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the business of Bio & Health Sciences

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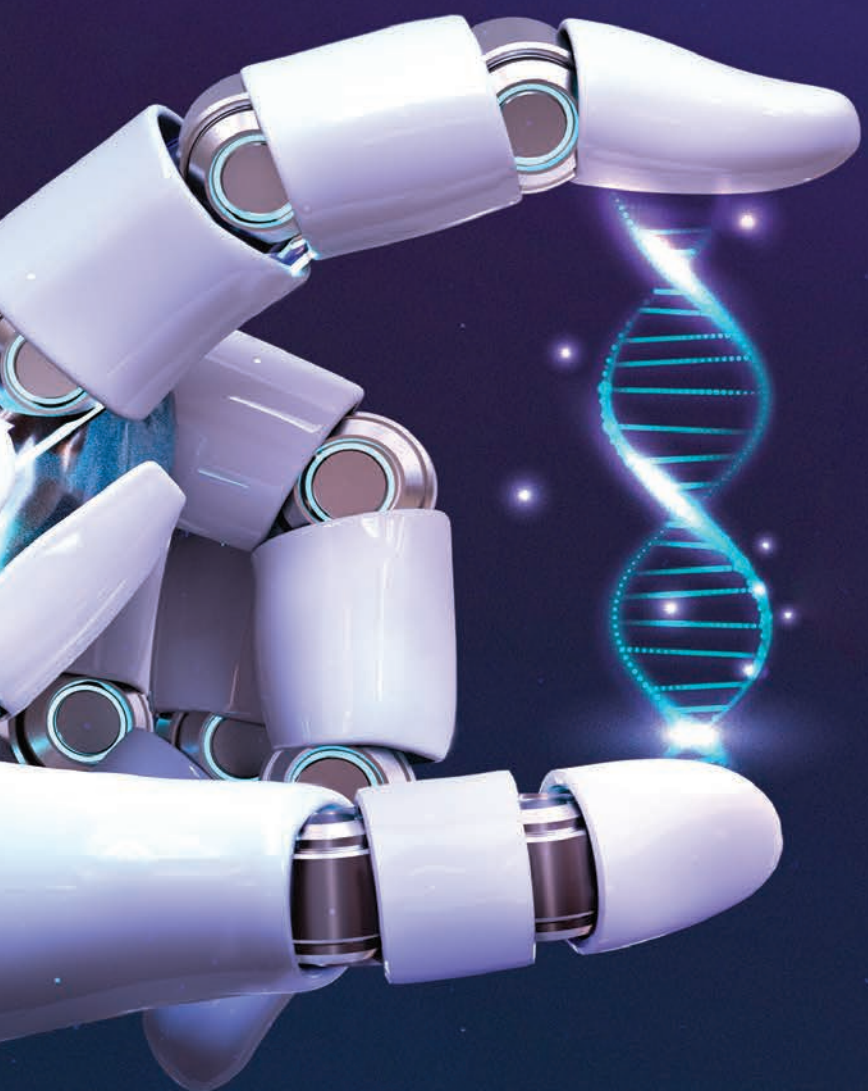

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For queries, please contact: GM & Head - Investment, BIRAC.

Email: investment.birac@gov.in

Vol 21; Issue 12; December 2023

Acknowledgement/ Feedback

Thank you so much BioSpectrum India for the wonderful interaction with Syngene International, featured in the December edition.

- Shotorupa Ghosh, Bengaluru

While artificial intelligence (AI) cannot supplant a capable clinician's knowledge, it can certainly be a useful investigating instrument to help pinpoint people who might benefit from additional scrutiny and succor, for mental healthcare.

- Dr Malini Saba, New Delhi

The API & CDMO segments in life sciences & single specialty in the healthcare sectors continue to be the focus segments for merger & acquisition deals.

- Bhanu Prakash Kalmath S J, Bengaluru

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Letter from Publisher

Ravindra Boratkar
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MD, MM Activ Sci-Tech
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Dear Readers,

As we welcome the new year, hoping to achieve targets by overcoming challenges and issues, the centre has initiated "Rationalisation of Autonomous Bodies" of the Department of Biotechnology (DBT), Ministry of Science and Technology in December. It is functioning as the nodal agency for promotion of Biotechnology in the country, to improve governance, efficiency, encourage collaborations through greater interdisciplinary interactions and democratise resources within its departments.

The DBT initiated this restructuring activity as per the directives issued by the Department of Expenditure, Ministry of Finance. The DBT will use it as an opportunity to introspect and overhaul the way research is conducted across its institutions and help build public private partnership and develop stronger collaborative networks with all its research centres.

Highlighting the need to work in a collaborative manner, our team has interacted with leading biotechnology industry players to get their views on "Biotech trends in 2024". The cover story takes us through India's target of achieving a $150 billion bioeconomy by 2025 and addressing market challenges while focusing on capital allocation, establishing beneficial partnerships, and leveraging technology. Though the path forward is complex, the future of the biotechnology industry remains bright in 2024 due to its inherent strengths and dedication to innovation.

At present, India's bioeconomy accounts for nearly 4 per cent of our $4 trillion national economy. While the innovation ecosystem continues to flourish, India aspires to become one of the top 5 global biomanufacturing hubs and among the top 10 global biotechnology destinations. Biotechnology Industry Research Assistance Council (BIRAC), a DBT undertaking, has announced that it will be organising the Global Bio-India Summit, as an annual event instead of keeping it a biannual affair from 2024.

Our team has covered this unique business networking platform for India's biotech R&D innovation and bio-manufacturing ecosystem and international stakeholders, as the world is looking up to India as an emerging biomanufacturing hub, and the biotechnology startups and institutional linkages with industry driving India's bioeconomy in the years to come.

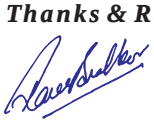
Karnataka has been at the forefront of the Indian biotechnology industry, owing to the prevailing ecosystem of the state. The bioeconomy of the state grew to $27.1 billion in 2022, with 155 new biotechnology startups getting registered in the state in 2022, and a cumulative total of startups grew to 632. Adding to these developments is the successful execution of the Bengaluru Tech Summit 2023, putting a spotlight on the biotech sector of Karnataka. The BioSpectrum team has ensured that the state will get appropriate coverage in the global platform as it launched its draft Biotechnology Policy.

Our team had also organised and covered a webinar titled "Navigating the Biotech Investment Landscape," wherein experts from diverse backgrounds in biotechnology and entrepreneurship shared their valuable insights into the challenges and opportunities facing startups in the biotech industry in India.

I am sure the insights from the industry leaders and the analysis presented will open up new avenues of discussion in the year to come.

Wishing all our readers, well-wishers and advertisers a Happy and Prosperous New Year 2024.

Thanks & Regards,



Ravindra Boratkar,
Publisher & Managing Editor

COVER 18

Can Biotech Industry Hit $150B by Leveraging Technology, Innovation & Startups?

The biotechnology industry is currently navigating a complex landscape. While revenues have normalised after the COVID's surge, the looming patent cliff and increased regulatory pressures pose significant challenges. Despite these obstacles, the industry's long-term potential remains strong, fuelled by a robust innovation pipeline and opportunities for operational efficiency. Biotech companies, according to a report by NoyMed CRO, can secure future growth and address market challenges by focusing on capital allocation, establishing beneficial partnerships, and leveraging technology. Though the path forward is complex, the future of the biotechnology industry remains bright in 2024 as India has set target of reaching $150 billion by 2025 due to its inherent strengths and dedication to innovation.

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Neurostimulation emerges as a promising migraine treatment. Jaideep Tiwari, Founder & Chief Executive Officer, BramhAnsh Technologies shares more details.

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Dr Deepak Sehgal, Professor at School of Natural Sciences, Department of Life Sciences, Shiv Nadar University focuses on the science behind developing anti-viral drugs, and the way forward.

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Regulars

Another Cautionary for Pharma

Ensuring that only safe and quality drugs are available in the market is an important responsibility of the drug regulator.

A study by researchers from India, Qatar and the UK, published recently, has brought forth some alarming facts. The study published in the Journal of Pharmaceutical Policy and Practice in December reveals that unapproved and even banned fixed-dose combinations (FDC) of antibiotics are being sold in the country.

For certain diseases, FDCs prove to be very effective, as it's a combination of more than one drug. In the course of a treatment programme, if the patient is required to take four drugs the patient may likely forget to take one sometimes. But, if these four drugs are combined into one tablet, the possibility of forgetting a dose of a particular drug is minimised, improving patient compliance.

Researchers have used sales data from the pharmaceutical industry for their study. They showed that 278 of the 395 FDCs of antibiotics, nearly 70 per cent, sold in the country in 2020 were banned or were not approved by the authorities. Of the 287 FDCs, 239 (about 60 per cent) formulations were unapproved, and 39 (about 10 per cent) formulations were banned. Still, they were available for the patients for consumption.

In their study, the researchers analysed data from 2008 to 2020. It also studied various steps initiated by the drug regulator CDSCO to control and stop the distribution of such wrong FDCs. Their study has revealed one more interesting point. The total number of FDCs under those steps by the regulator decreased from 574 in 2008 to 395 in 2020. In one way, that can be considered as a good sign since the number of bad FDCs is reducing. Still, 395 is quite a high number. Moreover, even if some of them find their way into the market despite the ban or non-approval, then it must be addressed with a commensurate step.

As several of these FDCs comprise antibiotics, the danger is not only for the specific patients who are consuming them but also for others. Hence it is a serious public health concern that needs attention. The rejection of these FDCs by the experts working with the regulator shows that the rejection is due to different problems including irrational or wrong combinations of drugs. Since it may trigger an antimicrobial resistance (AMR) problem, it must be addressed on a war footing.

Almost all those who are active in the healthcare field are aware of the seriousness of AMR. A 2019 study published in the Lancet showed that 1.3 million people in the world died due to bacterial antimicrobial resistance worldwide. Nearly 3.7 million more deaths in the world were associated with bacterial AMR. Inadequate and wrong use of antibiotics or their wrong combinations in FDCs, as well as patients discontinuing antibiotics treatment midway make the bacteria resistant to those drugs. Hence, those antibiotics and the treatment become ineffective. In such a case the viruses and bacteria keep spreading without the availability of effective treatment.

AMR has already reached an alarming level and will continue to become more serious if adequate steps are not taken. It is estimated that AMR will kill 300 million people in the world by 2050. When such an alarming situation emerges, cautious use of antibiotics is the most important step to prevent AMR. In such a situation, when banned or unapproved FDCs are being sold, the risk and danger of AMR spread increases a lot.

The image of the Indian pharmaceutical sector is already maligned abroad due to children's deaths in some countries due to cough syrups that allegedly caused deaths or sickness. In addition to that, when research articles on sales of banned or unapproved FDCs start appearing in research journals, it will further damage the image of Indian pharma and also that of the drug regulator. BS

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Assam partners with IIT-G, Tata MD to revolutionise healthcare delivery

The Indian Institute of Technology Guwahati (IIT-G) has joined hands with Tata Medical & Diagnostics (Tata MD) and National Health Mission, Assam, Health & Family Welfare Department, Government of Assam, to sign a Memorandum of Understanding (MoU) to implement the Tata MD's Healthcare Model for augmenting public healthcare delivery in the Kamrup district of Assam by establishing a Digital Nerve Centre. One major highlight of this project will be Bill & Melinda Gates Foundation's involvement as the strategic partner to provide inputs and share learnings of adapting and implementing innovative models, as well as taking the learnings from the initiative to other states and globally to ensure more women and children have access to lifesaving care. To implement this project, a Digital Nerve Centre – Command Centre (Hub) will be established at IIT Guwahati campus with technical, IT and physical infrastructure setup, and vendor coordination support from Tata MD. Another major initiative of this pilot project will be to set up Digital Nerve Centre (DiNC) components at Healthcare Centres in 30 District Hospital (DH), Community Health Centres (CHC), Primary Health Centres (PHC), and Sub-centre (SC) in Assam.

WHO & Ministry of Ayush ink Traditional and Complementary Medicine 'Project Collaboration Agreement'

The Ministry of Ayush and the World Health Organization (WHO) have signed a Traditional and Complementary Medicine 'Project Collaboration Agreement' in Geneva. Indra Mani Pandey, Permanent Representative of India to the United Nations, on behalf of the Ministry of Ayush, and Dr Bruce Aylward, Assistant Director General, Universal Health Coverage and Life Course Division, on behalf of WHO, signed the agreement. The main objective of this agreement is to standardise Traditional and Complementary Medical Systems, integrate their quality and safety aspects into the National Health System, and disseminate them at the international level. Through this cooperation agreement, efforts will be made to connect Traditional and Complementary Medical Systems with the mainstream of the National Health System. To fulfil this objective, Traditional Medicine Global Strategy 2025-34 will be prepared by WHO with the support of the Ministry of Ayush.

Centre puts forward "Bio-Vision" for Bharat at BRIC Society's maiden meeting

In a groundbreaking session marking the inaugural gathering of the BRIC Society, the Union Minister of State (Independent Charge) Science & Technology, Dr Jitendra Singh emphasised the need to define "Bio-Vision" for Bharat. This significant move comes after the recent registration of the Biotechnology Research and Innovation Council (BRIC) following Cabinet approval on November 10, 2023. The Department of Biotechnology (DBT), Ministry of Science and Technology, has received Cabinet approval to streamline its 14 Autonomous Institutions (AIs) under BRIC for centralised governance, maximising biotech research impact nationwide. Seeking input from accomplished institution-builders, the Minister urged the BRIC meeting to define the "Bio-Vision" for Bharat. BRIC will maintain distinct research mandates for its 14 subsumed institutions, governed by a unified Governing Body. To enhance scientific capabilities, BRIC will introduce new PhD programmes, common course curricula, & additional scientific positions.

Karnataka aims to attract Rs 40,000 Cr investment in KHIR City

The Karnataka government deliberated on conceptualisation of the development of Knowledge, Healthcare, Innovation and Research (KHIR) City on the outskirts of Bengaluru. The government aims to attract Rs 40,000 crore investment in the areas of healthcare, innovation and knowledge sectors besides creating 80,000 jobs in the proposed KHIR City. The new investment region will be spread over 2,000 acres within 60 kms from Bengaluru and developed in a phased manner.

With Karnataka being home to 60 per cent of India's biotech companies and over 350 medical devices and supplies manufacturers across categories, the development of KHIR near Bengaluru, the fastest-growing innovation cluster globally, augurs as an ideal location. The establishment of KHIR City has a strong global reference point with the Government of Karnataka aiming to bring this research city in line with Singapore's Biopolis Cluster or Japan's Kobe Biomedical Innovation Cluster.

Telangana DCA seizes Rs 4.05 Cr worth of spurious anti-cancer drugs

In a significant operation, the Drug Control Administration (DCA) authorities of Telangana government have unearthed an illicit stockpile of counterfeit anti-cancer drugs valued at Rs 4.05 crore. The crackdown on this criminal enterprise, involving an unlicensed firm named 'Astrica Healthcare', led to a series of raids across multiple locations in Hyderabad city. The Assistant Director of DCA Telangana, P. Ramu, disclosed that the operation was initiated based on credible information received by the Vigilance Cell of the Drugs Control Administration.

Upon discovering that the address provided by Astrica Healthcare was fictitious, the DCA officials collaborated with postal authorities at Alwal to trace the culprits. Subsequently, raids were conducted at courier offices in IDA Cherlapally, Nacharam, and Medchal, as well as at the premises of 'Astrica Healthcare' in Keesara. The investigation revealed that certain seized drugs bore labels with details of a non-existent company, 'Astra Generics Pvt. Ltd.,' whose licences were cancelled in July 2021. The manufacturing date on the spurious drugs was noted as March 2023, under the name of the said cancelled company. The spurious drugs were falsely labelled under various legitimate companies.

India releases document on National Circular Economy Roadmap for reduction of plastic waste

The Union Minister of State (Independent Charge) for Science & Technology Dr Jitendra Singh has released a flagship document on 'National Circular Economy Roadmap for reduction of Plastic waste in India', a collaborative exercise between leading research institutions from India and Australia. The document aims to foster research and industry partnerships between the two countries and co-develop a roadmap for India's transition to a circular economy in the plastics sector. India and Australia are active participants in the negotiations for formulation of a Global Plastics Treaty to be finalised next year. Both countries aim to leverage their respective strengths in waste management, recycling policies, and environmental initiatives to foster a circular economy that prioritises resource efficiency and environmental protection.

Fortis Healthcare to divest Fortis Malar Hospital, Chennai to MGM Healthcare for Rs 128 Cr

Fortis Healthcare has announced signing of definitive agreements by its certain subsidiaries for sale of the business operations along with the land and building assets pertaining to Fortis Malar Hospital situated at Gandhi Nagar, Adyar Chennai, to MGM Healthcare, a prominent healthcare delivery service provider, for a sale consideration of approx. Rs 128 crore. The transaction comprises the divestment of: (1) the business operations pertaining to Fortis Malar Hospital residing in the listed subsidiary of the company - Fortis Malar Hospitals in which Fortis Healthcare owns a 62.7 per cent equity stake; (2) The OPD and radiology business operations related to the Fortis Malar Hospital (including the land and building on which Fortis Malar Hospital is situated) and the land parcel adjacent thereto, all of which are residing in Fortis Health Management; and (3) An adjacent land parcel currently used as a parking premise, residing in Hospitalia Eastern. The business and assets specified in (2) and (3) reside in two wholly owned subsidiaries of Fortis Healthcare namely Fortis Health Management and Hospitalia Eastern.

Vibcare opens pharma manufacturing facility with Rs 40 Cr investment in Panchkula

Vibcare Healthcare has marked a significant stride in India's pharmaceutical industry with the inauguration of its state-of-the-art manufacturing facility in Panchkula, Haryana. The company's robust investment of Rs 40 crore underscores its dedication to excellence and innovation in pharmaceuticals. Spanning over 5 acres, the facility adheres to the highest international standards, including EU GMP, PIC/S, and UK MHRA GMP. The cutting-edge facility comprises four specialised production units for General Tablets, Liquids, Capsules, and Ointments, boasting over 500 approvals and aligning meticulously with global quality standards. This comprehensive infrastructure positions Vibcare Healthcare to comprehensively address diverse healthcare needs with an extensive array of pharmaceutical solutions.

Lord's Mark Industries aims to go public in 2024 with plans to raise up to Rs 500 Cr

Thane-based Lord's Mark Industries, a diversified business group, has announced that it is aiming to hit the capital markets and go for public listing in the first half of 2024 to raise up to Rs 500 crore. IDBI Capital and Mirae Asset are the merchant bankers for the listing. The company plans to invest the proceeds in its subsidiaries to develop medtech products, production of innovative diagnostic solutions, expansion of its pathology lab pan India and exports of its medical diagnostic products and machines. To facilitate mass production of its innovative diagnostic solutions, Lord's Mark Industries plans to leverage the funds for infrastructure development and skilled manpower. Additionally, the company aims to launch 400 pathology labs across India in the next 5 years under the Affordable Medical Infra scheme. Already making strides in global markets, exports to Nepal, Bangladesh, and Sri Lanka have commenced, with African operations set to begin by March 2024. Lord's Mark Industries reported revenue from operations at Rs 301 crore in FY23, registering a 41.31 per cent growth from the revenue reported in FY22 which stood at Rs 213 crore.

Dr. Reddy's inks ~$700M deal with Coya for Amyotrophic Lateral Sclerosis treatment

Dr. Reddy's Laboratories SA, wholly-owned subsidiary of Hyderabad-based Dr. Reddy's Laboratories, and American firm Coya Therapeutics, Inc. have entered into a development and licence agreement for the development and commercialisation of COYA 302, an investigational combination therapy for the treatment of Amyotrophic Lateral Sclerosis (ALS). Dr. Reddy's will make a $7.5 million upfront payment to Coya. Upon the first FDA acceptance of an investigational new drug (IND) application for COYA 302 for the treatment of ALS, Dr. Reddy's will pay Coya an additional $4.2 million. Upon dosing of the first patient in the first Phase 2 trial of COYA 302 for the treatment of ALS in the United States, Dr. Reddy's will pay Coya an additional $4.2 million. The Agreement also includes development and regulatory milestones up to $40 million should all such development and regulatory milestones be achieved. Additionally, Coya is eligible to receive sales-based milestone payments of up to $677.25 million linked to tiers of cumulative net sales being achieved over several years.

Rusan Pharma opens state-of-the-art API facility in Pithampur, with Rs 300 Cr investment

Rusan Pharma recently achieved a momentous milestone with the launch of its state-of-the-art API facility in Pithampur, Special Economic Zone (SEZ), Madhya Pradesh (MP). With an approach to sustainable development and technological advancements, the total investment over two phases will be up to Rs 300 crore, highlighting Rusan Pharma's commitment to the pharmaceutical sector and its potential impact on the industry's growth and development. The facility is designed to meet stringent international regulatory guidelines, ensuring the highest level of compliance. With the production capability of 400 metric tonnes of APIs annually, the facility significantly contributes to Rusan Pharma's growth and expansion plans, diversifying its portfolio and expanding its reach in India and other markets. During the construction phase of the Pithampur facility, over 3000 contract workers were employed, and once it is fully operational, the facility will directly generate more than 300 employment opportunities, and over the years, more than 500+ indirect employment opportunities will be created.

Cadila Pharma invests Rs 200 Cr in new API manufacturing plant at Dahej

Ahmedabad-based Cadila Pharmaceuticals recently inaugurated its state-of-the-art Active Pharmaceutical Ingredients (API) Plant at Dahej in the Bharuch district of Gujarat. The facility, set up with an investment of Rs 200 crore, is equipped with the latest Distributed Control System (DCS) automation technology, marking a significant milestone in Cadila Pharmaceuticals' dedication to innovation and excellence in drug manufacturing. The DCS technology used in this facility will allow the company to produce APIs with a high level of purity and consistency, while also reducing the environmental impact. The implementation of the plant project will further extend the impact by generating employment opportunities for both permanent and contractual positions. Cadila Pharmaceuticals had earlier signed an MoU with the government of Gujarat for investing Rs 1,000 crore in Gujarat. The Dahej API facility is one of the projects for which the MoU was signed.

Polymatech Electronics develops medical device for precise vein detection

Tamil Nadu-based Polymatech Electronics, at the forefront of semiconductor chip innovation in India, has unveiled its groundbreaking medical device - the Vein Detection Light. This cutting-edge technology promises to revolutionise the healthcare industry, offering a solution to a pervasive problem of accurate vein detection in medical procedures worldwide. The device features high-definition vein detection, delivering real-time full high-definition (FHD) visualisation (1920 X 1080) for unmatched clarity in identifying subdermal veins. Weighing a mere five lbs. and designed for mobility, the Vein Detection Light provides healthcare professionals with unparalleled convenience across various medical settings. According to industry estimates, there are around 174 million venipuncture failures worldwide every year, with a failure rate of one in five attempts in adults and one in three attempts in paediatrics.

Akums acquires new facility in Baddi to elevate tablet manufacturing capacity

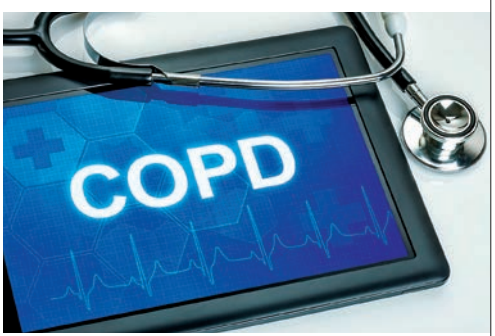
Akums Drugs and Pharmaceuticals, the contract manufacturing pharmaceutical company in India, has announced the acquisition of a new formulation facility located in Baddi, Himachal Pradesh. This marks the 12th formulation facility under Akums, and the second in Baddi, a strategic move with an aim to enhance Akums' manufacturing capabilities. The newly acquired facility, sprawling across approximately 6 acres, is currently undergoing upgrades and is slated to become operational in the year 2024. Once operational, it will serve as an oral solid dosage (OSD) pharmaceutical formulation facility, significantly enhancing Akums' tablet manufacturing capacity. This procurement is anticipated to boost Akums' tablet manufacturing capacity across various therapeutic areas, further enhancing Akums' ability to serve clients, improve time-to-market, and cater to the burgeoning Indian pharmaceutical market.

Indian Immunologicals unveils Measles and Rubella vaccine for children

Hyderabad-based Indian Immunologicals Limited (IIL) has launched Mabella (Measles and Rubella) vaccine for children, developed in partnership with Polyvac Institute, Vietnam. Through rigorous human clinical trials, Mabella has demonstrated both safety and effectiveness, addressing the global threat of Measles and Rubella, which claims around 1,00,000 children's lives annually. This launch took place along with Human Biologicals Institute (HBI), a branch of IIL, marking its 25th anniversary since its establishment in 1998. Founded in an era emphasising the need for indigenous vaccines, HBI has significantly contributed to India's self-reliance, aligning with the vision of "Atmanirbhar Bharat." HBI's legacy of innovation began in 1998 with the indigenous development of India's first safe Vero-cell rabies vaccine – Abhayrab, replacing the painful nerve tissue vaccine. Abhayrab is now the world's largest-selling Anti-Rabies vaccine, saving millions of lives globally. HBI subsequently introduced various childhood vaccines, including DPT, Pentavalent Vaccine, TT, Hepatitis-B, MR, and Td vaccines.

Lupin announces world's first fixed-dose triple combination drug for COPD management in India

Mumbai-based pharma major Lupin Limited has launched the world's first fixed-dose triple combination drug (FDC) under the brand name Vilfuro-G for the effective management of chronic obstructive pulmonary disease (COPD) in India. This milestone follows the approval granted by the Drug Controller General of India for the Dry Powder Inhaler (DPI) product. Lupin Vilfuro-G is the only FDC that uniquely combines Vilanterol, Fluticasone Furoate and Glycopyrronium Bromide, for the long-term management and treatment of moderate to severe COPD. The product is available in a single-strength fixed dose, with a recommended once-daily dosage. This therapeutic innovation by Lupin brings hope to more than 37 million individuals struggling with COPD in India, a condition that ranks among the leading causes of death and disability in the nation.



Sanjivani Paranteral and Hindustan Antibiotics to manufacture IV formulations and IV sets

Mumbai-based Sanjivani Paranteral has inked a significant agreement with Hindustan Antibiotics, the first drug manufacturing company to be set up in the public sector by Government of India, for the manufacturing of Intravenous (IV) formulations and IV sets. The agreement is backed by a confirmed purchase commitment from Hindustan Antibiotics. The partnership will see the establishment of a cutting-edge manufacturing facility within the premises of Hindustan Antibiotics at Pimpri works, Pune. Sanjivani Paranteral will soon initiate the process of upgrading facilities, and the production is likely to start from Q3FY25. The plant capacity will be 50 lakh IV fluids bottles and 10 lakh IV sets per month. This strategic move underlines both companies' commitment to meet the demand of IV formulations and IV sets. The total investment for the project would be Rs 50 crore.

Enzene Biosciences launches Ranibizumab as affordable alternative to treat neovascular AMD

After launching Bevacizumab for the treatment of metastatic colorectal cancer, Pune-based Enzene Biosciences has now followed it up with the launch of Ranibizumab, a biosimilar to innovator product Lucentis that is sold under the brand name Accentrix in India. A recombinant antigen-binding fragment (Fab) that is used as a therapy for neovascular age-related macular degeneration (AMD), the Ranibizumab biosimilar is the company's 7th biosimilar and could significantly lower treatment costs for thousands of Indian patients. Enzene is actively progressing with the development of three additional biosimilars in various stages. Furthermore, the company is in alliance with UK-based pharmaceutical firm Theramex to launch a biosimilar of Prolia in Europe, UK, Australia and Switzerland. The company is also developing a synthetic peptide pipeline and is focused on supplementing its manufacturing capabilities, with plans to expand into key international markets like the USA, at a rapid pace.

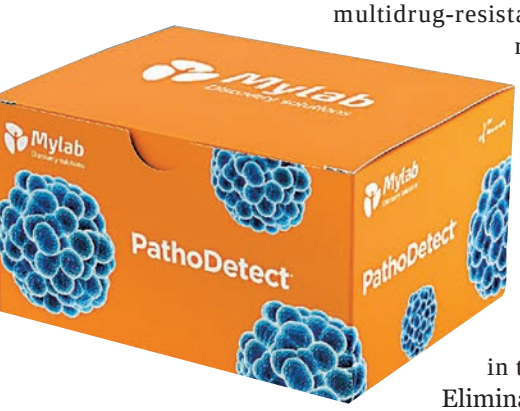
HempStreet raises $1M in Pre- Series A round, eyes global expansion

New Delhi-based startup HempStreet has raised $1 million in Pre-Series A round. The round was led by their existing investor Carl Waahlin, a serial entrepreneur and investor, with an investment portfolio of over $200 million (via Waahlin Holdings) across various verticals including CBD based products in North America. Other investors in this round include existing investor Andre Rodrigues and a clutch of HNIs from South East Asia, along with Abhishek Mohan, Founder and CEO of HempStreet

who also participated. The company will use the funds to expand its activities around clinical trials for proprietary formulations, solidify itself as a leader in the menstrual cramps and pain treatment segment and facilitate R&D to further develop ayurveda-inspired products that will be put through the clinical validation process. To expand its global footprint, HempStreet has partnered with MGC Pharma (UK), Gynica (Israel), Amrita School of Ayurveda (India), UIDI (Brazil) and Cannabis 360 (Brazil). In 2024, the company aims to enter Latam and North America to launch a line of clinically backed products starting with their proprietary formulation to tackle primary and secondary dysmenorrhea.

NTEP incorporates Mylab's PathoDetect kit to eliminate TB by 2025

In a significant stride towards eradicating tuberculosis (TB) from India, the National TB Elimination Programme (NTEP) has incorporated Pune-based startup Mylab's PathoDetect MTB RIF & INH Resistance Detection Kit to further its effort to eliminate TB by 2025. Recognised as India's first multidrug-resistant TB test, it is now integrated into the Nikshay portal, amplifying the nation's capabilities in the fight against tuberculosis. The inclusion of the PathoDetect kit in the National TB Elimination Programme marks a pivotal moment in India's commitment to combating tuberculosis, a disease that continues to pose a significant public health challenge. This manual-intervention free test, designed for the rapid and accurate detection of multidrug-resistant TB, offers advanced capabilities for identifying TB and resistance to Rifampicin (RIF) and Isoniazid (INH), two critical first-line drugs in TB treatment.



IIT-M introduces India's first information platform on incubators & accelerators

The Centre for Research on Startups and Risk Financing (CREST), an Institute of Eminence Research Centre at the Indian Institute of Technology, Madras (IIT-M) has developed India's first information platform on incubators and accelerators. The platform, developed in partnership with YNOS, an IIT Madras-incubated startup, contains comprehensive information on incubators and accelerators, which play an important role in helping startups navigate an uncertain entrepreneurial ecosystem. While India had about 1,000 active incubators, until now, the information about them was scattered and not easily available in a single location. Entrepreneurs had to spend a lot of time and effort to identify the incubator most suitable for their startup. The platform developed by CREST addresses this pain-point and helps the startup founders to identify, compare and analyse incubators very easily. Called 'Incubators', this artificial intelligence (AI)-powered platform will help startup founders to identify incubators and accelerators across India and shortlist one that best fits their requirements.

Varco Leg Care launches first-of-its-kind ulcer treatment product

Varco Leg Care, a New Delhi-based startup, has announced the launch of its new flagship product - 'Ulsr Soothe Max' – curated dedicatedly for treatment and cure of foot ulcer. Formulated with Varco's Phyto Transdermal Technology, the product stands out as a first-of-its-kind, revolutionary solution globally, with the potential to enable complete healing and recovery of individuals from foot ulcers (including varicose veins ulcer and diabetic foot ulcer) and related concerns such as foot blisters, calluses and corns. Of late, both in India and across other parts of the world, infections attributed to diabetic foot ulcer (DFU) are increasingly becoming one of the major causes for hospitalisation amongst diabetics. Studies have shown that roughly one in four diabetes patients have the likelihood of developing foot ulcers during their lifetime. Ulsr Soothe Max – an FDA-approved, made-in-India topical cream, that represents a blend of nature's healing touch and advanced scientific innovation, is Varco Leg Care's attempt to mitigate the growing public health burden caused by foot ulcer, while simultaneously redefining existing foot ulcer treatment methodologies and processes worldwide.

InMed AI receives US FDA 510(k) clearance for NeuroShield that quantifies brain volumes

Pune-based startup InMed Prognostics Inc. has received the US FDA 510(k) clearance for NeuroShield, a fully automated brain geometry-based quantifying analytics tool/cloud platform that uses artificial intelligence (AI)/Deep Net/3D Convolutional Networks to support physicians as a clinical decision support tool for neurologists & neuroradiologists. NeuroShield is currently in clinical use in over 220+ sites across the world. In-Med is supported by seed funding from Sriram Natarajan, Founder & CEO of Molbio Diagnostics. NeuroShield takes 3D MR images as inputs & automatically calculates brain volumes that can assist physicians in devising treatment plans for patients with neurodegenerative diseases such as Dementia, Alzheimer's Disease, Parkinson's, & Epilepsy. The product is the first in the world to provide reference ranges that can be adjusted to age, gender, and ethnicity, setting new standards in healthcare & bringing us closer to precision medicine that is relevant for everyone, everywhere.

SAMRIDH and Redwing unveil drone-based healthcare network in Rayagada, Odisha

The SAMRIDH Healthcare Blended Finance Facility, a multi-stakeholder innovation and financing platform supported by the United States Agency for International Development (USAID) and implemented by IPE Global, in collaboration with Bengaluru-based startup, Redwing, have launched a pilot drone network to enhance accessibility and affordability of healthcare services in the Rayagada district of Odisha. This pilot programme will use Redwing's electric hybrid drones to deliver medicine and medical equipment by air to isolated areas in Rayagada district, Odisha. The pilot project will use Redwing's 'made in India' electric hybrid Vertical Take-off and Landing (VTOL) drones. Key collaborators on the project include the district administration of Rayagada and the Indian Institute of Management, Ahmedabad, which will help evaluate the impact and feasibility of the initiative.

Can Biotech Industry Hit $150B by Leveraging Technology, Innovation & Startups?

The biotechnology industry is currently navigating a complex landscape. While revenues have normalised after the COVID's surge, the looming patent cliff and increased regulatory pressures pose significant challenges. Despite these obstacles, the industry's long-term potential remains strong, fuelled by a robust innovation pipeline and opportunities for operational efficiency. Biotech companies, according to a report by NoyMed CRO, can secure future growth and address market challenges by focusing on capital allocation, establishing beneficial partnerships, and leveraging technology. Though the path forward is complex, the future of the biotechnology industry remains bright in 2024 as India has set target of reaching $150 billion by 2025 due to its inherent strengths and dedication to innovation.

On December 2, India witnessed the first-ever meeting of the Biotechnology Research and Innovation Council (BRIC) Society after its registration on November 10, wherein Dr Jitendra Singh, Union Minister of State (Independent Charge) Science & Technology, who chaired the meeting, said that time has come for defining "Bio-vision" for Bharat.

Describing BRIC meeting as a historical event in India's Biotech Ecosystem, where elite 14 institutions of Department of Biotechnology (DBT) are consolidating their efforts to impact the biotech R&D ecosystem, the minister said that BRIC will prospectively enrich India's progress in every front including economy and employment.

Dr Jitendra Singh also pointed out that this is one of the first Departments in the Government of India to have successfully executed "Rationalisation of Autonomous Bodies" for process and performance enhancement of its Autonomous bodies. He said that Indian Bio-economy recorded 13 times increase in the last ten years.

It may be noted that in her Union Budget speech on February 1, Nirmala Sitaraman, Finance Minister, observed that joint Public and Private Medical research should be encouraged via select Indian Council of Medical Research (ICMR) labs for encouraging collaborative research and innovation. As a first step in that direction, DBT has formed BRIC Society.

As part of a slew of significant changes that will be actualised by BRIC, each of the 14 subsumed BRIC Institutions will maintain their distinct research mandates, governed by one Governing Body, at BRIC. Institutes would be allowed utilisation of institutional lab space, not exceeding one third, for researchers from outside DBT institutes and their collaborators (from industry or other institutes) to carry out R&D for startups emerging out of institutional research. Dr Jitendra Singh also underlined that BRIC and its institutes can engage in public-private research partnerships and receive endowments including funds from non-governmental resources for research-related activities. This will help in achieving "Minimum Government, Maximum Governance."

As Global Centres of Research and Innovation

Besides, at the beginning of 2023, Dr Singh launched the "One Week One Lab" Campaign of Council of Scientific & Industrial Research (CSIR), at the 108th Indian Science Congress held in Nagpur on January 6. Each of the 37 CSIR Labs spread across the country is dedicated to a different exclusive area of work and the "One Week One Lab" campaign offered an opportunity to each one of them to showcase the work being done by it so that others can avail of it and stakeholders learn about it. Common India will be turned into Global Centres of Research and Innovation in their respective fields of Specialisation.

Started with 5 laboratories in 1942, in its eight decades of journey CSIR has grown into an organisation with 37 labs of 3521 scientists, supported by 4162 technical staff, 2612 administrative and other support staff and about 5500 young scholars, that addresses every facet of scientific development required in the country.

There is a plethora of technologies developed by the scientists and researchers of CSIR laboratories for the society, but many of them remain confined to the laboratories. There is a need to establish the resourceful connection of people (stakeholder/ entrepreneur/ student/ industry) to know more about the technologies for the advancement of the technology and the progress of the society.

Harnessing Technologies

The world is on the verge of ending the first quarter of the 21st century, said Dr Jitendra Singh, adding that the next few years will be an opportunity to vindicate that 21st century as India's century. Spelling out thrust areas for the year 2023 in the context of science, technology and innovation on January 8, the minister said "Future belongs to technology blended with innovation and creative startups sustained through evolving technologies and new ideas."

While inaugurating the 3rd Global Bio-India, mega international congregation on Biotechnology, on December 4, the minister said "Biotechnology will provide the "future value addition" to India's economy in the years to come. Biotechnology will be the key to Amrit Kaal economy and also for making India a frontline nation in the world."

India's bioeconomy experienced robust growth in 2022, surging by 29 per cent to reach a substantial value of $137.24 billion. Also, the year 2022 saw a rise in private equity and venture capital investments in the biotech industry, reaching a record-breaking $938.8 million, a 19 per cent growth compared to the previous year.

The Indian biotechnology industry is expected to reach $150 billion by 2025 and has the potential to reach $270-300 billion by the year 2030. By 2025, the contribution of the Indian biotechnology industry to the global biotechnology market is expected to grow to 19 per cent. The Indian biologics market is forecasted to reach $12 billion by 2025, at a CAGR of 22 per cent.

With just 55 startups in 2014 to over 6000 as of 2023, the entrepreneurial landscape of the biotech industry in India witnessed dynamic growth in the last couple of years. Startups are emerging as key drivers of bioeconomic development. The number of startups is expected to reach 10,000 by 2024. Maharashtra, Karnataka and Telangana led the way in 2022, a year which saw a total of 1391 startups getting registered, reflecting a substantial 23 per cent growth from the previous year's count of 1128.

India is boosting the biotechnology sector under various flagship programmes such as 'Production Linked Incentive (PLI) scheme', 'Make in India' and 'Startup India'. These government schemes and programmes coupled with the application of latest technologies such as Gene Editing and CRISPR, Cell and Gene Technology, Artificial Intelligence and Machine Learning, Tissue Engineering and Bioprinting, Big Data, and Real World Evidence Trials, biotechnology industry in 2024 hope to develop innovative solutions in the meeting the unmet healthcare needs of the nation.

Collaborative Synergy

In addition to launching the new biologicals in the coming year, the biotech industry continues to witness a double-digit growth in the year 2024 by adopting or following the many well-established business approaches such collaboration with Full-Service and Specialty Contract Research Organisations (CROs), Outsourcing between Biotechnology firms (Bio-to-Bio) and M&A deals.

According to NoyMed CRO, biotechnology sponsors in 2024 are poised to embrace a significant trend: increased collaboration with both biometrics and full-service CROs. This strategic alliance allows access to specialised expertise, cutting-edge resources, and streamlined processes crucial for efficient drug development. By leveraging the strengths of CROs, biotech firms optimise costs, accelerate research timelines, and enhance innovation. This collaborative synergy between biotechnology firms and CROs not only expedites market entry but also ensures adherence to regulatory standards while focusing on core competencies.

As the drug development landscape evolves, 2024 will mark the rise of a strategic paradigm shift: biotechnology companies will increasingly collaborate, forming synergistic partnerships. Driven by expertise in areas like gene editing, AI-powered discovery,

and nanomedicine, these collaborations unlock significant advantages.

Efficiency grows as companies focus on their core strengths, accelerating development timelines and delivering life-saving therapies to patients faster. Resource optimisation takes centre stage, with shared expertise reducing overhead costs and fueling further advancements. Moreover, knowledge exchange thrives within these partnerships, fostering collaborative innovation and paving the way for groundbreaking solutions to intricate medical challenges. While challenges remain, such as intellectual property concerns and the crucial element of finding the right partners, the potential of this collaborative approach is undeniable.

In 2024, NoyMed CRO further noted that the "cautious optimism" of 2023 might turn into a strategic focus on mergers and acquisitions (M&A) within the biotech industry. Investors, staying cautious due to external challenges, will likely be picky, seeking deals that offer clear value and specific growth opportunities. There could be more consolidation, especially in areas like gene editing and AI-driven discovery, where specialised skills are highly valued. However, the potential for increased deals exists due to the interest in new technologies like mRNA vaccines.

Some companies aiming for a global presence might pursue M&A for market access, while others might surprise by acquiring promising research pipelines or startups. Navigating these uncertainties presents investment opportunities by identifying undervalued tech, anticipating regulatory changes, and predicting future successful treatments.

The biotechnology industry, according to a report by NoyMed CRO, is currently navigating a complex landscape. While revenues have normalised after the COVID's surge, the looming patent cliff and increased regulatory pressures pose significant challenges. Despite these obstacles, the industry's long-term potential remains strong, fuelled by a robust innovation pipeline and opportunities for operational efficiency. Biotech companies can secure future growth and address market challenges by focusing on capital allocation, establishing beneficial partnerships, and leveraging technology. In conclusion, though the path forward is complex, the future of the biotechnology industry remains bright in 2024 due to its inherent strengths and dedication to innovation. With this India is not too far from reaching the league of top-10 countries in Biotech's global ecosystem. BS

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(Inputs from Amguthr Raju)

What Does 2024 Hold for Biotech?

Kiran Mazumdar Shaw,
Executive Chairperson,
Biocon and Biocon Biologics

"India's bioeconomy is poised to reach $150 billion by 2024. To achieve our next goal of $200 billion, we must focus on biotechnology as a key driver of economic growth. Fortunately, we are living through a pivotal moment when information technology and life sciences are converging to spearhead a new future. Greater adoption of AI and ML in biotechnology-related fields coupled with gene editing will accelerate the development of products and services and usher in transformative change. An enabling ecosystem can empower India to be at the forefront of this transformation by unleashing the power of discovery and development of new drugs, devices, diagnostics, biomaterials, biofuels, biocatalysts and a host of other bio products."

Dr Himanshu Gadgil,
CEO,
Enzene Biosciences

"The Biosimilar space is bound to witness a surge. In the next two to four years, many biologics will come off patents, which will give an impetus to those companies who have invested heavily in building a strong human capital and infrastructure and give them an opportunity to cash in on this patent cliff. I therefore see that the Biosimilar development will see significant growth in the coming years. Another big opportunity is the evolving global dynamics, particularly the 'China plus one' strategy, positioning India as a key player in Contract Development and Manufacturing Organizations (CDMO). Beyond traditional realms, emerging fields like ADC's and cell and gene therapy are also gaining momentum. As biotech pioneers navigate this dynamic terrain, the confluence of biosimilar advancements, strategic CDMO positioning, and innovative modalities promises an exhilarating growth trajectory in 2024."

What Does 2024 Hold for Biotech?

Dr Krishna Ella,
Chairman and
Managing Director,
Bharat Biotech

"The success of mRNA-based vaccines in combating COVID-19 has paved the way for a new era in biopharmaceuticals. mRNA technology has demonstrated its potential in responding swiftly to emerging health threats. We are likely to witness expanded applications beyond infectious diseases, including cancer and other chronic conditions. The adaptability of mRNA platforms offers a versatile approach to vaccine development. New advancements in biotech in 2024 will allow us to address a wide range of diseases, providing a more targeted and effective solution."

Rajesh Kumar Singh,
Secretary,
Department for Promotion of Industry and Internal Trade (DPIIT) and and Invest India

"With a fast growing biotech startup environment, India is going to become the global startup base bringing in new and innovative solutions for various complex problems and challenges facing mankind. With AI, Machine Learning and other innovations encapsulating the advancements in the Biotech sector, 2024 will witness India as one of the leading Bio economies in the world. India's Biotech sector which is valued at about $100 billion in 2023, will easily cross its set target of $150 billion by 2025 and poised to even cross $300 billion by 2030, if the same momentum of growth is carried forward."

Dr S V Krishna Prasad,
CEO and Managing Director,
Cito Healthcare

"The year 2024 may witness new collaborations and more signing of MoUs to leverage the potential of biotechnology and its wide scope in drug development. I wish that the Government of India will come out with more initiatives in 2024 to push the biotech industry to engage in active collaboration with R&D institutions and the biotech industry. With more encouragement, new investment in research and development will create an environment that fosters the growth of the biotechnology sector. As the world looks toward India for future healthcare innovations, it is imperative to harness the immense potential that biotechnology holds and ensure a robust and ethically sound future for the sector."

Dr Anand Kumar,
Managing Director,
Indian Immunologicals

"Biopharmaceuticals are evolving towards a more personalised approach, tailoring treatments to individual patient characteristics. This not only enhances efficacy but also minimises side effects. Biologics, in particular, play a crucial role in this paradigm shift, offering precise and targeted therapies."

What Does 2024 Hold for Biotech?

Dr Vinay Kumar Nandicoori,
Director,
Centre for Cellular &
Molecular Biology (CCMB)

"The future of the Biotech sector in India is immense. With the strong research base, and India's positive policy initiatives to promote the startup and research environment, both in the government and private sectors, I foresee a flourishing Biotech Industry in 2024 in India. The flourishing private pharma and biotech companies, by leveraging their technology and financial resources, combined with the knowledge base from India's lead research institutions, will lead some of the breakthrough inventions. I am optimistic that in the coming year, India will lead the world in discovering new medicines and treatment procedures for complex chronic diseases."

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

"India, apart from becoming a global pharmacy for generic medicines, has also emerged as the leading supplier of vaccines to the world. Today, India exports vaccines to over 150 countries and is a leading destination for contract manufacturing & clinical trials. To contain healthcare costs, companies are leveraging generics and biosimilars. Catching up with the market potentials and by adopting new advancements in both pharma and biotech sector, India has become a global supplier of affordable high quality medicines and vaccines. With more startups coming in the biotech sector, in 2024, I foresee India's global biotech industry's share will definitely be doubled. "

Mutyam Vishweshwar,
Director,
Anvitha Life Care

"Gene therapy is emerging as a promising frontier in biopharmaceuticals in the coming days. The potential of biotechnology can be leveraged to cure diseases at the genetic level. "Gene therapy has the power to revolutionise treatment strategies for genetic disorders. As technology advances, we are moving closer to realising the full potential of correcting faulty genes and providing long-term solutions."

Dr Karishma Atul Shah,
Founder & Director,
Pronto Consult

"Advancements in genomics and molecular biology have paved the way for personalised medicine, where treatments are tailored to an individual's genetic makeup. This approach can lead to more effective and targeted healthcare interventions in 2024. In a survey Pronto Consult conducted, around 21 per cent of doctors in India feel that more discoveries will lead to a more personalised approach, leading to better patient outcomes."

8 Major Trends in Patient-Centric Care

Health policies and regulations influence the accessibility, affordability, and quality of healthcare services, striving to create a balance that meets the needs of diverse populations. However challenges persist within healthcare systems globally, including issues of healthcare disparities, rising costs, and the need for ongoing innovation. The integration of data-driven approaches, such as electronic health records and health informatics, seeks to enhance efficiency, coordination, and personalised care.

« **Dr Hari Natarajan,** Founder & Managing Partner, Pronto Consult

In recent years, COVID-19 highlighted the resilience and adaptability of healthcare systems worldwide. It prompted accelerated adoption of telehealth, emphasised the importance of global collaboration in research and vaccine development, and underscored the need for robust public health measures.

Ultimately, the pursuit of optimal healthcare involves a continuous evolution of practices, policies, and technologies to address emerging health challenges and meet the diverse and dynamic needs of individuals and communities.

Let's look at a few key trends:

1. Digital Health and Telemedicine: The integration of digital technology into healthcare, including telemedicine and remote patient monitoring, was already a growing trend. It allows for more convenient and accessible healthcare services. In 2024 we might be able to see some revolutionary changes in this space.

2. Artificial Intelligence (AI) and Machine Learning: AI applications in healthcare, such as predictive analytics, diagnostic tools, and personalised medicine, are on the rise. These technologies have the potential to enhance efficiency, accuracy, and patient outcomes. We would see better and more proficient systems as we move along.

3. Blockchain in Healthcare: Blockchain technology was being explored for its potential to improve data security, interoperability, and transparency in healthcare systems. It could be used for securely storing and sharing patient data. Patient education, especially to track medicines using QR code would lead to better patient understanding and would also help the Government to track various activities and schemes.

4. Patient Empowerment: There was a growing emphasis on empowering patients through access to their health data, shared decision-making, and health education. Patient-centric care and engagement were becoming key priorities for various organisations.

5. Mental Health Focus: The importance of mental health and well-being in overall healthcare was gaining recognition. There was an increasing focus on integrating mental health services into primary care and leveraging technology for mental health support. This is something which has come up in the last few years and is expected to leverage AI and HCPs.

6. Remote Monitoring and Wearables: The use of wearable devices and remote monitoring tools to track and manage health conditions was becoming more common. These technologies can help in preventive care and early detection of health issues. In a study conducted nearly 59 per cent of consumers today use various Wearables to monitor various health parameters.

7. Diagnostics and Hospitals: More patients are going for diagnostic tests as health is becoming a key for most people in the last three years. Various tests being done by the patients included Physical Examination, CT scan, X-ray Chest, USG of Abdomen and Pelvis, Lung Function Tests, Lipid Profile, Liver Profile, Kidney Profile, HbA1c, T3, T4 and TSH, Blood Fasting & PP. Also included Vitamin B12 levels, Vitamin D3 levels, Cancer Markers, CBC, Mammography, ECG, amongst others.

8. Generic Medicines: Generic Brands are becoming integral to modern consumer culture, offering quality and affordability in a wide range of products. The market share of generic brands continues to expand, driven by consumer demand and increased trust in their offerings. As the cost-and eco-conscious consumer trends persist, the influence of generic brands is likely to continue to grow in the coming years, shaping prescription and consumer choices. 'Jan Aushadi' is becoming an increasing part of the ecosystem. BS

Navigating Future of Life Sciences Clusters in India

« **Vishal Goel,**
Managing Director,
Rx Propellant

In the dynamic landscape of global healthcare, India emerges as a promising frontier for life sciences clusters, offering a unique blend of challenges and opportunities. Globally, it is recognised within the top 12 biotechnology destinations and ranks third in the Asia-Pacific region. India's BioEconomy exceeds a valuation of $92 billion in 2022, driven by bioinnovation and biomanufacturing. Estimates show the market is likely to reach a robust compound annual growth rate (CAGR) of 13 per cent, reaching $427 billion by 2030. At the cusp of 2024, stakeholders must understand the intricacies of this sector as well as its potential to not only revolutionise healthcare but also stimulate economic growth. Let's dig deeper.

Life sciences clusters in India play a pivotal role in ensuring creating and sustaining this momentum to foster innovation, drive research collaboration, and serve as catalysts for sustained economic prosperity. India, with its vast and diverse population, is on the precipice of a healthcare revolution. The life sciences sector, comprising pharmaceuticals, biotechnology, and medical technology, has witnessed unprecedented growth in recent years. This surge in demand positions India as a key market and an attractive location for fostering innovation and developing solutions. Government policies further support this measure, actively promoting a conducive environment for businesses.

Challenges on the Horizon

While the canvas appears ripe for transformation, navigating the challenges accompanying this journey is crucial for success. Some hurdles faced by the life sciences clusters include:

1. Regulatory Complexities: The regulatory framework in India, while evolving, can be intricate and time-consuming. Navigating through approvals, compliance, and licensing processes requires a nuanced understanding of the regulatory landscape. According to the Global Innovation Index (GII) report, published by the World Intellectual Property Organisation (WIPO) every year, India's regulatory environment ranks 68th.

2. Infrastructure Deficits: The development of life sciences clusters hinges on robust infrastructure, from state-of-the-art research facilities to efficient transportation networks. Investing in such infrastructure is imperative for attracting top talent, fostering research excellence, and promoting seamless collaboration between academia and industry. As the country aims to emerge as an R&D hub, world-class infrastructure will play a key role in attracting companies to both establish and expand their footprint here. A concerted effort is needed to bridge existing gaps and position India as a global life sciences hub.

3. Talent Acquisition and Retention: The life sciences sector demands a highly skilled and specialised workforce. Attracting and retaining top-tier talent is a challenge that must be addressed strategically. A high-level committee developing science & technology (S&T) clusters in India helmed

by the Office of the Principal Scientific Adviser and NITI Aayog notes that as of 2018, India had 156 researchers per million citizens, about a tenth of the global average of 1,500, and much lower than China and the U.S, where the numbers are 1,096 and 4,217 researchers per million people, respectively. Lack of intellectual assets is a shortcoming that educational institutions, in collaboration with industry players, should address by designing programmes that align with the evolving needs of the sector, ensuring a steady supply of skilled professionals.

Opportunities to Excel Unveiled

The hallmark of successful clusters is the high level of organic activity in which stakeholders experiment with different models of collaboration and partnership, with a willingness to try new models and not fear failure. India has four primary clusters for science & technology companies, including life sciences, in the top 100, where Bengaluru ranks 56, Delhi 64, Chennai 83, and Mumbai 84. When harnessed judiciously, the challenges of cluster-based infrastructure can pave the way for opportunities that can transform the life sciences landscape here into a thriving ecosystem of innovation and growth.

1. Global Collaborations: The interconnected nature of the life sciences industry opens avenues for global collaborations. India's immense market potential has been drawing some MNCs, who play a pivotal role in boosting innovation at various levels. By facilitating collaborative ventures with local entities and undertaking knowledge exchange, they create an environment ripe for innovation, navigating complex global regulatory frameworks all the while. Indian life sciences clusters can strategically partner with international counterparts, fostering knowledge exchange, joint research initiatives, and cross-border investments. This accelerates innovation while enhancing the global standing of the Indian life sciences sector.

2. Innovation Ecosystems: Life sciences clusters provide fertile ground for innovation ecosystems to flourish. By creating environments that encourage interdisciplinary collaboration, including partnerships with technology firms and startups, clusters can serve as incubators for groundbreaking ideas. Incubation programmes, funding mechanisms, and mentorship initiatives will be vital in nurturing the next generation of healthcare innovators. Strengthening local and state-level innovation should be a priority, an area where Karnataka has made a head start. Its pioneering Research, Development, and Innovation Policy recommends this as a focus area to nurture the S&T cluster in Bengaluru and incubate other similar clusters in the state. The state has recently launched an Rs 25 crore-strong deep tech cluster seed fund to nurture startups that can significantly impact the capabilities of the life sciences sector too.

3. Market Access and Affordability: India's life sciences clusters can act as a gateway to diverse markets, aiding in clinical trials and market access. It also presents an opportunity to diversify the life sciences portfolio by incorporating traditional medicine and biotechnology to cater to a broader spectrum of healthcare needs for India's vast and diverse population, a unique market for life sciences products and services. The development of clusters should be aligned with strategies to improve market access and affordability. This includes initiatives to reduce the cost of healthcare delivery, increase the penetration of advanced medical technologies, and enhance the accessibility of life-saving pharmaceuticals.

As they expand, life sciences clusters generate employment spanning R&D, manufacturing, marketing, and sales, reducing unemployment and fostering socio-economic development. A thriving sector positions India as a key global player, capitalising on cost-effective manufacturing and a skilled workforce. This enhances exports, fortifying the nation's economic resilience. Investments in education, research, and development within these clusters contribute to a knowledge-driven economy, attracting foreign investments and establishing India as a frontrunner in the global knowledge economy.

The future of life sciences clusters in India is both a challenge and an opportunity—a canvas awaiting the strokes of strategic vision and collaborative efforts. We must embark on this transformative journey, catalysing a brighter and healthier future for the nation. BS

7 Healthcare Tech Trends to Watch for in 2024

« **Srinivas Iyengar,** Vice President-Healthcare, Happiest Minds Technologies

The healthcare industry has seen unprecedented adoption of artificial intelligence (AI) and deep tech since 2015. This has been at the forefront of the healthcare industry's transformation from being extremely tech averse to leading tech adoption in less than a decade. COVID-19 also presented many challenges to the healthcare industry and accentuated the digital chasm that needed to be bridged. The solution was to enable rapid digitalisation of healthcare that would facilitate new ways of working and addressing the challenges. As a result, 2023 saw rising investments in healthcare technology, specifically in the areas of healthcare financing, personalised healthcare, clinical decision support and AI assisted medical imaging. What, then, can we expect from the new year in this sphere? Let's explore further.

2024 is going to be a watershed moment for the healthcare industry in terms of the scale at which it adopts digital technologies and the varied use cases made possible by it. As alluded to before, the momentum has been building for the last five years with rapid digitisation of healthcare data and large-scale investments by big tech companies and it's now time to combine investments with opportunities to improve patient outcomes and drive down healthcare costs. They are also influenced by various other factors such as technology, demographics, social values and policies.

As we look forward to the new year's, here are seven of the leading healthcare megatrends that will play an increasingly important role and redefine the healthcare industry in 2024.

1. Edge computing – With the market getting flooded with powerful processors, Edge computing which is a subset of Artificial Intelligence is all set to move out of innovation trigger and quickly move towards a steady state. Edge computing brings the entire computing paradigm to the point of data collection. This also means lesser dependency on cloud computing. For example: Most surgical robots will be edge enabled and computing and decision making do not need the internet or cloud. Hospitals today prefer robotic equipment used in operation theatres not to be dependent on connectivity due to the extremely critical nature of the operations being performed. According to IDC's June 2021 Edge spending guide, healthcare provider spending on Edge will reach $10.3 billion by 2025 with a CAGR of 17 per cent.

2. Generative AI For Healthcare & LifeSciences - Generative AI is becoming a crucial technology that Healthcare & LifeScience organisations are looking at leveraging, to enhance customer outreach, service delivery and apply its potential to increase efficiencies. Areas that are in focus that we see will need Generative AI are synthesising patient summary documents, tailoring & auto-generation content that is target-specific, personalising member services, education, and communication. Other areas that healthcare

organisations are exploring today to see if there is a potential use case are onboarding management and enhanced auditing, quality management & report generation. Additionally, fraud detection could very well seek help from Generative AI and move away from rule-based programmes that they have today.

3. Data Protection and Cyber security – Data privacy and Cyber security will be top priority for healthcare organisations and governments in 2024. With widespread digitalisation and new connected medical devices becoming part of a hospital network, healthcare organisations become extremely vulnerable to cyber-attacks. More than 65 per cent of healthcare organisations today see Cyber security as their top IT infrastructure challenge. The emergence of AI and machine learning in cyber security is also set to redefine how we protect our digital assets. But it doesn't stop there – in an age where information is the new currency, protection is the best investment.

4. Genomics – We have reached a point of technological advancement where DNA can be broken down into digital code to diagnose, treat diseases, and to develop medicines that are personalised for individuals. The key to making rapid advances in genomic research is to manage large volumes of data and improve our understanding of hidden patterns which can now be done more efficiently due to the computational power of Artificial Intelligence.

5. Wearables & IoT – By the end of 2024, it is predicted that there would be more than 207 billion devices connected to the worldwide network. It should come as no surprise then that we are already seeing smartwatches enabled with Generative AI that will act as your fitness assistants and personal coaches. Microsoft Bag and Humane AI pin are some examples which use Generative AI along with wearables.

6. Amalgamation of Point of Care diagnostics and telehealth – The pandemic-era telehealth flexibility is here to stay and expand its capabilities. With the emergence of smart medical devices & diagnostics, push towards care at home models, the need of consumers to travel for their routine diagnostic tests will decline. Point of care devices will empower patients to get bedside tests, receive care and health advice without leaving their homes or being restricted by geographic boundaries at their preferred times. A simple example would be blood tests - today, blood sample collection is predominantly done at home instead of a patient having to identify and visit their nearest testing lab.

7. AI TRiSM (Trust, Risk, and Security Management) - With the evolution of GenAI for Healthcare applications, there is an evident need for tackling the potential misuse of AI models. User acceptance becomes a major driver for wide adoption of AI thereby generating better outcomes. Diagnostic solutions built adhering to the Responsible and Ethical AI governance practices makes this possible. AI TRiSM framework with solutions focussing on explainability of models used in diagnostic applications, privacy and confidentiality of health data, monitoring of AI model operations (ModelOps), solutions to prevent AI adversarial attacks are being developed and are going to be the mainstay moving forward.

Foundation of a New Healthcare Ecosystem

We are in the midst of a transformative phase in healthcare and will witness several new use-cases and disruptions made possible by the emergence of digital technologies. In 2024, Generative AI will make its way into wearables to provide for highly bespoke and personalised experiences to users while enabling greater progress in genome research. Patients will become the epicenter of the healthcare ecosystem with DNA based treatments to facilitate greater care equity and personalisation. And finally, robotics will play a more prominent role in surgeries due to significant advancements in edge computing. The megatrends also reflect the opportunities and challenges that lie ahead for providers, payers, and consumers. We will be applying the human factors principles, knowledge and research methods to enhance safety, quality and efficiency of healthcare in remote and home settings.

A lot of what is likely to happen in the next 12 months will lay the foundation of a new healthcare ecosystem that will fundamentally change how healthcare experiences are delivered for the better. BS

Combating AMR with Bacteriophages

India is among the countries with a high burden of antibiotic-resistant infections. However, in recent years, the discovery of bacteriophages, simply referred to as phages, and phage-based therapy as an alternative to antibiotics, is witnessing rapid developments. BioSpectrum brings out an in-depth report on how bacteriophages are turning out to be one of the best choices to combat antimicrobial resistance (AMR), its advantages over antibiotics, and how Indian researchers and entrepreneurs are striving to make phage therapy a clinically-validated option to combat AMR. But are the regulations in favour?

It is known that India faces a significant challenge when it comes to antibiotic resistance and the menace of superbugs (largely owing to overuse and misuse of antimicrobials). Reports say that the economic impact of superbugs is significant in our country. Even in the United States, treating antibiotic-resistant infections costs an estimated $2.2 billion in extra healthcare expenses each year. These costs include longer hospital stays, additional testing, and more expensive medications.

The World Health Organisation (WHO) warns that as these superbugs become more prevalent, our arsenal of effective antibiotics will become less potent. This makes routine medical procedures such as surgeries, chemotherapy, and organ transplants riskier due to the increased likelihood of infection. This validates the immediate requirement as an alternative to antimicrobials and researchers trust their bet on bacteriophages as that alternative.

According to ***Rachna Dave, Founder & CEO of MicroGO,*** AMR is indeed a far more significant and pressing issue than it might initially appear, primarily due to underreporting. She says, “Estimates indicate that the toll of AMR could result in more than 10 million deaths by 2023. This looming crisis is exacerbated by the extremely limited availability of new antibiotics in the market, making it an incredibly challenging problem to address. In this dire context, bacteriophages are emerging as one of the most promising solutions to combat AMR infections. With the scarcity of effective antibiotics, bacteriophages offer a viable alternative. In India, there have been approximately 200 patients successfully treated with phage therapy, boasting an impressive success rate exceeding 80 per cent. This number is steadily increasing as more clinicians and infection prevention specialists embrace this innovative technology.”

India – The land of abundant bacteriophages

Phages are natural predators of bacteria. They can infect and kill specific bacterial strains, making them valuable tools for controlling bacterial populations, especially harmful pathogens. Phages are known for being highly specific in their host range. Each phage typically infects only one or a few closely related bacterial species, which means they do not harm beneficial bacteria in the body. This specificity is advantageous for targeted bacterial treatment and avoiding disruption to the common microbiota of the host organism.

Sharing more facts on bacteriophages, ***Dr Satheesh K, Senior Research Scientist, India Diabetes Research Foundation & Dr A Ramachandran’s Diabetes Hospitals***, says, “Bacteriophages or phages thrive in environments like rivers and sewage-contaminated waters. These microscopic predators have a unique potential to latch onto particular bacterial species, inject their genetic material, and hijack the bacterial machinery to copy themselves, and in the long run causing the

bacterial cellular to burst, and launch new phage particles. In essence, they are natural bacterial killers."

India is home to an abundant variety of phages. Researchers of the ICAR-Central Inland Fisheries Research Institute, West Bengal, have detailed in a research paper that Bacteriophages are abundantly present in the river Ganga.

Atif Khan, Scientist, Water and Steam Chemistry Division, Biofouling and Biofilm Processes Section, Bhabha Atomic Research Centre, Kalpakkam, says, "India is considered to be the richest source of bacteriophages compared to any other country. If you like to talk about the competitive advantage, the opportunity lies in the phages of the bacterial host that rarely cause any diseases (Staphylococcus simulans). In case of multidrug resistant S. simulans infection, most of the labs and their surrounding environment may not have phages for this host. India could be a country where the phages can be found in a system like local sewage."

Presently, more than 20 to 30 research facilities across the country are dedicated to isolating and characterising bacteriophages, with a specific focus on combating pathogens prioritised by the Indian Council of Medical Research (ICMR).

Phage Banks and Phage Engineering

In India, where antibiotic-resistant bacterial infections are a significant public health concern and where biodiversity is high, the establishment of phage banks can be particularly important. These banks can contribute to the development of phage-based therapies, facilitate research into new phages, and aid in the control of bacterial infections in various settings, including healthcare, agriculture, and environmental management.

Furthermore, they can play a crucial role in advancing the understanding of phage biology and their interactions with bacteria in India's unique ecological and clinical contexts.

According to ***Dr Hiren Joshi, Scientific Officer, Bhabha Atomic Reserach Centre, Kalpakkam,*** "It is imperative to leverage this rich resource to establish comprehensive phage libraries and cocktails. These collections can prove highly effective against a broad spectrum of bacterial infections. By tapping into the wealth of bacteriophages in India's diverse microbial ecosystems, we can potentially develop innovative solutions for combating infectious diseases and antimicrobial resistance on a global scale. This approach holds great promise for the future of healthcare and pathogen control."

Dr Ranga Reddy Burri, President, Infection Control Academy of India opines, "Phages hold significant promise in addressing AMR due to their specificity, adaptability, and potential for personalised treatment. While there are success stories in India like AIIMS-ICMR PhageBank, ongoing research, international academia, industry collaborations, regulatory support, and clinical validation are crucial for realising their full potential as alternatives or complements to traditional antibiotics.

Talking about the bacteriophage market Dr Burri says "The current market size of bacteriophage-based products and therapies in India is insignificant at the moment. Even globally the estimated size is less than $50 million. The rising threat of AMR and awareness about the benefits of phage therapy is expected to propel market growth. The use in agriculture, veterinary and consumption as phage probiotics will be major growth drivers. Aristogene, Gangagen, Sciinv Biosciences, Vital Therapeutics, Proteon Pharma are visible players in this market."

Sharing her thoughts on the market growth Rachna Dave, says "The growth is further substantiated by recent developments, such as the establishment of a new production facility in Nasik by Proteom Biotech, a Polish company. Additionally, several other companies are currently in the process of setting up pilot-scale plants for bacteriophage production, underscoring the increasing interest and investment in this promising field."

Adding her thoughts, ***Dr Ellie Jameson, Researcher, Bangor University School of Natural Sciences, UK*** says, "The next developments that will be expanded in India and across the globe are well stocked and characterised phage banks combined with a Good Manufacturing Practice (GMP) facility for phage production. These central repositories will hold thousands of characterised, sequenced phages to ensure that they do not contain any harmful elements, but

that phages can be quickly accessed to treat 100s of different bacteria, as needed. There is a strong call to ensure that phages are manufactured to GMP standard so that phage therapy can be controlled as a drug for widespread use."

She further says "To step up phage therapy I foresee that a GMP facility for phage production will need to be established in India to keep cost manageable and enable production to meet demand. This will ensure each batch is identical and that endotoxin levels are negligible to prevent adverse effects. With these in place I believe that due to the positive stories of phage therapy it will continue to grow and work with our antibiotics to help more and more patients."

Scope to expand from diagnostics to therapeutics

Phage engineering isn't always restrained to improving the phages themselves; it additionally opens doorways to growing novel phage-based equipment for various applications. For instance, researchers at the Indian Institute of Science in Bengaluru have validated the capacity of engineered phages within combat in opposition to mycobacteria—the causative dealers of tuberculosis and leprosy. By modifying the tail fibre proteins of a mycobacteriophage, they were able to apprehend distinctive receptors on the floor of mycobacteria. These engineered phages successfully lysed various lines of Mycobacterium tuberculosis and Mycobacterium leprae in both laboratory settings and in vivo.

Regulatory hurdles and market boundaries

India, though, has developed a National Action Plan on Antimicrobial Resistance (NAP-AMR) to address the growing threat of antibiotic resistance, plans that include strategies for promoting responsible antibiotic use, improving surveillance, and enhancing infection prevention and control need to be hastened along with making phage therapy a viable option.

Also, Dr Burri says that regulatory authorities classify bacteriophages as biological substances and currently, there is no established framework that explicitly defines the role of bacteriophages in the context of medicinal products for human use in India and globally. Very few countries have clear regulatory pathways.

One such example is Georgia, where bacteriophages have been seamlessly integrated into the healthcare system as a standard medical practice, and a range of phage preparations are

"I anticipate substantial global growth in phage therapy"

« **Pranav Johri,** Founder, Vitalis Phage Therapy and a Fellow of the Society of Bacteriophage Research and Therapy

Johri is a pioneer in establishing a company based on phage therapy. In a brief discussion, Johri reveals what led him to founding Vitalis Phage Therapy and his outlook to the future of bacteriophage therapy in India. ***Edited Excerpts:***

What made you venture and create a company based on phage therapy?

My personal experience with phage therapy, which proved to be a successful treatment for my multi-drug resistant infection in 2016, inspired me to establish Vitalis Phage Therapy, India's foremost phage therapy initiative. In 2016, I was diagnosed with chronic bacterial prostatitis, caused by a multidrug resistant polymicrobial infection. After months of extensive research, I embarked on a journey to the renowned 100-year-old Eliava Institute of Bacteriophages, Microbiology, and Virology to undergo phage treatment for my condition. The successful outcome of phage therapy in treating my multi-drug resistant infections fuelled my commitment to raise awareness of and provide access to phage therapy in India, ultimately resulting in me establishing Vitalis Phage Therapy. Thereafter, Vitalis inked partnerships with the Eliava Institute and the Eliava Phage Therapy

Centre to develop the necessary infrastructure for phage therapy in India.

What market opportunity do you envisage for phage therapeutics in the years to come?

The issue of antibiotic resistance is escalating worldwide. Forecasts predict increased fatalities due to antibiotic-resistant infections by 2050. The extensive and inappropriate use of antibiotics during the COVID-19 pandemic further amplified this trend. I am of the opinion that phage therapy represents one of the most promising approaches to combatting multidrug-resistant infections, thereby lessening the severity and fatality rates associated with such infections. Looking ahead, I anticipate substantial global growth in phage therapy. This growth will be propelled by increased phage research at academic institutions, the establishment of phage therapy units in hospitals, and the widespread adoption of phage therapy in cases where patients suffer from drug-resistant infections.

How do you think India has to progress in making phage therapy as the most suitable way of tackling AMR?

While India is the land where phages were first discovered over a century ago, our healthcare systems are still far away from adopting phage therapy as an efficient way to tackle AMR. Currently, phage therapy is only available as compassionate treatment for patients whose infections have become multidrug resistant.

To reach a situation where phage therapy is readily available and can be deployed by doctors across the country, from big cities to small towns, the following steps need to be enforced:

Awareness - Large scale awareness campaigns are needed to educate the healthcare sector of the mechanism and utility of phages in cases of antibiotic resistant infections.

Development of Phage Banks - Phage research and development needs to be accelerated so that as awareness increases, ready-to-use phage banks are made available at the same time for patients for whom antibiotic use is no longer an option.

Clinical Trials - These are needed to study the clinical application of phages so that they can be regulated for use beyond compassionate treatment. BS

available over-the-counter, along with a more extensive selection of products supplied directly to medical practitioners. The US FDA also approved several phage treatments, which are employed in the food industry, largely in the dairy and meat industry, to combat bacterial growth. To fuel rapid progress towards phage therapeutics, as a sustainable antibiotic alternative, regulatory processes must be refined and should be pragmatic to reach a tipping point sooner.

We cannot deny that India has made progress in adopting phage therapy, but to make it a more mainstream solution to combat AMR, concerted efforts in research, regulation, education, and infrastructure development are crucial. Collaboration between all the stakeholders and a dedicated approach from both government and private sectors will be essential. The funding into this sector is mostly from grants, philanthropy, altruistic researchers, and good Samaritans only.

There is a need to promote this therapy in the country. “The level of public awareness and acceptance of bacteriophages as an alternative to antibiotics in India is abysmal,” says Dr Burri and adds that compared to more established treatments like antibiotics. Even among healthcare professionals, the awareness is low, which is a significant deterrent to mainstreaming this alternative. Organisations like Society for Bacteriophage Research and Therapy, Infection Control Academy of India and others are working towards awareness and providing a platform for researchers, clinicians, and other stakeholders to collaborate.

Traditional life science and biotech companies have no participation in research or investments in this segment as the perceived demand is low and the risk of return is high. Maybe, providing incentives and financial support, including grants, tax incentives, or other financial benefits, to encourage investment for budding companies could be a possible way to lure them into phage therapy development.

Hence, in conclusion, it can be said that India has to step-up and establish clear regulatory pathways for phage therapy, ensuring safety, efficacy, and quality standards. The country needs specific guidelines and protocols for the approval and use of phage therapy. It is also important for the government to facilitate collaborations between pharmaceutical companies, research institutions, and government bodies to foster the development and distribution of phage therapeutics. BS

Anusha Ashwin

Dr Jitendra Singh, Union Minister of State (Independent Charge) Science & Technology releasing the India Bioeconomy Report 2023, along with other dignitaries, during the inaugural function of Global Bio-India 2023 Summit on December 4, in New Delhi.

Global Bio-India 2023

From Niche to Giant: India's Ambitious Bioeconomy Plan

India's bioeconomy currently accounts for nearly 4 per cent of our $4 trillion national economy. While the innovation ecosystem continues to flourish, and we aspire to become one of the top 5 global biomanufacturing hubs and among the top 10 biotechnology destinations globally, the government is providing a boost to both 'Make in India' and 'Startup India' initiatives for the biotech sector by making the Global Bio-India summit an annual event. The Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India and its Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC) are making numerous attempts to translate the vision that India's bioeconomy reaches $300 billion by 2030 and accounts for 5-6 per cent share of India's GDP.

Positioned as a business meeting that provided an engagement platform for the industry, startups, entrepreneurs, investors, regulators, incubators, public & private enablers, philanthropic organisations and relevant stakeholders, the Global Bio-India 2023 summit focused on biotech innovation, bio-manufacturing and its impact on the bioeconomy of the country, from December 4-6, when it took place in New Delhi. The event offered diverse opportunities for Indian biotech companies to showcase their innovations, products, and capabilities to a global audience.

"The world is looking up to India as an emerging biomanufacturing hub, and the biotechnology startups and institutional linkages with industry will drive India's bioeconomy in the years to come", said ***Union Minister of State (Independent Charge) Science & Technology Dr Jitendra Singh*** while inaugurating the 3rd edition of the Global Bio-India event.

He further said, "Biotechnology has

emerged as a trending career option among our youth, with tools like synthetic technology, genome editing, microbial bioresources, and metabolic engineering gaining increased attention."

The inaugural session of Global Bio-India 2023 was also addressed by Prof. Ajay Kumar Sood, Principal Scientific Adviser (PSA) to the Government of India; Dr Abhay Karandikar, Secretary, Department of Science & Technology; Dr Rajesh Gokhale, Secretary, Department of Biotechnology (DBT); Kiran Mazumdar-Shaw, Executive Chairperson, Biocon; Dr Jitendra Kumar, Managing Director, BIRAC; Freddy Svane, Ambassador at the Royal Danish Embassy; GS Krishnan, President, Association of Biotechnology Led Enterprises (ABLE); Dr Shirshendu Mukherjee, Mission Director, Grand Challenges India and Dr Subhra R. Chakrabarti, Director (Operations), BIRAC.

Laying the focus on India's current bioeconomy which stands at $137.24 billion, ***Dr Kiran Mazumdar Shaw, Executive Chairperson, Biocon*** said, "We need to set a new target for India's bioeconomy for 2025. We are set to achieve the target of $150 billion by the end of this fiscal. This means that a new target of approximately $200 billion lies ahead of us for 2025 now."

She also pointed out that scaling up of startups is a big challenge in our country that needs to be addressed. "The lab-to-market journey for the startups needs to be reduced. We should look at the US market, for instance. Biotech companies in the US get huge amounts of investment from venture capitalists because these VCs have an exit to capital markets which is missing in India. We should sensitise capital markets to back good ideas. We cannot depend entirely on the funds being provided by the government."

"The Department of Science and Technology, Government of India has several initiatives in the biotech innovation ecosystem and biomanufacturing, and there is a need to scale such efforts to a level where bioeconomy becomes a significant contributor to our GDP and India's economy. For that, we need a risk capital within the innovation ecosystem", pointed out ***Dr Abhay Karandikar, Secretary, Department of Science & Technology.***

Emphasising on the biotech startup sector, ***Dr Rajesh Gokhale, Secretary, Department of Biotechnology*** said, "The year 2022 has seen a rise in Private Equity (PE) and Venture Capital (VC) investments in the biotech industry, reaching a record-breaking $938.8 million, a 19 per cent growth compared to the previous year. The entrepreneurial landscape has also flourished, with 1391 new biotech startups joining the ecosystem, marking a significant chapter in innovation."

In his address, Prof. Ajay K Sood highlighted the importance of the biomanufacturing revolution and its transformative impact. He underscored the crucial role of the bioeconomy in the realisation of India's green emission goals. Prof. Sood also mentioned the significance of increased participation of biotech innovators in empowering the innovation ecosystem and contributing to India's self-sufficiency.

To support the deep tech startup ecosystem, ***Prof. Ajay K Sood, Principal Scientific Adviser (PSA) to the Government of India*** said, "The role of deep tech startups in bioeconomy is essential. The deep tech startup policy has been prepared and a Cabinet note is now being prepared with important recommendations."

Providing an overview of the entire Global Bio-India 2023 summit, ***Dr Jitendra Kumar, Managing Director, BIRAC*** said, "While India is still to emerge as an epicentre for capital access for biotech innovations, it definitely can be showcased as an innovation hub and a large market at the global level. Events like this can effectively facilitate not only the capital inflow to India from global players but also attract large global corporate to set up their R&D and manufacturing base in India. This coupled with DBT-BIRAC's plan for setting up biofoundries will have a combined effect of augmenting India's leadership position in biotechnology."

The inaugural day also witnessed the participation of ***Ashok Chandra Panda, Minister of Science & Technology, Government of Odisha.*** "The Odisha government is prioritising the biotech sector. While a special Biotech Park has been instituted by the government at Andharua near Bhubaneswar, a second biotech park might soon come up. Along with this, the new

Dr Rajesh Gokhale, Secretary, Department of Biotechnology (DBT); Vaidya Rajesh Kotecha, Secretary, Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH); Dr Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC), along with other dignitaries, sharing the stage with the winners of Global Bio-India 2023 awards.

Leading biotech innovators shine at Global Bio-India 2023 Awards

- Gennova Biopharmaceuticals, Bharat Biotech International, Zydus Lifesciences and Biological E (Outstanding contribution to pandemic management)
- Serum Institute of India (Affordable vaccine development)
- Eyestem Research and Levim Biotech (Innovator award in Healthcare-Therapeutics and Vaccines)
- Althion Tech Innovations (Innovator award in Healthcare- Devices & Diagnostics)
- OmniBrx Biotechnologies (Innovator award in Industrial Biotechnology)
- Acsen Hyveg and ICAR- Indian Agricultural Research Institute, Kullu (Innovator award in agriculture)
- Salcit Technologies and Christian Medical College, Vellore (Innovator award in artificial intelligence)
- Haystack Analytics (Innovator award in genomics)
- Bangalore Bioinnovation Centre (Best bioincubator in tier I)
- BioNEST Punjab University, Chandigarh and Yenepoya Technology Incubator, Mangalore (Best bioincubator in tier II)
- Association for Bio-inspired Leaders and Entrepreneurs of SASTRA TBI (ABLEST), Thanjavur (Best bioincubator in tier III)
- Centre for Healthcare and Entrepreneurship, IIT Hyderabad (Best Bioincubation Centre Exhibit)
- Pragmatech Healthcare Solutions (Startup award in Healthcare- Devices & Diagnostics)
- Zzwick Hygiene (Startup award in Healthcare-Therapeutics)
- Greenshift Energy (Industrial Biotech award in agriculture)
- Chimertech (Startup award in aquaculture and veterinary)
- Ahammune Biosciences (Award for Woman Entrepreneur)
- Water & Soil from Hungary (Award as an international participant)

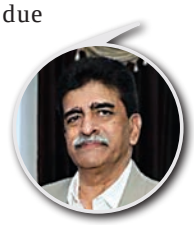
biotechnology policy that the state government is going to bring shall be instrumental in the rapid growth of bioeconomy in the state", he said.

ABLE announces launch of Bioeconomy Report 2023

Significant achievements of the national bioeconomy have been recorded in the India Bioeconomy Report 2023, brought out by the Make in India cell of DBT-BIRAC in partnership with the ABLE, which was launched during the inaugural session of the Global Bio-India 2023 summit.

According to the report, India's bioeconomy experienced robust growth in 2022, surging by 29 per cent to reach a substantial value of $137.24 billion. The dominant player has been the bioindustrial sector with $59 billion, followed by biopharma at $49.8 billion.

"The significant increase in India's Bioeconomy value for 2022, at $137.24 billion, is due to the inclusion of several categories of products in the Bio-industrial segment that use a key biotech product, enzymes, in a variety of ways to enhance its performance, use as catalysts in the manufacture of many other products as the country strives to incorporate more sustainable processes in the entire value chain of such products. In past reports, these aspects of enzyme use and their critical role in several product categories were underplayed due to non-access to some related data. This data gap has now been bridged after a lot of discussion with the experts engaged in this segment", said ***G S Krishnan, President, ABLE.***



The report further highlights that

Dr N. Kalaiselvi, Director General, Council of Scientific and Industrial Research (CSIR), and Dr Rajesh Gokhale, Secretary, Department of Biotechnology (DBT), along with other dignitaries, at the launch of JanCARE health-tech products for low-resource setting.

JanCARE health-tech products launched for low-resource setting at Global Bio-India 2023

- Spandan Portable ECG device (Sunfox Technologies)
- AI wearable-based virtual maternal care platform (Savemom)
- AI-assisted telepathology platform for improved diagnostic access (Onward Assist)
- Clinical chemistry analyser HaemurEx (Arogyam Medisoft Solution)
- Deep tech screening tool for dyslexia screening in children (Giftolexia Solutions)
- Multi-speciality e-clinic (Yuvitel Technology)
- AI/ML-based screening tool for neonatal infections and antibiotic resistance (Avyantra)
- Computational pathology platform (Aindra Systems)
- Virtual reality Metaverse platform to check brain functionality in children (Embright Infotech)

a total number of 35,000 cumulative startups is projected for 2030, and 13,470 for 2025. The entrepreneurial landscape in India witnessed dynamic growth in 2022, with startups emerging as key drivers of economic development. Maharashtra, Karnataka and Telangana led the way in 2022, a year which saw a total of 1391 startups getting registered, reflecting a substantial 23 per cent growth from the previous year's count of 1128.

In a groundbreaking achievement, Molbio Diagnostics achieved unicorn status following a remarkable funding round led by Temasek, which raised an impressive $85 million. This significant investment catapulted the company's valuation to a staggering $1.53 billion, showcasing an 8X increase from its previous valuation of $182.7 million. This milestone positioned Molbio Diagnostics as the second unicorn to emerge from India in September 2022 after Tata1MG.

While the bioeconomy presents immense opportunities, it is not without challenges. Pandemic-related volatility, for instance in the vaccines and diagnostics space, underscores the need for flexible strategies and continued investment in research and development for rapid response capabilities. Additionally, strong regulatory support and infrastructure development are essential for capitalising on emerging opportunities, emphasising the importance of collaboration between the government and industry stakeholders.

BIRAC inks MoUs with global organisations

Announcements regarding a few Memorandums of Understanding (MoUs) between Indian and international organisations and BIRAC were made during the Global Bio-India 2023 event.

BIRAC has signed an MoU with Germany-based Miltenyi Biotec for cell and gene therapy research. With its expertise in providing reagents, instruments, and services from research to clinical grade, Miltenyi Biotec will enable investigators in India to take early discoveries to clinical translation and commercial

New product launches at Global Bio-India 2023

- Liraglutide biosimilar for Type 2 diabetes treatment- Levim Biotech
- Fibroplug - Fibroheal Woundcare
- CHI-1-Chemically defined serum-free medium and feed - HiMedia Laboratories
- CellBRx-IST system for manufacturing of vaccines and viral vectors - OmniBRx Biotechnologies
- Surgical device DermaDice - Pacify Medical Technologies
- OncoDiscover - Actorius Innovations and Research
- BioSampler - IOTA Diagnostic
- NIBRA-CS for autonomic neurofunction testing - Inovocare Healthsoft Solutions
- Waterless solar panels self-cleaning technology - iPanelKlean Solar
- Water retainer system - Water & Soil
- Medically treated biobubble bedsheets for children- Fabiosys Innovations
- A reconstructed melanoma model - Biodimension Technology
- Single buffer system and PCR clean-up combo kit - Annapurna Biotech
- India's first vegan 'BioGuru3F Pro: Bio fermented fish feed - Translational Research and Innovations

manufacturing.

"This partnership with BIRAC is a one-of-its-kind. We are now entering India through this crucial collaboration. We want to enable scientific research in the country, focusing on enhancing cell and gene therapy capabilities; GMP manufacturing; to build a centre of excellence", said ***Annapurna Das, Area Head-India and South East Asia, Miltenyi Biotec.***

Another MoU has been signed with Japan-based Takeda Pharmaceutical to extend advisory and mentoring support to innovators and entrepreneurs while assisting them from ideation to market deployment of new-age healthcare solutions. The collaboration resonates with BIRAC's vision to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry for the creation of affordable products addressing the needs of the largest section of society.

"This partnership serves as a practical blueprint, highlighting how public and private players can join forces to propel substantial and enduring advances in healthcare", said ***Serina Fischer, General Manager, Takeda Biopharmaceuticals India.***

MoUs with the Foreign, Commonwealth and Development Office (FCDO) in the UK; and with India Health Fund have also been signed.

Current scenario of biomanufacturing in India

With biomanufacturing being identified as a priority area, especially for promoting 2G ethanol, bio-gas, enzymes, smart proteins, cell and gene therapy, vaccines, diagnostics and other biologics for human, plant and veterinary applications, exclusive meetings and panel discussions were held between the industry and government at the Global Bio-India 2023 summit to devise the final policy.

According to ***Sanjay Singh, Chief Executive Officer, Gennova Biopharmaceuticals,*** "We need to focus on how to boost the biomanufacturing segment in India with the utilisation of next-gen technologies, upskilling of the workforce, investment plans by the government, upgrading systems for biosafety, etc."

Sharing his thoughts on India's emerging role in the biomanufacturing sector, ***Dr Manish Diwan, Head - Strategic Partnership & Entrepreneurship Development Mission Incharge - Make In India for Biotech sector, BIRAC*** said, "Biotech product manufacturing requires high-end infrastructure, running cost, and skilled human resource. This also requires ecosystem support consisting of a talent pool driving innovations, funding support, regulatory and compliances to meet safety and efficacy/ efficiency. At present, a major proportion of products, equipment, reagents and tools for R&D and manufacturing are import-centric. Biomanufacturing upscaling in India is aimed to reduce this imbalance and import dependence by indigenisation of such finished goods and intermediaries. The innovation ecosystem acting as the flywheel completes the cycle of creating innovation-led solutions pipeline for addressing the unmet needs."

Other sessions during the Global Bio-India 2023 summit included topics such as cell and gene therapy, artificial intelligence (AI) and big data, sustainability, smart protein, genomics for personalised medicine, bio-based energy, and biologics.

Laying focus on Women in Biotech

The Global Bio-India 2023 summit saw the launch of numerous products by women-led biotech and health-tech startups, in the presence of dignitaries from the Council of Scientific & Industrial Research (CSIR), DBT, BIRAC, National Association of Software and Service Companies (NASSCOM) and TiE.

In addition, prizes worth Rs 25 lakh each were handed over to three women entrepreneurs for developing ground-breaking healthcare solutions, as a part of Women Biotech WInER Fellowship Awards- Pooja Goswami (Ramja Genosensor); Santosh Jangir (Newndra); and Rachna Dave (MicroGo).

An announcement of the 5th edition of BIRAC-TiE WInER Fellowship awards was also made during the event. Through the WinER Award (Women in Entrepreneurial Research) in association with TiE Delhi, BIRAC has been rewarding women in biotech entrepreneurship, to help all women startups excel in their field.

Dr N. Kalaiselvi, Director General, Council of Scientific and Industrial Research said, "BIRAC and DBT are doing a wonderful job in supporting biotech innovations in India, particularly the work being done by women entrepreneurs. With so many new products being launched so rapidly, I am looking forward to the future of digital healthcare in our country."

JanCARE health-tech innovations for low resource setting

At the Global Bio-India 2023 summit, numerous products by health-tech startups were unveiled as a part of the JanCARE Healthcare Innovation Challenge.

Along with the innovative products, the JanCARE Healthcare Innovation Challenge Field Deployment Report was also launched, which showcases the on-ground impact created by 15 health tech innovative solutions developed by the startups. These solutions have been deployed in primary and community health centres across 12 states bringing together state governments, industry and other stakeholders.

JanCARE in collaboration with Grand Challenges India (GCI), is a nationwide "Discover – Design – Scale" programme, envisioned to identify innovative health-tech solutions from startups for strengthening healthcare delivery in India.

In addition, SPARSH Social Innovator (SPARSH Fellows) awards were given to Abhishek Gaikar (Atal Incubation Centre- CCMB); Madhura Vinod Jadhav (Maker village); and Ekshika Bhagtani (Foundation for Innovation and Technology Transfer or FITT).

New products launched by women-led startups at Global Bio-India 2023

- Micro-Biozyme (Greenathon Technologies)
- Pesticide Smart Check (Agrovrddhi)
- MoveAxon (SynerSense)
- NaturActiv+ (Capsber Global Agro)
- Antimicrobial resistance detection biosensor (Ramja Genosensor)
- Sydantek ECG (Carditek Medical Devices)
- Remote healthcare interactive machine (Medaara)

Key Highlights of Global Bio-India 2023

- 300+ exhibits by Biotech Startups/SMEs
- 100+ Biotech Incubation centres
- 30+ Large Industries, Services and CROs
- 10 States' representation for promoting their Biotech policies
- 25 Universities and Research Institutions
- 30+ Country representation
- 40+ Startup pitches to Investors
- 100 Investors, Angels, VCs, HNIs
- Masterclass for Startups- Art of Pitching
- Public sessions on Science connect with society
- CEO Round tables – MNCs representing Biopharma, Medtech, Diagnostics, Industrial Biotech, Bio-Agri sectors
- Stakeholder Discussion on National and Global Regulatory Trends
- Sessions on Biomanufacturing and Biotech Innovation Ecosystem
- Industry-Academia interactions
- Biopartnering and B2B meetings

What's in store for the future?

Previously, two editions of Global Bio-India have been conducted in the years 2019 and 2021 and have been very well received by the national and international stakeholders. Taking the legacy of the Global Bio-India summit forward, Dr Jitendra Kumar, Managing Director, BIRAC, has announced the dates for the 4th edition which is all set to take place between September 19 and 21, 2024. Dr Jitendra Kumar also announced that the government is working towards developing a Global Bioincubators Network to further support the startups. BS

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L-R- M B Patil, Minister for Large & Medium Industries and Infrastructure Development, Government of Karnataka; D K Shivakumar, Deputy Chief Minister, Government of Karnataka; and Priyank Kharge, Minister for Information Technology (IT), Biotechnology (BT), Government of Karnataka, unveiled the draft Biotechnology Policy 4.0, along with other dignitaries, at the inaugural function of Bengaluru Tech Summit 2023 on November 29, 2023.

Bengaluru Tech Summit (BTS) 2023

Karnataka announces draft Biotechnology policy 4.0

Karnataka has been at the forefront of the Indian biotechnology industry, owing to the prevailing ecosystem of the state. The bioeconomy of the state grew to $27.1 billion in 2022, with 155 new biotechnology startups getting registered in the state in 2022, on an average a total of 13 biotech startups every day and a cumulative total of startups grew to 632. Further, Karnataka's biotech R&D spent crossed $200 million. Adding to these developments is the successful execution of the Bengaluru Tech Summit 2023, that took place from November 29 to December 1, 2023 putting a spotlight on the biotech sector of Karnataka.

At the inauguration of the 26th edition of Bengaluru Tech Summit (BTS) 2023 on November 29, 2023, Government of Karnataka's flagship event, Priyank Kharge, Minister for Information Technology (IT), Biotechnology (BT), Government of Karnataka, along with other dignitaries, unveiled the draft Biotechnology Policy 4.0, based on inputs gathered by the Association of Biotechnology Led Enterprises (ABLE) from many industry and academic experts in the State.

The first two millennium Karnataka Biotech Policies laid the foundation for an advanced biotechnology ecosystem in Karnataka and the third policy focused on to provide direction and support to the sustainable development of a thriving and world-class biotech ecosystem.

Also, the past policies have laid solid foundation, and provided required support and impetus leading to a matured ecosystem which has now reached the desired inflection point to bring the real 'Transformation'.

Hence, the focus of policy 4.0 will be 'transformation through impactful implementation' to take the growth from a linear to exponential level.

The new policy intends to support the concept of High-Tech Biotech Clusters (5- 10 acres) wherein the

developed industry would be encouraged to set-up their manufacturing units and support startups and SMEs with plug and play facilities.

The state proposes to set-up a green-field Bio Foundry at Bengaluru Helix Biotechnology Park as a joint venture between the Centre, under the Department of Biotechnology (DBT) initiative of 'Fostering High Performance Biomanufacturing' and the private sector. The private partner apart from investing in the project will also take on the responsibility of managing and operating the facility.

The government will support the establishment of Vaccine Research & Pilot Production Facility on Viability Gap Funding. The government further intends to support and incentivise setting up bio-manufacturing units related to CAR-T, mRNA vaccines, antimicrobial resistance (AMR) drugs, biofuel and alternate foods.

Also, the government will consider servicing a detailed study to chalk out the growth strategies and set-up support systems for setting up collaborative centres that can enable faster access to sites and patients for top pharma players for diseases with high unmet need.

Efforts are currently being made with support of the IT BT Department, Government of Karnataka to get feedback and further inputs on the draft policy, to come out soon with the futuristic Biotechnology Policy 4.0 for Karnataka.

Backing biotech innovation

The Karnataka Innovation and Technology Society, (KITS) and the Department of Agriculture, Government of Karnataka has announced a partnership with the Centre for Cellular and Molecular Platforms (C-CAMP) at the formal launch of Phase II of two of C-CAMP-KTech flagship innovation programmes, one in the agriculture domain and the other in the startup acceleration for scale-up of Karnataka's rapidly growing biotech startup community.

At the Bengaluru Tech Summit 2023, Government of Karnataka launched the Agri Grand Challenge II with problem statements relevant in plant pest and disease mitigation, post-harvest loss, cash crops processing and dairy farming domains.

Further, C-CAMP with the support from the government has initiated the Karnataka Startup Advancement Programme (K-SAP) BIO 50 for giving Karnataka based startups in the life sciences a global edge. In Phase II, C-CAMP will move towards scale up support of startups at the early and mid (venture-funded) stages through fast-tracking milestones and closing gaps in the last mile to market.

The event also saw the signing of a Memorandum

L-R- Priyank Kharge, Minister for Information Technology (IT), Biotechnology (BT), Government of Karnataka; D K Shivakumar, Deputy Chief Minister, Government of Karnataka; Dr Ekroop Caur, Secretary, IT, BT and S&T, Government of Karnataka; along with (behind) Darshan H.V, Director, Department of Electronics, IT & BT; Prashant Prakash, Chairman, Startup Council, Mission Startup Karnataka; and Jagdish Patankar, Executive Chairman, MM Activ Sci-Tech Communications.

New product launches at BTS 2023

- Skullmate (Armanium)
- Indoor Air Quality Improvement system (Tad Aircon)
- BioTraptor (Neofysis Biotech)
- Oxygen generator (Mystic clean energy tech LLP)
- Clean Air Helmet (Personal Air Quality Systems)
- Eye & Oral Screening Solution (Logy.AI)
- DocTrue Virtual Queuing App (DocTrue Technologies)
- Iom Gut Sens (Iom Bioworks)
- EyeD (Autoyos)
- Fertilator (Reprosci Biosciences)

Smart Bio Award Winners 2023

- **Innovator of the Year:** ImmunitasBio Pvt Ltd
- **Startup of the Year:** Cambrian Bioworks Pvt Ltd
- **Startup of the Year (Beyond Bengaluru):** Cosmos Bio Pvt Ltd
- **Startup of the Year (Campus):** Papersens Private Limited
- **Woman Entrepreneur of the Year:** Dr Pooja Tiwari (AAARNA Therapeutics Pvt Ltd)
- **Best Social Enterprise/Institute:** Foundation for Neglected Disease Research (FNDR)

Dr Raghunath Mashelkar, Former Director General of the Council for Scientific and Industrial Research (CSIR), delivered a Plenary Address at the Bengaluru Tech Summit 2023.

of Understanding (MoU) between Opportunities New Brunswick (ONB), Canada and the Association of Biotechnology Led Enterprises (ABLE). The MoU was signed by Narayanan Suresh, Chief Operating Officer, ABLE and Sushil Rana, Country Head- Trade & Investment, ONB, Government of Canada.

As a part of this MoU, ABLE will actively seek to educate and inform its members regarding New Brunswick, its economy, business ecosystem, government policies and initiatives with respect to various sectors. ABLE will also organise webinars, discussions, and talks to enable interactions between ONB and ABLE members.

Many panel discussions on biotech innovations were also held during the summit. For instance, a vibrant fireside chat on the topic, 'Basic Research to High-Impact Innovation' between Dr Kiran Mazumdar-Shaw, Executive Chairperson – Biocon, & Chairperson, Vision Group on Biotechnology, Government of Karnataka and Dr H. Robert Horvitz, Nobel Laureate & American biologist, revolved around India's investment focus in basic scientific versus applied research, advocating for government support in fundamental research through academic centres.

Dr Horvitz emphasised the importance of a balanced research portfolio, drawing from his experiences as both a researcher and entrepreneur. He highlighted the transformative impact of research on patient recovery, stressing the need for an open-minded, opportunistic approach to one's career journey, reflecting on his diverse academic background in English, maths, and physics, culminating in a career in biology. The dialogue underscored the necessity of diverse research investments, governmental backing for fundamental research, and the value of adaptability in shaping a fulfilling professional trajectory.

Another interesting discussion on the topic, 'India's Dynamic Role in the Biotech Landscape' had Dr Rajesh Gokhale, Secretary, DBT, virtually addressing the audience by stressing on India's emergence as a significant player in the global biotechnology sector, making substantial contributions to pharma biotech, industrial biotech, and bioenergy.

Further, a session on the topic "Biotechnology for a Fossil Carbon-free Future" was held. Discussions during the session explored diverse areas, including the utilisation of algae for sustainable aviation fuel, genetic engineering for advanced biomaterials, and waste-to-fuel technologies. The overarching theme highlighted the urgency to adopt sustainable practices in response to rising global temperatures and greenhouse gas emissions. Speakers emphasised the role of biotechnology in driving economic growth while prioritising environmental consciousness.

The Summit also featured a thought provoking session on biotech regulations, where Narayanan Suresh delved into Karnataka's biotechnology policy, research methodology, the biotech ecosystem in Karnataka, the ease of doing business, and initiatives promoting startups and entrepreneurship. He also discussed policy objectives, projects enhancing social impact, emerging biotechnology sectors and emphasised the crucial role of skilling in the biotech sector.

On the third day of Bengaluru Tech Summit 2023, Dr Raghunath Mashelkar, Former Director General of the Council for Scientific and Industrial Research (CSIR), delivered a Plenary Address. Known as the Father of Innovation in India, Dr Mashelkar indicated that Karnataka must now move from incremental growth to exponential growth.

New product launches, opportunities & recognition

The Department of Electronics, IT, BT, and S&T, Government of Karnataka, unveiled many ground-breaking products and solutions developed by startups during the 26th edition of the BTS 2023, especially in the field of health-tech and medtech.

BIO-Quiz 2023 showcased India's immense talent in biotechnology, encouraging students to explore the subject deeply. Bevan Mathew emerged as the winner, with Sancheti Kalyani as the runner-up. And, the Bio Poster exhibition featured innovative concepts in life sciences & biotechnology, providing a platform for young researchers to present ground-breaking ideas.

In addition, biotech innovators were given recognition by the Karnataka government in the form of Smart Bio Awards. BS

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Strategies for Sustainable Growth: Navigating Challenges for Biotech Startups

The incorporation of new biotech startups in 2022 marked a remarkable chapter in the entrepreneurial landscape. With a total of 1391 startups formed, the year not only showcased quantitative growth but also witnessed an impressive 23.3 per cent increase in the startup growth rate. This surge, compared to the previous year, highlights the resilience and adaptability of entrepreneurs amidst many challenges.

In a recent webinar organised by BioSpectrum, titled "Navigating the Biotech Investment Landscape," experts from diverse backgrounds in biotechnology and entrepreneurship shared their valuable insights into the challenges and opportunities facing startups in the biotech industry in India.

The webinar focused on the unique hurdles encountered by biotech startups, especially in the context of the COVID-19 pandemic, shedding light on securing funding, technological developments, market entry of innovative products and exit strategies.

Dr Shalini Singh, Funding Specialist, Venture Center highlighted the journey of startups in the biotech space and the role of business incubators in technology commercialisation. "There is availability of different forms of government funding for startups at different stages, whether it is an idea stage, at proof of concept, validation stage, early stage trial or commercial production. For instance, for a startup at an idea stage, a monthly funding of Rs 30,000 is there, for a startup with a proof of concept, we have funding worth Rs 10-50 lakh. Then for seed funding, an amount anywhere between Rs 30 lakh and Rs 1 crore is available", she said.

"Even though there are lots of funding avenues available, the amount of funding provided by these agencies is not enough to suffice the current needs of the startups. There is a need to have a funnel sort of a thing wherein 100s of grants are available in which at least 5-10 good companies can come up providing better investment space", she further added.

Sharing his views on the funds-related challenges, ***Rupinder Singh, Investor, Advisor & Startup Evangelist*** said, "The rising capital is critical for survival, and meticulous planning is required to ensure a seamless business model, considering specific timelines and financial needs. While the government grant agencies like BIRAC have a fair amount of understanding about the ideas being generated by the biotech startup companies, venture capitalists at times have concerns. They find it difficult to invest in biotech-based ideas as the gestation periods are longer." He further said that the biotech sector is a garden with a high wall, once you get onto it, you will reap the fruits for a longer period as biotech startups are not easy to wind up.

The discussion acknowledged the multitude of funding options that are available today, from angel investors to venture capitals (VC) and private equity (PE) funding. Despite the evolution in the Indian startup ecosystem, caution was advised against depending solely on government funding. The need for multiple revenue streams to ensure sustained growth and overcome potential delays in funding was underscored.

While securing sufficient funds is a hard task for biotech startups in India, revenue generation is equally critical. According to ***Manish Amin, Director, Avay Biosciences,*** "Beyond funding, revenue is the linchpin for success. Relying solely on government agencies like BIRAC may not be sufficient, and the runtime of a company becomes pivotal, making revenue generation a significant factor in defining its future trajectory."

A key element highlighted by Manish Amin is the trust factor. In addition to research endeavors, revenue generation emerges as a crucial factor for a

Biotech startups should emphasise on planning before applying for regulatory approvals. Startups should create checklists, seek expert advice, and collaborate at the right time for successful execution. Collaboration, seed funding, subsequent funding, and revenue generation plans are all crucial for long-term sustainability of a startup.

startup's sustainability, and building trust within the industry is essential, where revenue plays a major role in establishing credibility and long-term viability for a biotech startup.

In sync with this thought, ***Dr Prabhakar Kulkarni, Chief Executive Officer, NeoDx Biotech Labs*** said, "Irrespective of the industry, startups should have a set of revenue-generating ideas to maintain a runway for a specific period. This principle is not exclusive to biotech but holds true for fintech or FMCG startups as well."

"As entrepreneurs, initial investment, both in terms of money and time, is crucial. To sustain growth, continuous pitching of ideas and the formation of a strong team are vital", added Dr Kulkarni. He further stressed on the importance of diversifying the product portfolio to mitigate risks.

Further to this, Manish Amin noted that post-COVID-19, the government's initiatives have been instrumental in supporting startups. He commended the development of events such as Global Bio-India summit to attract investors' attention and foster collaboration among like-minded individuals globally. To increase revenue streams, he advocated for global platforms that bring together innovators to understand each other's needs.

Building on new product development, Manish Amin emphasised on the importance of incorporating suggestions & expertise of academicians, researchers, & domain-specific experts. "Product fitment is crucial for market competitiveness against global players. Maintaining a balance & fostering collaborations are essential for startups' success", he said.

Amin spoke about the importance of research, patent filing, and acquiring more intellectual properties (IPs) to attract larger pharmacy giants for collaboration. He also stressed on the need for a proper exit strategy for biotech startups, considering the potential redundancy of products over time. Continuous innovation and building ideas are essential for maintaining value.

Highlighting another critical aspect in the journey of biotech startups i.e. regulatory approvals, Dr Kulkarni said, "Understanding the regulatory framework is crucial, as regulatory errors can have a higher impact than revenue-related mistakes. The fast-changing regulatory regime in the European Union can be taken as an example. There is a need for a complete understanding of the product and its necessity for long-term sustainability. Startups need to be fast, first, and consistently communicate about barriers to ensure survival in the market."

In Rupinder Singh's opinion, biotech startups should emphasise on planning before applying for regulatory approvals. "Startups should create checklists, seek expert advice, and collaborate at the right time for successful execution. Collaboration, seed funding, subsequent funding, and revenue generation plans are all crucial for long-term sustainability of a startup", he said.

He underscored four crucial points for startups- maintaining revenue with a healthy balance sheet, continuous innovation and patent filing, staying ahead of the competition, and consistently pitching to investors to ensure a steady flow of capital for sustained growth.

Towards the end of the discussion, Dr Shalini advised biotech startups to properly build milestones for attracting funding through validation and certification. "Continuous pitching for new funds and attracting investors by adding value to the product is crucial. Startups must identify their needs for government grants, create a clear value proposition, & outline a roadmap for market entry while managing funds effectively", she said. She also cautioned against regulatory uncertainties and spoke about training sessions at Venture Center to help startups navigate regulatory certification and validation. BS

Amguthr Raju

Cloudnine signs MoU with British Association of Physicians of Indian Origin Training Academy

Cloudnine, India's premium birthing centre for maternal and childcare, has signed a Memorandum of Understanding (MoU), with the British Association of Physicians of Indian Origin (BAPIO) Training Academy, UK making it as the first hospital in India to initiate a global training programme for doctors. As a part of the MoU, Cloudnine Hospital and BAPIO Training Academy will work together to strengthen training programmes especially in the fields of Obstetrics, Paediatrics, IVF and Foetal Medicine. Cloudnine Hospitals will engage and invest in training of its doctors specialising in maternity, fertility, and paediatrics through these programmes. This programme is being offered for the first time in India for Membership of the Royal College of Obstetrics & Gynaecology (MRCOG) and Member of Royal College of Paediatrics and Child Health (MRCPCH) exams. This MoU will also enable doctors to take Royal College exams in Paediatrics and Obstetrics and Gynaecology (OBG). It further opens an opportunity to all the MBBS doctors across the country who have been unable to join postgraduate (PG) courses in India to become members of the Royal Colleges of UK.

Bharat Biotech joins hand with University of Sydney to advance academic research

Hyderabad-based Bharat Biotech International and the University of Sydney Infectious Diseases Institute (Sydney ID), Australia have announced a Memorandum of Understanding (MoU) to advance vaccine research initiatives, strengthen academic-industry partnerships and augment global efforts to combat infectious diseases. The international agreement aims to build strong sectoral and cross-organisational collaborations to design novel methodologies to tackle future epidemics and infectious diseases. Furthermore, leverage academia-industry strengths for advancing the science of vaccines and biotherapeutics. Both organisations intend to explore new opportunities to strengthen their shared vision, leverage the prowess of education, research capabilities to help build a healthier universe and improve people's lives by developing safer vaccine platforms. Most importantly, to build the talent of young scientists with a passion to innovate.

IIT-M partners with SRIHER to offer MD-PhD dual medical degree

The Indian Institute of Technology Madras (IIT-M) is partnering with Sri Ramachandra Institute of Higher Education and Research (SRIHER) in Chennai, Tamil Nadu, to offer a MD-PhD Dual Degree programme. The postgraduate medical degree will be awarded by SRIHER and a PhD degree by the Department of Medical Sciences and Technology of IIT-M. This partnership will concentrate on core clinical, interdisciplinary, and translational research. The objective of MD-PhD Dual Degree Programme is to produce well-

trained research scientists who will lead India's quest for self-sufficiency in the field of medicine and health. The programme will be operational from the next academic year. The postgraduates admitted to SRIHER through NEET and desirous of doing PhD will apply for the PhD programme at the end of the second year to the Department of Medical Sciences and Technology at IIT-M. The Department of Medical Sciences and Technology will follow established procedure to select candidates to pursue the PhD programme. Once selected, IIT-M will issue them a pre-PhD offer and they will be eligible to register after their degree in SRIHER. Such candidates will be mentored by IIT-M faculty and a SRIHER faculty during their third year at SRIHER.

“Tailor-Made” Solutions Will Better Support Biopharma Manufacturing

Mr. Leo Xie joined Duoning in 2022 as senior vice president, responsible for sales and marketing. He has more than 20 years of sales management experience, especially in the pharmaceutical and biotechnology industries. He is experienced with key process units and advanced application technologies in the upstream and downstream of biopharmaceuticals, and has in-depth insights into relevant regulations and policies, industry status quo, and development trends. Before joining Duoning, Mr. Leo Xie worked for Repligen as the general manager of Greater China area. Prior to this, Mr. Leo Xie also worked for several leading bio-process companies, including Pall and Saint-Gobain.

The challenges of the bioprocess supply chain during the COVID-19 pandemic have given many new players with opportunities for growth. Now, these suppliers are no longer limited to the local market and have started actively exploring a broader market. Among them, India stands out as an important emerging bio-pharmaceutical market. The bio-pharmaceutical industry here has experienced rapid growth in recent years, attracting the attention of an increasing number of bio-processing suppliers. These suppliers believe that India is key to supporting sustainable business growth. Duoning is one such bioprocessing supplier. One year after officially announcing its entry into the Indian market, BioSpectrum Editorial spoke with ***Mr. Leo Xie, Senior Vice President of Duoning Biotechnology Group,*** to learn about the company’s current operations in India and its future plans.

How do you perceive the market space for life science service companies in India?

India’s pharmaceutical industry is developing rapidly and has strong policy support. India has a vast demographic dividend and significant unmet medical needs. The Indian healthcare industry has expanded rapidly in recent years and is expected to surpass $500 billion by 2025. At the same time, the local government has been actively promoting the development of the pharmaceutical industry, which includes establishing funds to produce pharmaceutical ingredients domestically. As the pharmaceutical industry develops, the country is emerging as a high-potential market for life sciences services. This is backed by strong government support, rising private investments, and a growing trend of outsourcing to emerging Asian markets.

Improving efficiency and reducing financial stress are the primary objectives for the development of local biopharmaceutical companies. The Indian pharmaceutical industry accounts for a substantial share of the global pharmaceutical industry, and it is projected that pharmaceutical exports will reach $30 billion by 2025. Biopharmaceutical startups often face financial challenges due to the unique nature of their products. They require extensive research and development, as well as rigorous trials, to bring products to market. Therefore, increasing the efficiency of biopharmaceutical development and reducing development costs have become essential requirements. The biopharmaceutical manufacturing industry has become a key driver of development. As the pharmaceutical industry continues to evolve, ensuring the integrity and efficiency of the supply chain is critical. Key areas of the Indian pharmaceutical industry are experiencing continued

growth, including the expansion of physical and manufacturing capabilities, enhancement of cold chain and packaging capabilities, improvement of process capabilities, and increased investments in research and development (R&D), among others. This provides opportunities for life science service companies to enter the Indian market.

How does Duoning fulfill market demands, & what business progress has it made this year?

Duoning is dedicated to providing comprehensive bioprocessing solutions and assisting customers in establishing a seamless connection between all stages of bio-pharmaceutical development. This is achieved through solutions that encompass both the upstream and downstream processes. At the same time, biotechnology is a highly regulated industry, and internationally unified quality standards also enable us to serve the global market. The interconnected process flow from Duoning can reduce data errors in bio-pharmaceutical validation and better align the development needs of bio-pharmaceuticals at each stage. This, in turn, reduces development costs and improves efficiency.

In 2023, we expanded our product line and production capacity even further. Through the acquisition of Prefluid, a specialized supplier in the development and production of peristaltic pumps, we have expanded our product portfolio in fluid management and added a manufacturing site spanning approximately 10,000 square meters. Moreover, we anticipate that our new manufacturing site for bioreactors and fluid management systems will be completed and operational in the first quarter of 2024. At present, Duoning has 12 sites that cover a wide range of products, including cell culture media, bioreactors, filters, chromatography resins, single-use technologies, peristaltic pumps, and other process-related products. These facilities are capable of meeting the demands of mainstream bio-pharmaceutical production, including antibodies, mRNA, cell and gene therapies, and ADCs.

What are Duoning's plans for the Indian and other Asian markets?

The uniqueness of the Indian market lies in the burgeoning bio-similar industry, which necessitates large-scale production. Therefore, we will focus more on direct sales of biotechnology products and expand our coverage to include South and Southeast Asian countries, with India as a hub. In addition, considering India's diverse pharmaceutical manufacturing market, we will also provide technical services to offer customized product portfolios.

For other Asian countries, Duoning will rely more on economic cooperation policies among nations. This can help us overcome regional barriers more effectively and establish a network to distribute our products or even build new facilities to produce products locally. In fact, India and several other Asian countries are expected to emerge as significant players in the global bio-pharmaceutical market. The current substantial investment in bio-manufacturing infrastructure in these regions will be a crucial factor contributing to the high growth potential of these markets. We hope to seize this opportunity and be a part of it.

What challenges do you expect life science services companies to encounter when expanding into the Indian market?

For the biopharmaceutical supply side, there are primarily market and policy challenges. For biopharmaceutical manufacturers, the quality of products provided by suppliers is always the primary consideration, followed by stable supply chain and cost factors. The COVID-19 pandemic has provided small suppliers and those from emerging markets with an opportunity to expand. However, as the market recovers, it remains uncertain whether these suppliers can sustain their success against mainstream suppliers. This is true for many markets worldwide, including the Indian market. Therefore, in the future, we will focus more on product quality and technological innovation. While ensuring a faster and more stable supply chain, we will also listen to the genuine needs of our customers and provide "tailor-made" products to better support biopharmaceutical manufacturing.

Renowned diabetologist Dr V. Mohan receives Lakshmipat Singhania Award

Recognising outstanding contributions and exceptional leadership in Research on Diabetology, Dr V. Mohan, Chairman of Dr. Mohan's Diabetes Specialties and Madras Diabetes Research Foundation, was honoured with the Lakshmipat Singhania Award in the category of 'Leader in Science and Technology' at the Indian Institute of Management (IIM) Lucknow National Leadership Awards 2022-23 function in New Delhi. President of India, Droupadi Murmu, presented

the prestigious award to Dr V. Mohan. This well recognised platform is a joint initiative by IIM Lucknow and the industrial conglomerate JK Organization, in Delhi. In a career spanning over five decades, Dr V. Mohan has published 1635 papers including 1052 original papers which have received 193,000 citations and an h-index of 153. Dr Mohan has received numerous awards and accolades including the prestigious Dr. B C Roy Award from the Medical Council of India, the Dr. Harold Rifkin Award by American Diabetes Association and the Padma Shri in 2012 from the Government of India.

HealthPlix appoints Amitabha Mukhopadhyay as SVP for Pharma, Business Development

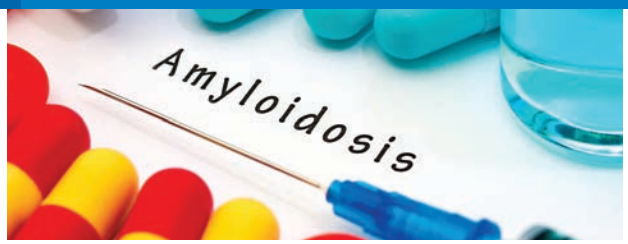
Bengaluru-based startup HealthPlix Technologies has announced the appointment of Amitabha Mukhopadhyay as the Senior Vice President (SVP) - Pharma, Business Development, and Growth Catalyst. In his new role, Mukhopadhyay will play a crucial role in fostering collaborations to enhance HealthPlix's presence in the pharmaceutical domain. He will also be responsible for identifying new growth opportunities in the healthcare sector and establishing new verticals. Mukhopadhyay is an accomplished leader with 23 years of experience in strategic marketing and business development. He joins HealthPlix following a successful tenure at Glenmark Pharmaceuticals, where he served as General Manager & Head Marketing Excellence. Before joining Glenmark, Mukhopadhyay held leadership positions in both the Centre of Excellence and Marketing departments at Dr. Reddy's Laboratories.

Dr Arun Shukla wins Infosys Prize 2023 in Life Sciences

Infosys Science Foundation (ISF) has announced the winners of the Infosys Prize 2023 in six categories – Engineering and Computer Science, Humanities, Life Sciences, Mathematical Sciences, Physical Sciences, and Social Sciences. The Infosys Prize 2023 in Life Sciences is awarded to Arun Kumar Shukla, Professor, Biological Sciences and Bioengineering (BSBE), IIT-Kanpur, for his outstanding and far-reaching contributions to the field of G-protein coupled receptor (GPCR) biology. Dr Shukla's research has established a new understanding of GPCRs, which are one of the most important classes of drug targets. His work has opened up previously uncharted avenues for designing novel and effective therapeutics. Dr Shukla obtained M.Sc. in Biotechnology from the Jawaharlal Nehru University (JNU) in New Delhi and pursued his Ph.D. with Prof. Hartmut Michel at the Max Planck Institute of Biophysics in Frankfurt, Germany. He subsequently joined the laboratory of Prof. Robert J. Lefkowitz at Duke University as a Research Associate and worked in a very close collaboration with Prof. Brian Kobilka's laboratory at Stanford University.

Study of novel virus might help in developing diagnostics & therapeutics

Probing the haemorrhagic disease (HD) among Asian elephant population, a new study assessed the circulation of the elephant endotheliotropic herpesvirus subtypes (EEHV) responsible for the recent rise in the disease, as well as its pathogenesis. The research on the patho-epidemiology for the study of the determinants, occurrence, and distribution of the disease can help develop sero-diagnostics, vaccines and therapeutics against the disease. The study by ICAR-Indian Veterinary Research Institute (ICAR-IVRI), Izatnagar, Bareilly, supported by Science and Engineering Research Board (SERB), an attached institution of Department of Science and Technology, has found the exact status of EEHV and its subtypes circulating among Asian elephant population in India. The research published in the journal Microbial Pathogenesis characterised the genome of the virus circulating in the Indian elephant population and traced the molecular mechanism of dysfunction of endothelial cells associated with this disease. Work has been initiated to facilitate developing diagnostic kits and vaccines based on this work.



IASST fabricates 2D protein monolayer to help study diseases like Amyloidosis

Scientists from the Institute of Advanced Study in Science and Technology, Guwahati (IASST), an autonomous institute of North-East India under the Department of Science and Technology (DST), have fabricated a 2D protein monolayer by assembling lysozyme molecules, a model protein in studying diseases like Amyloidosis. Amyloidosis is a rare disease that occurs when a protein called amyloid builds up in organs. This amyloid build-up can affect the working of organs like heart, kidneys, liver, spleen, nervous system and digestive tract. Lysozyme, a protein present in mucosal secretions and a principal component of airway fluid, can be regarded as a model protein in studying diseases like Amyloidosis which ultimately leads to multi-organ dysfunction. The research group used the 2D protein monolayer to understand the behaviour of lysozyme molecules at air-water as well as at air-solid interface with the help of a technique called Langmuir-Blodgett (LB) technique.

IIT Guwahati explores use of graphene oxide to bridge biomedical innovation

Researchers at the Indian Institute of Technology Guwahati (IIT-G) have made important discoveries regarding the use of modified graphene oxide for biomedical applications. The team has developed cost effective experiments for modifying graphene oxide that can be used by other academic institutions to train personnel needed for cutting edge projects in semiconductors, nanoelectronics, healthcare, and quantum technologies supported by the Indian government. Graphene, a Nobel Prize winning material, is exceptionally strong and possesses outstanding electrical and thermal conductivity. Its oxidised form, called Graphene Oxide (GO), offers a large surface area and low cytotoxicity, making it suitable for medical applications. The team's extensive knowledge of Graphene-based materials has led to the development of innovative laboratory experiments designed to provide students with hands-on skills and inspire them to explore the possibilities of advanced materials.

VFL Sciences launches Penguin Classic Laboratory Freeze Dryer / Lyophiliser

Chennai-based VFL Sciences Private Limited has announced the launch of Penguin Classic, Laboratory Freeze Dryer / Lyophiliser. VFL Sciences Freeze dryer has been designed with focus on customers to deliver a state-of-the-art instrument that fits comfortably on a lab bench. Advanced 7" touch screen display allows users to programme all the parameters easily. The instrument comes with features such as auto defrost, auto restart after power restoration, flexibility to use flask, vials, petri dish etc. For the first time in India, a laboratory freeze dryer is being offered that can be customised to one's requirements. Currently India is importing over 90 per cent of all laboratory instruments. With the Indian manufacturing sector growing and the government supporting make in India, it is now time to produce scientific instruments in India. Freeze dryer is VFL's first product and the company plans to launch several instruments in the coming years.

Waters Corp invests Rs 130 Cr in new state-of-the-art global capability center in Bengaluru

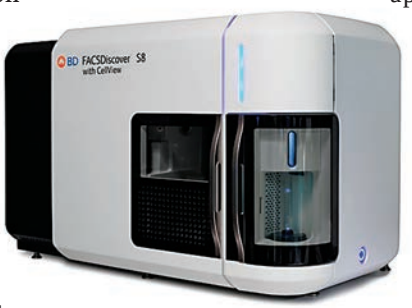
American firm Waters Corporation has inaugurated its new Global Capability Center (GCC) in Bengaluru, a strategic investment to accelerate technology adoption, innovation, digital transformation, and business efficiencies through a concentrated hub of talent that will operate across the Waters global enterprise. Waters India GCC will employ 300+ for roles in software engineering, technology & product development, data analytics and IT. The Waters India GCC is in a newly built facility in Bengaluru's RMZ Ecoworld technology park, a WELL and LEED Platinum-certified campus that exemplifies a commitment to a healthy and eco-conscious workspace.

Agilent enhances BioTek Cytation C10 Confocal Imaging Reader with innovative water immersion technology

US-based Agilent Technologies Inc. has announced the addition of water immersion and new confocal spinning disk technology to the BioTek Cytation C10 confocal imaging reader. These features improve image quality and results by reducing deleterious effects on live-cell samples and enhancing clarity for thicker samples such as tissues and 3-D spheroids. In light microscopy, water immersion technology automatically and consistently places a layer of water between the objective lens and the sample. The higher refractive index of water, as compared to air, effectively increases the numerical aperture of the objective lens; this reduces z-axis distortion, resulting in higher image quality and a more true-to-life representation of thick and three-dimensional cell models. Water immersion also benefits researchers who are increasingly turning to physiologically relevant live-cell (as opposed to fixed-cell) applications by reducing exposure times, thus lowering the phototoxic effects traditionally associated with these experiments.

BD India instals first spectral cell sorter with high-speed cell imaging at IIT-Jodhpur

To celebrate the inauguration of its first image enabled high-speed spectral flow cytometry sorting facility in South Asia, BD Life Sciences-Biosciences, a segment of BD (Becton Dickinson and Company) in association with Indian Institute of Technology Jodhpur (IIT-Jodhpur) recently conducted a scientific exchange event recently at IIT Jodhpur. IIT-Jodhpur has taken a pioneering step to get the first BD BD FACSDiscover S8 in South Asia installed in their FACS Facility. BD FACSDiscover S8 Cell Sorter with BD CellView Image Technology and BD SpectralFX Technology, is the first spectral flow cytometer sorter with sort capable image analysis. The BD FACSDiscover S8 has the potential to reshape research practices in the country as it brings applications in the areas such as gene therapy, cancer immunology, stem cell research etc. and many other areas of research in biology. BD FACSDiscover S8 Cell Sorter combines flow cytometry data with spatial and morphological insights to obtain detailed information about cells that were previously invisible in traditional flow cytometry experiments. The technology enables answering complex biological questions, such as how cells grow, function and interact, or to study exact locations of viruses or proteins within a cell, all at a highly accelerated pace.



Revvity launches easy-to-use molecular diagnostics workflow for newborn screening

US-based Revvity, Inc. has announced the launch of its EONIS Q system, a CE-IVD declared platform enabling laboratories in countries that accept the CE marking to adopt molecular testing for spinal muscular atrophy (SMA) and severe combined immunodeficiency (SCID) in newborns. For both inherited conditions, immediate detection is critical to advancing a positive outcome. For SMA, disease modifying therapies exist to stop progression of disease, and for SCID, immunoglobulin treatments combined with stem cell therapies can potentially cure a child, if intervention comes in time. However, to date, molecular testing for these and other congenital disorders is relatively low, due in part to cost restrictions and the technical expertise required to perform and interpret these tests. The EONIS Q system simplifies and streamlines molecular testing for SMA and SCID with an innovative workflow, inclusive of the EONIS Q96 instrument, the EONIS SCID-SMA kit and dedicated EONIS EASI software.

Cytiva transforms protein purification with new affinity technology

US-headquartered Cytiva, a global leader in life sciences, has introduced the innovative Cytiva Protein Select technology, designed to streamline and accelerate recombinant protein purification. The self-cleaving traceless tag and complementary affinity chromatography resin standardises purification for any protein, rendering it unnecessary to use specific affinity binding partners for each protein. Protein purification is integral to basic research, drug discovery, process development, and bioprocessing. However, the diverse family of recombinant proteins - of which there are 1800 in the global pipeline this year alone - often lacks affinity binding partners to facilitate purification. A common strategy to facilitate the purification has been to add a tag to the protein; however, it cannot be removed cleanly for biotherapeutic applications. Owing to Cytiva Protein Select technology, scientists can purify proteins using a simple protocol and receive highly pure, native proteins free of tag amino acids.

Efficacious Therapies for Leprosy

One of the oldest diseases known to man, leprosy is primarily a disease of the skin and nerves. However, according to a recent study conducted by scientists at King George's Medical University in Lucknow, the disease can majorly affect the brain and spinal cord.

With this new observation, a concern regarding the effective treatment of leprosy is on the rise to protect the brain and spinal cord functions of the patients. The fact remains that India continues to account for 55 per cent of new cases reported globally each year and is among the 22 global priority countries that contribute 95 per cent of world numbers of leprosy warranting a sustained effort to bring the numbers down.

As per the National Strategic Plan (NSP) & Roadmap for Leprosy (2023-27) launched by the government in 2023, the objective is to achieve zero transmission of leprosy by 2027 i.e. three years ahead of the Sustainable Development Goal (SDG) 3.3.

While the strategy and roadmap focus on awareness for zero stigma and discrimination, promotion of early case detection, prevention of disease transmission by prophylaxis and roll out of a web-based information portal (Nikusth 2.0) for reporting of leprosy cases, there is still a long way to go in eliminating this disease in India.

Although leprosy is curable with a combination of drugs in the form of multi-drug therapy (MDT), supplied through the National Leprosy Eradication Programme (NLEP) in the country, relapse cases of leprosy add up to the trouble. In addition, the growing burden of antimicrobial resistance (AMR) worldwide is making things worse.

From its introduction in 1982 till date, the same three drugs (dapsone, rifampicin and clofazimine) constitute MDT for leprosy, and with emerging resistance to these drugs, there is a need to expand the repertoire of drugs to treat leprosy. Clinical and laboratory studies suggest the emergence of secondary drug resistance in treated/relapsed patients to dapsone, and rifampicin.

The rollout of MDT in the 1980s was a major factor in bringing down the burden of leprosy cases until 2005, after which a plateau was observed in the number of cases on treatment. As rifampicin is the backbone of the MDT regimen, it is important to monitor the emergence of rifampicin-resistant strains.

The mapping of the causal organism, Mycobacterium leprae, genome has identified sites at which mutations occur, conferring resistance to drugs. Rifampicin binds to the beta-unit (coded by the rpoB gene) of the RNA polymerase and certain mutations in the rpoB gene lead to rifampicin resistance in M leprae.

Studies have revealed that ofloxacin, minocycline, clarithromycin, rifapentine, and moxifloxacin are some of the other drugs known to be effective in the treatment of leprosy but there is no standard recommended or approved protocol to use them, except in cases of proven resistance to rifampicin.

Thus an effective AMR surveillance system for leprosy treatment can prove to be helpful to tackle this disease. We need to estimate the burden and monitor trends of AMR in leprosy among both new and relapse cases including patients seeking treatment in government health facilities, medical colleges, and dermatologists. This also includes the establishment of national reference laboratories regionally.

The Indian government had previously instituted surveillance of drug resistance emergence in programmes related to tuberculosis, vector-borne diseases etc. Likewise, the execution of country-wide surveillance for AMR management in leprosy is something to look forward to, as we move closer to World Leprosy Day on January 28, 2024.

Alternatively, we need to keep exploring new treatment strategies for leprosy. For instance, a scientific collaboration between Japan and the Netherlands has resulted in the identification of a receptor or a glycolipid molecule that could offer an alternative to the current, antibiotic-heavy treatment for leprosy. Researchers maintain that the special structure-activity relationship between the identified molecules could be replicated to create other immune-stimulatory drugs in the future. BS

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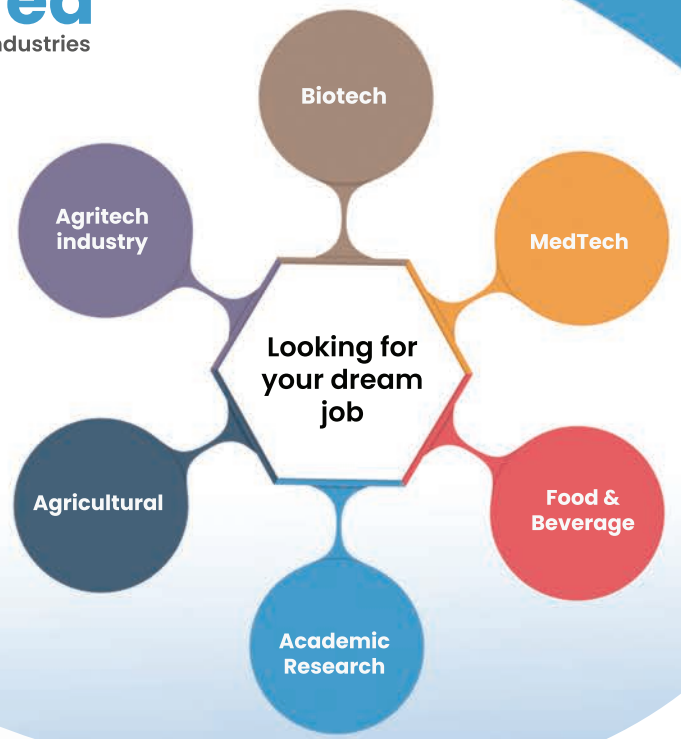

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