, Merck has partnered with prominent academic institutions and organisations. Recently, under our Umeed programme, we collaborated with the Rajiv Gandhi Cancer Institute and Research Centre (RGCIRC) and the Kalyan Singh State Cancer Institute in Lucknow. This initiative aims to improve treatment accessibility and raise awareness for patients affected by head and neck and colorectal cancers. Rooted in a multifaceted approach, the Umeed Program seeks to empower patients, foster awareness, and serve as a knowledge partner to healthcare professionals.

The government's decision on exemption of customs duties on three cancer drugs is a commendable step towards making advanced treatments more accessible and affordable for patients in India. This initiative aligns with the country's growing focus on improving cancer care, especially as the disease burden continues to rise. However, there are still significant challenges, including late diagnosis, limited access to specialised treatment centres, and disparities in care across urban and rural areas.

Currently, we are also in discussions with the National Institute of Pharmaceutical Education and Research (NIPER), Mohali, to explore further collaborations.

Are there any major investment plans in the healthcare space on the horizon in India for the coming year?

At Merck Healthcare, we are deeply committed to strengthening our foothold in India by expanding our reach and impact across key therapeutic areas. A critical component of this strategy is investing in new talent and enhancing the capabilities of our teams. By bringing in highly skilled professionals and fostering a culture of continuous learning and innovation, we aim to ensure that our teams are equipped to meet the growing healthcare demands in India. These new hires will play a pivotal role in driving our mission to provide innovative treatments, improving patient outcomes, and expanding access to high-quality care across the country.

We are also focused on building advanced capabilities through strategic training programmes and digital initiatives. By investing in the professional growth of our workforce, we are enhancing their ability to deliver cutting-edge healthcare solutions while staying aligned with the evolving healthcare landscape. This holistic approach, combining new talent, upskilling, and technology, will not only strengthen our market position but also ensure that we can continue to positively impact the lives of patients across India. BS

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"While the regulatory landscape is evolving, long approval processes and strict compliance requirements still act as barriers to local production"

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

Kalavathi GV has recently stepped in as the Head of Development Centre (DC) and Executive Director at Siemens Healthineers India. In her new role, she is leading over 3,500 DC employees in India and Slovakia, driving the development of precision healthcare solutions using artificial intelligence, automation, and digital transformation for all business lines of Siemens Healthineers. She is a strong advocate of the representation of senior female leaders in the Indian IT ecosystem. In conversation with BioSpectrum India, Kalavathi shares her vision of strengthening the medtech ecosystem in the country, based on her global experiences. ***Edited excerpts;***

With three decades of industry experience in the medtech and healthcare sector, what new strategies are you bringing to the table to enhance the company's growth this year & beyond?

At Siemens Healthineers, we focus on a horizontal strategy to accelerate vertical business growth, driven by our global development centres in India and Slovakia. One key priority is enhancing customer service by aligning our teams with the global vision to ensure seamless service delivery. We are focusing on integrating our expertise in Artificial Intelligence (AI) and digital transformation to enhance manufacturing capabilities. For instance, in India, we have announced the manufacturing of the Multix Impact E digital radiography X-ray machine in India to further our commitment to providing better access to care in the country. Strengthening resilience in the supply chain and moving from SKD (Semi-Knocked Down) to fully localised manufacturing are critical goals.

Lastly, we are focusing on leadership development, with an emphasis on diversity and inclusion. It is important to note here that diversity is associated with that in thoughts and ideas too, which can only be achieved by bringing in representative demographics and experience.

What major plans are in store for the Indian market in 2025? How is Siemens strengthening local production of medical technologies in India, cost-effectively?

In 2022, Siemens Healthineers committed to invest Rs 1,300 crore to establish an innovation hub in Bengaluru. We are well on our path to adding 2,000 skilled experts to expand our digital capabilities here. This investment is the largest we have ever made in India and will play a key role in taking our business to the next level by driving digitalisation and expanding our portfolio for emerging markets. The Bengaluru campus will be one of the four innovation hubs for Siemens Healthineers globally and will include centres of competence in digital technologies such as data analytics, artificial intelligence, immersive technologies like augmented and virtual reality (VR), user experience, and cybersecurity.

For us, our collaboration with local and global entities, R&D partners, HCPs, educational institutions, startups, peers, and industry fora is paramount to achieving our purpose. Some of our recent collaborations include A Master Research Collaboration (MRA) with the Manipal Academy of Higher Education (MAHE), to strengthen industry-academia engagement; An MoU with SAMEER, India's premier R&D Institute of the Ministry of Electronics and IT (MeitY) to create a deep tech healthcare R&D and supply chain ecosystem in India; A partnership with Qure.ai and the Global Fund to accelerate the use of AI to diagnose tuberculosis, and to boost the adoption of AI & ML programmes that can read chest X-rays and spot the signs of TB-related lung abnormalities.

This year, we also established the Siemens Healthineers-Computational Data Sciences (CDS) Collaborative Laboratory for AI in Precision Medicine along with the Indian Institute of Science (IISc) to provide biomedical equipment at the upcoming multi-specialty hospital at IISc.

What are your views on the current challenges facing the medtech sector in India, concerning import dependency? What are your expectations from the government to strengthen domestic production and development of medical devices in India?

While the regulatory landscape is evolving, long approval processes and strict compliance requirements still act as barriers to local production. Additionally, there is a shortage of skilled professionals and technology transfer challenges that hinder our ability to compete globally.

To overcome these obstacles, the first step is to take stock of our systems knowledge and assess what can be produced locally. By understanding the entire system architecture i.e. pricing, suppliers, and the local ecosystem, we can strategically collaborate with partners to start mapping which components can be sourced or produced in India. This approach allows us to achieve short-term wins that build momentum towards reducing import dependency.

In terms of policy actions, streamlining regulatory hurdles is crucial. Simplified regulations, faster approvals, and the creation of domestic testing facilities can reduce the time and cost spent on overseas certifications. Specific government initiatives aimed at promoting local innovation and setting ambitious export goals would also be beneficial.

We are working to localise production through partnerships like our collaboration with SAMEER to develop indigenous technologies. A balanced approach to local manufacturing is key, while design can take place globally, it is more practical to align manufacturing closer to where the products will be used. This also ties into lifecycle management, repair, and ensuring high standards of quality throughout the process.

Simplifying operations is another focus. For example, overly complex systems can increase the burden on an already limited skilled workforce. Our goal is to design intuitive systems, such as "one-button" MRI operations, to reduce training needs and improve efficiency. By focusing on these areas and supporting them with a clear return on investment (ROI) analysis, we can foster a more self-reliant medtech sector in India, eventually reducing the country's dependence on imports.

There are a lot of challenges related to integrating AI in medical technologies. How can those challenges be addressed, particularly for the Indian market? What steps are being taken by Siemens Healthineers to ease out this integration?

AI in healthcare relies heavily on high-quality data and robust privacy measures. At Siemens Healthineers, we gather global datasets, including clinical images, genomic data, and patient histories, while ensuring strict data privacy through anonymisation. Our AI models are built on this data, providing reliable insights for healthcare professionals.

For the Indian market, integration challenges include data diversity, infrastructure gaps, and the need for skilled professionals. To address these, we are focusing on collaborations with local healthcare providers and academia to develop solutions tailored to India's needs. We are also investing in making AI-based tools more accessible by simplifying their operation, ensuring that healthcare professionals can easily adopt and benefit from AI in improving diagnostics and patient outcomes.

There is a lack of skilled workforce in the country, in the healthcare and medtech sectors. How is Siemens Healthineers working in this regard? What more needs to be done?

Siemens Healthineers India currently makes up over 54 per cent of the global software/digital technology teams, making it the largest Siemens Healthineers Technology Center outside of Germany. The team has expertise in digital transformation (AI, cloud, immersive experience, and cybersecurity) and systems engineering (advanced therapies, diagnostics, and molecular imaging). These teams co-create healthcare breakthroughs with our local partners such as clinical, government, academia, and startups.

We acknowledge that the number of people who seek healthcare services and those equipped to deliver them is disproportionate. To improve the skilled workforce, a multifaceted approach is essential. First, it is important to increase the focus on STEM education and foster industry-academia collaborations. Collaboration between the public and private sectors is also critical, particularly in Tier 2 and Tier 3 cities where upskilling programmes can train the next generation of talent. Integrating digital technologies such as VR and AI into training programmes can further accelerate skill development by providing healthcare professionals with hands-on experience in a controlled environment. BS

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Why industry-academia collaboration is crucial for biomedical sciences

« **Vaibhav Patel,** Director of Quality Assurance and Regulatory Affairs, University of Minnesota

India's growing biomedical sciences sector is ripe with potential, yet it faces several challenges. In recent years, there has been a notable shift in government policies, private investments, and educational reforms aimed at boosting research and innovation in this critical area. One of the key factors that can significantly influence this growth is the collaboration between industry and academia. Such partnerships have the power to not only fuel the biomedical sector but also strengthen India's position as a global player in healthcare research and innovation.

Biomedical sciences encompass a wide array of disciplines, from biotechnology and pharmacology to clinical research and medical device development. This field is crucial to the development of therapies, diagnostics, vaccines, and other medical innovations that directly impact public health. With a population exceeding 1.4 billion, India's healthcare needs are immense, creating an urgent demand for new solutions in healthcare.

India has already established itself as a global hub for pharmaceutical manufacturing, earning the nickname "pharmacy of the world." However, while the country excels in generics and large-scale production, its contribution to cutting-edge biomedical research and innovation still lags. Addressing this gap requires collaboration between academia, which can provide fundamental research and innovation, and industry, which can offer resources, funding, and practical implementation.

Opportunities for Growth Through Industry-Academia Collaboration

Accelerating Research and Development (R&D)

One of the primary benefits of industry-academia partnerships is the acceleration of research and development. Academia has a rich talent pool of researchers and scientists, while industry offers access to funding, infrastructure, and practical know-how. When these two sectors collaborate, they can pool their strengths to drive innovation in areas such as drug discovery, medical devices, diagnostics, and biopharmaceuticals.

For example, research institutions can focus on early-stage discoveries, and once promising leads are identified, industries can step in to support translational research and commercialisation. This not only fast-tracks the R&D process but also increases the likelihood of bringing new technologies to market.

In India, government-backed initiatives such as the Biotechnology Industry Research Assistance Council (BIRAC) have been pivotal in encouraging such collaborations by providing funding and incubation opportunities for joint projects between industry and academia.

Bridging the Talent Gap

A well-educated workforce is essential for the growth of biomedical sciences. Academia plays a critical role in providing students with foundational knowledge, but the industry offers hands-on experience and application-based learning. By working together, industry and academic institutions can create specialised training programmes and internships that better prepare students for the demands of the biomedical sector.

Collaborative programmes that include joint degrees, internships, and co-operative education can create a seamless transition for students from the classroom to the workplace. Furthermore, industries can benefit from access to a pipeline of well-trained, job-ready graduates, while academia can ensure that its curriculum aligns with the latest industry trends and demands.

Driving Innovation in Medical Technologies

India's biomedical sector stands to benefit from a wave of medical technology innovations, from artificial intelligence (AI) and machine learning (ML) in diagnostics to the development of more accessible and affordable medical devices. Industry-academia partnerships can significantly influence

the pace at which these innovations are developed and deployed.

Collaboration can facilitate the development of technologies that address India's unique healthcare challenges, such as improving access to healthcare in rural areas or addressing the growing burden of non-communicable diseases (NCDs). Furthermore, by collaborating with global industry leaders, Indian academia can ensure that local innovations meet international standards, opening the door to export and global collaboration.

Access to Funding and Resources

One of the most significant challenges for academic research in India is the lack of adequate funding. By collaborating with industry, research institutions can gain access to the financial resources necessary to support high-quality research. Industry can also provide access to cutting-edge technologies, infrastructure, and technical expertise that may otherwise be unavailable to academic researchers.

For instance, large pharmaceutical companies or medical device manufacturers often have access to the latest tools for drug testing, imaging, and data analytics. Academic researchers can leverage these resources to enhance the quality and scope of their studies. Furthermore, industries that invest in academic research stand to benefit from the commercialisation of innovative products that emerge from these collaborations.

Challenges in Industry-Academia Collaborations

While the potential for growth is significant, industry-academia collaborations in India face a number of challenges that need to be addressed for successful partnerships.

Differences in Objectives and Timelines

One of the biggest barriers to successful collaborations is the difference in goals and timelines between academia and industry. Academic institutions are often driven by the pursuit of knowledge and the desire to publish their findings, while industries are focused on market-driven outcomes and the commercialisation of products. Moreover, industries usually operate on tighter timelines, aiming for quick returns on their investments, while academic research may take years to yield results.

Overcoming this challenge requires clear communication and alignment of objectives from the outset. Establishing shared goals that benefit both parties, such as focusing on translational research with commercial potential, can help bridge this gap.

Intellectual Property (IP) Issues

Ownership of intellectual property is another challenge that can complicate industry-academia partnerships. When research leads to new discoveries or inventions, disputes may arise over who holds the rights to these innovations. Academic institutions may seek to retain control over their research, while industries may want exclusive rights to commercialise the products.

Establishing clear IP agreements at the beginning of a collaboration can mitigate conflicts. A balanced approach that protects the interests of both parties while encouraging innovation is essential.

Funding Limitations

While industry involvement can provide much-needed funding for academic research, not all institutions have the same access to industry partners. Smaller universities or those in rural areas may struggle to attract industry interest, leading to unequal opportunities for collaboration. Additionally, industries may be hesitant to invest in early-stage research that does not promise immediate returns, limiting the scope of innovation.

To address this, government initiatives could play a critical role in providing seed funding and incentives for industries to collaborate with academic institutions, especially in underserved regions.

Regulatory and Bureaucratic Hurdles

The regulatory landscape for biomedical research in India can also pose challenges. Lengthy approval processes, bureaucratic red tape, and complex compliance requirements can slow down innovation and discourage industry involvement. Streamlining these processes and creating more favourable policies for industry-academia collaboration could help remove some of these barriers.

The Way Forward

Fostering collaboration between industry and academia is not just an opportunity—it is a necessity for the growth of biomedical sciences in India. As the country continues to evolve as a global healthcare leader, bridging the gap between research and practical application will be key to meeting both domestic and international healthcare needs.

To capitalise on the opportunities presented by such partnerships, both sectors must address the challenges that currently hinder collaboration. By aligning goals, securing funding, and navigating regulatory frameworks, industry-academia partnerships can unlock the full potential of India's biomedical sector.

With the right support, India can position itself at the forefront of biomedical innovation, driving advancements that benefit not only its own population but the global community as well. BS

Dignitaries seen releasing the India BioEconomy Report 2024 at the inaugural session of Global Bio India 2024 on September 12 in New Delhi.

Global Bio India 2024

Bharat BioEconomy to touch $30 trillion by 2050: IBER 2024

"The Indian BioEconomy is projected to rise to $30 trillion by 2050, within a global economy valued at $228 trillion, representing a significant increase in its economic share from 4 to 13 per cent," according to the India BioEconomy Report (IBER 2024), prepared for 'Make In India Facilitation Cell for Biotechnology' of Biotechnology Industry Research Assistance Council (BIRAC), by Association of Biotechnology Led Enterprises (ABLE).

Releasing the India BioEconomy Report at the three-days Global Bio-India (GBI) 2024 event on September 12 in New Delhi, Dr Rajesh Gokhale, Secretary, Department of Biotechnology (DBT) said"With more than five sectors generating over $1 billion each month, India's BioEconomy reached a value of $151 billion in 2023. This growth is matched by a thriving entrepreneurial landscape, with 1,776 new biotech startups joining the ecosystem, showcasing India's robust innovation capabilities".

The report highlights the sector's increasing significance as it now accounts for 4.25 per cent of India's Gross Domestic Product (GDP) of $3.55 trillion in 2023. India's BioEconomy registered a 10 per cent growth rate in 2023, characterised by a strong industrial focus, with BioIndustrial and BioPharma collectively accounting for over 83 per cent of the sector's value.

Indian startups have developed over 800 products and raised more than $600 million in follow-on funding, as per the report. However, while 2022 saw 31 deals totalling $938.8 million, 2023 saw a dip, with only 16 deals worth $199.6 million. On a positive note, the medtech sector witnessed a robust growth in Foreign Direct Investment (FDI), rising from $370 million in 2022 to $480 million in 2023. In contrast, FDI in pharmaceuticals dropped from $2 billion to $1 billion in the same period, signalling shifting investment priorities.

The report predicts a surge in biotech startups, from 8,531 in 2023 to an impressive 35,460 by 2030. This growth will significantly boost employment, creating 35 million jobs. The report highlights five states as leaders in the biotech startups space, which includes Maharashtra (1,421), Karnataka (1,054), Telangana (872), Delhi (875), and Uttar Pradesh (699). These states account for over 50 per cent of all biotech startups in India.

Global Bio-India (GBI) 2024 opened in New Delhi as a much bigger event as compared to 2023 with participation from 30+ countries, 500+ exhibitors, 5000+ delegates, 1000+ startups, B2B, B2G, G2G meetings and much more. Science and Technology Minister Dr Jitendra Singh inaugurated the event virtually.

"There are a billion reasons to invest in India, the reasons being India has 60 per cent share of global vaccine production, and it has the second highest number of USFDA approved manufacturing plants outside the US. Opportunities for investments are available in Bio-Pharma, Bio-Agri, Bio-Industrial, Bio-energy, Bio-Services and Med-Tech sectors", said Dr Jitendra Singh, Minister for Science & Technology, Government of India.

The event witnessed the official launch of the BioE3 policy recently approved by the government. The goal of the policy is to fast-track innovation-to-technology in a sustainable manner by weaving together fragmented activities under the umbrella of biomanufacturing and to incentivise concrete options to build a sustainable future.

BIRAC signed Letters of Intent with leading international organisations in biotechnology namely- United States Pharmacopeial Convention (USP); UK Research and Innovation (UKRI); Danaher India; Mauritius Institute of Biotechnology (MIBL); La

Trobe University; Blockchain for Impact (BFI); US-India Strategic Partnership Forum (USISPF); IBioM (Indian Biotech MSME and Startup Foundation); and Bharat Startup and Innovation Society (BSIS)-Bharat Startup Festival; Children's Investment Fund Foundation; and IPE Global.

Further, special booklets namely BIRAC Compendium of Products and Technologies 2024, Insights into BIRAC Equity Fund and Amrit Grand Challenge JanCARE Innovations Report were also launched during the inaugural session of GBI 2024.

GBI 2024 also marked the Launch of Calls for Proposals under the i4 (Innovation for Industry) and PACE (Promoting Academic Collaboration and Entrepreneurship) programmes, furthering the government's commitment to fostering innovation.

The event also witnessed a series of discussions between DBT Secretary and State government representatives on the current challenges and opportunities in store for the biotech sector. With participation of 13 states namely, Odisha, Meghalaya, Assam, Kerala, Karnataka, Bihar, Punjab, Uttarakhand, Goa, Tamil Nadu, Telangana, Gujarat and Uttar Pradesh, the State Showcase & Roundtable during GBI 2024 provided a platform and an interactive forum for states to highlight their investment ecosystem, policy framework, and research initiatives to drive accelerated growth of the Indian bioeconomy.

A similar roundtable session took place between the industry captains and the DBT Secretary where industry expectations and requirements were discussed to enhance innovation in India. Increased focus on faster regulatory mechanisms, clinical research, affordability, data informatics, biosimilar policy, bioprocess engineering, large scale manufacturing, use of bioplastics was conveyed by the industry players to the government.

Another key highlight at GBI 2024, among multiple sessions on new generation therapeutics, use of non-animal methods for biomedical research, clinical trial networks, global partnerships, was that the Indian biotech startups took centerstage by unveiling new products to showcase the country's emerging talent in biosciences. These included advancements in med tech, probiotics, skin care, zero-calorie sugar, animal-free proteins, foetal bovine serum alternatives, and many more.

Further, exceptional contributions to the biotech industry were recognised by the government with awards namely- BIRAC Innovators Awards; Best Startup Awards; and Best Incubation Centre Awards. A Science Quiz Competition was held for the first time for school students (11th &12th class) at the Global Bio India event. This interactive quiz was organised to challenge young minds, ignite curiosity, and deepen their understanding of the latest innovations, research, and advancements in biotechnology. In addition, the Expo at GBI 2024 showcased groundbreaking innovations, and cutting-edge biotech advancements, for shaping the future of the biotech ecosystem. BS

BIRAC Innovators Awards

- Therapeutics & Vaccines- Immuneel Therapeutics
- Biomedical Devices & Diagnostics and Bioinformatics- Piscium Health Sciences; Sensivision Health Technologies, and Sunfox Technologies
- Agriculture- Indian Veterinary Research Institute and Genomis Carl
- Industrial Biotechnology- GPS Renewables and Shriram Institute for Industrial Research
- Innovation with High Social Impact- Genrobotic Innovations
- AI-based Innovation- Torchit Eigatronics
- Special Recognition- Interactive Research School for Health Affairs

Best Incubation Centre Awards

- Best Incubation Centre (Tier I cities)- BSC BioNEST Bio-Incubator, Regional Centre for Biotechnology (RCB)
- Best Incubation Centre (Tier II cities): PSG-Science & Technology Entrepreneurial Park (STEP), Coimbatore and Manipal - Government of Karnataka Bioincubator
- Best Incubation Centre (Tier III cities): Technology Innovation and Development of Entrepreneurship Society (TIDES), IIT Roorkee
- Best Incubation Centre Exhibit- E-Yuva Centre, Career College, Bhopal

BIRAC Best Startup Awards

- Agriculture- Ekosight Technologies
- Industrial Biotechnology- Rigel BioEnviron Solutions
- Healthcare Therapeutics- Apramitha Innovations
- Healthcare Devices and Diagnostics- Denovo Bioinnovations
- International Participant- Biopesticide Summit
- Women Entrepreneur- Inte-e-Labs (Sonia Madan)

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School of Economics and Public Policy launches Centre for Global Health and Development in Bengaluru

RV University's School of Economics and Public Policy (SOEPP) recently inaugurated the Centre for Global Health and Development (CGHD) in Bengaluru. The Centre was jointly inaugurated by distinguished experts in the fields of health and public policy. Prof. Ranjini C. Raghavendra who heads the Centre, presented the Centre's vision, mission, and focus areas, along with a tentative roadmap of activities planned for the academic year 2024-25. The launch of the Centre for Global Health and Development at RV University addresses critical health challenges in India. By combining expertise in non-communicable diseases, capacity building, and sustainable development, the CGHD is aimed at influencing both policy and practice. The Centre's establishment is timely, given India's health-related economic burdens and recent progress in digital health and SDGs. Through its multidisciplinary approach focusing on research, education, and community engagement, the CGHD aims to drive improvements in global health outcomes and contribute to India's development agenda.

Apollo Hospitals opens research academy to lead global healthcare innovation

Apollo Hospitals has announced the launch of the Apollo Research Academy, a groundbreaking initiative aimed at positioning Apollo as a global leader in healthcare research and innovation. The Academy, led by Professor Ravi P Mahajan CBE, is set to harmonise the efforts of various Apollo entities, including Apollo Health Education and Research Foundation (AHERF), Apollo University, ARI, Apollo Research Centre, Apollo Clinical Innovation Group, and others, to create a cohesive and internationally recognised hub of research excellence. The Academy will focus on five key areas: Capacity and Culture, Sponsored Research, Investigator-Driven/Grant-Funded Research, Data Sciences, and Innovation. The academy will provide a comprehensive programme of educational courses, skill-enhancing events, and resource sharing, and with ambitious collaborative projects for research and innovation across and beyond the Apollo ecosystem.

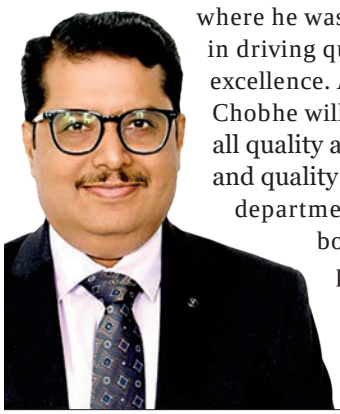
Meril expands healthcare education network with opening of Satellite Academy in Kochi

Meril, a global medical technology and education leader, has expanded its healthcare education network by launching the Meril Satellite Academy in Kerala's port city, Kochi. In the fast-changing world of medicine, continuous learning and hands-on training are vital for healthcare providers. Recognising this necessity, Meril Satellite Academies aim to balance theoretical learning and practical implementation, offering professionals a platform to enhance their skills and engage in global collaboration.

The new academy is equipped with cutting-edge facilities, including advanced simulators and robotic systems, providing participants with an immersive, hands-on learning environment. The academy features lecture rooms, state-of-the-art audio-visual systems, and specialised simulation spaces, offering the right blend of theoretical knowledge and practical training. Meril's educational network already includes two prominent academies: the Vapi Academy in Gujarat, serving as the central hub for Meril's global educational initiatives, and the Delhi Academy, which caters to healthcare professionals in Northern India with specialised training programmes and advanced facilities.

Akums names Shantanu R Chobhe as Corporate Quality Assurance Head

New Delhi-based Contract Development and Manufacturing Organisation (CDMO), Akums Drugs & Pharmaceuticals has announced the appointment of Shantanu R Chobhe as the Corporate Quality Assurance Head. Chobhe brings over 30 years of extensive experience in quality and regulatory management within the pharmaceutical industry. His career has spanned across several leading companies, including Lupin, Glenmark Generics, UniChem Laboratories, Wockhardt, and Cipla. Prior to joining Akums, he served as a key member of Abbott Healthcare, where he was instrumental in driving quality excellence. At Akums, Chobhe will take charge of all quality assurance (QA) and quality control (QC) departments, overseeing both active pharmaceutical ingredients (API) and formulations.



Cactus Communications appoints Akhilesh Ayer as new CEO

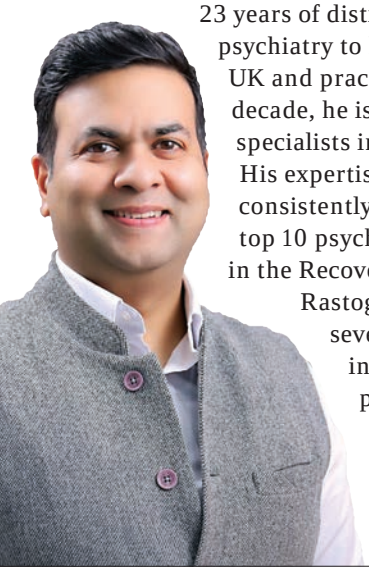
Cactus Communications, a leading science communication and technology company, has announced the appointment of Akhilesh Ayer as its new Chief Executive Officer (CEO). Abhishek Goel, founder and outgoing CEO will continue to serve as a board member and transition into the role of Chief Mentor. Ayer comes with over 25 years of leadership experience in running global businesses, managing clients and running transformation programmes across a range of industry verticals, products and services. His previous experience includes leadership stints at WNS, GE and Crisil amongst others. Akhilesh Ayer joins Cactus from WNS Global Services, where he served as Executive Vice President; Head of Data, Analytics, AI & Research (Triange) business unit. At WNS, he successfully transformed the business unit by adopting a differentiated go-to-market strategy, re-imagining the product-service mix, building a best-in-class operational ecosystem and bringing in industry-leading people practices that helped achieve stellar results. He also played a key role in the business unit's M&A strategy, leading successful acquisitions and integrations.

Amit Mookim steps in as CEO of Immuneel Therapeutics

Bengaluru-based Immuneel Therapeutics, a pioneering cell and gene therapy platform, has announced the appointment of Amit Mookim as its new Chief Executive Officer (CEO). Mookim brings over two decades of extensive experience across life sciences, technology and private equity, making him ideally suited to lead Immuneel into its next phase of growth and innovation. Mookim joins Immuneel from IQVIA, a Fortune 500 global leader in clinical research, technology and analytics, where he served as Managing Director for South Asia. At IQVIA, he played a pivotal role in integrating two large organisations post-merger, overseeing the site operations for a combined workforce of 20,000+ professionals across India. His leadership was instrumental in growing the South Asia commercial business both organically and inorganically. Prior to his tenure at IQVIA, Mookim was Head of Healthcare at KPMG India. He built KPMG's healthcare business from the ground up and worked extensively with leading hospitals, PE funds and international healthcare companies to establish and grow their presence in India. His deep expertise in healthcare transactions, M&A, and private equity investments positioned him as a thought leader in the industry. Mookim possesses significant experience in developing innovative business models and supporting entrepreneurship in the healthcare industry.

Dr Vipul Rastogi joins Sukoon Health as Clinical Regional Head of Delhi-NCR

Gurugram-based startup Sukoon Health, a mental health hospital chain, offering residential and outpatient psychiatry, psychology, and de-addiction services, has onboarded Dr Vipul Rastogi as the clinical regional head of Delhi-NCR. At Sukoon Health, Dr Rastogi will spearhead a team of skilled professionals, leading them to deliver empathetic and evidence-based treatment to patients in the region. Dr Rastogi brings over 23 years of distinguished experience in psychiatry to his new role. Trained in the UK and practicing in India for the past decade, he is one of the few dual-trained specialists in psychiatry and neurology. His expertise and dedication have consistently placed him among the top 10 psychiatrists in India. Trained in the Recovery Model in the UK, Dr Rastogi has expertise in treating severe mental health disorders including deaddiction, acute psychosis, severe anxiety and depression and is proficient in the safe retrieval of psychiatric emergency cases.



Enzene appoints Norm Stoffregen to lead biologics manufacturing facility in US

Pune-based Enzene Biosciences, a fully integrated Contract Development and Manufacturing Organisation (CDMO) with services spanning discovery, development and commercial supply, has announced the appointment of Norm Stoffregen as SVP, site head, and head of biologics manufacturing at the company's new $50 million manufacturing facility in Hopewell, near Princeton, New Jersey, US. As well as taking responsibility for Enzene's global biologics business, Stoffregen will lead the final stages of work to commission the 54,000-square-foot facility. He will then lead ongoing operations at the site, where the company intends to transfer-in existing customers' manufacturing projects and expand to add further bioreactor capacity, employing a workforce of 300 by the end of 2025. Significantly, Stoffregen brings a vast experience of building manufacturing businesses, having worked in the area since 2015 when the Hopewell facility was owned by Bristol Myers Squibb (BMS).

Medikabazaar onboards Dinesh Lodha as Group Chief Executive Officer

Mumbai-based startup Medikabazaar, India's largest B2B e-commerce marketplace for medical supplies, has announced the appointment of Dinesh Lodha as its new Group Chief Executive Officer (CEO). With over two decades of experience in the medtech industry and a distinguished career marked by leadership roles across various sectors, Lodha brings a wealth of expertise to Medikabazaar. Before joining Medikabazaar, Lodha managed large B2B and B2C operations in FMCG and healthcare sectors. He has worked with multinational, private equity-led businesses and large publicly listed Indian companies. His experience spans medical consumables category at Healthium & TI Medical, and equipment category at GE Healthcare and Samsung. Regarded by the ecosystem for his ability to drive substantial growth and profitability, Lodha upholds a robust culture of compliance and customer success. He was pivotal in successful private equity transactions at Healthium and spearheaded significant profitability growth for the publicly listed B2C giant. His leadership also drove the transformation of GE Healthcare's supply chain operations.

New smart sensor for adjusting drug dosage to manage Parkinson's Disease

Scientists at Guwahati-based Institute of Advanced Study in Science and Technology (IASST), an autonomous institute of the Department of Science and Technology, have developed an affordable, user-friendly, portable smartphone-based fluorescence turn-on sensor system that can assist in managing Parkinson's disease. The sensor would help in accurately detecting the concentration of L-dopa in the body, thereby helping to determine the precise dosage required for effective control of the disease. Parkinson's disease is marked by a continuous decrease in neuron cells, which leads to a significant reduction in dopamine (neurotransmitter) levels in our body. L-dopa is a chemical which is converted to dopamine in our body and so acts as anti-Parkinson's drugs. It helps in compensating the deficiency of dopamine. As long as the correct amount of L-dopa is administered, the disease remains manageable. However, due to the progressive nature of Parkinson's, as the patient ages, more L-dopa is needed to compensate for the ongoing loss of neurons.

New heat-based approach to cancer treatment can reduce chemotherapy doses: Study

Scientists of Institute of Nano Science and Technology (INST), Mohali, an autonomous institute of Department of Science and Technology, have shown that a therapy consisting of combination strategy that uses 17-DMAG, an inhibitor of Heat Shock Protein 90 (HSP90), in conjunction with magnetic hyperthermia-based cancer therapy (MHCT) can improve the effectiveness of heat-based cancer treatments. The technique could significantly enhance treatment efficacy by reducing the required chemotherapy dosage, serving as an adjuvant therapy that minimises side effects. The treatment of animal models by administering the combination through intra-tumoural injections, resulted in maximum glioma cell death in a rat glioma model with tumour inhibition rates reaching 65 per cent and 53 per cent at the primary and secondary tumour sites, respectively, within 8 days. Extensive global research is needed to realise the clinical application of the new therapy, potentially developing an adjuvant or alternative cancer therapy.

Study reveals role of Ayurvedic Whole System in management of Rheumatoid Arthritis

A new scientific study has revealed the significant effectiveness of the Ayurvedic Whole System (AWS) in the management of Rheumatoid Arthritis (RA), a chronic autoimmune disorder affecting millions worldwide. This pioneering research demonstrates that AWS not only alleviates the symptoms of RA but also induces a metabolic shift towards normalisation in patients, offering a promising complementary approach to conventional treatments. The study was conducted by a group of senior researchers from reputed research institutions, including Arthritis Treatment and Advanced Research Center (A-ATARC), Department of Kaya Chikitsa, State Ayurvedic College and Hospital, Lucknow University; Centre of Biomedical Research (CBMR), SGPGIMS Campus, Lucknow; Academy of Scientific and Innovative Research (AcSIR), Ghaziabad. The study highlights substantial improvements in key clinical parameters among RA patients who underwent AWS intervention. There was a notable reduction in Disease Activity Score-28 Erythrocyte Sedimentation Rate (DAS-28 ESR), as well as decreases in both the total number of swollen and tender joints.

“Bridge the gap and accelerate India's advancements in innovative therapies”

« **Dr Ramesh Mundlamuri**
Technical Director, Duoning Biotech

Dr Ramesh Mundlamuri has over 19 years of experience in various biopharmaceutical organizations and has ample experience in various divisions and sections of the biopharmaceutical industry, including Research & Development, Technology Transfer, Commercial Manufacturing, Product & Process Development, Operations Management and so on.

Prior to joining Duoning, he worked at Biological E in Hyderabad, India. In his role as Assistant General Manager, he led the commercial manufacturing of polysaccharide conjugate and protein-based Vaccines. Before that, he worked for Panacea Biotech, Sartorius, Sanofi and Krebs Biochemical Industries.

Dr Ramesh Mundlamuri is well-versed in cGMP, GLP, GDP and various regulatory bodies (WHO, EU, ROW, FDA, NRA). He also possesses extensive experience in the management of several vaccines, including polysaccharide vaccines, recombinant viral proteins, conventional vaccines and carrier protein.

Attributed to the BioE3 (Biotechnology for Economy, Employment and Environment) Policy, India's bioeconomy has seen exponential growth, ballooning from $10 billion in 2014 to a staggering $130 billion in 2024, with expectations to reach $300 billion by 2030. This policy also emphasizes the strategic objective of transitioning from chemical-based industries to sustainable bio-based models, promoting a circular bioeconomy. In this context, India has attracted numerous international biopharmaceutical companies to engage in business, which have absorbed a large number of local talents to better meet the demands of the domestic market. Dr Ramesh Mundlamuri joined Duoning Biotech (a comprehensive bioprocessing solutions provider) as the Head of Technology in 2023. In a discussion, he talked about the opportunities available in the Indian market and shared his insights and experiences in conducting bioprocessing business within the country.

We notice that most of Duoning's product offerings are centered around biomanufacturing, which may require customization or extensive testing. How do you provide support to local customers quickly and efficiently?

We understand that biomanufacturing often necessitates tailored solutions and rigorous testing. To ensure rapid and efficient support for our local customers, Duoning has implemented a comprehensive approach that includes:

- **Dedicated local support teams:** We have established specialized teams with in-depth product knowledge to provide timely assistance.
- **Accelerated testing protocols:** We've optimized our testing processes to expedite product evaluation and customization.
- **Strong partnerships:** Collaborations with local research institutions (CDMO) and service providers enable us to access specialized expertise and resources.
- **Remote support capabilities:** Our digital platforms facilitate remote troubleshooting and technical assistance.

The Duoning R&D team conducted extensive brainstorming to design the product so that it can meet any type of application and any type of solution. Nonetheless, taking into account the requirements of the customer's process, Duoning standard products are available in a variety of options, from Bag tube end connectors (CPC, quick connectors, TPA, sterile connectors, etc.), different mixing paddles, different configurations and different membrane to simulate customer applications. Therefore, it is very easy for application and sales teams to provide the required Duoning products to meet customers' different applications. In the unlikely event that a customer requires any changes to the standard design outside of the available standard configurations, the Duoning team will analyze the changes and provide rapid support via P&ID at the earliest opportunity. Furthermore, our commitment to value propositions such as customer centricity, innovation, drives us to provide timely and effective assistance throughout the product lifecycle, by prioritizing knowledge

sharing (technical demonstrations, presentations, exhibitions and documentation planning to be implemented) to empower customers with self-service problem-solving tools.

Duoning has developed a one-stop solution for biomanufacturing, offering nearly all the necessary technologies for bioprocessing. However, when it comes to India, do you have any specific priorities? Which product lines do you believe will be more readily accepted by local customers, based on your experience?

While Duoning offers a comprehensive solution of biomanufacturing technologies, we recognize the unique needs of the Indian market. Our primary focus is on addressing the specific challenges and opportunities within the local biopharmaceutical landscape. Based on our experience, product lines that align with India's growing emphasis on the following areas - affordable healthcare, biosimilars, or vaccines or allied life sciences are likely to garner significant interest. Additionally, technologies that facilitate rapid scale-up, downstream processing optimization, or data analytics will be particularly well-received by Indian customers that prioritize [e.g., cost-effectiveness, scalability, or regulatory compliance] will resonate well with Indian customers.

From the existing Duoning equipment there is more scope for SUS Welder, SUS Sealer, Homogenizer and Mixing systems in India as these systems are more competitive with different salient features and customization. We are educating various customers by providing technical demonstrations of our equipments at customer sites with their customer products. During the exhibition we demonstrated differences in all aspects compared to existing competitors, which lack distinctive features and characteristics. Also, Duoning products are economical compared to available competitors.

In India, we have a mature market for small chemical molecules, and the field of biologics is also growing rapidly. However, when it comes to emerging therapeutics such as cell and gene therapies, it appears that Indian companies are lagging behind their western counterparts. What is your perspective on the current state of this landscape, and how do you propose to support these specialized markets?

The Indian pharmaceutical industry has undoubtedly made significant strides in small molecules and biologics. However, the landscape for cell and gene therapies is still evolving. We recognize the challenges and opportunities presented by this emerging field. To support this specialized market,

There is an increasing focus on using the latest in digitization and digitalization technology including AI and ML tools. The global biotech landscape is undergoing a significant transformation, with legislative actions like the BIOSECURE Act acting as catalysts for change. Indian CDMOs are well-positioned to capitalize on these shifts and emerge as key players in the global pharmaceutical industry. By focusing on operational excellence, quality assurance, safety and risk management, supply chain management, talent development, strategic partnerships, and innovation, they can seize the opportunities presented by this evolving landscape and contribute to the growth of the global biotech sector.

Duoning is committed to strategic sectors, such as technology transfer, collaborative partnerships, or tailored product development. By positive approach actions, such as providing specialized equipment, offering technical expertise, or investing in research and quality product development, we aim to bridge the gap and accelerate India's advancements in cell and gene therapies.

Our goal is to provide the necessary tools and expertise to bridge the gap between Indian companies and global advancements in cell and gene therapy.

"In the last decade, CDMOs from Asia have emerged as major players in the global market, like Samsung, Fujifilm, and Wuxi, some of them have established manufacturing sites in North America and/or Europe. How will this trend

impact CDMOs in India, and what implications will it have for bioprocess companies?"

There is no doubt that the CDMO has evolved in the past decade with an increase in demand to reduce cost while keeping a high level of service throughout.

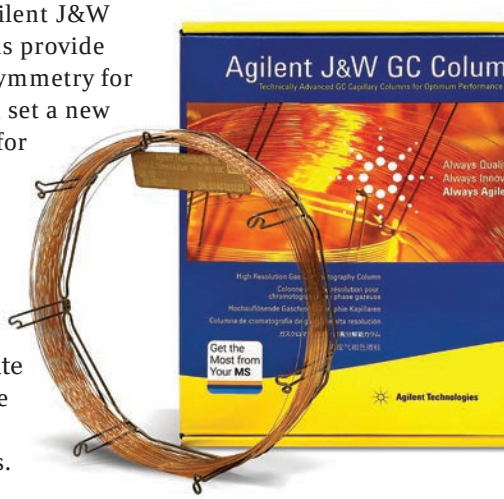
India has already set a reputation for small molecule manufacturing and has a large number of U.S. FDA-approved (Food and Drug Administration) facilities. Indian CDMOs like Biocon, Syngene, Enzene, Aragan, Lambda and others are now increasingly investing in setting up biologics manufacturing capacities to replicate this success in the large molecule space. With the evolving technology landscape, there is an increasing focus on using the latest in digitization and digitalization technology including artificial intelligence (AI) and machine learning (ML) tools. The global biotech landscape is undergoing a significant transformation, with legislative actions like the BIOSECURE Act acting as catalysts for change. Indian CDMOs are well-positioned to capitalize on these shifts and emerge as key players in the global pharmaceutical industry. By focusing on operational excellence, quality assurance, safety and risk management, supply chain management, talent development, strategic partnerships, and innovation, Indian CDMOs can seize the opportunities presented by this evolving landscape and contribute to the growth and development of the global biotech sector. The BIOSECURE Act, while presenting challenges, ultimately opens doors for Indian CDMOs to showcase their capabilities and establish themselves as reliable and innovative partners in the global pharmaceutical supply chain. India-based biopharmaceutical company Biocon, who are heavily involved in the Biosimilar market, are currently launching products with the likes of Sandoz and Mylan in the U.S which is very promising to see. However, it is essential for Indian CDMOs to focus on building strong regulatory compliance, quality standards, and technological expertise to effectively capitalize on this potential growth.

After about 2 years in the Indian market, do you think you have achieved your initial targets? Are there still challenges, and what are your plans for the next steps?

One of our goals over the past two years has been to make Duoning Biotech known to a large number of customers in India, and we have been very successful in doing so. We launch Duoning as a one-stop complete end-to-end solution from cell culture media and upstream bioreactors to filtration, downstream chromatography and compliance validation services. So far, only Western companies have been able to offer this range of end-to-end solutions products in Asia. Our initial market entry strategy has yielded positive results, with key performance indicators demonstrating progress towards our objectives. While we have made substantial strides, certain challenges persist, requiring ongoing adaptation and refinement of our approach. Our next phase focuses on expanding market reach, deepening customer relationships, or launching new product lines or providing solutions to bioprocess hurdles to solidify our market position and drive sustainable growth. ◆

Agilent unveils innovative J&W 5Q GC/MS columns for superior GC performance

Agilent Technologies Inc. has announced the release of its new Agilent J&W 5Q GC/MS Columns, representing a major advance in gas chromatography/mass spectrometry (GC/MS) column technology. Agilent has a 50-year history of innovation in GC, continually setting the standard for GC column performance. The new Agilent J&W 5Q GC/MS columns combine Agilent's industry-recognised ultra-inert performance and ultra-low-bleed technology, delivering unmatched performance and durability for the most demanding applications. In modern GC/MS workflows, GC/MS columns are often subjected to complex matrices and chemically active analytes that require reporting at trace levels. Under these conditions, maintaining the data quality needed to meet regulatory targets or other analytical requirements necessitates more frequent column changes, source cleaning, and potential sample re-runs, which decreases laboratory efficiency and increases costs. Agilent J&W GC/MS 5Q columns provide exceptional peak symmetry for active analytes and set a new industry standard for minimal column bleed, enabling high sensitivity, maintaining accuracy and mass spectral fidelity, and accurate quantitation for the most challenging trace-level analytes.



VFL Sciences announces foray into Fermentors and Bioreactors

Chennai-based VFL Sciences has announced the launch of GreatFlo range of Benchtop Fermentors / Bioreactors. The GreatFlo Expert and Proficient versions feature unparalleled versatility and are available in capacities up to 10 litres, and offered both in autoclavable and in-situ sterilisable versions. These are "Better Alternative" to the available models and are built with the best technologies currently available in the market. The GreatFlo Expert model features a fully stainless-steel body with a 10.2 inch colour touch screen. The system offers ease of use, with in-situ sterilisable glass vessels. The system is offered with extensive accessories and controls including DO cascades and SCADA software. With Biomanufacturing expected to grow due to the BioE3 initiative from the government, the GreatFlo products can help the institutions and companies focusing on this area.

Qiagen to develop first QIAstat-Dx IVD panel for neurodegenerative applications

Qiagen has entered into a collaboration with Eli Lilly and Company to support the development of a QIAstat-Dx in-vitro diagnostic (IVD) to detect APOE genotypes which can play a role in the diagnosis of Alzheimer's disease. This collaboration represents a significant milestone as the QIAstat-Dx panel would be the first commercially available IVD for APOE genotyping. The panel will be integrated with Qiagen's multiplex testing platform QIAstat-Dx, marking the first publicly disclosed collaboration for a clinical application of the system in neurodegenerative diseases and adding to two more collaborations for diagnostics development programmes with other companies. The QIAstat-Dx IVD panel will detect all APOE genotypes (APOE2, APOE3, APOE4). They can play a role in the diagnosis of patients with Alzheimer's disease, which is the most common cause of dementia. People carrying the APOE4 genotype have a higher risk of developing Alzheimer's and are likely to do so earlier in life compared to others. Those who carry two copies of this genotype (homozygous) are most likely to develop clinical symptoms of the disease.

Bio-Rad introduces Annexin V StarBright Conjugates

Bio-Rad Laboratories has announced the launch of annexin V conjugated to eight StarBright Dyes: SBUV400, SBUV795, SBV440, SBV515, SBV790, SBB675, SBB765, SBY800. The new Annexin V StarBright conjugates support detection of early apoptotic cells by flow cytometry, offering an increased range of fluorophore options. Bio-Rad's range of annexin V conjugates provides researchers with a variety of choices, especially important when including apoptosis detection in multi-colour immunophenotyping panels in both conventional and full spectrum flow cytometry. Annexin V StarBright conjugates enable full utilisation of all the common laser lines found in flow cytometers such that common viability dye and fluorescent protein emission wavelengths can be avoided. This, combined with the narrow excitation and emission of StarBright Dyes, reduces spillover and spreading to provide high-resolution data.

Beckman Coulter Life Sciences and Illumina accelerate oncology research

Beckman Coulter Life Sciences, a global leader in laboratory automation and innovation, in partnership with Illumina, a leader in DNA sequencing and array-based technologies, offers a promising new approach to oncology research delivering faster results with fewer touchpoints. The Illumina TruSight Oncology 500 DNA/RNA assay on the Biomek NGeniuS System from Beckman Coulter Life Sciences provides an innovative automated solution enabling comprehensive genomic profiling of tumour samples. The application supports both DNA and RNA inputs, enabling the detection of critical cancer biomarkers including single nucleotide variants (SNVs), insertions, deletions, gene amplifications, fusions, and splice events. Complete library preparation can be achieved in less than three days, providing faster results with automated precision from sample preparation to sequencing.

Takara Bio launches large-scale qPCR system to advance broad surveillance of AMR

Takara Bio USA, Inc. has announced the launch of the SmartChip ND Real-Time PCR System, an automated, research-use-only (RUO), high-throughput qPCR solution for monitoring antimicrobial resistance (AMR), supporting efforts to ensure environmental safety and sustainability. The flexible system covers a variety of configurations, enabling users to run broad surveillance panels. The platform can process up to 5,184 reactions per chip in less than 30 minutes of direct hands-on time. Each nanolitre-scale reaction reduces variability by eliminating the need for preamplification and reduces costs due to decreased reagent volumes. Takara Bio USA is now accepting orders of the SmartChip ND Real-Time PCR System for shipment in Q4. While SmartChip technology has already been used extensively by groups monitoring AMR, with hundreds of published research studies, the new platform allows these groups to take their research to the next level. Resistomap Oy is one such group that has submitted its SmartChip-based protocol for the EU AMR Surveillance programme.

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Leaning on AI to Tackle AMR

Even though global sepsis mortality has reduced, the mortality from antimicrobial resistance (AMR) increased slightly between 1990 and 2019, followed by a slight reduction during COVID-19, as per a Lancet study published in September 2024. The study forecasts 1.91 million AMR attributable deaths and 8.22 million associated deaths in 2050. Evidently, it is unlikely that we will reach the 10 per cent reduction in AMR mortality proposed in the 10-20-30 by 2030 target.

This also means that added efforts on drug development, infection prevention, better treatment of severe infections, and better access to currently available antibiotics, need to be made.

AMR is driven largely by the misuse and overuse of antimicrobials, yet, at the same time, many people around the world do not have access to essential antimicrobial medicines. According to reports, ESKAPE pathogens (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter spp.) are the top priority pathogens as these have developed resistance against certain antibiotics.

India has one of the highest age-standardised infectious disease mortalities in South Asia, and the rates of antibiotic resistance are alarming. More than half of the Klebsiella spp isolates from hospital-acquired infections are resistant to carbapenems, with case fatality rates of around 50 per cent. In particular, India leads the world in human antibiotic use, a prime driver of AMR.

As a result, a multifaceted problem like AMR requires a multidimensional approach, where technology must be a part of the solution. For instance, researchers at Stanford Medicine and McMaster University are tackling this problem with generative artificial intelligence (AI). A new model, SyntheMol, has created structures and chemical recipes for six novel drugs aimed at killing resistant strains of Acinetobacter baumannii, one of the leading pathogens responsible for antibacterial resistance-related deaths.

Likewise, using an AI algorithm, researchers at Massachusetts Institute of Technology (MIT) and McMaster University have identified a new antibiotic that can kill a type of bacteria responsible for many drug-resistant infections. If developed for use in patients, the drug could help combat Acinetobacter baumannii, often found in hospitals and can lead to pneumonia, meningitis, and other serious infections.

Also, researchers from Broad Institute of the Massachusetts Institute of Technology and Harvard University are using AI to identify novel compounds effective against methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant enterococci, some of the most stubbornly hard-to-kill pathogens. Further, researchers from the University of Manitoba, Canada, have deployed explainable AI (XAI), a branch of AI that provides a rationale for model judgments to develop antibiotics with less side effects.

Quoting another example of how technology can be best used to combat the growing health burden of AMR, scientists at Oxford University have shown that AI can detect antibiotic resistance in as little as 30 minutes. This method relies on training deep-learning models to analyse bacterial cell images and detect structural changes that may occur in cells when they are treated with antibiotics. The method was shown to be effective across multiple antibiotics, achieving at least 80 per cent accuracy on a per-cell basis.

Alongside the academicians, researchers within the pharma industry are also equally exploring the use of AI to fix this problem. Eli Lilly and Company has recently announced a collaboration with OpenAI that will allow Lilly to leverage OpenAI's generative AI to invent novel antimicrobials to treat drug-resistant pathogens. AI is also being deployed in the development of effective phage therapies to combat AMR, which includes identifying phages from metagenomic samples, annotating phage virion proteins from phage genome sequences, predicting phage hosts, and determining phage lifestyles, etc.

With multiple developments taking shape across the globe, the significant increase in the use of AI platforms could hopefully result in the discovery of efficient antibiotic alternatives with lower chances of resistance generation. BS

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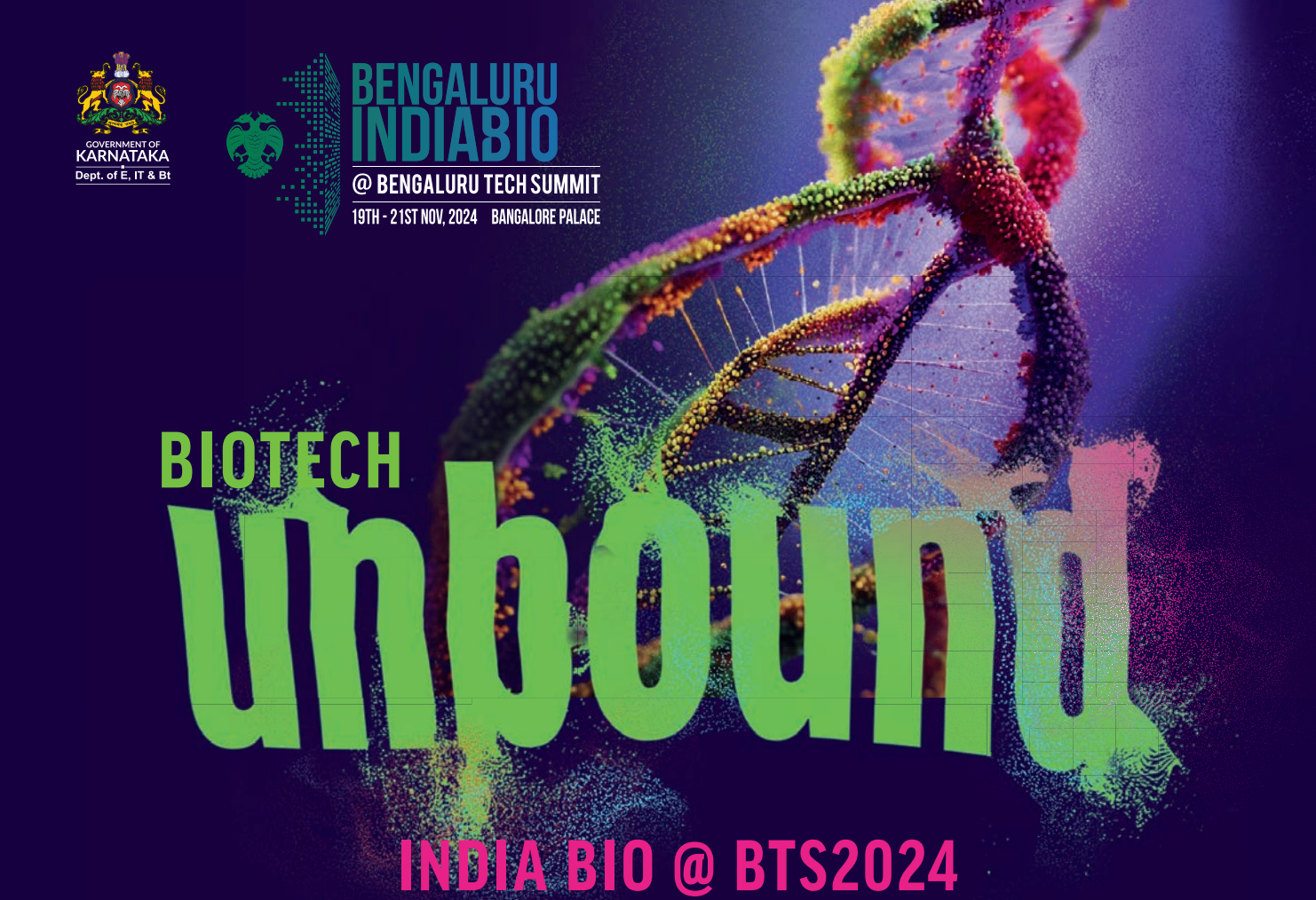

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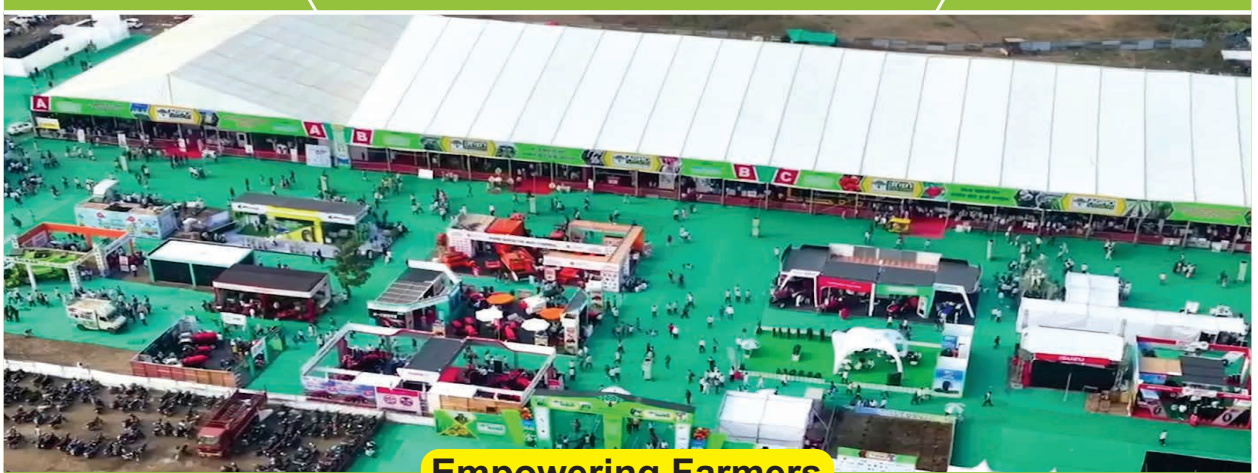

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