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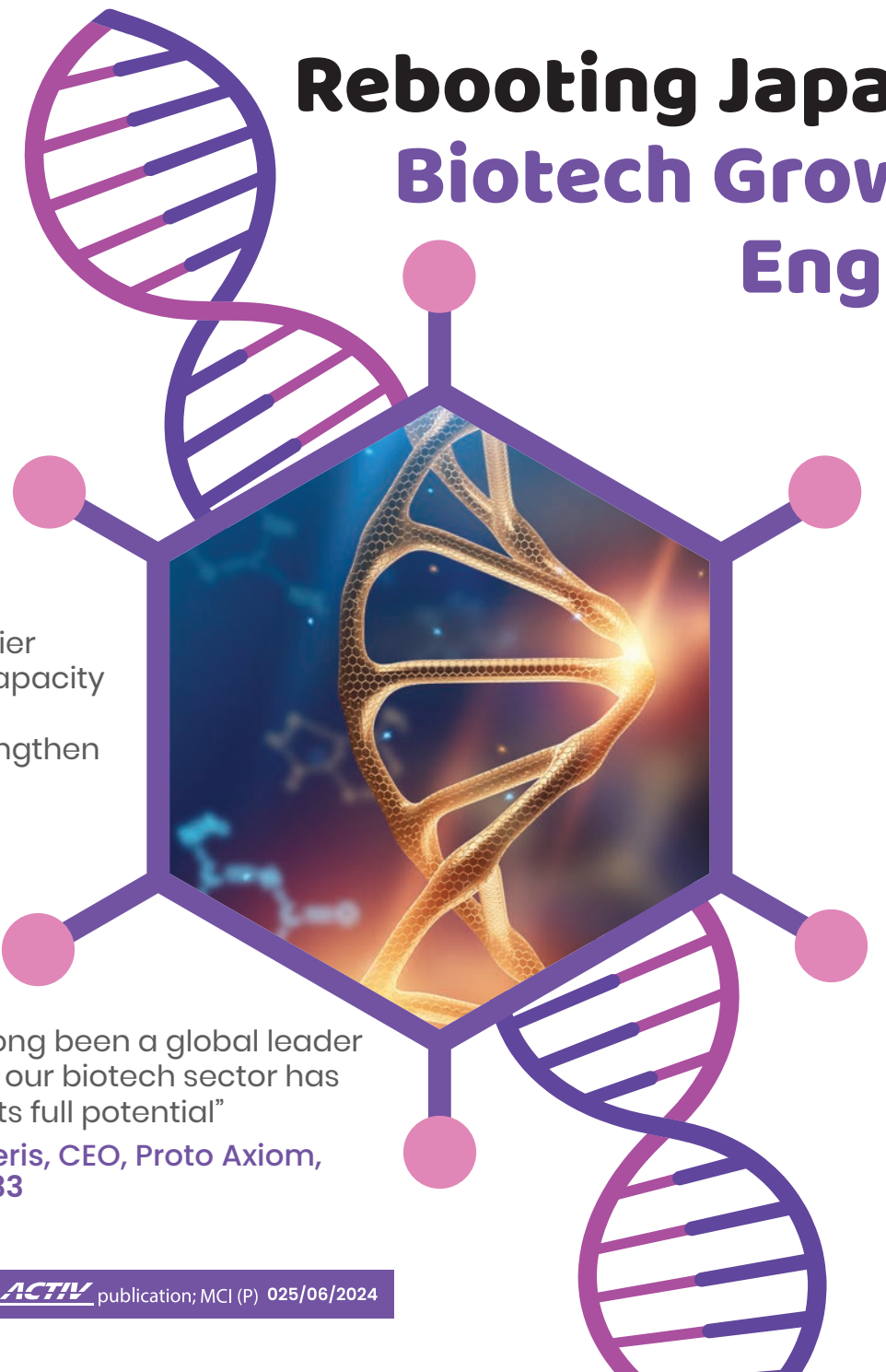
the business of Bio & Health Sciences
ASIA EDITION

Volume 19 | Issue 9 | September 2024

Rebooting Japan's Biotech Growth Engine



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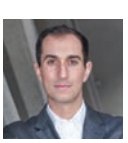
23rd AUGUST 2024

Indian BioSupplier sector needs capacity and capability building to strengthen local presence: Experts - **39**



"Australia has long been a global leader in research, yet our biotech sector has not lived up to its full potential"

- Anthony Liveris, CEO, Proto Axiom, Australia - **33**

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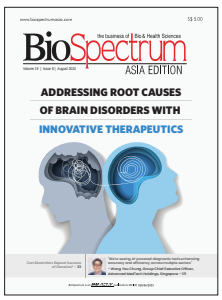

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Thanks much for the interaction with NeuroSigma for the cover story of BioSpectrum Asia.
- Colin, US

Thanks for including Neurowyzr's comments in your cover story in the August edition.
- Rumaizah, Singapore

Thanks a lot for the publication on the Global Capability Centres focusing on the pharma sector, in the August 2024 edition of BioSpectrum – truly appreciate your support.
- Anil Matai, India

Thank you BioSpectrum Asia for publishing our article that explores the shifting landscape of biotech investments and M&A megatrends, in your latest edition.
- Frost & Sullivan

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Letter from Publisher

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

Japan had a glorious past in the life sciences sector just a few years back. Japanese biopharma companies, that were industry leaders once, made Japan a global leader in innovation in life sciences. In the 1980s, Japanese companies introduced nearly 30 per cent of the new drugs approved by the USFDA. However, it started losing its glory. The percentage of new drugs introduced by these companies came down to just 7 per cent of the US FDA-approved drugs in the last decade. Between 1995 and 2018, Japan's contribution to the global pharmaceutical industry's value-added offerings declined by 70 per cent, from 18.5 to 5.5 per cent. Japanese companies' share of clinical trials also dropped from 11 per cent in 2013 to 4 per cent in 2023.

Several reasons could be cited for the decline. Japan lagged in transitioning from small molecule development to biologics when the world was moving in that direction. Prioritising social welfare over commercial innovation by strict price controls of the 1980s and removing financial incentives for biotech innovations contributed to further decline. Other factors included reduced government investment in basic research, weak collaboration between industry and universities, and a slow regulatory process.

Recognising this, after decades of lacklustre performance, despite award-winning science, Japan's government and big pharma players are now taking steps to spur biotech growth. The government has launched a series of reforms and initiatives to revitalise the country's faltering pharma and biotech industry. Our content team is appraising the steps initiated by the Japanese government and pharma industry to come out of this weak patch.

Companion diagnostics (CDx) are the cornerstone of precision medicine and play a critical role in optimising patient outcomes and reducing healthcare costs by ensuring that therapies are tailored to individual patient profiles. Currently, there are 51 CDx tests approved by the US FDA. We have a feature on how enhanced collaboration between diagnostic and pharmaceutical companies could help drive innovation, ensuring that companion diagnostics are seamlessly integrated into personalised treatment regimens.

The incidence of chronic wounds is rising, especially in the Asia-Pacific region. Globally, around 2 per cent of people are affected by these conditions. Our correspondent has presented an article that discusses the recent breakthroughs in smart bandages, hydrogels, and tissue regeneration that are setting the stage for a new era in chronic wound treatment.

While the Indian biosupplier market is growing at a rapid pace, a large chunk of it is governed by global players. Thus, it becomes imperative to strengthen local development of analytical instruments and supplies required for biotech innovation in the country. BioSpectrum had organised a one-day event in Mumbai, on August 23, highlighting the efforts being made by domestic and international biosuppliers to facilitate biotech innovation in India through new technologies. We have also honoured the best technologies at the mega event's 'Supplier Excellence Award' session.

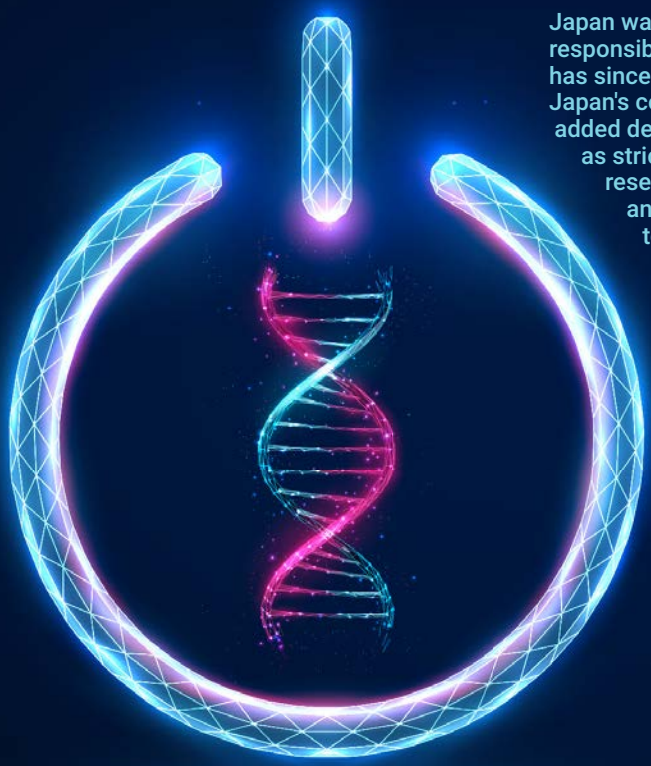
I am sure you will love reading this edition.

Thanks & Regards,

Ravindra Boratkar
Publisher & Managing Editor

COVER 19

Rebooting Japan's Biotech Growth Engine



Japan was once a global leader in life sciences innovation, responsible for nearly 30 per cent of all new drugs. However, its share has since dropped to less than 10 per cent. Between 1995 and 2018, Japan's contribution to the global pharmaceutical industry's value-added declined by 70 per cent, from 18.5 to 5.5 per cent. Factors such as strict price controls, reduced government investment in basic research, weak collaboration between industry and universities, and a slow regulatory process have significantly contributed to the decline in Japan's biopharmaceutical competitiveness, as noted in a 2022 paper by the Centre for Life Sciences Innovation, part of the Information Technology and Innovation Foundation, US. Japanese companies' share of clinical trials also declined from 11 per cent in 2013 to 4 per cent in 2023. An IQVIA report found that the number of trials initiated by Japanese companies dropped from 501 in 2013 to 244 a decade later. Additionally, Japan launched only 20 new medicines in 2023, the lowest total since 2014, trailing behind the US and other major markets. Recognising this, the Japanese government has announced several initiatives designed to reshape the country's biopharma ecosystem. These efforts include substantial increases in capital for venture funds, targeted subsidies for therapeutic drug development, and a suite of tax incentives aimed at empowering investors, entrepreneurs, and startup employees.

CDx

Wound Care

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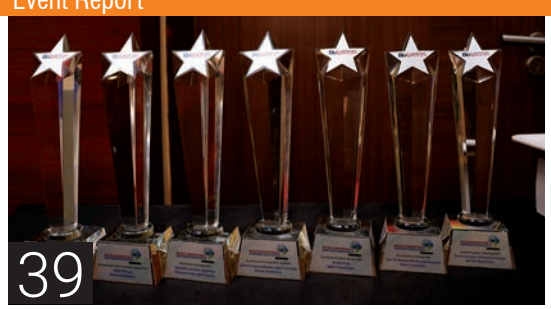

REGULARS

ENSURING ESSENTIAL DRUG AVAILABILITY

Dr Milind Kokje
Chief Editor
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Non-availability or shortage of drugs has become a complex issue that several countries are facing, putting patients' lives at risk, increasing their suffering and adding to the healthcare professionals' problems in treating patients. COVID-19 was the starting point for drug shortages in some countries since the normal operations of any activity, including pharma companies, got disturbed during that period.

However, some countries were facing shortages even before the pandemic began. The problem of shortage of medicines supplies even before the pandemic was so serious that the publications of papers on it increased 13 times from 2000 to 2020. The pandemic increased the intensity of the problem so much that shortages in Australia increased by 300 per cent when the pandemic started. Though some countries came out of that phase, some have not been able to come out of the pandemic effect even two years after that.

In Sri Lanka, there was a financial and political crisis last year. The country relied on 85 per cent of imports of drugs, worth $815 million in 2021. Post-crisis, by May 2022 it came down to $25 million.

Japan has been witnessing prolonged shortages of even cough suppressants and antimicrobial agents. Exactly about a year back shipments of about 20 per cent of all drugs were either suspended or the quantity was reduced, Japanese newspaper Asai Shimbun quoted a survey by a pharmaceutical industry organisation in October 2023. The reason cited for the drug shortage by the Japanese media is complicated approval processes. Thus, Japan has recently come out with a road map seeking to address the unavailability of foreign drugs in the country. It includes the development of in-demand medicines and envisions the establishment of more than 10 pharma startups through doubling the investment.

In the Philippines, the drug regulator is planning changes that will shorten the review time for generic drugs from 120 days to 45 days. The regulator has decided to rely on the work of other regulators such as the US FDA or the Pharmaceuticals and Medical Devices Agency (PMDA), a Japanese pharma regulator. The Philippine regulator will look at what they evaluate, the very paper they used, and when it has satisfactorily complied with the requirements of the ASEAN common technical documents, it will not be repeated, relying on a stringent regulatory authority. Though there is no drug shortage in India, the Central Drug Standard Control Organisation (CDSCO) has decided to adopt a similar strategy of waiving local clinical trials for imported drugs in case of some new drugs for rare diseases and also gene and cell therapy.

The Drugs Controller General of India (DCGI) has issued the order depending upon the approvals of drug regulators of the US, UK, Japan, Australia, Canada, and the European Union. If the drug regulator of these countries and regions approves a drug for cancer, Alzheimer's, rare diseases and weight loss, which is awaiting approval in India, then those drugs are not required to undergo clinical trials in India. Pharma companies can obtain regulatory clearance if they fulfill two conditions – proving that the new drug offers a "significant therapeutic advance over the current standard of care" and it is approved by one of the drug regulators of the six countries.

While waiving the local clinical trials there are issues like the absence of examining the drug in local conditions on local people. But to have a precaution for that one condition is that the drug companies will have to carry out phase IV post-marketing surveillance to monitor serious adverse events, if any. With no local clinical trial requirements, even the cost of some essential drugs may come down.

One question is when New Drugs and Clinical Trials Rules, 2019 provided for the waiver of local clinical trials, why did it take over four years to issue the concerned order? But, it is better late than never, as the move will provide a much-required relief to suffering patients. BS

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Singapore and the Philippines to enhance cooperation in healthcare human resource development

A Memorandum of Understanding (MoU) has been signed between the Singapore Ministry of Health (MoH) and the Philippines Department of Migrant Workers (DMW) by Singapore Minister for Health, Ong Ye Kung, and the Philippines Secretary of the DMW, Hans Leo Cacdac. Under the MoU, Singapore and the Philippines will enhance cooperation in healthcare human resource development. This includes

upholding fair treatment and promoting the welfare of Filipino healthcare workers recruited to work in Singapore, and sharing best practices and support programmes that will develop their skills, which can benefit the development of healthcare in both Singapore and the Philippines. The signing of the MoU reaffirms the close working relationship between Singapore and the Philippines, and demonstrates the shared commitment to enhance existing cooperation and establish new areas of collaboration.

Hong Kong to develop rare disease centre

Professor Chung-mau Lo, Secretary for Health, has said that Hong Kong is developing a rare disease centre in collaboration with Mainland. The centre will be situated in Hong Kong Children's Hospital where there are specialist genetic disease experts. He

mentioned that the Mainland bureaus and departments recently facilitated the smooth delivery of a cord blood haematopoietic stem cell unit from the Mainland to Hong Kong for the treatment of a five-year-old girl suffering from thalassaemia. In the past, the only treatment for thalassaemia patients was blood transfusions every month or so with iron chelation therapy, but many patients could only live to 20 or 30 years of age, Prof. Lo explained. Prof. Lo noted that stem cell transplant therapy, cell therapy such as chimeric antigen receptor T-cell therapy and genetic therapy, are the objectives of Hong Kong's future development as a medical innovation hub.

India hosts policymakers and drug regulators from 15 countries

The Union Minister of Health and Family Welfare & Chemicals and Fertilizers, J P Nadda inaugurated the 'First Policy Makers' Forum', which ran from August 19-22, 2024. To elevate India's position in the global pharmaceutical sector, the Indian Pharmacopoeia Commission (IPC), in collaboration with the Ministry of Health & Family Welfare and the Ministry of External Affairs, hosted an international delegation of policymakers and drug regulators from 15 countries. The forum witnessed participation from various countries including Burkina Faso, Equatorial Guinea, Ghana, Guyana, Jamaica, Lao PDR, Lebanon, Malawi, Mozambique, Nauru, Nicaragua, Sri Lanka, Syria, Uganda and Zambia. The forum aims to foster meaningful discussions on the recognition of the IP and the implementation of India's flagship Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), popularly known as the Janaushadhi Scheme. A key highlight of the event was the launch of two significant digital platforms by the Minister of Health and Family Welfare-the IP Online Portal and the Adverse Drug Reaction Monitoring System (ADRMS) software. The IP Online Portal represents a major step towards digitalising the Indian Pharmacopoeia, making drug standards more accessible to stakeholders worldwide. The ADRMS software, developed as part of the Pharmacovigilance Programme of India, is India's first indigenous medical product safety database tailored to the needs of the Indian population.

Merck buys investigational B-cell depletion therapy for $700 M from Curon Biopharma

Merck, known as MSD outside of the United States and Canada, and Curon Biopharmaceutical, a China-based biotechnology startup, has announced that the companies have entered into a definitive agreement under which Merck, through a subsidiary, has agreed to acquire CN201, a novel investigational clinical-stage bispecific antibody for the treatment of B-cell associated diseases. Under the terms of the agreement, Merck through a subsidiary will acquire full global rights to CN201 for an upfront payment of $700 million in cash. Curon is also eligible to receive up to $600 million in milestone payments associated with the development and regulatory approval of CN201. CN201 is currently being evaluated in Phase 1 and Phase 1b/2 clinical trials for the treatment of patients with relapsed or refractory non-Hodgkin's lymphoma (NHL) and relapsed or refractory B-cell acute lymphocytic leukemia (ALL), respectively. Preliminary data suggest CN201 has activity in patients with relapsed or refractory B-cell hematologic malignancies and is well tolerated, with the potential to induce significant and sustained reductions in B-cell populations.

Otsuka Pharma acquires Jnana Therapeutics for $1.1 B

Japan-based Otsuka Pharmaceutical Co. and Jnana Therapeutics Inc. have entered into a definitive merger agreement pursuant to which Otsuka will acquire Jnana, making it a wholly owned subsidiary through Otsuka's 100 per cent owned subsidiary, Otsuka America, Inc. (OAI). The acquisition is expected to be completed in the third quarter of fiscal 2024, subject to customary closing conditions. Based on the terms of the agreement, Otsuka will pay $800 million to the shareholders of Jnana upon completion of the acquisition, as well as up to an additional $325 million in development and regulatory milestones. US-based startup Jnana's novel approach to drug discovery is enabled by RAPID, the company's next-generation chemoproteomics platform designed to discover medicines for highly validated but challenging-to-drug targets. The platform leverages a high-throughput, binding-based screening approach that is inherently flexible, enabling the discovery of binding sites across the surface of a target protein and the identification of small molecules that elicit diverse pharmacologies.

Pfizer upgrades pharma production plant in Melbourne

Australia is stepping up to the global fight against antimicrobial resistance, as Pfizer Australia announces a major upgrade to its manufacturing facility in Melbourne, Victoria. Pfizer has invested AU$150 million to offer advanced pharmaceutical production facilities in Australia for new antimicrobial treatments aiming to help address rising levels of antimicrobial resistance, considered one of the biggest threats to global health. Natalie

Hutchins, Victorian Minister for Jobs and Industry visited the site to mark the milestone installation of key technology known as lyophilizers and witness the site's highly specialised capabilities, including productivity enhancements, such as the use of robotics. Investment in the Melbourne site has included the construction of a new separate facility that hosts two newly installed freeze-drying machines known as lyophilizers, which are used in the antimicrobial manufacturing process. The site has also been selected for a trial of Artificial Intelligence (AI) technology designed to support key site processes.

Mankind Pharma acquires 100% stake in Bharat Serums and Vaccines for Rs 13,630 Cr

India-based Mankind Pharma has entered into a definitive agreement to acquire a 100 per cent stake in Bharat Serums and Vaccines Limited (BSV) from Advent International, one of the world's largest and most experienced private equity investors, for an enterprise value of approx. Rs 13,630 crore, subject to closing related adjustments. This strategic move marks a significant leap for Mankind Pharma, positioning it as a market leader in the Indian

women's health and fertility drug market alongside access to other high entry barrier products in critical care with established complex R&D tech platforms. With over five decades of leadership in biopharmaceuticals, BSV has developed recombinant and niche biologic products in-house, demonstrating its strong R&D capabilities and boasts of a robust branded product portfolio across Women's Health, Fertility and Critical Care, with a few of its marque brands enjoying a strong leadership position in their respective therapy areas. BSV has a niche portfolio offering in Women's Health, encompassing the entire lifecycle, from fertility to post-pregnancy.

Taiba invests $12 M in Immuneel Therapeutics to advance CAR T-cell research

In a significant move aimed at providing new hope to blood cancer patients, Oman-based taiba Healthcare Group has announced a strategic investment in Indian startup Immuneel Therapeutics for $12 million. This strategic investment is intended to advance CAR T-cell research, with a particular focus on making CAR-T cell therapy commercially available at affordable prices and developing the first Phase 2 trial for CD19 CAR-T (IMN-003A) targeting B-cell malignancies, including leukaemia and lymphoma. CAR (Chimeric Antigen Receptor) T-cell therapy is a cutting-edge treatment pioneered in the United States, primarily used to treat blood cancers. Over the past few years, CAR-T therapies have seen significant growth, and the Indian CAR-T therapy is estimated to cost about one-tenth of comparable commercial products available globally.

SK bioscience invests $2 M in Sunflower Therapeutics

SK bioscience, a global innovative vaccine and biotech company based in South Korea, has signed a Simple Agreement for Future Equity (SAFE) totaling $2 million (KRW 2.78 billion) with Sunflower Therapeutics, a US-based biotech startup. Founded in 2018, Sunflower has developed its own yeast-based protein manufacturing technology, facilitating the development and production of diverse antigens and antibodies. The company's proprietary yeast expression system enhances vaccine development and production efficiency, offering a cost-effective solution. SK bioscience anticipates leveraging Sunflower's technology to optimise its vaccine development and manufacturing process. Integrating Sunflower's yeast culture system into its Andong L HOUSE, vaccine manufacturing plant, is projected to increase yields by up to 7.7 times while reducing production costs by 88.7 per cent per dose compared to the existing process. The SAFE agreement builds upon SK bioscience and Sunflower's existing partnership, which began with a joint agreement last year to develop a human papillomavirus (HPV) vaccine.

Insulet opens 400,000 sq ft manufacturing facility in Malaysia

US-based Insulet Corporation, the global leader in tubeless insulin pump technology with its Omnipod brand of products, opened its new manufacturing facility in Johor Bahru, Malaysia. The new manufacturing facility will strengthen the company's global operational capabilities and supply chain resiliency. Located on the southern end of the Malay Peninsula just north of Singapore, the 400,000-sq-ft facility is twice the size of Insulet's highly automated manufacturing facility in Acton, Massachusetts. Currently, more than 350 full-time Insulet employees work at the new facility with plans to grow to more than 1,000 in the coming years, part of a $200 million investment in the area. The new facility was designed with sustainable elements to eventually achieve both Green Building Index (GBI) certification and Leadership in Energy and Environmental Design (LEED) Silver certification, which is part of Insulet's global efforts to minimise its environmental impact in the areas where it operates.

Kyowa Kirin, NewBridge Pharma to improve access to rare diseases medicines across MENA

Kyowa Kirin International (KKI), a wholly owned subsidiary of Japan-based Kyowa Kirin Co., has announced the signing of a promotion and distribution agreement with NewBridge Pharmaceuticals for the distribution of its existing rare disease portfolio across the Middle East and North Africa (MENA). Under the terms of the agreement, NewBridge will commercialise CRYSVITA (burosumab) for the treatment of X-Linked Hypophosphataemia (XLH) and Tumour-Induced Osteomalacia (TIO), as well as POTELIGEO (mogamulizumab) for two subtypes of cutaneous T-cell lymphoma (CTCL), a rare non-Hodgkin's lymphoma. As part of the agreement, NewBridge will exclusively distribute the two products across MENA countries of Algeria, Iraq, Libya and Jordan. KKI and NewBridge also hope to collaboratively address a number of challenges facing the rare disease community in the region by supporting disease awareness, improving time to diagnosis, and improving access to innovative treatments indicated for rare and orphan diseases.

Biogen, Beckman Coulter and Fujirebio to develop new tests for tau pathology

Biogen Inc., Beckman Coulter, Inc. (both based in the US) and Japan-based Fujirebio have announced a collaboration to potentially identify and develop blood-based biomarkers for tau pathology in the brain and to potentially clinically advance and potentially commercialise new tests for tau pathology in Alzheimer's disease (AD). The development of tau-specific blood-based biomarkers that can measure a patient's tau burden could provide critical insights into the underlying pathological processes of AD and may help

advance the development of a new generation of therapies impacting tau pathology. Through this collaboration, the companies will work to identify new blood-based biomarkers and advance known blood-based biomarkers for tau pathology in AD. The collaboration aims to develop and clinically advance new tools that measure brain tau pathology to potentially stratify patients or monitor treatment response in AD clinical trials. Under the terms of the collaboration, Biogen will provide Alzheimer's clinical study data and expertise in biomarker research to prioritise markers for tau pathology. Fujirebio and Beckman Coulter will be responsible for providing diagnostic development, manufacturing and commercialisation.

Novo Nordisk, Bio Farma announce partnership for insulin production in Indonesia

Novo Nordisk Indonesia and Bio Farma have announced the signing of a Memorandum of Understanding (MoU) to collaborate in the production process of diabetes medication in Indonesia. By combining the expertise of both companies, Novo Nordisk Indonesia and Bio Farma aim to support the Indonesian government in providing essential diabetes medications. This collaboration aligns with the government's agenda for healthcare resilience. The increasing prevalence of diabetes in Indonesia underscores the importance of this collaboration. Currently, it is estimated that 19.5 million people live with diabetes, and this number is projected to rise to 28.6 million by 2045. This chronic condition is among the top three causes of death in Indonesia, highlighting the need for effective diabetes management. Many people with diabetes in Indonesia face significant challenges in managing their condition due to limited knowledge and awareness about the disease and proper management. A 2020 report by the Social Security Administration (BPJS) revealed that only 2 million people are diagnosed and treated under the national healthcare system (Jaminan Kesehatan Nasional, JKN).

BeiGene opens new clinical R&D and biologics manufacturing facility in US

BeiGene, a China-based oncology company, has announced the opening of its flagship US facility in Hopewell, New Jersey, at the Princeton West Innovation Campus. The new facility features state-of-the-art biologics manufacturing capabilities and a clinical research and development centre that reinforces the company's distinctive model as an innovator in oncology. With more than 30 molecules in clinical or commercial stage, the 42-acre facility provides the flexibility to scale up production of its innovative medicines today and in the future, meeting the needs of cancer patients. BeiGene's $800 million investment is the result of a three-year project to expand the company's integrated presence in manufacturing and research and development in the US. BeiGene will create hundreds of highly specialised jobs in the area by the end of 2025.

Warburg Pincus, Lendlease establish life sciences and R&D real estate platform in Singapore

Warburg Pincus, a leading global growth investor, and Lendlease, an integrated Australian real estate group with international investment capabilities, have reached the final closing on a life sciences real estate joint venture platform. Each party will commit 50 per cent of the co-investment capital over the next few years as the new platform attracts third party investors and additional capital and seeks to grow into a multi-billion-dollar platform. Headquartered in Singapore, the new platform will focus on investing, acquiring, developing, constructing, managing, and operating real estate projects in the fast-growing life sciences and R&D real estate markets in Asia Pacific (APAC). Leveraging the unparalleled sector expertise and deep market experience of both Warburg Pincus and Lendlease, the joint venture aims to become a leading life sciences and R&D real estate platform in APAC, capturing the attractive opportunities in the region's rapidly expanding life sciences and R&D real estate sector. With over 30 years of experience in life sciences real estate, Lendlease has successfully delivered first-class pharmaceutical, biotechnology, and life sciences facilities across the US, APAC, and Europe.

Aevice Health secures funding to expand remote monitoring for chronic respiratory disease

Aevice Health, a leading provider of remote monitoring solutions for chronic respiratory disease management, has raised a $7 million Seed Plus Round led by Coronet Ventures, the Singapore-based venture unit of Cedars-Sinai Intellectual Property (CSIP) Co. Participating in the round include East Ventures, A&D Company, Limited, NTUitive, Farquhar Venture Capital and existing investor Silicon Solution Venture, along with SEEDS Capital, the corporate investment arm of Enterprise Singapore. The funding will be used to advance Singapore-based startup Aevice Health's operations in key markets including US, Japan, and Singapore, leveraging the unique network each investor brings to each key market. This investment builds on recent commercial and clinical milestones for Aevice Health, including successfully obtaining regulatory approvals for AeviceMD in the US and Singapore, entering a partnership with A&D Company, Limited in Japan, and establishing a clinical collaboration with Cedars-Sinai through the Cedars-Sinai Accelerator.

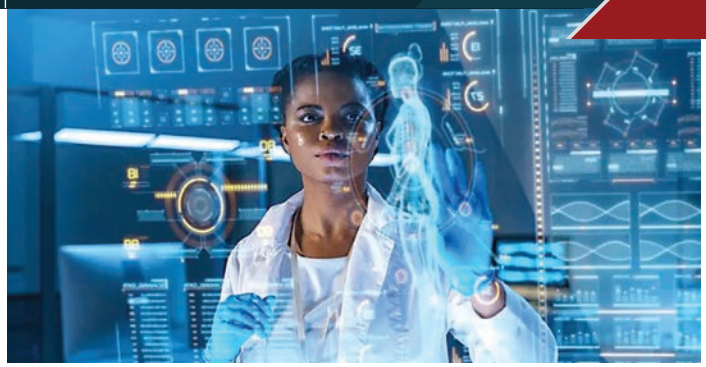
NSG BioLabs and Merck to support biotech startups to advance research & innovations

NSG BioLabs, Singapore's largest provider of biotech co-working laboratory and office space, and the Life Science business of Merck Singapore, have announced partnership giving biotech startups access to resources and expertise to bolster the research and development capabilities of NSG Biolabs' tenants, thereby facilitating opportunities for funding, partnerships, production, and commercialisation. Since 2019, NSG BioLabs has been assisting innovators in creating impactful solutions in the health, biomedical, agrifood, and industrial biotechnology sectors, working in areas such as precision medicine, nucleic acids, AI-enabled drug discovery, synthetic biology, and other areas. With the largest co-working biotech laboratory and office footprint in Singapore, coupled with extensive networks with local and international partners, suppliers, and industry experts, NSG BioLabs has helped over 40 companies as residents.

Australian biotech incubator Proto Axiom announces $20 M Series B first close

Proto Axiom, the Australian biomedical technology incubator, has announced a $20 million first close of its targeted $30 million Series B, to bolster Australia's biotechnology sector through increased intellectual property (IP) retention. The Series B first close and $15 million Series A announced in September 2022 gives Proto Axiom a cash value of $90 million. Series B investors join the significant institutional support Proto Axiom received in its Series A from investors such as Catalio, Parkview International,

Churchill Asset Management and HOF Capital. Proto Axiom distinguishes itself from traditional funds by operating as a holistic enterprise to onshore sovereign capacity through a comprehensive partnership model, covering technical oversight, administrative support, future financing, and hands-on research assistance. This new funding would allow Proto Axiom to continue investing in projects like University of New South Wales' spin-out, Swan Genomics. Proto recently led the funding round and invested $2 million in Swan, a cutting-edge new technology for rapid, highly accurate long-read, low copy number DNA sequencing, using a highly innovative Plasmonic Nanoantenna based approach.



AITRICS inks MoU with ezCaretech to advance AI-based healthcare services

South Korea-based startup AITRICS has announced the signing of a Memorandum of Understanding (MoU) with ezCaretech, also based in South Korea. Both parties will jointly explore new businesses related to Artificial Intelligence (AI) solutions for predicting patient condition deterioration using Hospital Information System (HIS) services. The two companies plan to mutually discuss detailed plans for linking AITRICS' patient condition deterioration prediction software technology with ezCaretech's HIS technology, and to concretise various exchanges and cooperation in the future. Both parties expect to promote new businesses and strengthen their competitiveness in the domestic and international medical markets. In addition, they expect to enhance the product by combining AITRICS' AI solution for predicting patient condition deterioration with ezCaretech's cutting-edge HIS, thereby providing medical staff with a higher possibility of treating patients.

Terumo establishes corporate venture capital to support innovation

Japan-based Terumo Corporation has established Terumo Ventures, a Corporate Venture Capital (CVC) organisation responsible for leading the Group's venture investments, as a department within Terumo Americas Holding, Inc. Terumo Ventures operates in global innovation hubs around the world, such as Massachusetts and California in the United States, and invests $75 million over the next five years in early-stage companies primarily in the fields of cardiovascular disease treatment, chronic disease treatment, and digital technologies. This will enable Terumo to enhance its access to innovative technologies and business ideas from startups, promote open innovation, and pursue synergies with its internal R&D efforts. Terumo has been building relationships with medtech startups by investing in venture capital funds in the United States and China since 2013.

Surglasses deploys Caduceus S surgical navigation system in Thailand

Leading augmented reality (AR) medical technology startup Surglasses, based in Taiwan, has announced that in collaboration with exclusive distributor Goodlife Intertrade, it has successfully registered and clinically implemented its AR-based Caduceus S surgical navigation system in Thailand. This groundbreaking system is designed to assist various minimally invasive surgeries, significantly enhancing surgical precision and patient outcomes. The first AR-guided surgery using only the C-arm

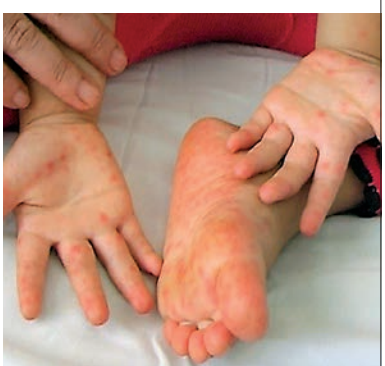
in Thailand was successfully performed at Thailand Veterans General Hospital by Dr Chaiyos Chaichankul. The 78-year-old patient had preoperative symptoms of leg numbness, radiating pain, and difficulty walking. After the surgery, the patient's nerve numbness in the legs disappeared, and the pain was significantly reduced. The Caduceus S AR surgical navigation system is an advanced tool specifically designed for augmented reality spine surgery. Through its 3D visualisation capabilities, surgeons can clearly view the internal anatomy of patients during procedures, including bones, tissues, and organs, thereby improving surgical accuracy and outcomes.

US FDA increases access to first step of syphilis diagnosis

The US Food and Drug Administration (FDA) has granted marketing authorisation to NOWDiagnostics for the First To Know Syphilis Test. This is the first at-home, over-the-counter test to detect Treponema pallidum (syphilis) antibodies in human blood. Results from this type of test alone are not sufficient to diagnose syphilis infection and should be followed by additional testing to confirm a diagnosis of syphilis. According to the US Centers for Disease Control and Prevention, reported syphilis cases increased 80 per cent in the United States between 2018 and 2022 (from 115,000 to more than 207,000), continuing a decades-long upward trend. Prior to this action, there was no over-the-counter test to inform a user about a potential syphilis infection. The test provides an at-home result without a prescription, in approximately 15 minutes, which individuals can use to better inform next steps with a health care provider. This announcement follows last year's authorisation of the first diagnostic test for chlamydia and gonorrhea with at-home sample collection, which was the first FDA-authorised test with at-home sample collection for any sexually transmitted infection other than HIV.

PAHO, SLIPE join forces to reduce childhood infectious diseases

The Pan American Health Organization (PAHO) and the Latin American Society of Paediatric Infectious Diseases (SLIPE) have signed a cooperation agreement aimed at reducing infectious diseases prevalent among children and adolescents in Latin America. PAHO and SLIPE will collaborate on projects in key areas such as vaccination, paediatric infectious diseases, arboviruses (such as dengue, Zika, and chikungunya), perinatal infections, and neonatal sepsis. Additionally, they will work to strengthen surveillance systems, promote ongoing research to inform clinical practices, and implement awareness campaigns. This five-year, renewable technical cooperation framework agreement aligns with other PAHO initiatives aimed at addressing infectious diseases and promoting child and adolescent health in the region. These include the Action Plan for the Health of Women, Children, and Adolescents 2018-2030 and the Disease Elimination Initiative, which seeks to eliminate more than 30 communicable diseases and related conditions by 2030.



New global initiative to advance mRNA vaccine development against H5N1

A new project aiming to accelerate the development and accessibility of human avian influenza (H5N1) messenger RNA (mRNA) vaccine candidates for manufacturers in low- and middle-income countries has been launched. The Argentinian manufacturer Sinergium Biotech will lead this effort leveraging the World Health Organisation (WHO) and the Medicines Patent Pool (MPP) mRNA Technology Transfer Programme. Sinergium Biotech has developed candidate H5N1 vaccines and aims to establish proof-of-concept in preclinical models. Once the preclinical data package is concluded, the technology, materials, and expertise will be shared with other manufacturing partners, aiding the acceleration of the development of H5N1 vaccine candidates, and bolstering pandemic preparedness efforts. This initiative exemplifies why WHO established the mRNA Technology Transfer Programme, to foster greater research, development and production in low- and middle-income countries, so that when the next pandemic arrives, the world will be better prepared to mount a more effective and more equitable response.

Mozambique introduces malaria vaccines into routine immunisation

Mozambique has introduced the lifesaving malaria vaccine into routine immunisation, a critical step forward to revitalise the fight against malaria and improve children's survival. With the introduction, Mozambique marks an important step towards reducing the vulnerability of children and consequently reducing thousands of malaria cases and saving thousands of children's lives. Through Gavi, the Vaccine Alliance, and co-financing from the Government of Mozambique, the country has over 800,000 doses of the malaria vaccine for the Expanded Programme on Immunisation, with the aim of immunising around 300,000 children in the first phase, which began on August 5. The vaccine is distributed in 22 districts in the province of Zambézia and administered in a four-dose schedule; the first dose covering children aged 6 to 11 months. The R21 malaria vaccine is safe, effective and recommended by the World Health Organization (WHO). This vaccine is an advancement for child health, disease control and reduction of child mortality in Mozambique, where malaria is an endemic disease, with prevalence in children under 5 years of age at 32 per cent (IDS 2022-2023).

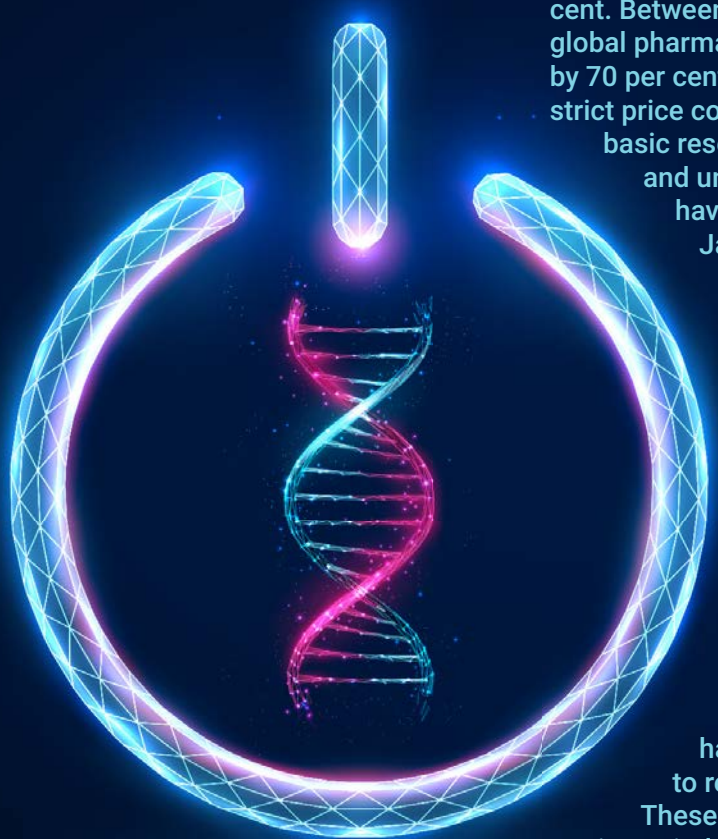
Clinical trial in Africa to assess if mpox vaccination works after virus exposure

A clinical trial in the Democratic Republic of Congo (DRC) and other countries in Africa will assess whether an mpox vaccine can protect people against the disease after they have come into contact with the potentially deadly infection. The 'SMART' trial has received $4.9 million from Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) and the Canadian Institutes of Health Research to find out if post-exposure vaccination of Bavarian Nordic's MVA-BN mpox vaccine could reduce the risk of secondary mpox cases, or, if a person contracts mpox, could reduce their severity of illness. Led by Mark Loeb, a Professor of Pathology and Molecular Medicine with Canada's McMaster University, the research will invite over 1500 participants (aged over 10) in households with a laboratory-confirmed mpox infection at sites in the DRC, Uganda and Nigeria to take part in the trial. The study is enrolling participants from Kamituga, South Kivu province, an area which has recently reported mpox cases.

Global scientists explore innovative tech to rapidly make new vaccine antigens

Researchers in the US are pursuing pioneering technology that may be able to rapidly create safe and effective vaccines against deadly epidemic and pandemic diseases that are more stable and less expensive than current vaccines. This has the potential to benefit more people globally. Norway-based Coalition for Epidemic Preparedness Innovations (CEPI) is giving Denmark-based Boost Biopharma a $5 million cash injection to advance its cutting-edge rapid antigen design process that has the potential to quickly create new vaccines against troublesome viruses, like SARS-CoV-2, the virus behind COVID-19, and its constantly evolving variants, along with other vaccines of global interest. Boost's vaccines are made with protein antigens, molecules that mimic a part of a virus which our bodies then recognise and respond to, in order to provide protective immunity. Accelerating the development of protein vaccines could meet or exceed the speed at which other types of vaccines, like mRNA vaccines, are made.

Rebooting Japan's Biotech Growth Engine



Japan was once a global leader in life sciences innovation, responsible for nearly 30 per cent of all new drugs. However, its share has since dropped to less than 10 per cent. Between 1995 and 2018, Japan's contribution to the global pharmaceutical industry's value-added declined by 70 per cent, from 18.5 to 5.5 per cent. Factors such as strict price controls, reduced government investment in basic research, weak collaboration between industry and universities, and a slow regulatory process have significantly contributed to the decline in Japan's biopharmaceutical competitiveness, as noted in a 2022 paper by the Centre for Life Sciences Innovation, part of the Information Technology and Innovation Foundation, US. Japanese companies' share of clinical trials also declined from 11 per cent in 2013 to 4 per cent in 2023. An IQVIA report found that the number of trials initiated by Japanese companies dropped from 501 in 2013 to 244 a decade later. Additionally, Japan launched only 20 new medicines in 2023, the lowest total since 2014, trailing behind the US and other major markets.

Recognising this, the Japanese government has announced several initiatives designed to reshape the country's biopharma ecosystem. These efforts include substantial increases in capital for venture funds, targeted subsidies for therapeutic drug development, and a suite of tax incentives aimed at empowering investors, entrepreneurs, and startup employees.

On July 30 2024, Japanese Prime Minister Fumio Kishida unveiled a roadmap to establish Japan as a 'drug discovery land,' marking it as a top government priority. The plan includes creating international-level clinical trial systems, attracting global pharmaceutical companies and venture capital, and doubling private investments in drug discovery startups by 2028. The aim is to foster an environment that supports both academia and startups, accelerates innovation, and enhances Japan's role in the global pharmaceutical industry.

Drug lag is a serious concern in Japan. As of March 2023, 143 drugs approved in Europe or the US had yet to be approved in Japan, with 86 of these having no plans to seek approval in Japan. To address this issue, Japan has introduced measures to support innovative drugs. Under the 2024 drug pricing reform, the Ministry of Health, Labour and Welfare (MHLW) has maintained and, in some cases, increased the Price Maintenance Premium (PMP) and initiated an early launch programme. This programme encourages the introduction of drugs in Japan either first or shortly after their global launch. Additionally, Japan plans to speed up regulatory approvals for pharmaceuticals starting 2025, with a new deadline of approximately three weeks from when a drug or indication clears the review of its key advisory panel.

Moreover, MHLW promotes the development of drugs through tax deductions, drug-price incentives, as well as subsidies to offset R&D and application fees. The Ministry of Economy, Trade and Industry (METI) launched an initiative worth 300 billion yen in fiscal 2022 to support biopharmaceutical manufacturing, specifically vaccines.

Creating innovation ecosystem

Japan was ranked comparatively low in innovation, startups, and entrepreneurship. The United Nations' 2022 Global Innovation Index placed Japan 13th globally, a significant drop from its 7th place in the 1970s and in 2007. In response to this decline, the Japanese government is significantly strengthening the startup ecosystem. At the 2023 BIO International Convention in Boston, METI organised the 'Japan Innovation Night,' where Prime Minister Kishida announced a $7 billion budget to support Japanese startups, with 30 per cent of the funds specifically designated for drug discovery.

The Japanese government launched the Startup Development Five-Year Plan in 2022. The plan, spearheaded by METI, aims to increase startup investment tenfold by 2027 through public-private partnerships. The ambitious goals of the plan include creating 100 unicorns, establishing 100,000 startups, and transforming Japan into the largest startup hub in Asia and one of the world's leading clusters of startups. Over the past five years, investment in startups has already grown by 2.3 times, from 360 billion yen in 2017 to 820 billion yen in 2021. However, METI's five-year plan seeks to further increase investment to 10 trillion yen by 2027. Japan also unveiled plans for a 10 trillion yen national endowment fund to boost the research capabilities of the universities.

METI's other efforts include the creation of the Japan Agency for Medical Research and Development (AMED) to accelerate medical research into treatments. The agency's key initiative, the Strengthening Program for the Pharmaceutical Startup Ecosystem, with a budget of 350 billion yen in subsidies to support pharmaceutical startups.

"AMED operates the Strengthening Program for Pharmaceutical Startup Ecosystem Project, offering substantial subsidies of up to $60 million per project. This programme specifically supports therapeutic drug development by pharmaceutical startups, with more than one-third of the subsidised costs covered by AMED-registered venture capitalists who provide specialised commercialisation support. Saisei Ventures, one of these registered Venture Capitalists (VCs), has successfully leveraged this programme, significantly enhancing the value of its portfolio companies," said Dr Jonathan Yeh, Co-founder and Managing Partner at Saisei Ventures.

In January 2024, METI launched the Japan Innovation Campus in Silicon Valley, an innovation hub that connects Japanese startups with international partners. This campus supports

startups aiming to expand globally by working with local VCs, accelerators, and top universities.

"Japan's biotech ecosystem has seen several notable initiatives and collaborations in recent years to drive innovation and growth in the sector. One critical development has been the government's efforts to promote public-private partnerships and encourage greater collaboration between industry, academia, and research institutions," said a spokesperson from Chugai Pharmaceuticals.

Ecoching similar views, Dr Hide Goto, Head of Open Innovation Management, Astellas says, "The presence of academia and startups in drug discovery research is increasing, and Japanese pharmaceutical companies are now in an era where they imagine value not only through their research but also through collaboration with external stakeholders like academia, small startups/biotech and other pharma companies. Japan lags behind the West in terms of the maturity of the biotech ecosystem. Hence industry, government, and academia need to work together to foster a culture of innovation. Some efforts to promote the development of the biotech ecosystem in Japan have begun in various places."

Pharmaceutical companies are increasingly establishing incubation facilities to support startups. For example, Takeda Pharmaceutical Co. Ltd. launched Shonan iPark in 2018. As of April 2023, Shonan iPark hosts approximately 150 companies and over 2,000 individuals, spanning not only pharmaceutical firms but also sectors such as next-generation medicine, cell agriculture, AI, government, and others, creating a vibrant ecosystem. In 2023, Astellas also launched SakuLab-Tsukuba, an open innovation hub in Astellas' Tsukuba Research Center, to help nurture and support new startups, small businesses and academic institutions to pursue their cutting-edge science. Leveraging presence in Tsukuba and Kashiwa-no-ha, leading life science hubs in Japan, the firm also aims to activate Japanese innovation through various initiatives such as hosting pitch events and strategic partnerships with academia.

"Not only in the Japanese market but globally, more and more of the drugs and therapies approved in recent years have originated from academia or startups, making open innovation essential for the creation of new medicines," says Dr Hide Goto.

In April 2024, Takeda, Astellas and Sumitomo Mitsui Banking Corporation announced a master agreement to establish a joint venture company for the incubation of early drug discovery programmes primarily originating from Japan and toward the creation of innovative therapeutics.

Lack of funding has been a major roadblock for Japanese startups, as historically big pharma companies and VC firms have invested more outside Japan. However, recent government actions—including initiatives to establish a global startup ecosystem and relaxed regulations—have spurred many venture capital firms to announce funds specifically for Japan. Notable examples include American VC firm Arch launching a $3 billion biomedical fund with a focus on Japan, Kyoto University's VC fund investing $140 million in AI and biotech, and Otsuka Pharmaceutical investing $30 million with AN Venture Partners to support global biotech companies leveraging Japanese science.

Evolving trends

Japan is a frontrunner in conducting induced pluripotent stem cell (iPSC) therapeutic trials. Out of the 19 iPSC clinical trials worldwide, 10 were conducted in Japan, followed by 4 in the US and the rest in Australia, China, Iran and Germany, according to AE Research Management. Apart from regenerative medicines, the country is now prioritising cell and gene therapies, antibody-drug conjugates, etc.

"Japan is increasingly prioritising next-generation therapies, including monoclonal antibodies, gene therapies, and stem cell research. Significant investments are being funnelled into these areas, with a strong emphasis on developing treatments for conditions that were once considered untreatable. The rise of personalised medicine is also gaining momentum, aligning with global trends toward more precise and individualised healthcare solutions," said Dr Yeh.

INNOVATIVE JAPANESE BIOTECH STARTUPS

Chordia Therapeutics, is a clinical-stage biotech company focused on developing innovative anti-cancer drugs. Spun out from major companies and supported by academic discoveries from Kyoto and Miyazaki Universities, Chordia is advancing cancer therapies like CTX-712, a CLK inhibitor currently in clinical trials in Japan and the US. In 2020, Chordia out-licensed its MALT1 inhibitor CTX-177 to Ono Pharmaceutical, securing significant upfront and milestone payments. Committed to collaborative research, Chordia aims to deliver new treatments for cancer patients and contribute to Japan's drug discovery ecosystem. The startups received the Minister of Education, Culture, Sports, Science and Technology Award at the 'Japan Startup Awards 2024'.

PeptiDream Inc. is leading the translation of macrocyclic peptides into a whole new class of innovative medicines to address unmet medical needs and improve the quality of life of patients worldwide. In its radiopharmaceutical business, through its wholly-owned subsidiary PDRadiopharma, PeptiDream markets and sells a number of approved radiopharmaceuticals and radiodiagnostics in Japan, as well as leveraging its proprietary Peptide Discovery Platform System (PDPS) technology to discover and develop a deep pipeline of innovative targeted radiotherapeutics and radiodiagnostics, spanning both wholly-owned internal programmes and globally partnered programmes. In its non- radiopharmaceutical business, PeptiDream is similarly leveraging PDPS to discover and develop a broad and diverse pipeline of investigational peptide therapeutics, peptide drug conjugates (PDC) and multi-functional peptide conjugates (MPC) across an extensive global network of discovery and development partners.

EditForce, Inc., a Kyushu University-originated startup developing a unique DNA/RNA editing technology (PPR platform technology), was established in May 2015 by KISCO Co., Ltd. and Prof. Takahiro Nakamura of Kyushu University (former president of EditForce and currently its scientific advisor) and funded by companies and funds that have track records of investing in life sciences and biotechnology. EditForce aims for drug discovery that applies the PPR technology through joint research with universities and private companies.

PRISM BioLab is a discovery and development biotechnology company utilising proprietary PepMetics technology to discover orally available small molecule inhibitors of protein-protein interaction (PPI) targets and transform lives of patients suffering from cancer, autoimmune, fibrosis and other diseases. PepMetics are a unique class of small molecules that mimic three-dimensional structures of alpha-helix and beta-turn, the peptide structures commonly found in intracellular PPI interphases and receptor-ligand interactions. By combining proprietary chemistry, know-how around PPI targets and AI-supported design,

PepMetics technology can deliver inhibitors of challenging PPI targets. The technology holds promise to expand the field of drug discovery by turning previously undruggable PPIs into targets readily druggable with small molecules and by generating oral small molecule alternatives for injectable biologics. PRISM BioLab is collaborating on new PPI targets with global and Japanese pharmaceutical companies. PepMetics targeting CBP/beta-catenin PPIs licensed to Eisai Co., Ltd. and Ohara Pharmaceuticals Co., Ltd. are in clinical development for cancer and liver disease, respectively. The firm listed on Tokyo Stock Exchange in July 2024.

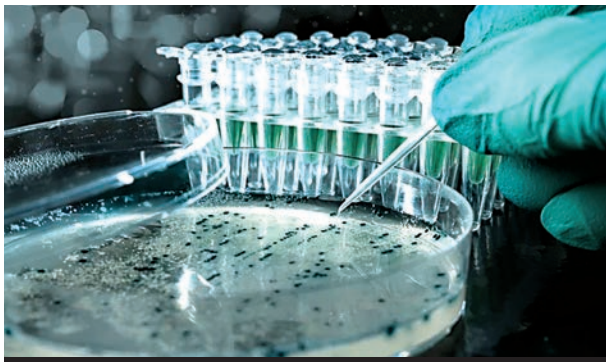
Restore Vision Inc., a biopharmaceutical company based in Japan, is pioneering the development of gene therapy to restore vision in patients blinded by photoreceptor loss. Their lead product, RV-001, utilises adeno-associated virus (AAV) vectors to deliver a unique functional gene coding 'Chimeric Rhodopsin,' a protein-based optical sensor designed to restore sight. Recently securing 1.9 billion yen in Series A financing and receiving support from Japan's AMED, Restore Vision is rapidly advancing RV-001 towards pre-clinical development and clinical trials, with the goal of becoming the world's first gene therapy for vision restoration.

Healios is advancing research on an immuno-oncology treatment for solid tumours by using gene-edited NK cells (eNK cells) with enhanced killing abilities. Healios is advancing research on UDCs, which are next-generation iPS cells with a low risk of immune rejection regardless of HLA type created using gene-editing technology, aiming to establish a next generation technology platform to develop more efficient and safer regenerative medicine products. It is also working on the development of therapeutic medicines for ischemic stroke and ARDS in Japan using somatic stem cells.

Aculys Pharma is a clinical stage biopharmaceutical company that is pioneering ways to eliminate drug lag/drug loss in Japan, and is working to resolve social issues related to neurological and psychiatric diseases. Its corporate name was created from the philosophy of serving as a 'Catalyst to Access.' Aiming to act as a bridge for innovative medical care in the field of neuropsychiatry, Aculys Pharma develops and commercialises novel pharmaceuticals and provides innovations for better medical care to patients, their families, healthcare professionals, and society.

Heartseed Inc. was founded in 2015 to develop and commercialise cardiac revascularisation therapy developed by Professor Keiichi Fukuda and his group at the Department of Cardiology, Keio University, Tokyo, Japan. Heartseed has proprietary technologies throughout the entire manufacturing process of the cardiomyocyte-cell product, including purification, cell delivery and iPSC production. Heartseed announced the global collaboration and licence agreement with Novo Nordisk A/S for HS-001 in June 2021. Heartseed received 'Minister of Science and Technology Policy Award' at Japan Venture Awards 2021 and 'Ministry of Education, Culture, Sports, Science and Technology Award' at Academic Startups 2021, and 'Most Promising Pipelines Awards (iPSC)' at Asia Pacific Cell & Gene Therapy Excellence Awards 2022.

CureApp is involved in the research and development, production, and sale of therapeutic apps which have demonstrated their effectiveness in a clinical trial, and are prescribed by doctors to patients at medical clinics. In 2020, CureApp developed the world's first smartphone-based medical device program for disease treatment to receive regulatory approval and insurance coverage in the field of smoking cessation. The company later was the first to receive regulatory approval in the field of hypertension in April 2022, followed by insurance coverage in September of the same year. CureApp is also proceeding with the development of a number of other therapeutic apps for other diseases, including NASH, alcohol addiction, cancer, chronic heart failure, and chronic low back pain. BS



Top Pharma Companies

- Daiichi Sankyo
- Takeda Pharmaceutical
- Chugai Pharmaceutical
- Astellas Pharma
- Otsuka Holdings
- Shionogi
- Eisai
- Kyowa Kirin
- Ono Pharma
- Rohto Pharmaceutical

"The presence of academia and startups in drug discovery research is increasing, and Japanese pharmaceutical companies are now in an era where they imagine value not only through their research but also through collaboration with external stakeholders like academia, small startups/ biotech and other pharma companies."

- Dr Hide Goto,
Head of Open Innovation Management, Astellas

"Japan is increasingly prioritising next-generation therapies, including monoclonal antibodies, gene therapies, and stem cell research. Significant investments are being funnelled into these areas, with a strong emphasis on developing treatments for conditions that were once considered untreatable. The rise of personalised medicine is also gaining momentum."

- Dr Jonathan Yeh,
Co-founder and Managing Partner, Saisei Ventures

Japan's rapidly ageing population presents significant challenges, including an increased risk of degenerative diseases. Therefore, many Japanese pharmaceutical companies are focusing on treating neurological disorders like Alzheimer's, epilepsy, Parkinson's, and depression.

The government has also made extending healthy life expectancy to 100 years one of the 10 goals of Japan's national moonshot research and development policy, which supports challenging R&D projects that aim to resolve difficult societal issues by drawing on the wisdom of researchers around the world.

"The Japanese pharmaceutical market is undergoing various changes, including addressing an ageing society, promoting generic drugs, pioneering efforts in regenerative medicine, focusing on rare diseases, and the rise of digital health. Opportunities may arise for domestic and international companies to develop innovative therapies, address the healthcare needs of the elderly, enter the generic drug market, and expand into new fields like regenerative medicine and remote/telemedicine," said a spokesperson from Chugai Pharmaceuticals.

This ageing landscape is driving the need for scalable, efficient healthcare solutions. Digital health technologies, including AI-powered diagnostic tools and digital therapeutics (DTx) offer vital solutions. CureApp, a startup company pioneering digital therapeutics in Japan, received Japan's first regulatory approval in 2020 for its 'CureApp SC' nicotine addiction treatment app, followed by the world's first regulatory approval for hypertension in 2022 for its 'CureApp HT' high-blood-pressure-management app. Big pharma firm Shionogi is actively engaged in the DTx space. The company is collaborating with US medical tech specialist Akili to commercialise mobile games aimed at helping children with attention deficit hyperactivity disorder (ADHD). Additionally, Shionogi has partnered with NTT DATA KANSAI Corporation and QUNIE CORPORATION to develop a distribution platform for digital therapeutic services.

The biotechnology sector in Japan has grown steadily, reaching 5.2 trillion yen in 2020, a 70 per cent increase over the last five years. According to the National Institute of Technology and Evaluation, this market is expected to continue its growth, reaching 15 trillion yen by 2030. With such a large market size, an ageing population, high-quality fundamental research and government initiatives, Japan is perfectly positioned to reclaim the top spot and become a global leader in biotech. BS

Ayesha Siddiqui

Boosting Japan's Biotech Ecosystem

Japan's biotech ecosystem is at a pivotal moment, characterised by both challenges and opportunities. Despite a rich history of scientific achievement, including significant contributions to biochemistry and medicinal chemistry, Japan has struggled to cultivate a vibrant startup culture in biotechnology. This stagnation is partly attributed to stringent drug pricing controls that have stifled innovation and investment in the sector.

The Japanese government and major pharmaceutical companies are now recognising the need for a robust biotech ecosystem. Initiatives are being launched to foster innovation, including increased support for startups and collaboration with global partners. For example, Kobe's Port Island, home to the Kobe Biomedical Innovation Cluster (KBIC), has become a significant biotech hub. Established in 1998, KBIC has attracted over 350 institutions and companies, ranging from promising startups to multinational healthcare giants.

Entities such as Intrinsic Japan aim to increase activity in this sector and grow international collaboration. Intrinsic Japan, a subsidiary of the Canadian incubator and venture capital firm Intrinsic Innovations and Intrinsic Venture Capital, has established its first Japanese base in Kobe to support medical and biotech ventures in entering Japanese and overseas markets.

Key facilities in biotech clusters often include research institutes, innovation centres, and support networks. For instance, the Creative Lab for Innovation in Kobe (CLIK) offers state-of-the-art research facilities and promotes open innovation among startups, large companies, research institutions, and academia.

« **Andrew Sanden,**
Co-CEO,
Intrinsic Japan K.K. /
Intrinsic Innovations

However, Japan's biotech sector still faces significant hurdles, particularly in attracting venture capital. In 2023, Japanese biotech investments were a mere fraction—3 per cent—of those in the United States, indicating a critical funding gap that needs to be addressed. Moreover, Japan's integration into the global biotech ecosystem is crucial. Recent discussions between Japanese and U.S. leaders emphasise a mutual interest in enhancing biopharmaceutical collaboration, particularly as Japan seeks to leverage its scientific expertise to compete internationally. However, challenges remain, particularly in developing the skilled workforce necessary for a thriving biotech sector. There is a pressing need to attract talent and foster an environment that embraces risk and innovation, which are essential for success in this competitive field.

In conclusion, while Japan's biotech ecosystem has significant potential, realising this potential will require concerted efforts from the government, industry, and academia to create a supportive environment for startups, increase funding, and enhance global collaboration. BS

Strategies for Success in Japan's Biotech Ecosystem

« **Stefan Sandström,** Founder and CEO, Biosector, Tokyo

Japan's biotech sector is a landscape rife with opportunity, yet also a complex market that requires a deep understanding of local ecosystems and cultural nuances. For nearly two decades, successful commercialisation projects in Japan have often depended on our ability to navigate these challenges. Having facilitated projects with 32 of Japan's 40 largest pharmaceutical companies and as a writer of an award-winning blog on biotech business strategies and opportunities in Japan, I have seen firsthand what it takes to succeed in this complex environment.

Successful Market Entry

Entering Japan's biotech market demands more of you than showing up at a tradeshow. You must consider aspects like regulatory, pricing, reimbursement, MAH, KOLs and who to partner with. Companies successful in Japan often form alliances with local entities. That means immediate access to market insight and gaining market access. A beneficial partner also provides paramount credibility. Moreover, complying with Japan's regulatory requirements is another critical aspect. The process is manageable when approached with sound strategies and guidance. Two pieces of advice: Study the regulatory environment and then work with a regulatory consultancy.

Trust is Key

I cannot overstate the importance of understanding Japan's business culture. Trust is the cornerstone of all business relationships, and in Japan, it is built through consistent and respectful engagement over time. For instance, signing a distribution agreement in Japan can take up to one year after the first handshake or bow. This lag is due diligence being conducted the Japanese Way.

A key aspect of this trust-building process is understanding the Japanese approach to decision-making. Unlike in many Western cultures, where decisions may be swift, Japan sees consensus-building. While this process may appear slow, it ensures decisions are well-considered and supported by all stakeholders, leading to stronger and more enduring business relationships. Over time, this means Japanese companies are risk-averse and make very few, costly mistakes.

The Future is Here

The sector is seeing significant transformation, driven by national initiatives like BioStrategy 2030, which aims to position Japan as a global leader in biotechnology. Underpinned by government support and strategic investments, it fosters innovation in all segments.

Central to this transformation is the Greater Tokyo Biocommunity (GTB), a key innovation hub in Japan that connects companies, research institutions, and investors. Biocommunity Kansai (BiocK) is similar but in the Kansai region. For those aiming to enter the Japanese market, aligning with such initiatives offers a strategic advantage, providing access to cutting-edge research and collaborative opportunities.

Key Points to Success

Take a strategic approach to commercialisation in Japan's biotech sector. Working with local experts means invaluable insights and guidance at your fingertips. Japan External Trade Organization (JETRO) is a government-affiliated organisation that offers free support services, including market research and business matching. Since networking in Japan is inherently slow and relationship-based, tapping into the existing networks of professionals already established in the biotech community will speed things up. BS

Advancing Japan's Biotech Ecosystem: Current Initiatives and Future Outlook

Japan has a robust drug discovery capability, having developed an interleukin-6 inhibitor, a programmed cell death protein 1 inhibitor, and, in earlier years, an acetylcholinesterase inhibitor for Alzheimer's disease. Additionally, in stem cell research, Professor Shinya Yamanaka's discovery of induced pluripotent stem cells (iPSCs) has placed Japan at the forefront of regenerative medicine (RM). Despite its strong basic research capabilities, Japan has fallen behind in building its biotech ecosystem due to the lack of venture financing and lower labour mobility to startups. To address this and make drug development a growing industry in Japan, the Japanese government has been implementing measures to enhance the biotech ecosystem.

Initiative to Enhance the Ecosystem: Most importantly, the Japanese government introduced the "Strengthening Drug Discovery Venture Ecosystem Project" with a budget of 300 billion yen starting in 2022. This initiative provides subsidies of up to twice the investments from multiple certified Venture Capitalists (VCs) through the completion of Phase II clinical trials, as long as the biotech does not go public. This subsidy enhances VC returns and provides more funding for biotech than would otherwise be available. The project requires that the investment amount from a lead certified VC, including already executed investments, be 1 billion yen or more, to reinforce commitments from the VC. Since the subsidies do not apply to investments made before the project period, this system primarily targets early to mid-stage startups that are yet to receive new VC investments.

Challenges in Late-Stage Funding: However, financial challenges remain for later-stage biotechs. While advancing pivotal trials would significantly increase corporate value, many companies are forced to go public or be acquired before reaching such value inflection points due to insufficient private funding. Because the development stages are too early for investors specialising in biotech, relatively small funds are raised at biotech IPOs in Japan. Consequently, post-IPO growth has been limited, and Japanese biotechs have yet to produce globally successful drugs. Since the risk of drug development is dramatically reduced after confirming early clinical data, activation of late-stage financing, including from public market investors, is crucial to strengthen the ecosystem in Japan.

« **Kikuo Yasui,**
Chief Operating Officer, Director of the Board
Heartseed

Anticipated Success Stories: For late-stage investors to turn their attention to Japan, successful examples are indispensable. Japan has the potential for breakthroughs in the field of RM, supported by favourable regulatory policies and world-leading technologies. To accelerate the practical application of RM, the Japanese government introduced a conditional approval scheme, allowing companies to initiate commercialisation based on Phase II trial data, demonstrating efficacy through post-marketing surveillance as an alternative to Phase III trials. This scheme is vital for keeping Japan an attractive market for RM development. In fact, public companies that have clinical pipelines in RM are valued relatively highly on the Tokyo Stock Exchange. Among them, Heartseed, a leading biotech in cardiac RM, went public in July 2024. Heartseed has established a global partnership with Novo Nordisk, aiming to accelerate global development, manufacturing, and commercialisation. This partnership combines the agility of biotech with the quality and scale of a mega pharma, and could serve as a model for global expansion.

Biotech growth as National Priority: The Japanese government positions startup support as a key priority and is actively developing truly effective measures to produce home-run success stories. As a result of these efforts, the ecosystem has been strengthened, as seen in the influx of experienced talent from pharmaceutical companies and the emergence of venture capital firms capable of supporting new company creation. As signs of success cases are beginning to emerge, it is expected that groundbreaking medicines from Japan will have a significant impact globally in the near future, presenting compelling investment opportunities in Japan's biotech sector. BS

Cutting Clinical Costs with Companion Diagnostics

Advancing personalised medicine has become a key goal for many pharma firms, evident from the rising number of such therapies under clinical development. In 2022 alone, 12 new personalised medicines were approved, marking these treatments as accounting for at least a quarter of new drug approvals over the past eight years. This contrasts sharply with a decade ago when personalised medicines constituted less than 10 per cent of new approvals annually, according to The Personalised Medicine Coalition report. As the trend towards precision medicine and targeted therapies continues, companion diagnostics (CDx) are becoming increasingly vital, particularly in oncology. Let's explore the opportunities that CDx presents and the hurdles in their development and implementation.

Companion diagnostics (CDx) are the cornerstone of precision medicine and play a critical role in optimising patient outcomes and reducing healthcare costs by ensuring that therapies are tailored to individual patient profiles. Currently, there are 51 CDx tests approved by the US Food and Drug Administration (FDA). The majority of these are for haematological malignancies and solid tumours. In fact, of the 170 approved indications listed on the FDA website for companion diagnostics, only three are for non-oncology drugs.

In addition to their role in personalised medicines, CDx can also enhance clinical trials and expedite drug development by pinpointing appropriate patient populations. Research and Markets indicates that CDx-guided drug development has the potential to cut clinical trial costs by up to 60 per cent. This allows pharmaceutical companies to bring proven drugs to market more quickly and at a lower cost through clinical trials. That's why there has been a rise in partnerships between pharmaceutical companies and diagnostics firms. Notable examples include Incyte's collaboration with Agilent on CDx development, Foundation Medicine's partnership with Repare Therapeutics to provide genomic profiling services and develop CDx., Additionally, there's Roche and Janssen's strengthened collaboration to develop CDx tests for targeted therapies.

Challenges in CDx development

There are several key stages involved in developing a CDx test all of which must be synchronised with drug development. "CDx development and commercialisation processes are rigorous and involve close alignment across multiple stakeholders, which can make meeting clinical timelines a big challenge. Navigating the complex and evolving regulatory landscape across different regions can also delay approval and implementation," said ***Karina Kulangara, Associate Vice President, R&D, Companion Diagnostics at Agilent Technologies.***

Currently, approval of a CDx test is mandatory in four major markets—the US, EU, Japan, and China—where it is linked to the market approval (and sometimes reimbursement) of the therapeutic product. This landscape is evolving, with additional countries such as Australia, Canada, and South Korea planning to gradually implement mandatory CDx test approvals for therapeutic products in the coming years.

"In the intricate and dynamic landscape of global regulations, an increasing number of countries are adopting advanced regulatory frameworks. This shift necessitates that companies specialising in diagnostics and therapeutics engage in early-stage coordination during their development processes. Such proactive collaboration is essential to achieve strategic harmony among industry players and to align with the mandates of external regulatory authorities. Ensuring this alignment is crucial for navigating the complexities of the global market and for the successful deployment of medical innovations,"

said ***Randy Evans, Vice President, Medical Affairs at BD Biosciences.***

Molecular diagnostics is a fast-paced and ever-changing field, with new markers and technologies advancing at a significant rate. Keeping up with these changes can be both a challenge and an opportunity.

"The main challenge I see is that their development and implementation are fragmented, even within the same tumour subtypes driven by the same genetic alteration and therapeutically addressed with molecules with comparable mechanisms of action. This increases the complexity in their implementation and the associated development costs," said ***Dr Francesco Hofmann, Head of R&D at Pierre Fabre Laboratories.***

And of course, another major challenge in CDx development is clinical uptake, especially without a clear path to test commercialisation. Research from Diaceutics indicates that, on average, there is a 4.5-year gap between the launch of a new test and its clinical adoption among the biomarker-positive patient population it targets. As a result of this delay, up to 50 per cent of oncology patients may not have access to the testing needed to identify the most suitable biomarker-guided treatment for their condition.

"Without effective strategies for distribution, provider awareness and education, CDx may face delays in reaching both healthcare providers and patients. However, collaborating with a company that excels in commercialisation can help overcome these barriers. It helps to ensure that the CDx are not only ordered efficiently but also that providers are well-informed and educated about their use. This leads to quicker access to targeted and more effective therapies for patients and improves overall adoption and integration into clinical practice. It's best to work in parallel with drug development to create a test tailored to a novel therapeutic, which helps make the most of the opportunity to reach the right patients at the right time," said ***William Finger, Vice President and General Manager, Pharma Services, Quest Diagnostics.***

Road ahead

Currently, approximately 50 per cent of drug approvals in oncology include a CDx or biomarker on the label. Moving on to the future, the use of CDx is anticipated to grow beyond oncology, potentially covering other areas such as metabolic, cardiovascular, and neurological disorders.

"While CDx have historically focused on oncology applications, we anticipate significant expansion into other therapeutic areas as more clinically relevant markers are discovered for different disease states. We're already seeing CDx moving beyond oncology into hereditary and chronic diseases," said ***Victoria Fox, Senior Director, Global Marketing Excellence MDx & Head of APEC Regional Marketing, QIAGEN.***

QIAGEN has partnered with pharmaceutical firms on QIAstat Dx for Metabolic Dysfunction-Associated Steatohepatitis (MASH), a liver disease that can progress to fibrosis and cirrhosis if untreated. In 2022, Neuron23 and QIAGEN announced their collaboration to develop a CDx – the first to be developed for Parkinson's.

Genomic data serve as the core of CDx, and advancements in genomic technologies are driving the development of more effective diagnostics. Moving forward though, beyond genomics, multi-omics approaches—including proteomics, metabolomics, and more—will enable a more comprehensive understanding of disease pathways, thereby increasing the accuracy of personalised treatment through integrated multi-omics data.

"As precision medicine becomes more widely adopted, we expect the use of CDx to grow. Over the next five years, we anticipate CDx will continue to evolve along two simultaneous paths. One path involves leveraging multi-omics approaches,

Growing Market

The global companion diagnostics market, valued at $8.51 billion in 2023, is expected to grow to $22.37 billion by 2032, with an 11.5 per cent CAGR. The rising prevalence of cancer is driving market growth, alongside regulatory approvals. The cancer segment is projected to dominate due to the surge in targeted cancer therapies, while the neurology segment is set to expand with the increasing incidence of CNS diseases like Parkinson's and Alzheimer's, creating opportunities for precision medicine.

Source: Fortune Business Insights

Top CDx players

- Hoffmann-La Roche Ltd (Switzerland)
- Thermo Fisher Scientific Inc. (US)
- Agilent Technologies, Inc. (US)
- QIAGEN N.V. (Germany)
- Abbott Laboratories, Inc. (US)
- Leica Biosystems Nussloch GmbH (Germany)
- Illumina, Inc. (US)
- Foundation Medicine, Inc. (US)

integrating genomics, transcriptomics, proteomics and metabolomics to offer a comprehensive view for patient stratification and treatment personalisation. With multi-omics providing broader insights and focused tests ensuring the right patients receive the most effective targeted treatments," said William.

Randy agrees, "As the number of therapeutic options increases, there will inherently be more solutions and CDx can provide a competitive advantage for biopharma. From a technology perspective, using a multimodal approach (e.g. genomic and proteomic) could lead to even better outcomes by enabling an even more personalised approach."

As with everything these days, AI is expected to enhance the accuracy, turnaround and efficiency of CDx tests.

"With advancements in genomic technologies, the integration of big data and AI will become increasingly important. AI will play a pivotal role in efficiently interpreting genetic information, discovering new biomarkers, and predicting potential treatment options, thereby significantly enhancing the precision and effectiveness of CDx," said a spokesperson from Macrogen.

"Advances in biomarker discovery and next-generation sequencing technologies will likely drive the development of new and more sophisticated CDx tools, such as AI-enabled CDx," said ***Adrianna Shen, International Business Leader for Personalised Healthcare Solutions, Roche.***

Companies like Agilent and Roche are incorporating AI into CDx development through strategic partnerships and technological advancements. Roche entered into an agreement with PathAI, a provider of artificial intelligence (AI)-powered technology for pathology. Under the terms of this agreement, PathAI will exclusively work with Roche Tissue Diagnostics (RTD) to develop AI-enabled digital pathology algorithms in CDx space. Agilent has also partnered with several digital pathology providers to combine their assay development expertise to create integrated solutions that enhance the accuracy and efficiency of CDx tests by leveraging AI for better data interpretation and analysis.

Next-generation sequencing (NGS)-based in vitro diagnostic (IVD) testing has been expanding rapidly over the last five years to become the preferred CDx for many drugs and experts believe this trend will continue in the future as well.

"In the next five years, CDx will play an increasingly important role in ensuring patients receive the best treatment possible for their disease based on their unique genomic profile. Specifically, NGS-based CDx tests are the future of CDx as they can simultaneously evaluate multiple biomarkers at an accelerated rate compared to single biomarker testing," said ***Kathy Davy, President of Clinical Next-Generation Sequencing at Thermo Fisher Scientific.***

As healthcare systems continue to embrace precision medicine, CDx will play a critical role in optimising patient outcomes and reducing healthcare costs by ensuring that therapies are tailored to individual patient profiles.

"The ultimate goal is to make therapies available sooner to the correct cohort of patients, closing the gap between diagnosis and treatment. As CDx technologies continue to improve in speed, accuracy, and cost-efficiency, we expect to see more personalised treatment approaches across a broader range of diseases," said Victoria.

"Evolving regulatory frameworks and increased collaboration between pharmaceutical companies and diagnostic developers is expected to facilitate smoother integration of CDx into clinical practice. Overall, while there are hurdles to overcome, the benefits of CDx in enhancing precision medicine are immense and transformative for patient care," said Adrianna.

With a shift towards precision medicine and targeted therapies becoming more prominent, it's only natural that a shift towards CDx, and tests that can qualify patients for gene therapy, will follow. Enhanced collaboration between diagnostic and pharmaceutical companies will help to drive innovation, ensuring that companion diagnostics are seamlessly integrated into personalised treatment regimens. BS

Ayesha Siddiqui

Unleashing Innovative Wound Care Solutions

The incidence of wounds is rising, especially in the Asia-Pacific (APAC) region. In Australia alone, 420,000 individuals are impacted by chronic wounds, leading to direct healthcare costs of AUD $3 billion, representing 2 per cent of the country's total healthcare expenditure. Similarly, data from Singapore between 2000 and 2017 revealed that the incidence of wounds among hospitalised adults was 300 per 100,000 for those over 18 and 800 per 100,000 for those over 50. Let's explore further.

In March 2024 the Albanese Government announced over $3 million fund for new initiatives to tackle the hidden epidemic of chronic wounds in Australia. It is estimated that approximately 450,000 Australians currently live with a chronic wound.

Wounds Australia and the Australian College of Nursing (ACN) will receive grants to enhance wound care education and awareness. Wounds Australia will use $2 million to launch a national campaign focused on chronic wound prevention and treatment, aiming to improve public awareness and patient knowledge. ACN will receive $1.073 million to fund scholarships for nurses and Aboriginal Health Workers, enhancing wound management in primary care settings.

In Singapore, the Wound Care Innovation for the Tropics (WCIT) program represents a pioneering research initiative focused on wound care in tropical climates. This programme aims to transform chronic wound care, improve health outcomes, and reduce economic burdens in the region.

Advancements in wound care

Recent breakthroughs in smart bandages, hydrogels, and tissue regeneration are setting the stage for a new era in chronic wound treatment. Chronic wounds, such as diabetic ulcers, surgical wounds, and pressure injuries, present significant health risks. These wounds are susceptible to infections, have prolonged healing times, and can result in serious complications like sepsis or amputation. Globally, around 2 per cent of people are affected by these conditions.

Smart bandages are advanced wound coverings that incorporate technology to optimise the tissue repair process. Equipped with various sensors, these bandages detect, record, and regulate physical and chemical factors that influence the rate of wound healing. By providing real-time data, smart wound bandages enable wound care experts to effectively plan, prognosticate, and manage acute to chronic wounds of various etiologies compared to traditional bandages.

A research team led by Professor Lim Chwee Teck at the National University of Singapore has developed a cutting-edge smart wearable sensor for chronic wound assessment. Integrated into the VeCare platform, this sensor provides real-time, point-of-care data on temperature, pH, bacteria type, and inflammatory factors through a mobile app. The system includes a wound-sensing bandage, electronic chip, and mobile application, allowing comprehensive analysis within 15 minutes. Featuring a microfluidic collector and flexible immunosensor, VeCare enhances fluid delivery and ensures accurate detection of chronic wound biomarkers, regardless of wound size or shape.

Similarly, researchers have developed smart wound dressings with built-in nanosensors that glow to alert patients when a wound is not healing properly. These multifunctional, antimicrobial dressings feature fluorescent sensors that glow brightly under UV light if infection begins to set in, allowing for monitoring of the healing process. The smart dressings, developed by a team of scientists and engineers at RMIT, leverage the powerful antibacterial and antifungal properties of magnesium hydroxide.

Cuprina, a Singapore-based medtech company, specialises in developing products to treat chronic wounds. One of its products, MEDIFLY, is a bio-dressing made of live, medical-grade maggots, used in both private and public hospitals in Singapore and Hong Kong for Maggot Debridement Therapy (MDT). Clinically proven to reduce amputation rates and eliminate infections in chronic wounds, especially diabetic foot ulcers and pressure ulcers, MEDIFLY is ISO 13485 certified and registered with the HSA as a class C medical device. Cuprina is also developing

collagen wound dressing products derived from bullfrog skin, which have shown promising results in wound healing.

Hydrogels are engineered materials that absorb and retain water, making them useful in medical treatments like wound dressings. However, they often adhere indiscriminately to all surfaces, risking damage to delicate tissue during healing. Additionally, conventional hydrogels lack inherent antibacterial properties and often rely on antimicrobial drugs or metal ions, which can contribute to antibiotic resistance and hinder cell growth. To address these challenges, companies and researchers are developing advanced hydrogels with improved properties. Chinese startup Lingel Tech focuses on wound care. The company's core technology involves the use of photo-crosslinked hydrogels for wound dressings, tissue sealants, adhesives, and hemostats. These advanced hydrogels aim to address some of the limitations of traditional hydrogel dressings.

Researchers from the University of Sheffield and the University of South Australia have developed a novel method to enhance hydrogel dressings, offering a promising solution to antibiotic-resistant pathogens. Their approach involves plasma activation of hydrogel dressings, utilising a unique mix of chemical oxidants. This method not only effectively decontaminates wounds but also aids in the healing of chronic wounds, including diabetic foot ulcers and internal injuries.

Tissue regeneration focuses on repairing or replacing damaged tissues to restore normal function. New Zealand-based Aroa Biosurgery is at the forefront of this field, developing and distributing advanced medical and surgical products designed to enhance healing in complex wounds and soft tissue reconstruction. Similarly, Australian firm AVITA Medical is revolutionising wound care and skin restoration through its innovative devices. Their FDA-approved RECELL system is specifically designed for the treatment of thermal burn wounds and full-thickness skin defects, as well as for the re-pigmentation of stable depigmented vitiligo lesions. AVITA Medical also holds exclusive rights in the United States to market and distribute PermeaDerm, a biosynthetic wound matrix, further advancing the possibilities in tissue regeneration and wound management.

Novel Therapies for wound infections remain limited, with only three FDA-approved treatments available for surgical wound infections, and no non-antibiotic options currently in development globally, according to GlobalData. Additionally, 25 therapies previously marketed for surgical wound infections have been withdrawn over the years.

"Proper care for chronic wounds was transformed in the 1990s with the acceptance of moist wound healing as the standard of care. These basic moist wound dressings have been the mainstay of the market since that point. Except for negative pressure and some of skin substitutes, no new technologies or therapeutics have meaningfully changed the trajectory of wound healing since then. The majority of chronic wounds require debridement of nonviable tissue to heal in a timely fashion. Current methods are either literally painful or painfully slow. Our drug under development, EscharEx, aims to change that dynamic by providing fast and safe debridement. It will achieve in 5-6 days what the current standard of care enzymatic debridement drug achieves in around 6-8 weeks. This will have a significant impact on the clinical and economic outcomes associated with chronic wounds," said ***Ofer Gonen, CEO of MediWound, Israel.***

The Australian company Argent BioPharma has announced a strategic collaboration with SINTEF, one of Europe's largest independent research organisations, to tackle chronic wound management through innovative nano-formulations. This collaboration will focus on developing nano-encapsulated active ingredients to target chronic wound infections. These ingredients, many of which have not been used as antimicrobial agents before, will be carefully selected and dosed to enhance their effectiveness while supporting antimicrobial stewardship. The project also emphasises the design of nano-formulations to improve drug delivery and pharmacological efficacy, offering a promising new approach to wound care.

These advancements are leading to better ways to treat even the most difficult wounds, which will ease the burden on healthcare systems and improve patients' lives around the world. BS

Ayesha Siddiqui

"Australia has long been a global leader in research, yet our biotech sector has not lived up to its full potential"

Australia's first true biotech incubator, Proto Axiom, has secured $20 million in the first close of its $30 million Series B round to strengthen the nation's biotech sector through greater IP retention. Anthony Liveris, CEO of Proto Axio discusses the incubator's selection criteria, identifying the most promising biotech trends for global health, and outlining the key strengths that make Australian biotech globally competitive. ***Edited excerpts:***

« **Anthony Liveris,** CEO, Proto Axiom, Australia

Can you provide insight into the selection process for ventures at Proto Axiom? What key factors determine which ideas or projects receive mentorship and funding?

We focus on supporting proof-of-concept research that is poised to reach key commercial milestones. Our primary criteria include groundbreaking research with a well-defined pathway to clinical development. We seek projects that demonstrate strong potential for real-world impact and align with our vision for advancing innovative healthcare solutions.

Could you highlight some of the main support services that you provide to your startups?

We build companies with a tailored approach, recognising that there is no one-size-fits-all support model. Our services generally fall into two categories: back-office and technical support. From legal and accounting to future fundraising and clinical trial design, we take an active and hands-on role in all our investments. Far too often, groundbreaking science fails for reasons that could have been prevented, and we're committed to ensuring that doesn't happen. Additionally, companies Proto Axiom currently have in incubation include EndoAxiom and Swan Genomics, with other companies entering the incubation services shortly. Proto Axiom is also offering the incubation programme to winners of the Challenger Summit, this October.

What unique challenges have you encountered in nurturing early-stage biotech ventures in Australia, and how has Proto Axiom addressed these challenges?

Australia has long been a global leader in research, yet our biotech sector has not lived up to its full potential. Government-subsidised programmes have often crowded out private investment, while market power dynamics have led to rent-seeking behaviours. Moreover, exclusivity clauses often lack transparency, stifling innovation and delaying the path from discovery to patient care. As a result, groundbreaking ideas are not reaching the market, and our collective promise to advance public health remains unfulfilled. Accordingly, existing investors in Australia have struggled to make material gains in the sector. Proto Axiom has structured itself not to compete, but rather to fill a critical gap in biotech commercialisation. We are a first-in-country model, building companies to grow the pipeline of investments for follow-on funds.

What would you say is the goal for startups?

The goal of our companies is to follow the commercial path that best aligns with their unique strengths and opportunities. This could involve sublicensing, acquisition, securing additional venture capital financing, pursuing an IPO, or forming strategic partnerships with pharmaceutical companies. We tailor our approach to support each venture's optimal route to success.

What future trends in biotech have the most potential for global health impact?

Proto Axiom is keenly focused on the potential of Australia's world-leading intellectual property in drug development and medical devices. Despite producing some of the highest-quality science globally, Australia has struggled with commercialisation, ranking among the lowest in the OECD for translating IP into market-ready solutions. We see immense potential in bridging this gap. By positioning our ventures at the forefront of emerging biotech trends, we aim to lead in areas such as advanced therapeutics and innovative medical technologies, ensuring that groundbreaking research can achieve global health impact. BS

Ayesha Siddiqui

“Our priorities will include identifying and understanding the challenges while engaging regularly with industry leaders to address their concerns”

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K Raja Bhanu,
Director General, Pharmaceuticals Export Promotion Council of India (Pharmexcil)

K Raja Bhanu has been elevated from Executive Director to Director General of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), effective July 1, 2024. Bhanu brings a wealth of experience from his distinguished career in drug control and regulation. He has a proven track record in advancing drug quality, safety, and regulatory compliance. His leadership at the Drug Control Administration (DCA) was marked by significant initiatives that enhanced drug regulation standards and reinforced India's pharmaceutical reputation globally. In his current role, Bhanu is set to drive the expansion of India's pharmaceutical exports, boost global competitiveness, and adeptly navigate the complexities of international regulations, leveraging his extensive expertise to foster industry growth and global prominence. In an interaction with BioSpectrum, he shared his plans on addressing many challenges before the Indian pharma industry to stay compliant with international regulations. ***Edited excerpts:***

How do you feel after being appointed as Director General at Pharmexcil and what are your priorities?

I am truly honoured to assume the role of Director General of Pharmexcil. I am grateful to all the industry stakeholders and the government for their trust in my leadership. This position is a significant responsibility, and I am committed to addressing the key challenges facing the pharmaceutical export sector. Building on the successful initiatives of my predecessors, my priorities will include identifying and understanding these challenges, engaging regularly with industry leaders to address their concerns, and representing their interests to both state and central governments, as well as international agencies, to achieve effective solutions.

Could you provide an overview of the current export scenario of Indian pharmaceuticals in the global markets?

India’s pharmaceutical sector has experienced significant growth in recent years, with the country now exporting medicines to over 190 nations. By the end of April 2024, pharmaceutical exports had reached $27.9 billion. In the last quarter alone, we saw a growth rate exceeding 9.6 per cent, and we expect this figure to hit double digits by year-end. This growth highlights India's expanding ability to meet global healthcare needs through affordable generic drugs. When comparing India’s exports to global market trends, our sector is thriving. In the calendar year 2022-23, the global pharmaceutical market had a turnover of $1,407 billion with just a 1 per cent growth. In contrast, India’s pharmaceutical exports grew by over 3.25 per cent during the same period, reaching $25.394 billion. This growth accelerated in the following year (2023-24), reaching $27.9 billion. Overall, India’s drug and pharmaceutical exports increased by 7.36 per cent, rising from $2.26 billion in April 2023 to $2.43 billion in April 2024. Key exporters from India include prominent companies such as Dr. Reddy’s Laboratories, Elkos Healthcare, Aurobindo, Cipla, Lupin, and Sun Pharmaceuticals, among others.

What is India's share in the global pharmaceutical export market and which are the major markets where India is growing?

India holds a 5.71 per cent share of the global pharmaceutical export market. The major portion of its exports comprises formulations and biologics, accounting for 72.54 per cent of the total, with drug intermediates and bulk drugs following. For FY24 (up to February 2024), India's pharmaceutical exports

totalled $25.02 billion, compared to $25.4 billion in FY23 and $24.59 billion in FY22. The key export destinations are the USA, Belgium, South Africa, the UK, and Brazil. India has the highest number of US FDA-compliant companies with facilities outside the USA, houses about eight of the top 20 global generic companies, and directs over 55 per cent of its exports to highly regulated markets. Additionally, India is the largest global vaccine exporter, meeting approximately 65-70 per cent of the World Health Organization's vaccine needs.

Which initiatives have Pharmexcil undertaken to promote pharmaceutical exports from India? How do these initiatives facilitate Indian companies' entry into global markets?

Pharmexcil has been actively working to enhance the global presence of Indian pharmaceutical companies. We have launched several initiatives, including trade fairs, buyer-seller meets, & promotional campaigns in key markets. These activities help Indian companies understand international market demands and regulatory requirements, facilitating smoother entry into global markets.

What are the key regulatory challenges Indian pharmaceutical companies face globally? How is India addressing these challenges to stay compliant with international regulations?

Indian pharmaceutical companies face several regulatory challenges, including compliance with varying international standards & frequent updates to regulations. To address these challenges, India is continuously updating its regulatory framework & ensuring that domestic companies adhere to international standards. The implementation of stringent regulations & regular training programmes for industry professionals are steps taken to stay compliant. Apart from helping companies navigate complex global regulatory requirements, we are also giving the highest priority in addressing concerns related to quality and safety. Pharmexcil is actively involved in overcoming these challenges by organising awareness campaigns, providing industry training, & facilitating dialogue between regulatory bodies & pharmaceutical companies. Our goal is to ensure that Indian pharmaceutical products meet the highest standards globally.

In what ways is India upgrading its pharmaceutical industry to align with global regulatory standards?

India is making significant strides to align its pharmaceutical industry with global standards. Recent improvements include the overhaul of regulatory frameworks such as Schedule M, which mandates rigorous quality and safety standards. The central govt. has also introduced regulatory reforms aimed at enhancing production practices & environmental compliance, ensuring that Indian pharmaceutical products meet international benchmarks.

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How is India faring in the Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs) sector?

The API sector remains a challenging area for India. Currently, we rely on imports for more than 80 per cent of intermediates and KSMs, primarily from countries like China. However, there is a strong push towards achieving self-sufficiency. The government's Production-Linked Incentive (PLI) scheme is designed to boost domestic production and reduce dependence on imports, which we hope will significantly enhance our capabilities in the API sector.

How do the PLI scheme and other government initiatives contribute to the improvement of the pharmaceutical sector in India?

The PLI scheme is a crucial initiative aimed at enhancing the domestic production of APIs and other pharmaceutical products. It offers incentives to both domestic and international players to invest in India, thereby boosting our production capabilities and reducing import dependence. This scheme, along with other government initiatives, provides significant financial support and encourages technological advancements, contributing to the overall growth and competitiveness of the Indian pharmaceutical sector. BS

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mRNA as novel active ingredient- PlasmidFactory providing the template for tomorrow's vaccines

« **Dr. Martin Schleef,** Founder and Managing Director, PlasmidFactory GmbH, Germany

PlasmidFactory GmbH was founded in 2000 in Bielefeld/Germany with 4 employees. In the meantime, under the founder and managing director Dr. Martin Schleef, the company has become a well-known contract manufacturer (CDMO) for plasmid and minicircle DNA. Today, PlasmidFactory has ~50 highly qualified employees, and has established a GMP manufacturing facility.

The usage of messenger RNA (mRNA) as novel active ingredient has attracted public attention in recent years, and it has become clear that it has profoundly changed biotechnology. How did this come about?

RNA, especially mRNA, has shown its capability to catalyze the development of advanced therapeutics, including engineered proteins, next-generation vaccines, and novel pharmaceuticals, whereby its versatility is unmatched, with its potential applications spanning infectious diseases, oncology, and rare genetic disorders. Besides the platform's inherent adaptability, its scalability facilitates rapid production and deployment, particularly critical during pandemic responses or personalized pharmaceuticals.

These properties streamline the preclinical and clinical development phases, accelerate the path from laboratory to bedside and make mRNA an extremely valuable drug with great potential that has not yet been exhausted.

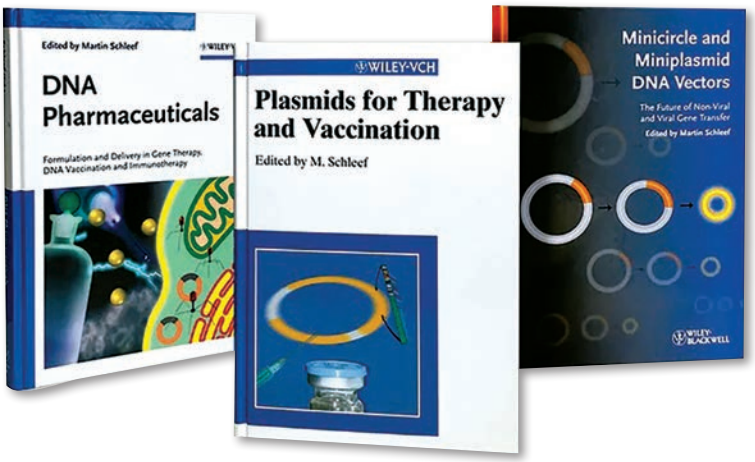
Usage of RNA as new active ingredient represents a paradigm shift in modern medicine. Especially the deployment of mRNA vaccines against SARS-CoV-2 has underscored their transformative potential in vaccinology. What are the main components and what are the advantages?

RNA-based vaccines are genetic vaccines, often based on mRNA molecules that have been encapsulated in a lipid shell for both stability and efficiency of membrane transport. Though initially thought to be limited by its instability, RNA vaccines have improved over the years due to important innovations such as nucleoside modifications, better purification strategies, modifications to the untranslated regions, and better delivery through lipid nanoparticles. Even though RNA vaccine manufacturing is a cost-intensive in vitro process, it has been possible to optimize it to be more productive. The processivity of RNA polymerases makes it possible to yield mRNA products several orders higher than the input of template plasmid DNA.

Generally, the DNA from the template plasmid is transcribed in vitro into mRNA. mRNA contains cis-acting structures, namely, 7-methylguanosine cap and polyadenylate tail along with other sequence motifs. These structures are crucial for translation initiation and elongation, and they can be targeted to enhance RNA expression efficiency. The novel mRNA vaccines developed during the last pandemic showed excellent effectiveness in combating COVID-19, thus definitely ushering in the next generation in vaccine technology.

The manufacture of mRNA is a multistep in vitro

process that depends on multiple enzymes and intermittent purifications. Finally, the mRNA molecules must be modified for stability and enhanced expression (cap and tail) and then formulated within its special lipid capsule which acts as an efficient vehicle for delivery into the cells. Such mRNA-based vaccines offer the advantage that they never enter the nucleus in the cells of the recipient. They do not integrate into the chromosome and are degraded in time after expression has taken place. This offers transient expression of the antigenic protein without any undesirable consequences of long-term continued expression.



The demands on mRNA are high, and the same applies to the starting material. Are there hurdles in the production process? Which are the most significant, and what are their consequences?

Crucial to the efficiency and scalability of this process is the availability of sufficient amounts of the starting material, plasmid DNA, in the necessary quality. Any errors in the plasmid sequence, especially in the promoter region, the coding sequence or in the polyA homopolymer sequence element, will have consequences for the quality of the produced RNA. Single strand breaks in the plasmid DNA sequence due to degradation will result in reduced efficiency of in vitro transcription. This is e.g. manifested in the generation of mRNAs of shortened length. Recombination events during plasmid replication leading to a loss or shortening of the polyA homopolymer sequence stretch results in downstream production of shortened unstable mRNAs. All these basically lead to a possibility of inhomogeneous mRNA population and therefore represent a quality risk in biopharmaceutical production.

So, depending on the application, the starting material must be of very high quality and fulfill all requirements. How can this be guaranteed?

At PlasmidFactory, we offer different quality grades, tailored to the customer's various applications. Thus, we ensure that individual requirements can be fully met.

Our Research grade quality is a kit alternative for basic research based on a fermentation workflow. This cost-efficient option is recommended for early-stage research.

The CCC grade quality provides optimized, highly efficient DNA for basic research, pre-clinical and toxicology studies. The DNA provided in this quality grade consists of ≥ 95% ccc-form, the only intact and most efficient plasmid topology present in E. coli bacteria used for high yield production.

High Quality (HQ) grade DNA is produced based on a cell bank (RCB) created at PlasmidFactory and the uniquely effective proprietary ccc Grade DNA technology. For both the cell bank and the DNA product, PlasmidFactory offers a wide range of in-process and quality controls, so a product is ultimately created that is tailor-made for the respective application. HQ grade DNA meets the requirements for use as a starting material for GMP production of RNA for clinical applications.

The production process is supported by PlasmidFactory's proprietary POLYARESCUE® technology, which can amplify plasmid DNA containing long (> 120A) polyA stretches, which is of highest value when regarding mRNA applications. Moreover, our Next Generation Sequencing technology complements the optimized fermentation process, allowing sequencing and quantification of polyA sequences while maintaining intact plasmids, thus leading to homogenous products for efficient mRNA production.

For product safety reasons, only raw materials with TSE/BSE certificates are used throughout the entire production chain. Moreover, the highest possible product purity is guaranteed through reliable separation of impurities, e.g., bacterial chromosomal DNA or damaged plasmids. To prevent further contamination, only one plasmid is produced at a time in the facility used exclusively for High Quality (HQ) Grade plasmids; no parallel plasmid productions occur in the same facility.

Moreover, the HQ fermentation is physically separated from the purification (chromatography) to ensure that downstream processing of the sensitive

DNA is not affected by live contaminants.

PlasmidFactory's HQ grade DNA is already used as a starting material in clinical trials studies, being also ready to support our clients with starting material for their mRNA market supply. To also be able to provide plasmid and minicircle DNA as API for direct human application, PlasmidFactory has established a GMP facility in which plasmids and minicircles can be produced. In this facility, we exploit single-use equipment. The qualification process is ongoing, enabling us to begin the next year with a brand-new GMP facility ready for operation. DNA produced in this facility will be GMP-certified and meet the stringent requirements for therapeutic products for human application.

Has this GMP facility exclusively been built for the production of plasmids?

No, it was not. Actually, this facility was primarily built for the production of minicircle DNA, making it the worldwide first minicircle GMP production facility.

What exactly is the difference between a plasmid and a minicircle them?

Basically, the two products are similar, but the minicircle is much smaller, as the name implies. PlasmidFactory uses a proprietary technology to produce non-synthetic minicircle DNA.

A plasmid containing the gene of interest (GOI) serves as the starting material, which is why the facility can be used for production of both plasmid and minicircle DNA.

The GOI is inserted into the so-called parental plasmid, followed by intramolecular recombination. The resulting minicircle DNA contains almost exclusively the customer's sequence and its regulatory sequence motifs as well as a short residual sequence region (~150 bp). Superfluous bacterial backbone sequences such as the origin of replication or the antibiotic resistance genes are completely removed.

Especially in the field of cell and gene therapy, the smaller size of minicircles compared to standard plasmid vectors is an advantage. It makes for increased cargo capacity as well as greater transfection and expression efficiency, while a reduction in the number of CpG motifs reduces the risk of immunogenicity.

To sum it up, minicircles are structurally identical to plasmids as they are supercoiled covalently closed circular (ccc), but without a classical bacterial backbone, resulting in an extremely small but at the same time highly efficient molecule. In contrast to other small minimalistic vectors, no selection process is used in their production and, of course, no sequence element as such is included.

Where are these plasmids and minicircles produced? Is your new GMP facility based in close proximity to your other facilities?

All manufacturing, research and development is concentrated at the Bielefeld site in Germany, for almost 25 years now. In 2000 the company was founded, and it has grown ever since, including dedicated facilities for each quality grade. In parallel to the constructional expansion, various products and proprietary technologies have been developed.

Over the years a great deal of fruitful cooperations and partnerships have been forged with academic institutions, industrial companies as well as strategic partners. The partnership with ARCHIMED has enabled us to invest in further expansion and created a broad network of healthcare partners. Another strategic relationship was recently entered into to expand our network to the Asian market.

Speaking of the Asian market, what is your connection to Asia and what are your plans for the future?

For almost 25 years, PlasmidFactory has been supplying customers around the world and has delivered its innovative products to researchers in over 40 countries around the globe, including Asia. Since the Asian continent is vast and the biotechnology and pharmaceutical market is growing exhilaratingly fast, PlasmidFactory has started implementing a network of agents all over Asia, beginning with Dr. Nagaraj Rao, RRR Labs, who supports our customers in India.

Besides this new network, the team at Bielefeld is always available to all our global customers, with a quick response time and highly competent customer support. Just feel free to reach out and find out for yourself.

BIOTECH INNOVATIONS & SUPPLIERS CONCLAVE'24
23rd AUGUST 2024

Indian BioSupplier sector needs capacity and capability building to strengthen local presence: Experts

The experts from the BioSupplier industry discussed the need of the hour on August 23, 2024 at the Biotech Innovations & Suppliers Conclave 2024, organised by BioSpectrum, in Navi Mumbai, to develop cost-effective and best quality solutions for the Indian market, as a strategy to boost domestic production and maintain an overall global competitiveness. The importance of bringing global technologies to India and adapting them to local needs, as well as introducing innovations around existing technologies are some of the key agendas of the biotech industry-based suppliers in India currently.

The biosupplier market is undoubtedly a critical part of the biotech industry catering to the different requirements in public and private sectors comprising academia, pharma and biotech companies, contract/ clinical research organisations (CROs) etc. While the Indian biosupplier market is growing at a rapid pace, a large chunk of it is governed by global players. Thus, it becomes imperative to strengthen local development of analytical instruments and supplies required for biotech innovation in the country because the biotech innovation ecosystem's potential and its rapid growth are recognised as the key contributor to the growth of the global bioeconomy. However, many hurdles need to be addressed before we achieve that.

During a panel discussion at the event which focused on the challenges being faced by the biosuppliers for developing new age technologies and instruments locally, an intriguing point was brought forth by ***V Sankaranarayanan, Managing Director, VFL Sciences*** where he mentioned that there is a requirement of institutions focusing on the building and development of complex, new-age analytical instruments in India. "Compared to the density of such facilities in the Western counterparts in the US or Europe, the Indian biosupplier sector has not seen enough of such institutions yet, except for one in Chandigarh", he said.

Adding to this crucial element of building the 'Capacity and Capability' to strengthen domestic development of advanced analytical instruments, ***Yogeendra Dawalkar, General Manager-Commercial, Premas Life Sciences*** further extrapolated, "The amount of encouragement or scope required for doing that in India is not there. Although certain initiatives are being taken by the industry and the government, I think a lot more needs to be done in this direction."

A key takeaway of the discussion also broadly highlighted the idea that suppliers are currently working on developing cost-effective tools and technologies that enable Indian players to compete with multinational corporations.

Sharing a global perspective in this direction, ***T. Anil Kumar, President, Waters India*** said, "If we have to help the industry to go into the similar way of the generics for biosimilars, we need collaborations, partnerships with the government. We are also making efforts to establish centres of excellence, where we can partner with academic institutions. For example, recently we established a centre of excellence at the Indian Institute of Toxicology Research, where we are addressing risk assessment of carcinogenic drugs. So, partnerships with the government, and initiatives from the government's side are essential. As a biosupplier in the instruments area, we are ready

"Suppliers are the ones who really accelerate the pace of the biotech sector, and we must recognise their efforts and challenges. Although BioSpectrum has been recognising the efforts of the life sciences industry players across verticals since 2014 in the form of our Excellence Awards programme, it is for the first time that we have organised an elaborate programme to recognise the efforts of the biotech industry suppliers in detail".

- Ravindra Boratkar,
Publisher and Managing Editor, BioSpectrum, and Managing Director, MM Activ Sci-Tech Communications

to come to the Indian market. We want the Indian industry to produce biosimilars because these are the need of the hour, to tackle chronic diseases in the India centric scenario."

Critical for novel research

Given the rapidly evolving landscape of the biosupplier sector, emphasising its critical role in advancing biotech and biopharma manufacturing in India is impertinent. While India has made strides in small molecule generics, the trajectory graph for biosimilars, and other trending innovative biopharma and biotech products, such as cell and gene therapy technologies, remain comparatively underdeveloped to their full potential. Case-in-point made during another panel discussion at the Biotech Innovations & Suppliers Conclave 2024, focused on the challenges encountered and the way forward in accelerating biotech, pharma research, and innovation with new technologies.

"While the biopharma companies in India are looking at reducing the cost, the yields and titres of many of the companies manufacturing biosimilars are relatively lower, close to, or even less than a gram per litre, as compared to giants like Samsung that are operating at five grams, eight grams, 20 grams titres. So, you cannot only keep on reducing the cost. You need to bring your titres up. But things are shaping up now, and as suppliers, this is where we can bring in a lot of value, for making Indian companies a lot more competitive, especially if you need to compete with Taiwanese or Koreans or even Chinese, it's not an easy market", pointed out ***Aditya Sharma, Head Process Solutions, Merck Life Science, India.***

Panelists spoke about the complexity of the research and innovation environment of the biopharma, and biotech sectors, as well as the need for multiple players to work together. The discussion also focused on the importance of developing the right infrastructure for innovators, emphasising the need for a conducive environment and collaboration between government, private partners, and scientists. Experts also advocated for increasing communication between the researchers and suppliers so that the right technology is made available to the innovator in the best way possible.

Another significant factor that the panelists highlighted is the role of academic research and young scientists as important flag-bearers of biotech innovations. The conversation highlighted the importance of capacity building, innovation, and partnerships between academia, industry, and suppliers to drive scientific advancements and commercialisation in India.

Highlighting the government's role in strengthening the biosupplier sector for promoting biotech innovation, in his inaugural address ***Dr Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC),*** talked about the critical role of innovation clusters and robust R&D institutions in driving the growth of the biosupplier and biopharma/biotech markets. He emphasised that a dense network of vendors and suppliers for advanced equipment is a crucial factor in fostering innovation, as seen in the thriving ecosystems of Hyderabad, Bengaluru, and Pune. He also underscored the need for India to better showcase its innovations to a global audience. Dr Kumar also touched upon the collaborative challenges in India's ecosystem, noting that there is still a need for stronger cooperation across the ecosystem. "The world is moving towards sustainable bio-manufacturing, including advancements in green chemistry, precision fermentation, and AI-enabled technologies. With continued cooperation and innovation, India's bio-economy is poised for

Panelists

L-R- Dr Prudwidhar S, Director of Medical Affairs, Miltenyi Biotec; Aditya Sharma, Head Process Solutions, Merck Life Science, India; Dr Neelima Khairatkar Joshi, Founder & President, Promethean Drug Ideas, Ex- Sr VP & Head, NCE Research, Glenmark Pharmaceuticals; Dr Ashutosh Kumar, Professor, Department of Biosciences and Bioengineering, IIT Bombay; Chaitanya Gundu, Country Leader, Sales & Marketing, Beckman Coulter Life Sciences; and Dr Asad Shahzada, Principal Product Specialist, Revvity Inc.

L-R- Shivani Thakkar, Content Creator, BioSpectrum; Manas Kumar, Global Director Pharma & Director Strategic Marketing and Business Development-APAC, Lindström Oy; Vivek Gupta, Chief Operating Officer, Symbio Generrics; Shyam Khante, President, Shyam Khante & Associates; and Naresh Kumar, Application Support Manager, BioMérieux Industrial Applications, South Asia.

L-R- Dr Manbeena Chawla, Executive Editor, BioSpectrum; Dr Girish Mahajan, Senior Vice President - Microbiology Division, HiMedia Laboratories; V Sankaranarayanan, Managing Director, VFL Sciences; Yogeendra Dawalkar, General Manager Commercial, Premas Life Sciences; Raghavendra Goud Vaggu, Executive Director, PharmNXT; and T Anil Kumar, President, Waters India.

Winners of Suppliers Excellence Awards 2024

BioTek Gen6 from Agilent Technologies receives Best Software for Biotech Research 2024 Award.

End-to-End Gene Synthesis Technology by Barcode Biosciences gets Special Recognition Technology 2024 Award.

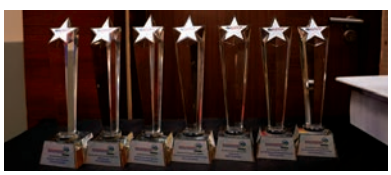
Spectrum Compact CE System by Promega Corporation bags Best Analytical Instrument 2024 Award.

CytoFLEX Nano Flow Cytometer from Beckman Coulter Life Sciences receives Best Advanced Technology 2024 Award.

XELTA 3D from PharmaNXT Biotech bags Best Sustainable Solution for Biotech Research 2024 Award.

Olink's Proximity Extension Assay from Premas Life Sciences gets Best Advanced Technology 2024 (Distributor) Award.

Xevo TQ Absolute IVD Mass Spectrometer by Waters Corporation bags Next Generation Technology 2024 Award.



Ravindra Boratkar, Publisher and Managing Editor, BioSpectrum, and Managing Director, MM Activ Sci-Tech Communications; and Dr Milind Kokje, Chief Editor, BioSpectrum handed over the Suppliers Excellence Awards 2024 to all the winners.

The biosupplier market is undoubtedly a critical part of the biotech industry catering to the different requirements in public and private sectors. While the Indian biosupplier market is growing at a rapid pace, a large chunk of it is governed by global players. Thus, it becomes imperative to strengthen local development of analytical instruments and supplies required for biotech innovation in the country because the biotech innovation ecosystem's potential and its rapid growth are recognised as the key contributor to the growth of the global bioeconomy. However, many hurdles need to be addressed before we achieve that.

significant growth in the coming years", he said.

The event also took into consideration a few more aspects of biotech and pharma research such as quality assurance, cleanroom technology, hygiene, and sterility, as these are foundational pillars of the biopharma and biotech sector, ensuring the safety, efficacy, and reliability of products. As regulatory standards continue to evolve, maintaining high levels of hygiene and sterility is essential for compliance and for upholding the industry's commitment to producing safe and effective therapeutics.

Sharing his views about the supplier sector, ***Manas Kumar, Global Director Pharma & Director Strategic Marketing and Business Development-APAC at Lindström Oy*** pointed out the new trends towards outsourcing sterilisation for ready-to-use products and adopting newer techniques like E-beam and X-ray. The discussion with other industry experts around this topic, focused on the current rapid advancements in sterility testing. As it turns out, this acceleration is crucial for getting products, especially in cell and gene therapy, to market faster while maintaining high-quality standards.

"When talking about portraying ourselves as a pharmacy of the world, I would say that basic thing about quality is adherence to ethics, adherence to integrity, and finally, adherence to everything concerning the data and concerning the research which goes into that", said ***Shyam Khante, President, Shyam Khante & Associates.***

This panel discussion also addressed the global perception of Indian biopharma quality, noting significant improvements and the potential for future innovations, such as digital therapeutics and artificial intelligence (AI) in clinical trials. The industry's ability to adapt to emerging technologies and business models, including potential partnerships with tech giants as critical for maintaining global competitiveness was a key takeaway from the conversation.

Suppliers Excellence Awards 2024

Another key highlight of the event was the debut of Suppliers Excellence Awards 2024, which was organised for the very first time to recognise the efforts of the biotech industry based suppliers, across categories such as Analytical Instruments, Next generation technology, Research softwares, etc.

"Suppliers are the ones who really accelerate the pace of the biotech sector, and we must recognise their efforts and challenges. Although BioSpectrum has been recognising the efforts of the life sciences industry players across verticals since 2014 in the form of our Excellence Awards programme, it is for the first time that we have organised an elaborate programme to recognise the efforts of the biotech industry suppliers in detail", said Ravindra Boratkar, Publisher and Managing Editor, BioSpectrum, and Managing Director, MM Activ Sci-Tech Communications.

The awards were jointly presented to the winners by Ravindra Boratkar, and Dr Milind Kokje, Chief Editor, BioSpectrum. "There is immense potential for innovation that India holds for its biotech and biopharma industries, and the supplier market is a critical part of it. India hopes to take the lead in the bio-supplier sector, especially with the domestic players occupying the large chunk of the market in the coming years", said Dr Kokje in his welcome address.

The first edition of the Biotech Innovations & Suppliers Conclave 2024 played its part by bringing industry captains together who deliberated on a number of thought provoking topics, and sharing their knowledge on the same. The event was well supported by BIRAC as the Title Partner, and Eppendorf, Plasmid factory, Takara, Revvity, Lindstrom, HiMedia, and Biomerieux as industry partners. BS

Shivani Thakar
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PW Skills launches School of Healthcare to solve India's critical shortage of medical professionals

PW Skills, the upskilling vertical of Physics Wallah (PW) has announced the launch of School of Healthcare across five cities in India, namely, Noida, Indore, Lucknow, Patna and Delhi. This initiative comes in response to the increasing demand within India's healthcare sector, which has been growing at a CAGR of 22 per cent since 2016 and currently employs 4.7 million professionals directly. The School of Healthcare aims to solve the shortage of skilled healthcare workers by offering specialised courses. These programmes are meticulously designed to meet industry standards and cater to the diverse needs of the healthcare market.

PW Skills has launched the School of Healthcare to ensure comprehensive education and career readiness. The courses integrate practical internships as a unique component, offering hands-on experience crucial for professional development. For B. Vocational courses such as Medical Lab Technician (MLT) and Operation Theatre Technician (OTT), students will spend two years in classroom training followed by a year of intensive internship.

Singapore strengthens focus on computational biology

Singapore's National Quantum Office (NQO), Agency for Science, Technology and Research (A*STAR), National University of Singapore (NUS), National Supercomputing Centre (NSCC) and Quantinuum have signed a Memorandum of Understanding (MoU), enabling access to Quantinuum's advanced quantum computer, and to explore and collaborate on quantum computing use cases, focusing on computational biology. Under the MoU, the parties agree to leverage Quantinuum's H-Series and Helios quantum computers, to promote joint research and development (R&D) activities in various quantum computing applications. Scientists from A*STAR's Bioinformatics Institute (A*STAR's BII), the Centre for Quantum Technologies (CQT) at NUS and Duke-NUS Medical School's Centre for Computational Biology will be able to leverage Quantinuum's machines to enhance capabilities in modelling complex biological systems, advancing drug discovery and personalised medicine.

IIT Kharagpur, University of Leeds sign MoU for joint supervision of PhD programmes

Indian Institute of Technology Kharagpur (IIT KGP) has signed a Memorandum of Understanding (MoU) with the University of Leeds (UoL), England in recognition of the growing importance of India and a long-term partnership with University of Leeds. This collaboration aims to enhance academic and research cooperation through the joint supervision of PhD programmes in the fields of Civil Engineering, Transport Studies, and Biological Sciences. In an endeavour to continue the path of sustained collaboration with University of Leeds, IIT KGP has already started discussions on the 'Jointly Funded Bilateral Mobility Agreement' and it is also expected that IIT KGP will be a part of the 'Joint Virtual Centre of Excellence on Sustainable Development' which is being envisioned by the University of Leeds. IIT KGP is also looking into the possibility of participating in the 'Leeds International Partners Conference' which is slated to take place in December 2024 and will be the first of its kind for Leeds. It is expected that this would give IIT KGP an opportunity to make its existing collaboration with the University of Leeds more robust and effectively use the platform to engage with its partners and share knowledge on topics of mutual interest.

Healthium Medtech names Sudeep Dhariwal as Group CFO

India-based Healthium Medtech, a global player in medical devices, focused on products in the surgical and post-surgical ecosystem including wound closure, advanced wound care, arthroscopy and infection prevention segments, has announced the appointment of Sudeep Dhariwal, as their new Group Chief Financial Officer (CFO). Dhariwal joins Healthium Medtech after a successful stint at Danaher - Cepheid, where he was the Vice President - Finance, for APAC. With over 24 years of experience in strategic, operational and financial roles across global MNCs, Dhariwal will spearhead the vision for overall business and finance. A qualified Chartered Accountant and certified Treasury Manager, Dhariwal comes aboard with more than 24 years of diverse experience in building and leading highly engaged teams that deliver robust business partnerships, best-in-class financial reporting capabilities, good accounting practises, efficient risk and strict compliance management. In his previous stints, he has worked with organisations like Perfetti Van Melle, Reckitt Benckiser, Nokia, Mars and Medtronic, with a proven track record in establishing vision and strategy for both business and finance functions.

Avance Clinical appoints Jessica Han as Asia Regional Director

Avance Clinical, a contract research organisation (CRO) for biotechs, has announced the appointment of Jessica Han as Director, Asian Operations based out of Avance Clinical's Seoul, Korea office. Jessica's career began as a registered nurse in the critical care unit at Samsung Medical Center, where she focused on patient care and clinical research. Transitioning into the clinical trial sector, she has worked in various roles at leading contract research organisations in the region, such as Parexel, PRA Health Sciences (now ICON), and Novotech. The expansion into South Korea and Asia aligns with Avance Clinical's GlobalReady drug development solution, which has already garnered significant interest from over 75 Korean biotechs and pharmaceutical companies.

Rosanne Hyland steps in as AusBiotech Deputy CEO

Rosanne Hyland has been appointed Deputy Chief Executive Officer (CEO) of AusBiotech, Australia's peak association for the life sciences industry, after serving as Business Manager and Chief Operating Officer for five years. Over the past five years, Rosanne has led the day-to-day operations of AusBiotech, covering finance, human resources, IT/operations and events. She also served as Acting CEO for the six months until May 2024, providing steadfast leadership and continuity of the organisation. Within her new capacity as Deputy CEO, Rosanne will continue to oversee day to day operations while also working closely with the CEO, Rebekah Cassidy, to embed member value in all parts of the organisation's operations.

Rosanne is a senior executive with more than 20 year's experience growing teams and leading the operations of large, complex organisations. She joined AusBiotech in 2019 as Business Manager, was appointed Chief Operating Officer in 2021 and served as Acting CEO for the period between December 2023 and May 2024. Prior to joining AusBiotech, Rosanne was General Manager of The Prince Hospitality Group for 15 years where she was responsible for 20 individual businesses, employing over 700 people.

Philips names Ling Liu as Chief Region Leader of Greater China

Royal Philips, a global leader in health technology, has announced the appointment of Ling Liu as the Chief Region Leader of Philips Greater China. Liu is now a member of Philips' Executive Committee, reporting to Philips CEO Roy Jakobs. She succeeds Andy Ho, who has decided to retire after a long and successful career. Liu joined Philips in 1998 and has held multiple roles across the business, living and working in Greater China, the Netherlands and North America. Most recently, she was Chief Commercial Officer in Greater China, following her role as Head of Finance for Philips in North America. She has a track record of driving execution and boosting performance, developing teams and delivering outstanding value to customers and partners. She is passionate about delivering quality care and contributing to sustainable healthcare in China.

HanAll Biopharma on-boards Christopher W Slavinsky as Chief Business Development and Legal Officer

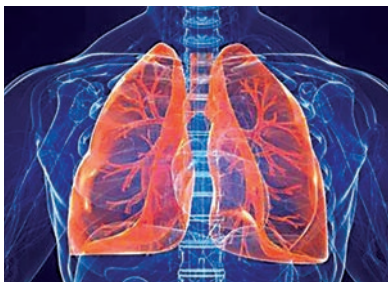
HanAll Biopharma, with operations in the US and South Korea, has announced the appointment of Christopher W. Slavinsky as Chief Business Development and Legal Officer. Slavinsky is expected to leverage his extensive background as a strategic and operationally focused leader with over 25 years of expertise in legal and business development roles within large pharmaceutical companies and small, emerging biotechnology firms. Spanning annual revenues from $50 million to $50 billion, he has overseen more than $20 billion in strategic transactions, including transformative M&A, integration efforts, asset acquisitions, and divestitures aimed at driving growth, ensuring regulatory compliance, and optimising the company's market position across R&D, commercial operations, and investor relations functions. He joins HanAll from Coherus BioSciences, where he served as Chief Business and Legal Officer and led its $65 million all-stock acquisition of Surface Oncology and a groundbreaking biosimilars partnership with Cost Plus Drugs.

Griffith appoints Prof. Paul Clarke as inaugural Executive Director for Institute for Biomedicine and Glycomics

Griffith University in Australia has announced that Prof. Paul Clarke will join the University as the inaugural Executive Director of the new Institute for Biomedicine and Glycomics and the Raymond James Chair of Translational Biomedicine. In the new executive leadership role, Prof. Clarke will work alongside colleagues who are dedicated to the development of novel therapies, vaccines and diagnostics for diseases of global impact, and the translation of world-leading biomedical research to improve human health. Prof. Clarke brings an enormous depth of experience to the role as both a leader and internationally recognised biomedical researcher who has worked at the translational interface between medicine and biology for more than 25 years. His area of discipline focuses on investigating cancer cell biology and cellular responses to anti-cancer drugs. Prof. Clarke comes to Griffith from the University of Queensland where he is the Director of the Frazer Institute which he has led to significant success since 2017.

Korea develops micro-structured artificial lung model using bioprinting technology

A team of Korean researchers has made a breakthrough that will greatly enhance the efficiency of respiratory disease research, garnering attention. The research team from the Department of Materials Science and Engineering at Pohang University of Science and Technology (POSTECH), in collaboration with the Infectious Diseases Therapeutic Research Center of the Korea Research Institute of Chemical Technology (KRICT), has successfully created artificial



lungs. These artificial lungs are designed to study infections and test drugs for respiratory diseases including COVID-19. The 3D artificial lung created by the researchers consists of three layers- vascular endothelium, extracellular matrix, and epithelium, just like the human respiratory tract. This model closely resembles the structure and function of the human lung including cell-cell junctions and mucus secretion. It also contains high levels of proteins (ACE2, TMPRSS2) that serve as entry points for the COVID-19 virus at the epithelial layer, making it susceptible to infection even at very low doses.

Singapore discovers new fungus type, a possible global public health threat

Researchers from the Singapore General Hospital (SGH), A*STAR's Genome Institute of Singapore (GIS) and Yong Loo Lin School of Medicine at National University of Singapore (NUS Medicine) have discovered a new clade (or type) of Candida auris, bringing the number of clades known globally to a total of six. Candida auris, or C. auris, is a fungus that is highly transmissible and hard to eradicate. It mostly affects patients with severe underlying medical conditions. Those with invasive medical devices like breathing or feeding tubes and catheters tend to be at higher risk of getting C. auris and developing a range of infections from superficial to more severe, life-threatening ones.

SGH has an active surveillance programme which screens high-risk patients for C. auris through a routine swab upon admission. Patients who are tested positive are immediately isolated and all inpatients who share the same ward or room will be screened as part of the hospital's strategy to contain its spread. The team is now working on a proof-of-concept machine learning approach that can automatically detect new clades early.

Hong Kong makes smartphone stethoscope to support valvular heart disease detection

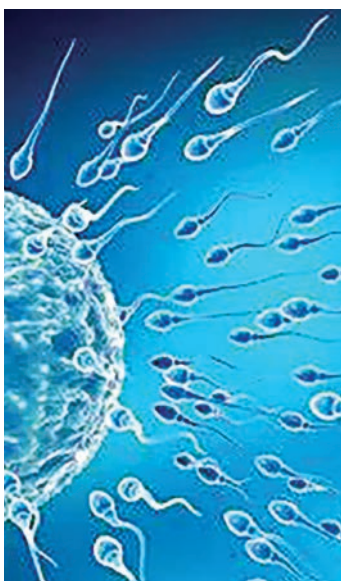
An interdisciplinary team from the Li Ka Shing Faculty of Medicine of the University of Hong Kong (HKUMed) has developed an innovative artificial intelligence (AI) software system that can turn an ordinary mobile phone into a medical-grade stethoscope, allowing anyone to use a smartphone to detect heart disease symptoms at their fingertips, and subsequently seek immediate medical attention, without the need for other specialised devices. This patented AI technology enables the detection of valvular heart disease, with an estimated accuracy of 81 per cent, a level comparable to a doctor's assessment using a stethoscope. This invention promotes early detection of valvular heart disease, personalised health management, heart disease screening, the use of telemedicine, and remote disease monitoring. The HKU Laboratory of Data Discovery for Health has registered the product 'Vitogram' in the medical device listing of the United States Food and Drug Administration (FDA), and established a spin-off company, called Vitome Limited, to commercialise the product.

New protein discovery by New Zealand may influence future cancer treatment

Researchers from the University of Otago, New Zealand, have spearheaded the discovery of a protein function which has the potential to guide the development of novel cancer treatment options and improve the diagnosis of various cancers. The research finding, carried out alongside Dr Vanessa Morris from the University of Canterbury's School of Biological Sciences as well as researchers in Australia and Denmark, centres on the activity of a tumour-suppressing protein called p16. The discovery has shown that p16 has the ability to dramatically alter both its structure and its function. Under normal conditions, the protein p16 protects cells from uncontrolled cell division. However, once it changes to what's known as the amyloid (or dysfunctional) state, it loses this protective function. p16 is amongst the top five proteins found to be mutated in various cancers, with the ability to actively cause certain types of cancer when damaged.

India paves way for new drugs against infectious diseases

A research team from the Indian Institute of Technology Kanpur (IIT-K), led by Prof. Arun K. Shukla of the Department of Biological Sciences and Bioengineering, has made a significant scientific breakthrough with the first-ever visualisation of the complete structure of the Duffy antigen receptor. This receptor protein, found on the surface of red blood cells and other cells in the human body acts as a gateway into the cell, facilitating infections by destructive pathogens like the malaria parasite, Plasmodium vivax and the bacterium, Staphylococcus aureus. While the Duffy antigen receptor is common in most populations, a significant percentage of people of African descent do not produce the Duffy receptor on their red blood cells due to a genetic variation. This makes them naturally resistant to certain types of malaria parasites that rely on that specific 'gateway' to infect those cells. This shows how important the Duffy antigen receptor is for these diseases and how targeting it could lead to new treatments.



Australia develops AI sperm checker to enhance IVF success

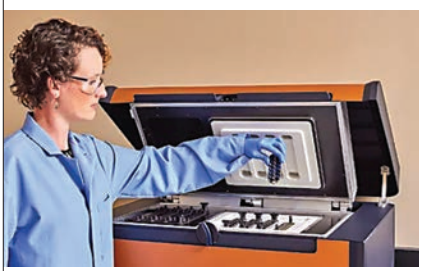
Engineers in Australia have developed an artificial intelligence (AI) technology that accurately assesses the quality of live sperm in seconds, removing the need for invasive procedures that compromise sperm viability in in vitro fertilisation (IVF) treatments. Current clinical practices to evaluate sperm morphology require human analysis and chemical staining of the sperm cells which can cause damage. But this new method, from Monash University's Department of Mechanical and Aerospace Engineering in collaboration with Monash IVF, works on live, unstained sperm, preserving their viability. The newly published study found the AI model could analyse sperm imaging with over 93 per cent accuracy in just a few seconds. By precisely choosing the highest quality sperm without affecting its viability, the technology could pave the way for standardised sperm selection through automation in IVF clinical settings.

Thermo Fisher introduces novel pre-transplant risk assessment assay

Thermo Fisher Scientific has introduced a new pre-transplant risk assessment assay via its CLIA laboratory that helps assess risk of early acute rejection in kidney transplant recipients, providing data that may inform a more personalised approach to post-transplant immunosuppression management. Standardised immunosuppression protocols based on broad clinical and demographic features are a routine part of care for most of the 250,000 Americans living with a kidney transplant. While effective in reducing overall rates of rejection, such protocols can also result in over-immunosuppression, which may lead to poor long-term outcomes; patient complications such as toxicity, cancer and serious infections; and considerable costs to the healthcare system. The PTRA Assay utilises an mRNA signature of 29 markers to help stratify patients into high- and low-risk categories for early acute rejection. A recent clinical validation study observed that patients with high PTRA scores were six times more likely to experience early acute rejection than patients with low-risk scores, a statistically significant finding.

Waters announces global release of new Differential Scanning Calorimeter

Waters Corporation has announced the global release of the TA Instruments Rapid Screening-Differential Scanning Calorimeter (TA Instruments RS-DSC), designed for biopharmaceutical developers. The TA Instruments RS-DSC is a high-throughput DSC for precise thermal stability testing of high-concentration biologic formulations specifically for antibody drugs and engineered proteins. The TA Instruments RS-DSC offers a more convenient and accurate solution to assess biological drug stability and quality by employing disposable, low sample volume microfluidic chips (MFCs) that enable up to 24 simultaneous measurements. This reduces or eliminates the need for sample dilution, repetitive instrument cleaning, and lowers contamination risk. Its unique design avoids the sensitivity challenges of DSF methods, enabling it to produce more accurate data on high-concentration samples. Additionally, the TA Instruments RS-DSC features state-of-the-art automated software that provides rapid, effortless, precise, and in-depth insights about a sample's thermodynamic properties.



PerkinElmer introduces next generation ICP-MS and thermal analysis portfolio in India

PerkinElmer has launched the new NexION 1100 ICP-MS and the next generation Pyris TGA/ DSC/ STA Thermal Analysis Instruments in India. These solutions have been designed to help lab teams simplify their operations, drive precise results, and perform more flexible monitoring. The NexION 1100 ICP-MS offers the combination of efficient interference removal and high throughput with a modernised workflow and the lowest maintenance ICP-MS in the industry. It is the latest entrant in PerkinElmer's long lineage of atomic spectroscopy portfolio that was first made commercially available 40 years ago. The Syngistix Software v.4.0 enhances the user experience with a modern database backend for easier LIMS integration and new FastQuant Data Viewer for easy data review, reprocessing and exporting. The new Pyris TGA 9, DSC 9, and STA 9 systems are compact, durable, and low-maintenance thermal analysis systems. The interchangeable furnace design is intended to enhance lab versatility, while the intuitive touchscreen interface simplifies operation and boosts productivity.

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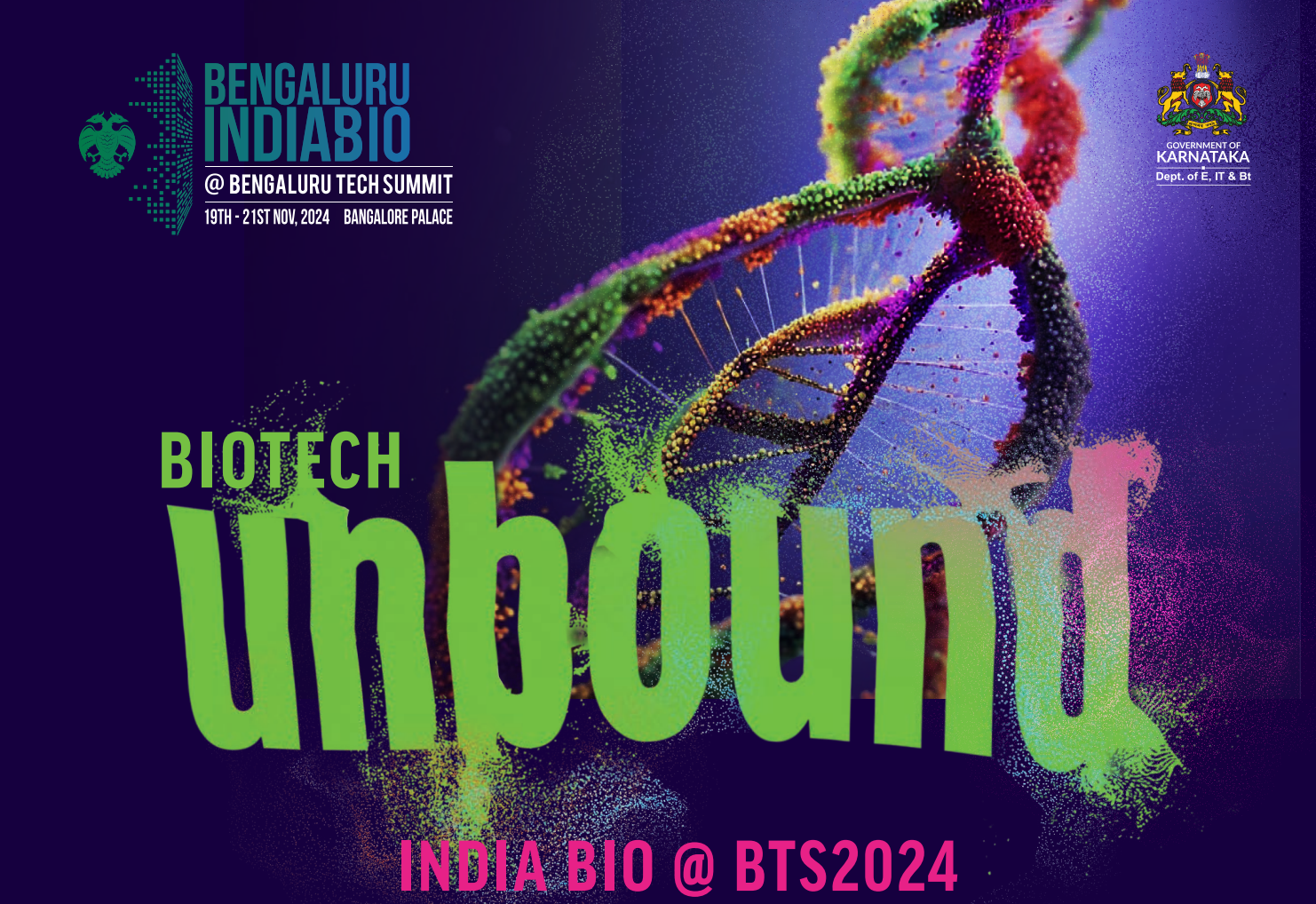

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Another Pandemic as Predicted?

A total of 107,725 confirmed cases of Mpox have been reported globally between 2022 and as of August 26, 2024. The Region of the Americas (64 per cent) contributes the largest proportion of cases, followed by Europe (27 per cent) and the African Region (5.4 per cent). In the Region of the Americas, as of August 26, 2024, 68,728 confirmed cases of Mpox, including 142 deaths, were reported in 32 countries and territories. The highest proportion of cases was recorded in 2022 (61,477 cases, 90 per cent), with a progressive downward trend in 2023 (4,261 cases, 6.2 per cent) and 2024 (2,990 cases, 4.4 per cent).

Scientists are puzzled over how a disease that wasn't thought to be easily transmissible was spreading so widely in non-endemic countries. It soon emerged that most of the cases across Europe and the US were in homosexual men, especially those who had closely connected sexual networks, allowing the virus to spread in a way it hadn't in the general population.

Meanwhile on August 14, 2024, the World Health Organization (WHO) declared the ongoing mpox outbreak in Africa a Public Health Emergency of International Concern (PHEIC), while the Africa Centres for Disease Control (Africa CDC) declared it a Public Health Emergency of Continental Security. This declaration was prompted by a surge of mpox cases in countries like Democratic Republic of the Congo (DRC), but also in neighbouring countries that had never seen mpox before, such as Burundi, Kenya, Rwanda and Uganda. And this time it was being caused by the more deadly clade I strain. Sweden also, on August 15, has reported the first case of the new Clade 1b variant outside of Africa.

A new clade of the virus developed and began to spread last year. So far this year, over 17,000 suspected cases have caused 517 deaths across the continent, outstripping 2023's toll. The WHO reported that over 120 countries have reported mpox between January 2022 and August 26, 2024, with over 100,000 laboratory-confirmed cases reported and over 220 deaths among confirmed cases. This is the second PHEIC determination related to mpox within the past two years. In July 2022, a multi-country outbreak of mpox was declared a PHEIC due to its rapid global spread across multiple countries as it spread rapidly across a range of countries where the virus had not been seen before. That PHEIC was declared over in May 2023 after a sustained decline in global cases.

There are currently two vaccines in use against the disease, both of which have been recommended for use by the WHO Strategic Advisory Group of Experts on Immunization (SAGE). Gavi noted that two vaccines, Jynneos (Bavarian Nordic) and ACAM2000 (Emergent Biosolutions), have been licensed in the US, Canada and Europe for mpox, both for people older than 18. LC16m8, an attenuated, replicating smallpox vaccine, is currently licensed in Japan for both children and adults. However, it's not clear yet how long immunity lasts. At present, WHO recommends use of MVA-BN or LC16 vaccines, or the ACAM2000 vaccine when the others are not available. BioNTech, in partnership with Coalition for Epidemic Preparedness Innovations (CEPI), started a Phase 1/2 clinical trial of the mRNA-based mpox vaccine candidate, BNT166, due to be completed in May 2025. Serum Institute of India (SII) is also working on developing a vaccine for Mpox with positive outcomes expected in a year's time.

Africa CDC estimates that currently about 200,000 doses of mpox vaccines are available compared to a requirement of at least 10 million doses, based on estimates from countries that have prepared vaccination plans. Given that in the short and medium term, vaccine availability is expected to be very limited, countries are recommended to consider vaccine deployment in phases in their vaccination plans, according to the epidemiological scenario and prioritisation of groups at higher risk of severe disease. To this end, it is important to maintain an updated analysis of the Mpox situation in order to guide prevention and control actions, in which vaccination is one of the components. To prevent and respond to outbreaks of mpox, currently WHO has been coordinating research on vaccines and treatments, strengthening country health systems, and working to facilitate equitable access to vaccines, therapeutics, diagnostics and other tools. BS

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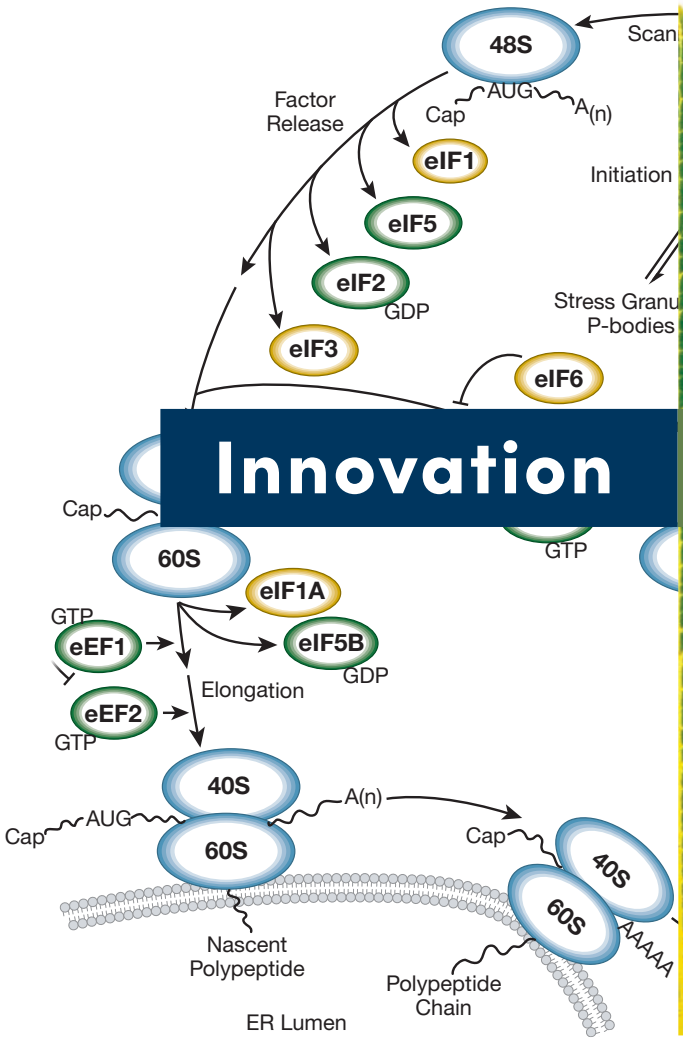

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