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APAC VACCINE POWERHOUSES

Flex Capacity & Quality Muscle

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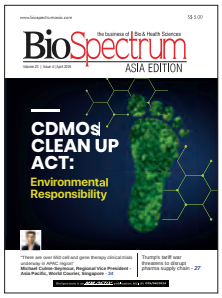

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Thanks BioSpectrum Asia for the coverage on Zai Labs in the April 2025 edition.

Laura, US

Thank you for the April edition that figured about CDMOs Clean Up Act. Bushu Pharmaceuticals appreciates having been able to contribute this very interesting feature.

Yasuko Watanabe, Japan

Thank you for including Vetter's comments in the cover story on the CDMO industry.

Sarah, Germany

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Letter from Publisher

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

Dear Readers,

Asia-Pacific (APAC) is spearheading a shift in the global vaccination supply chain. According to the WHO Vaccine Report 2024, the WHO South-East Asia region now self-supplies 87 per cent of its vaccines—thanks largely to India, which accounts for 84 per cent of the doses procured in the region and produces 99 per cent of its requirements. Similarly, China supplies 54 per cent of vaccinations and 90 per cent of domestic demand in the Western Pacific region. While government-run manufacturers are essential in nations like Thailand, the Philippines, Indonesia, and Vietnam, private enterprises predominate in China and India. APAC's manufacturing ecosystem is diversified. The cover story explores the manufacturing footprint of Asia's leading vaccine manufacturers, tracking their current capacity, expansion plans, and the strategic shifts that are transforming the region into a global vaccine production hub.

South Korea has made notable strides in biosimilars, contract manufacturing, etc. According to Citeline's Pharmaprojects database, over 320 South Korean companies have developed over 1,300 new drug candidates in the past three years, representing 10 per cent of the global total. Now, South Korea is setting its sights even higher, with a concerted effort to become the world's leading biotech and pharmaceutical innovation hub. In an article, our correspondent takes a closer look at how South Korea is putting this ambitious vision into action.

As APAC positions itself as the next global hub for medtech innovation, it becomes imperative for the academic sector to modernise the courses and programmes, with inputs from the industry and by keeping pace with new developments. Our team points out that, additionally, it requires investment in faculty development, recruitment professionals with commercial and clinical experience, and creating regional medtech academies and hubs for efficient training and practice, keeping the ethical guidelines in mind. With these steps being taken in the right direction, the APAC region will not only become a medtech talent leader but also an exporter of medtech innovation for the world.

In 2025, India celebrates 25 years in the biosimilar sector, having achieved a remarkable 135 approvals. This milestone underscores the country's status as a global leader in biosimilar approvals. As the industry celebrates this silver jubilee, we have an interaction with Dr Jitendra Kumar, Managing Director of Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Enterprise, set up by Department of Biotechnology, Government of India, who explains the sector's evolution and discusses India's increasing prominence in the global biosimilars landscape for the next decade.

China's share of global medtech trade soared from under 3 per cent in 2000 to 12.4 per cent by 2021, equating to nearly $40 billion in exports, while traditional leaders like the U.S. experienced a decrease. The country now boasts the second-largest medical device market, driven by over 32,000 manufacturers and expected to generate around $160 billion by the end of 2023. This growth stems from a strategic national initiative and active market dynamics. An expert analyses the factors fuelling China's medtech rise, examines global strategies, assesses competitive positioning, and forecasts the industry's future.

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

Thanks & Regards,

Ravindra Boratkar
Publisher & Managing Editor

COVER 19

APAC Vaccine Powerhouses Flex Capacity & Quality Muscle

Asia is the epicentre of global vaccine manufacturing, with India and China together supplying over a billion doses annually. Now, emerging players like South Korea, Singapore, and Australia are stepping up, investing in next-gen platforms and expanding capacity to meet global demand. Let's map the manufacturing footprint of Asia's leading vaccine manufacturers, tracking their current capacity, expansion plans, and the strategic shifts that are transforming the region into a global vaccine production hub.

Dr VJA Gutla Harshavardhan,
Director General, Indian Vaccine Manufacturers Association (IVMA)

Suchitra Ella,
Managing Director of Bharat Biotech, India

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REGULARS

TARIFF WAR PUTS PHARMA IN CROSSHAIRS

Dr Milind Kokje
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While several other countries in the world have probably heaved a sigh of relief, though, for three months, China has launched an onslaught on the US in the bitter trade tariff war. Like bidding in an auction, both the US and China are increasing the 'reciprocal' tariffs against each other. From the US side, it has reached the level of 145 per cent in response to China's announcement to raise tariffs on imported US goods from 84 to 125 per cent, responding to the US's first salvo of raising tariffs to 104 per cent. With that, the countries appeared to be locked in an intense trade war, with pharmaceuticals, soon, likely to be part of it.

Though medicines were exempted from the tariffs till now, the US President Donald Trump said that he would soon announce major tariffs which could be as high as 25 per cent on imported pharmaceuticals. Due to the 1995 World Trade Organisation (WTO) agreement, medicines attracted less or no import duty in several countries, including the US, to keep the drug prices low. Some active pharmaceutical ingredients (APIs) used to make drugs attract duty. But the US president's announcement in the first week of April makes it mandatory to take note of the issue, particularly considering the pharmaceutical trade volume between the US and China.

Between 2020 and 2022, the US's imports of Chinese pharmaceuticals increased by 485 per cent, from $2.1 billion to $10.3 billion. It raised China's share of U.S. pharmaceutical imports from 2.5 per cent to over 6 per cent. From 2023 to 2024, the export to the US grew by 11.7 per cent to $ 19.05 billion worth of pharmaceutical goods.

Trump's move is expected to end years of low-cost global trade in medicines, beginning with the US. Anticipating Trump's moves, the American Hospital Association wrote to the US President on February 4, stating that the new US tariffs will affect the supply of drugs from China. Nearly 30 per cent APIs also come to China, which may attract increased duty. Net result? An inordinate increase in the cost of the medicines.

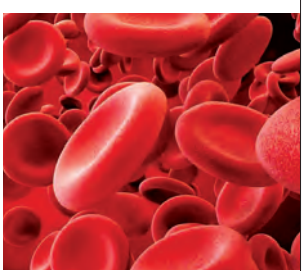
Experts, however, feel that this would adversely impact in more ways than imagined. Import tariffs on APIs and finished products from China could raise manufacturing expenses. As supply chains rely on global partnerships, higher tariffs could lead to bottlenecks, delays and shortages. Innovations in drug discovery and new treatment methods may slow down since high operational costs may compel the manufacturers to shift funds away from R&D. This will lead to higher prices and limited access, further leading to economic burden on consumers. Interestingly, both countries had tasted the aftereffects of increased tariffs in the 2018-19 trade war, involving over a $450 billion trade of all kinds of goods, which increased tariffs and reduced trade between the two countries.

US exports to China fell by 26.3 per cent and China's exports to the US reduced by 8.5 per cent, said a 2022 research paper, The US-China Trade War and Global Recollections, published on the National Bureau of Economic Research (NBER) website. This reduction gap seemed to have been filled by some other countries as their exports grew. For instance, France and Spain increased their exports to the US. But South Africa and the Philippines reduced their exports to the US as well as to the rest of the world. Out of 48 countries studied by the researchers, the exports of 19 countries increased significantly, while only one country reported significantly reduced exports. In the case of 28 countries, statistically, there was no significant impact.

Five years after that, both countries are now once again locked in a trade war. Chinese Premier Xi Jinping had said then, "The Chinese economy is a sea, not a pond. Storms can overturn a pond, but never a sea." Whether China will be able to say the same again, in the current situation, will be worth watching. BS

China gives nod to first haemophilia B gene therapy

Belief BioMed (BBM) and Takeda China have jointly announced that BBM-H901 (Dalnacogene Ponparvovec Injection), has been officially approved by the National Medical Products Administration (NMPA) for the treatment of adult patients with moderate to severe haemophilia B (congenital coagulation factor IX deficiency). As the first approved haemophilia B gene therapy in China, BBM-H901 is developed and manufactured by BBM, and Takeda China is responsible for its commercialisation in mainland China, Hong Kong and Macau. The two parties will integrate their respective resource advantages to accelerate the provision of this breakthrough gene therapy to patients and jointly open up a new landscape in the field of haemophilia B treatment. Haemophilia B is an inherited bleeding disorder caused by the deficiency of factor IX (FIX). BBM-H901, based on a recombinant adeno-associated virus (rAAV) vector, can deliver the optimised human coagulation FIX gene into liver cells of patients.



Taiwan's ACRO Biomedical gains regulatory approval for regenerative medicine

ACRO Biomedical Co. has announced that its ABCcolla Collagen Ophthalmic Matrix has received regulatory approval from Taiwan's Ministry of Health and Welfare (MoHW). This milestone marks a significant advancement in regenerative medicine and provides new hope for millions awaiting corneal transplants worldwide. ABCcolla Collagen Ophthalmic Matrix is the world's first and only product to utilise supercritical carbon dioxide decellularisation technology, ensuring the complete removal of cells and impurities from animal-derived corneal tissue while preserving its intact collagen scaffold. This innovative approach enhances biocompatibility, biodegradability, and tissue regeneration. The product has received patents in 15 countries. ACRO Biomedical has developed this product using porcine corneas, which closely resemble human corneal structure.

India to establish Centre of Excellence for Traditional Medicine in Thailand

Indian Prime Minister Narendra Modi has announced the establishment of a Centre of Excellence to promote research and dissemination of Traditional Medicine during the Bay of Bengal Initiative for Multi Sectoral Technical and Economic Cooperation (BIMSTEC) Summit recently held in Bangkok, Thailand. Thailand and India have robust Traditional Medicine Systems with close mutual ties. With this announcement by the Prime Minister, the research and development activity in the area is set to get a significant boost. The two countries have been working together to strengthen, promote, facilitate and develop academic & research collaboration in Traditional Medicine. In 2024, the National Institute of Ayurveda, Jaipur, under the Ministry of Ayush of the Government of India and the Department of Thai Traditional and Alternative Medicine of the Ministry of Public Health of the Government of the Kingdom of Thailand, signed a Memorandum of Understanding (MoU) on the establishment of an Academic Collaboration in Ayurveda and Thai Traditional Medicine. India and Thailand have a long history of cooperation in various sectors including Traditional Medicine.

Korea and Romania to strengthen cooperation in healthcare

The Ministry of Health and Welfare, South Korea recently held a bilateral meeting with Alexandru Rafila, Minister of Health of Romania. During the meeting, South Korea's Health Minister Cho KyooHong and Minister Rafila discussed key areas of mutual interest in the healthcare sector, including strengthening cooperation in ICT-based healthcare systems, expanding medical training, and enhancing partnerships in the pharmaceutical, biotech, and medical device

industries. Minister Rafila expressed Romania's interest in collaborating with Korea on several fronts, including sharing best practices in hospital digitalisation, attracting investment in pharmaceuticals and medical devices, improving access to medical services through telemedicine, and establishing healthcare personnel exchange and training programmes, as well as promoting academic cooperation. Following the bilateral meeting, a Memorandum of Understanding (MoU) was signed between George Emil Palade University of Romania and Korea University Guro Hospital to promote comprehensive cooperation, including healthcare professional education.

Singapore launches national standard to validate antimicrobial disinfectant products

As public awareness of hygiene and infection control grows in a post-pandemic world, Singapore has launched a strategic national standard to strengthen public health and industry accountability in the rapidly expanding disinfectant market. Jointly developed by the Duke-NUS Centre of Regulatory Excellence—

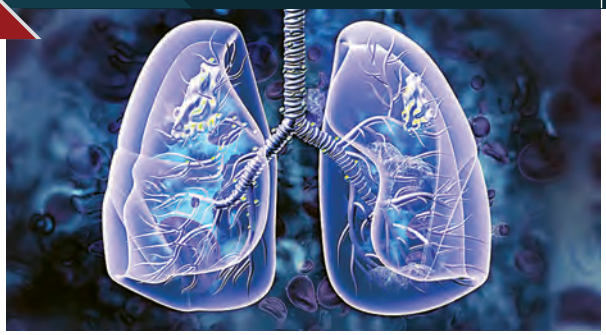
Standards Development Organisation (CoRE-SDO) and Enterprise Singapore (EnterpriseSG), through the Singapore Standards Council (SSC), the new Singapore Standard (SS) 705 provides a robust, science-based methodology of assessing the effectiveness and durability of antibacterial, antiviral and antifungal surface disinfectants and coatings. With the global antimicrobial market projected to reach $65.7 billion by 2035, SS 705 comes at a critical moment to fill this gap in industry-wide guidance. It equips manufacturers with a credible validation framework for their claims, offers regulators a consistent reference for monitoring product quality and empowers consumers with confidence in the choices they make to protect their homes, workplaces and communities.

Indonesia strengthens collaboration for improving maternal and neonatal health outcomes

The UK Government and United Nations Population Fund, in collaboration with Indonesia's Ministry of Health and midwifery stakeholders, has launched the Midwifery Capacity Advancement for Equitable Sexual and Reproductive Health and Reproductive Rights (MARCH) project in Jakarta, Indonesia. The project aims to empower midwives as key agents in reducing maternal and neonatal mortality in Indonesia. Investing in midwives' competence is critical to improving maternal and neonatal health outcomes as well as advancing Sexual and Reproductive Health and Reproductive Rights (SRH & RR). The MARCH project launch coincides with the Faculty Development Programme Training, which brings together 48 midwifery lecturers from selected midwifery education institutions, including health polytechnics, universities, and private schools. This training equips midwifery lecturers with the skills to deliver the international standard competency curriculum, fostering a cadre of competent and skilled healthcare professionals capable of delivering high-quality & evidence-based care.

Merck signs billion-dollar agreement with Hengrui Pharma for cardiovascular drug

Merck, known as MSD outside of the United States and Canada, and Jiangsu Hengrui Pharmaceuticals Co., a global pharmaceutical company focused on scientific and technological innovation, have entered into an exclusive license agreement for HRS-5346, an investigational oral small molecule Lipoprotein(a), or Lp(a), inhibitor currently being evaluated in a Phase 2 clinical trial in China. Elevated blood concentrations of Lp(a) provide a well-documented risk factor for atherosclerotic cardiovascular disease, affecting as many as 1 in 5 adults globally. HRS-5346, an investigational oral small molecule inhibitor of Lp(a) formation, is an important addition that expands and complements cardio-metabolic pipeline. Under the agreement, Hengrui Pharma has granted Merck exclusive rights to develop, manufacture and commercialise HRS-5346 worldwide, excluding the Greater China region. Hengrui Pharma will receive an upfront payment of $200 million and is eligible to receive milestone payments associated with certain development, regulatory and commercial milestones up to $1.77 billion, as well as royalties on net sales of HRS-5346, if approved.



Apollomics, LaunXP ink $50 M deal for NSCLC treatment in Asia

US-based Apollomics Inc., and Taiwan-based LaunXP International Co., an affiliate of LaunXP Biomedical Co., have entered into an agreement for the development and commercialisation in Asia (excluding mainland China, Hong Kong and Macau) of vebreltinib, Apollomics' proprietary c-Met inhibitor, in combination with an EGFR inhibitor (EGFRi) for the treatment of non-small cell lung cancer (NSCLC). The EGFRi class of targeted kinase inhibitors is currently a foundational targeted therapy for the treatment of NSCLC and other tumour types. Under the terms of the agreement, Apollomics is to receive upfront payments totaling $10 million within 60 days of the date of the agreement. Apollomics is also eligible for regulatory and other pre-commercial milestones up to $50 million, and royalties on net product sales. LaunXP will be primarily responsible for the development of vebreltinib in combination with an EGFRi in the LaunXP territory for the treatment of NSCLC.

Marubeni buys Sumitomo's Asia pharma biz for ¥45 B

Japan-based Marubeni Corporation has concluded a Share Purchase Agreement with Sumitomo Pharma Co. to acquire shares in a newly established company that will take over Sumitomo Pharma's pharmaceutical sales business in Asia through a simplified absorption. Marubeni will acquire 60 per cent of the issued shares of the new company for approximately 45 billion yen (¥). Marubeni has positioned its pharmaceutical-related

business as one of the next-generation businesses in demand in countries around the world and has built a pharmaceutical sales business that handles more than 10,000 products, mainly in China, the Middle East, and Africa. Going forward, Marubeni will position the new company as its pharmaceutical strategic platform and will work to expand its products and the target regions to deliver needed products to patients around the world. This will enable Marubeni to grow its pharmaceutical-related business, with sales anticipated to reach more than 100 billion yen by FY2029. In its Mid-Term Management Strategy (GC2027), Marubeni is focusing on Strategic Platform Investments.

AstraZeneca invests $2.5 B to establish sixth global strategic R&D centre in China

British pharmaceutical company AstraZeneca has announced an investment of $2.5 billion in Beijing to establish its sixth global strategic R&D centre together with major research and manufacturing agreements that will further advance life sciences in China. This investment over the next five years is part of a strategic partnership with the Beijing Municipal Government and the Beijing Economic-Technological Development Area Administrative Office and

includes agreements with three biotechs; Harbour BioMed, Syneron Bio, and BioKangtai, and follows the recent Fibrogen announcement. AstraZeneca expects its Beijing workforce to grow to 1,700 employees. The new global strategic R&D centre in Beijing, AstraZeneca's second in China following the opening of the Shanghai R&D centre, will advance early-stage research and clinical development and will be enabled by a new state-of-the-art AI and data science laboratory. The new R&D centre will be located near leading biotechs, research hospitals, and the National Medical Products Administration in the Beijing International Pharmaceutical Innovation Park (BioPark).

LigaChem Bio injects $25 M in UK-based Iksuda Therapeutics

South Korea-based LigaChem Biosciences has announced a $25 million strategic investment in its partner, Iksuda Therapeutics, with the purpose of participating in its management. This funding will accelerate the clinical development of Iksuda's Antibody-Drug Conjugate (ADC) pipeline, bringing forward the timeline for global commercialisation. In particular, Iksuda plans to expand its global clinical trials for its Caxmotabart Entudotin (HER2-ADC) by focusing on patients who have developed resistance to currently marketed competing ADC drugs, thereby accelerating its sub-license to third parties and increasing its overall value. Alongside the equity investment, LigaChem Bio has secured rights to purchase shares from existing major investors in Iksuda, thereby gaining majority ownership and substantial control over Iksuda's pipeline. Of the $25 million investment, the first tranche of $15 million was completed in Q4 of last year, and an additional $10 million is scheduled for mid-2025. Upon completion, LigaChem Bio will hold a 26.6 per cent stake in Iksuda.

India's BioEconomy hits $165.7 B in 2024, with moderate decline in growth momentum

The India Bioeconomy Report 2025, developed by the Association of Biotechnology Led Enterprises (ABLE), was unveiled by Union Minister of State (Independent Charge) Science & Technology Dr Jitendra Singh, at the 13th Foundation Day celebration of Biotechnology Industry Research Assistance Council (BIRAC), recently in New Delhi. According to the report, India's Bioeconomy continues to expand reaching $165.7 billion in 2024. In 2023, the bioeconomy registered a 10 per cent growth, while in 2024, it registered 9.7 per cent growth. The report reveals that the BioIndustrial segment has contributed nearly half of the total bioeconomy (47.2 per cent), followed by biopharma standing at 35.2 per cent. In terms of States contribution to the bioeconomy, Maharashtra again takes the lead with $35.45 billion, followed by Karnataka ($32.4 billion) and Telangana ($19.9 billion).

Siemens Healthineers partners with Singapore General Hospital for healthcare innovation

Siemens Healthineers and Singapore General Hospital (SGH) have recently signed a Memorandum of Understanding (MoU) to establish a five-year strategic partnership to advance healthcare solutions and support SGH in medical innovation. Working together, the two organisations aim to strengthen Singapore's healthcare ecosystem by driving continuous learning, innovation, and excellence in patient care. The MoU, signed at the Siemens Healthineers headquarters in Erlangen, Germany, focuses on improving patient care by developing new technologies, clinical solutions, and data-driven approaches to enhance diagnostics and treatment protocols. The collaboration emphasises hands-on training, workshops, and knowledge-sharing initiatives to build expertise and capacity, while also laying the foundation for future advancements in AI-driven diagnostics, digital health solutions, and sustainability initiatives. Siemens Healthineers and SGH aim to develop new technologies, clinical solutions and data-driven approaches to enhance diagnostic and treatment capabilities and protocols.

Shionogi inks commercial deal for Cefiderocol in Australia and New Zealand

Japanese pharmaceutical company Shionogi & Co. has entered into an exclusive licensing agreement with Link Medical Products, a part of Clinigen, the global specialty pharmaceutical services group, for the development and commercialisation of cefiderocol in Australia and New Zealand. The Therapeutic Goods Administration (TGA) regulatory authority in Australia accepted the market authorisation application for cefiderocol and the application is under evaluation. Under the terms of the agreement, Link will in-license cefiderocol from Shionogi and obtain exclusive rights for its development and commercialisation in Australia and New Zealand. Shionogi will receive an upfront payment, milestone payments based on development progress, and royalties from Link. In Japan, cefiderocol is commercially available under the brand name Fetroja and received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare for various infections caused by strains resistant to carbapenem antibiotics among sensitive strains of Escherichia coli, Citrobacter species, Klebsiella pneumoniae, Enterobacter species, Serratia marcescens, Proteus species, Morganella morganii, Pseudomonas aeruginosa, Burkholderia species, Stenotrophomonas maltophilia, and Acinetobacter species.

Bio-Thera inks biosimilar deal with Dr. Reddy's for Southeast Asia

Bio-Thera Solutions, a China-based biopharmaceutical company developing a pipeline of innovative therapies and biosimilars, and Dr. Reddy's Laboratories SA, wholly-owned subsidiary of India's Dr. Reddy's Laboratories, have reached commercialisation and license agreements for BAT2206, a Proposed Stelara Biosimilar, and BAT2506, a Proposed Simponi Biosimilar. Under the agreement, Bio-Thera will maintain

responsibility for development, manufacturing, and supply of BAT2206 and BAT2506. Dr. Reddy's will be responsible for seeking regulatory approvals as well as commercialisation in the licensed territories in Southeast Asia, including Cambodia, Indonesia, Malaysia, Philippines, Thailand, Vietnam. In addition, Dr. Reddy's will also receive the exclusive commercial rights to BAT2206 in Colombia. BAT2506 is a proposed golimumab biosimilar developed by Bio-Thera. Golimumab, a human monoclonal antibody, inhibits the biological activity of tumour necrosis factor alpha (TNF-alpha).

Amcor launches Malaysia's first-of-its-kind healthcare packaging coating facility

Amcor, a global leader in developing and producing responsible packaging solutions, has completed construction of its advanced coating facility for healthcare packaging in Selangor, Malaysia. This state-of-the-art facility is the first in Asia to leverage cutting-edge air knife coating technology, strengthening the supply of high-quality, sterile packaging for healthcare customers across the region. The new facility expands Amcor's existing healthcare packaging plant in Selangor, creating an integrated campus that makes Amcor the first in Asia to produce both top and bottom substrates for medical device packaging. This development delivers critical benefits to customers, including enhanced supply chain resilience and reduced lead times. Equipped with advanced technologies such as water-based coating systems, online inspection systems and air knife technology, the facility sets new standards for precision and efficiency. The air knife technology, in particular, uses high-speed air streams to ensure uniform coating application, enhancing product consistency and reducing material waste.

Saisei Ventures introduces Executive Fellows Programme for Japan's biotech leadership pipeline

Saisei Ventures, a leading venture investment firm focused on advancing Japanese biotechnology and therapeutic innovations, has announced the launch of its Executive Fellows Programme, a structured mentorship initiative designed to strengthen the next generation of biotech entrepreneurs and executives in Japan. By pairing experienced global biotech leaders with executives from Saisei's Japanese portfolio companies, the Executive Fellows Programme will facilitate knowledge transfer, leadership development and create a network effect of entrepreneurship, helping to bridge this gap and advance Japan's biotechnology entrepreneur sector. The Executive Fellows Programme is a key part of Saisei Ventures' broader mission to not only provide capital but also cultivate the leadership and strategic capabilities required to build a globally competitive biotechnology industry in Japan.

Seegene unveils next-gen fully automated PCR solution, Cureca

Seegene Inc., a global leader in molecular diagnostics (MDx), is advancing its vision for innovation in laboratory automation with the development of CURECA — a next-generation system currently under development, designed to streamline automation in Polymerase Chain Reaction (PCR) testing and laboratory environments. CURECA — short for Continuous Unlimited Random access Expandable and Customisable full Automation — is Seegene's envisioned PCR testing solution, intended to enable full automation of the PCR testing workflow. The system is expected to include two core components: the Customisable Pre-treatment System (CPS), responsible for sample loading and pre-treatment processing; and Customisable and Expandable Full Automation (CEFA), which would carry out sample loading and preparation for nucleic acid extraction, PCR setup, gene amplification, and result analysis. Seegene aims to lead innovation in automating pre-treatment processing for all PCR specimen types through the development of CPS. The system is designed to automate key steps such as sample sorting, centrifugation, vortexing and heat treatment.

Singapore expands startup hub in Tokyo to propel deep tech innovation

NUS Enterprise, the entrepreneurial arm of the National University of Singapore (NUS), is expanding its presence in Japan with the launch of its second BLOCK71 office in Tokyo. This follows the successful opening of its first location in Nagoya in November 2024. In collaboration with key partners, Central Japan Innovation Capital (CJIC), Kyoto University, and TIS Inc., NUS Enterprise aims to support startups, researchers, and students while connecting them with investors. These partnerships align with Japan's efforts to accelerate the growth of its startup ecosystem. BLOCK71 Tokyo will support the growth of Southeast Asian technology-driven startups in Japan, contributing to the urban development's focus on environmental sustainability, mobility and robotics, and smart health. It will also provide Japanese startups with the resources needed to expand into Southeast Asia and beyond.

JelloX Biotech establishes research base in US

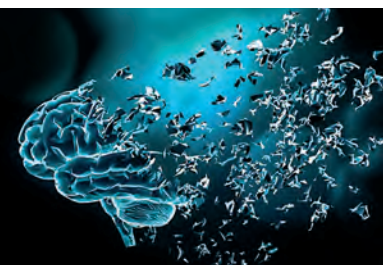
JelloX Biotech Inc., a Taiwan-based startup at the forefront of cancer pathology, is opening a lab in the Discovery Oasis biotechnology space in Phoenix, Arizona. An expansive 120-acre development, Discovery Oasis is envisioned as a biotechnology corridor of collaboration to advance groundbreaking solutions to humanity's most complex medical challenges. With around 1,100 square feet of space housing some of its most advanced equipment, JelloX will leverage its new lab for applying cutting-edge technologies like 3D imaging and AI to cancer pathology. As the company's research has consistently shown, the higher sensitivity of 3D methods has real implications for improving diagnosis and treatment in oncology. Traditional methods of tissue sampling offer limited information on a tumour. Methods using 3D pathology can not only identify cases previously classified as false negatives but also enable early cancer detection. This allows for earlier treatment initiation and greater precision. JelloX's recent research collaborations with major healthcare institutions in Japan and Taiwan have consistently shown the value of 3D pathology across demographics and in a variety of cancers, including colorectal cancer, oesophageal cancer, and HER2 detection in breast cancer.

AdvanCell gets $18M funding for defeating prostate cancer with targeted alpha therapy

AdvanCell, a clinical-stage radiopharmaceutical startup developing innovative cancer therapeutics, has announced $18 million in Australian Federal Government Funding from the Medical Research Future Fund (MRFF) Frontiers Initiative for 'Defeating Prostate Cancer with Targeted Alpha Therapy'. With the support from the MRFF Frontiers Initiative, the goal of the multidisciplinary multi-institutional investigator team is to transform the clinical management of prostate cancer by leveraging leading therapeutic radiopharmaceutical technology paired with innovative clinical development and a deep understanding of tumour biology to improve the lives of patients with prostate cancer. The research programme is enabled by Australian startup AdvanCell's proprietary (Lead-212) 212Pb alpha isotope production technology along with the delivery of a first-in-field clinical platform trial to accelerate the translation of 212Pb-based targeted alpha therapies, one of the most exciting breakthroughs in cancer treatment.

GSK joins hands with Korea's ABL Bio for treatment of neurodegenerative diseases

South Korea-based startup ABL Bio Inc. has announced a worldwide licensing agreement enabling GlaxoSmith-Kline Pharmaceuticals (GSK) to develop novel medicines for neurodegenerative diseases by utilising ABL Bio's blood-brain barrier (BBB) shuttle platform, Grabody-B.



The agreement aims to develop multiple programmes for novel targets across therapeutic modalities including antibody, polynucleotide or oligonucleotides, such as siRNA and ASOs, to address significant unmet medical needs of patients suffering from neurodegenerative conditions. The blood-brain barrier (BBB) serves as a protective barrier that restricts the entry of harmful substances and agents into the brain and is considered a significant obstacle in the development of treatments for neurological diseases. ABL Bio's Grabody-B was developed to overcome the limitations of existing drugs that have difficulty crossing the BBB by targeting the Insulin-like Growth Factor 1 Receptor (IGF1R), facilitating drug penetration across the BBB and enabling efficient delivery into the brain.

Docquity and Novartis collaborate to tackle retinal health challenges in Malaysia

Singapore-based startup Docquity, Southeast Asia's largest network of healthcare professionals (HCPs), and global healthcare company Novartis, have announced a multi-year partnership in Malaysia to address the rise of retinal health challenges, such as diabetic macular edema (DME) and age-related macular degeneration (AMD). Harnessing Docquity's insights-driven, omnichannel commercial capabilities under its Awareness to Advocacy (A2A) Programme, Novartis enhances retinal health education for thousands of ophthalmologists and medical retina doctors across the country, while increasing access to two products within its retina portfolio. As part of Docquity's A2A Programme, Novartis connects with a wide base of its target HCPs across various relevant learning channels. This includes the latest clinical articles, infographics, and interactive webinars offered on the Docquity platform, as well as real-time updates on medical advancements via social media and chat forums.

TeleMedC partners with AND Healthcare to expand AI-based eye disease screening in India

TeleMedC, an Australia-based leader in artificial intelligence (AI)-powered retinal disease diagnostics is expanding its footprint in India, through a strategic partnership with India-based startup AND Healthcare Solutions to deliver low-cost, AI-driven eye screening solutions to millions. The move aims to tackle the growing burden of preventable eye diseases by enabling early detection and intervention. Through its AI-powered technology, the

company enables early detection of conditions such as diabetic retinopathy, glaucoma, and macular diseases, helping to prevent vision impairment and blindness. Supported by Trade and Investment Queensland (TIQ), the Queensland Government's global business agency, TeleMedC and AND Healthcare Solutions will roll out advanced eye imaging and AI-powered diagnostics across India. This initiative is poised to strengthen India's healthcare innovation ecosystem, making critical eye care more affordable and accessible to all.

Guyana launches One Health Project to boost health resilience

The World Bank's Board of Executive Directors has approved a new project to strengthen health resilience in Guyana. The $22 million Guyana One Health Project will focus on empowering the country to prevent, prepare for, & respond to health emergencies. The project will adopt a One Health approach, which integrates human, animal, & environmental health systems. The Guyana One Health Project will further upgrade & decentralise the laboratory network, including transforming the National Public Health Reference Laboratory into a state-of-the-art facility. Veterinary & wildlife diagnostic capacity will also be expanded utilising the One Health approach, improving the ability to detect zoonotic diseases, those that spread from animals to humans, as well as illnesses such as dengue & malaria. Additionally, laboratories will be weather-resilient & energy-efficient, ensuring continuity of operations even in extreme weather conditions. The project builds upon previous partnerships, including the now concluded Guyana COVID-19 Emergency Response Project. The project will also work to digitise the country's health surveillance systems, replacing outdated paper records with integrated, real-time platforms that link data from across human & animal health sectors critical for addressing anti-microbial resistance.

World Bank to strengthen healthcare in El Salvador

The World Bank has approved a project that will help improve access to quality health services in El Salvador, with a focus on primary health care. The investment covers improvements in the areas of health promotion and disease prevention, diagnosis, and treatment, as well as palliative care to ensure the highest possible level of health care and well-being for the population. The Improving Health Care in El Salvador Project (PROMAS) is a $120 million, five-year project that aims to strengthen the country's healthcare system by improving infrastructure and equipment, expanding specialised care services, and developing a health network model. PROMAS will directly benefit users of public health facilities, including women, children, rural communities, persons with disabilities, and Indigenous Peoples. The project will also help boost the health ministry's operational capacity, indirectly benefiting the entire population of El Salvador. It will invest in key areas such as digital health system transformation and supply chain management, as well as in human resources through training and capacity-building activities to enhance skills and knowledge.

Africa CDC unveils strategic plan to transform health financing

With external health aid to Africa expected to plunge by 70 per cent between 2021 and 2025, the Africa Centres for Disease Control and Prevention (Africa CDC) has launched a continent-wide strategy to radically transform how health systems are financed, putting African resources at the centre of African health. In collaboration with African Union Member States, the agency will guide efforts to revise national health financing plans, strengthen domestic investment in health, and pilot innovative, context-specific revenue mechanisms designed to mobilise sustainable and predictable funding. The strategy urges governments to fulfil the Abuja Declaration by allocating at least 15 per cent of national budgets to health. It also introduces innovative financing ideas such as solidarity levies on airline tickets, alcohol, and mobile services, while exploring how Africa's $95 billion in annual diaspora remittances can support national health priorities. Blended finance tools will be used to unlock public and private capital for critical investments in infrastructure, digital health, and local production of vaccines and medical supplies.

Swiss awards 5-Year grant to FIND for innovative malaria testing

The FIND Board has received notice of an award from the Swiss government of a grant to develop an innovative point-of-care rapid diagnostic test (RDT) for P. vivax malaria. FIND will work with partners to develop a digital reader to support accurate interpretation in field settings, facilitate the transfer of technology from the laboratory to a local manufacturing partner, diaTROPIX (Institute Pasteur de Dakar's new regional diagnostics manufacturer) and conduct a comprehensive market assessment and regulatory mapping exercise to guide future deployment. This project is part of a larger response to malaria diagnosis known as P. vivax Serology RDT (PvSeroRDT) overseen by the European and Developing Countries Clinical Trials Partnership (EDCTP) and awarded to a consortium led by Institut Pasteur Paris.

UK accelerates discovery of life-saving drugs

The Prime Minister of the United Kingdom (UK) has announced action to accelerate the discovery of life-saving drugs, improve patient care and make Britain the best place in the world for medical research. The government and the Wellcome Trust will invest up to £600 million to create a new health data research service. This will transform the access to NHS (National Health Service) data by providing a secure single access point to national-scale data sets, slashing red tape for researchers. Clinical trials will also be fast-tracked to accelerate the development of the medicines and therapies of the future, with the current time it takes to get a clinical trial set up cut to 150 days by March 2026 - where latest data collected in 2022 was over 250 days. This will be achieved by cutting bureaucracy and standardising contracts so time isn't wasted on negotiating separate details across different NHS organisations, and ensuring transparency by publishing trust level data for the first time. Through this new drive, patients will have improved access to new treatments and technologies. We already saw the power of health data during the pandemic and this will allow the NHS to make huge strides in patient care. The changes are a major boost for the life sciences sector as the government goes further and faster in delivering the Plan for Change and reshaping the economy in response to the new era of global insecurity.

US FDA to phase out animal testing requirement for monoclonal antibodies

The US Food and Drug Administration (FDA) is taking a groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods. The new approach is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development (R&D) costs, and ultimately, drug prices. The FDA's animal testing

requirement will be reduced, refined, or potentially replaced using a range of approaches, including AI-based computational models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies or NAMs data). Implementation of the regimen will begin immediately for investigational new drug (IND) applications, where inclusion of NAMs data is encouraged, and is outlined in a roadmap being released. To make determinations of efficacy, the agency will also begin to use pre-existing, real-world safety data from other countries, with comparable regulatory standards, where the drug has already been studied in humans.

APAC Vaccine Powerhouses Flex Capacity & Quality Muscle

Asia is the epicentre of global vaccine manufacturing, with India and China together supplying over a billion doses annually. Now, emerging players like South Korea, Singapore, and Australia are stepping up, investing in next-gen platforms and expanding capacity to meet global demand. Let's map the manufacturing footprint of Asia's leading vaccine manufacturers, tracking their current capacity, expansion plans, and the strategic shifts that are transforming the region into a global vaccine production hub.

Asia-Pacific is driving a transformation in the global vaccine supply landscape. According to the WHO Vaccine Report 2024, the WHO South-East Asia region now self-supplies 87 per cent of its vaccines—thanks largely to India, which accounts for 84 per cent of the doses procured in the region and produces 99 per cent of its requirements. Similarly, in the Western Pacific region, China supplies 54 per cent of vaccines and meets 90 per cent of its domestic demand. Manufacturers affiliated with the Developing Countries Vaccine Manufacturers Network (DCVMN) accounted for 54 per cent of global vaccine volumes sold in 2023, further emphasising the role of emerging economies in shaping vaccine access. Together, these two countries are not only meeting regional needs but are scaling up rapidly, with production capacities growing by 15–20 per cent annually. At the same time, Asia as a whole manufacturing base is broadening. The number of companies producing between 10 and 100 million doses annually has jumped from 28 in 2019 to 42 in 2023, with half of this growth coming from China.

While India and China remain the undisputed leaders in vaccine manufacturing, other countries in the Asia-Pacific region are stepping up. South Korea has carved out an impressive niche playing a key role in the global COVAX initiative by supplying vaccines to lower-income countries. Japan and Singapore have focused on high-value, specialised vaccines, with Japanese manufacturers particularly strong in regulated markets like North America and Europe. APAC has a diverse manufacturing ecosystem, while private companies dominate in India and China, government-run manufacturers play a vital role in countries like Thailand, the Philippines, Indonesia, and Vietnam.

"The way vaccine manufacturing has evolved in the Asia-Pacific (APAC) region is truly incredible. With 46 per cent of global preventive and 31 per cent of therapeutic vaccines, the APAC region is now a leader in vaccine development, promoting innovation through advanced technologies and strategic collaborations. According to Astatute Analytica, the Asia-Pacific Vaccines Market was valued at $20.9 billion in 2023 and is projected to surpass $63.11

billion by 2032, with a CAGR of 13.07 per cent growth rate annually! What stands out the most are the figures and the shift in capabilities. India's story exemplifies this evolution. Indian companies now supply over 60 per cent of global vaccines used in the National Immunisation Programme worldwide," said Dr VJA Gutla Harshavardhan, Director General of the Indian Vaccine Manufacturers Association (IVMA).

Many regional manufacturers have moved beyond downstream processing and are now developing novel products like oral cholera, hepatitis E, typhoid conjugate, and rotavirus vaccines, as well as region-specific solutions such as Japanese encephalitis vaccines.

"Over the past decade, vaccine manufacturing capacity in the Asia-Pacific (APAC) region has undergone a transformational shift — moving from a largely recipient and production-oriented role to becoming a strategic hub for innovation, scale, and resilience," said Dr N Erlyani Abd Hamid, Head of Strategy Planning and Public Relations, Hilleman Laboratories, Singapore.

Dr Harshavardhan echoes the same sentiments, "Asian manufacturers have now shifted from supplying basic UIP vaccines to developing and exporting advanced biotherapeutic products globally. For example, Indian and Korean manufacturers made affordable DTwP-Hib-Hep B combination vaccines, allowing many developing countries to introduce the Hib antigen into their immunisation schedules. Indian-made Measles vaccines were instrumental in eliminating that disease in Latin America. The current progress in global polio elimination would have been impossible without Asian manufacturers."

Manufacturing muscle of Asia's top vaccine producers

Serum Institute of India (SII) (India)
Manufacturing Capacity:
3 billion doses annually

Serum Institute of India (SII) is the world's largest vaccine manufacturer by volume, with a mission rooted in producing life-saving immunobiologicals that are both affordable and accessible. Since its inception, SII has significantly impacted global health by reducing the cost of essential vaccines for diseases such as Diphtheria, Tetanus, Pertussis, HIB, BCG, Hepatitis B, Measles, Mumps, and Rubella.

Notably, SII developed Pneumosil, the world's most affordable pneumococcal conjugate vaccine (PCV), and introduced Cervavac, India's first indigenous quadrivalent HPV vaccine. During the COVID-19 pandemic, SII played a central role globally, supplying over 2 billion doses of COVID-19 vaccines.

SII's state-of-the-art facility in Manjri, Pune, is one of the largest multifunctional vaccine manufacturing sites globally, contributing to the company's impressive annual output. This infrastructure has helped save an estimated 30 million lives worldwide.

Recent Developments (2024):

- **Mpox Vaccine Partnership:** Entered a license and manufacturing agreement with Bavarian Nordic to produce its Mpox vaccine.
- **CEPI Investment:** The Coalition for Epidemic Preparedness Innovations (CEPI) pledged $30 million to enhance SII's capacity to supply affordable investigational vaccines for epidemic and pandemic threats.

Bharat Biotech (India)
Manufacturing Capacity:
4 billion doses annually

Founded on a mission to address unmet public health needs through innovation, Bharat Biotech has built one of the most diversified vaccine portfolios in the world, with over 20 vaccines covering viral, bacterial, and recombinant technologies. It has been a pioneer in developing vaccines for influenza H1N1, Rotavirus, Japanese Encephalitis (JENVAC), Rabies, Chikungunya, Zika, and Cholera, and introduced the world's first tetanus-toxoid conjugate vaccine for typhoid. Bharat Biotech also launched HILLCHOL, an oral cholera vaccine, in 2024 to address the global shortage of oral cholera vaccines, with new manufacturing lines in Hyderabad and Bhubaneswar capable of producing up to 200 million doses annually.

The company has four manufacturing facilities

in Hyderabad, Gujarat, Karnataka, and Pune. On January 18, 2025, Bharat Biotech, through its subsidiary Sapigen Biologix, unveiled a new facility in Odisha that can produce 8 billion vaccine doses annually, designed to handle up to 10 different vaccines. This large-scale infrastructure signals the company's readiness to respond to routine immunisation needs and future pandemic threats.

Panacea Biotec (India)
Manufacturing Capacity:
1 billion doses annually

Panacea Biotec is one of India's leading vaccine manufacturers, globally recognised for its contributions to the Global Polio Eradication Initiative (GPEI) through the supply of billions of WHO prequalified oral polio vaccine doses to over 50 countries. The company was the first in the world to develop a fully-liquid, whole-cell wP-IPV-based hexavalent vaccine (DTwP+HepB+Hib+IPV), launched as EasySix in 2017. Panacea's current portfolio includes EasySix, Enivac-HB (Hepatitis B), Ecovac-4 (DTwP+HepB), EasyFour (DTwP+Hib), and EasyFourPol (DTwP+Hib+IPV), while its pipeline includes next-generation vaccines such as a recombinant chimeric dengue tetravalent vaccine and a pneumococcal conjugate vaccine. The company's state-of-the-art facility in Baddi features two independent formulation suites and three filling lines, supporting production in pre-filled syringes and vials. With large-scale lyophilisation capabilities, the plant can produce up to 600 million doses per annum. In 2024, Panacea Biotec received a $20 million long-term loan commitment from the U.S. International Development Finance Corporation (DFC) to support capacity expansion for its hexavalent vaccine programme.

Biological E (India)
Manufacturing Capacity:
1.2 billion doses annually
(excluding COVID-19)

Biological E is a long-established Indian vaccine developer and manufacturer, supplying vaccines and therapeutics to over 130 countries. With a strong focus on both chronic and communicable diseases, its portfolio includes vaccines for diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type B, measles, rubella, Japanese encephalitis, typhoid, and more. The company currently produces around 700 million vaccine doses annually, excluding COVID-19 vaccines, from four manufacturing facilities—three in Hyderabad and one in Dehradun. Biological E holds 10 WHO-prequalified vaccines.

In 2022, Biological E announced a major expansion plan with an investment of over Rs 1,800 crore to ramp up manufacturing of vaccines, generic injectables, and R&D operations across its three facilities in Genome Valley, Hyderabad.

> "Over the past decade, vaccine manufacturing capacity in the Asia-Pacific region has undergone a transformational shift — moving from a largely recipient and production-oriented role to becoming a strategic hub for innovation, scale, and resilience."
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> **- Dr N Erlyani Abd Hamid,**
> Head of Strategy Planning and Public Relations, Hilleman Laboratories, Singapore

Biological E is also extending its global impact through strategic partnerships. In 2025, Bavarian Nordic partnered with the company to expand access to its chikungunya vaccine across low- and middle-income countries. In 2024, the company joined forces with Takeda to scale production of the dengue vaccine Qdenga, aiming to produce up to 50 million additional doses annually.

With a pipeline that includes pneumococcal conjugate, inactivated polio, and human papillomavirus vaccines, Biological E continues to invest in the development of next-generation products.

CanSino Biologics (China)
Manufacturing Capacity:
280 million doses annually (Tianjin) +
100 million doses planned
(Shanghai, mRNA facility)

Founded in 2009, CanSino Biologics is a rising leader in China's vaccine industry, focused on developing innovative, high-quality, and affordable vaccines that address global public health challenges. The company operates over 200,000 square meters of modern manufacturing space across its facilities in Tianjin and Shanghai. Its flagship campus in Tianjin spans nearly 130,000 square meters, built with an investment of nearly RMB 10 billion and an annual production capacity of 280 million vaccine doses. In Shanghai, CanSino is constructing a state-of-the-art mRNA manufacturing facility within the Life Blue Bay Industrial Park of the Lin-gang Special Area. With a Phase I investment exceeding RMB 1 billion, the site aims to add another 100 million doses per year in mRNA capacity.

CanSino's diverse portfolio is underpinned by five integrated technology platforms and includes more than 10 vaccines. Notable achievements include

Asia's only Ebola virus vaccine (Ad5-EBOV), its WHO Emergency Use Listed COVID-19 vaccine Convidecia, and Asia's first quadrivalent meningococcal conjugate vaccine (Menhycia).

CNBG – Sinopharm (China)
Manufacturing Capacity:
Over 7 billion doses annually

China National Biotec Group (CNBG), a subsidiary of Sinopharm, is China's largest and the world's fifth-largest manufacturer of human vaccines. With a legacy spanning over a century, CNBG has played a central role in the history of China's biological products industry, from developing the nation's first smallpox, cholera, typhoid, and rabies vaccines to eliminating polio and controlling major infectious diseases. Today, CNBG produces 50 types of vaccines annually, including all Class I vaccines under China's National Immunisation Programme, supplying over 80 per cent of the country's vaccine needs.

CNBG operates six major production bases across China, with nearly 100 GMP-certified production lines and a manufacturing capability exceeding 200 biological products for prevention, treatment, and diagnostics. It is home to the world's largest inactivated COVID-19 vaccine production facility, with an annual output capacity of over 7 billion doses. The company has developed four different COVID-19 vaccines and has made significant contributions to China's and the world's pandemic responses, including past efforts against SARS, H1N1, and other outbreaks.

Sinovac Biotech (China)
Manufacturing Capacity:
Estimated over 150 million doses annually (based on available line-wise capacity data and excluding COVID-19 vaccine)

Sinovac Biotech is a leading China-based biopharmaceutical company specialising in the research, development, manufacturing, and commercialisation of vaccines that protect against human infectious diseases. Headquartered in Beijing, Sinovac has played a crucial role in public health, both in China and globally, through its wide-ranging vaccine portfolio and rapid response to emerging infectious diseases.

Sinovac's product portfolio includes vaccines against COVID-19 (CoronaVac), enterovirus 71 (Inlive) for hand-foot-mouth disease, hepatitis A (Healive), influenza (Panflu and Panflu.1), varicella, poliomyelitis (Sabin-strain inactivated polio vaccine, sIPV), and pneumococcal disease. Sinovac was the first to receive approval in China for an H1N1 influenza vaccine (Panflu.1) and remains the sole supplier of the H5N1 pandemic influenza vaccine (Panflu) for the national stockpiling programme. It also continues to lead in the production of Category 1 Preventative Biological Products, with innovative vaccines like Inlive commercialised in China.

The company operates four manufacturing sites across Beijing (Haidian, Changping, and Daxing Districts) and Dalian with a combined output of nearly 150 million doses.

Chongqing Zhifei Biological Products (China)
Manufacturing Capacity:
1 billion doses

Chongqing Zhifei Biological Products is one of China's leading private vaccine manufacturers. With a workforce of around 4,500 employees and assets totalling RMB 23.9 billion, the company integrates R&D, manufacturing, marketing, and distribution of human vaccines. Zhifei's product portfolio includes a recombinant COVID-19 vaccine (CHO cell-based), tuberculosis fusion protein (Ekear), Hib vaccine (XiFeiBei), meningococcal polysaccharide and conjugate vaccines (Menwayc, Mening A Con), and Mycobacterium Vaccae for injection (Vaccae). It is also the exclusive distributor in China for key MSD vaccines (Gardasil, Rotateq, Pneumovax, Vaqta) and GSK's Shingrix. The annual production capacity is estimated to be 1 billion doses.

CSL Seqirus (Australia)
Manufacturing Capacity:
150 million doses (6-month pandemic capacity at Holly Springs facility)

CSL Seqirus, a division of global biotechnology leader CSL, is one of the largest influenza vaccine manufacturers in the world and the only company operating an influenza vaccine manufacturing facility in Australia. The company's manufacturing network spans three continents and includes advanced facilities such as the Holly Springs plant in the United States, designed for rapid pandemic response with the ability to produce up to 150 million doses within six months, and its upcoming state-of-the-art facility in Australia, set to be operational by 2026. This new Australian facility will manufacture both seasonal and pandemic cell-based influenza vaccines, the MF59 adjuvant, the world's only human Q fever vaccine, and various antivenoms for Australia's unique wildlife. In addition to its robust seasonal flu vaccine portfolio, CSL Seqirus is advancing next-generation technologies, including self-amplifying messenger RNA (sa-mRNA) platforms, aimed at improving vaccine efficacy across diverse age groups and global markets. This scientific and manufacturing innovation positions CSL Seqirus as a key global partner in both routine immunisation and pandemic response.

Lessons from COVID-19

Dr VJA Gutla Harshavardhan,
Director General, Indian Vaccine Manufacturers Association (IVMA)

COVID-19 was a significant turning point for vaccine manufacturers around the globe. It tested the strengths and capabilities of the industry, revealing areas for improvement that will influence and shape the industry in the future.

First and foremost, APAC learned about the significance of record-time scalability and flexibility in vaccine manufacturing. When COVID-19 struck, Indian manufacturers had to scale production to more than 100 million doses within a few months. Despite having the world's largest population to be vaccinated, India donated vaccines to over 95 countries. The crisis reinforced India's ancient philosophy of 'Vasudhaiva Kutumbakam' – the world is one family – which manifested through the 'Vaccine Maitri' friendship initiative. This experience prompted many Asian manufacturers to invest in modular facilities that can quickly pivot between different vaccines based on demand.

The second most important lesson was the highlighting of supply chain vulnerabilities, especially regarding excipients and other critical materials. For instance, the global shortage of specialised filters and bioreactor bags in 2021 led to temporary slowdowns in some production lines. Many manufacturers discovered an over-reliance on imported raw materials, such as foetal bovine serum, media, adjuvants, bioreactors, and packaging materials, including vials, rubber bungs, seals, and consumables like single-use disposable bags, filters, and tubing. Consequently, we are now seeing an increase in local investments in these essential materials, reflecting the lessons learned from COVID–19.

We also witnessed the power of collaboration. Numerous private manufacturers collaborated with the governments, sharing technology and expertise worldwide. Throughout COVID-19 and beyond, digital transformation accelerated by adopting tools for cold-chain monitoring, batch tracking, and post-vaccination surveillance. These systems are now being expanded to routine immunisation programmes, simplifying monitoring and evaluation.

COVID-19 highlighted gaps in equitable distribution. This experience reinforced the commitment to developing adequate regional capacity to ensure no country is left waiting during future pandemics. In the coming years, more novel vaccines are likely to be developed in Asia or licensed first here for the world. Governments, too, are keenly interested in national and regional vaccine security.

Perhaps most significantly, we learned that regulatory processes can be expedited without compromising safety. The Emergency Use Authorisations during COVID-19 showed that parallel review processes and rolling submissions can save valuable months. In the future, there is a consensus on developing effective vaccines within 100 days of identifying the new pathogen, requiring unprecedented collaboration among all stakeholders.

These lessons aren't theoretical—they are driving real changes across our industry. The future of vaccine manufacturing will not be in silos or an emergency response manner, as was observed during this pandemic. Strong sectoral and cross-organisational collaborations shall design novel methodologies to tackle future epidemics and infectious diseases. Financial and strategic investments will push the development of new vaccine manufacturing technologies such as continuous flow processing, additive, and integrative manufacturing.

A positive takeaway is that we are now better prepared, with Asia-Pacific vaccine manufacturers playing an increasingly central role in global health security. BS

Top 10 vaccine players of APAC with manufacturing capacities

Company	Capacity (vials/ year) (doses/ year)	Vaccine Types	Diseases
Serum Institute of India, India	3 billion	Protein-based, recombinant vaccines, viral vector	Diphtheria, Tetanus, Pertussis, HIB, BCG, Hepatitis B, Measles, Mumps, Rubella, Pneumonia, Cervical cancer
Bharat Biotech, India	4 billion	Whole cell, Inactivated, recombinant, Conjugate	influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika, and Cholera, and introduced the world's first tetanus-toxoid conjugate vaccine for typhoid.
Panacea Biotec, India	1 billion	Combination (Hexavalent) Vaccine, recombinant,	Diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type B, measles, rubella, Japanese encephalitis, typhoid
Biological E, India	1.2 billion	Whole cell, recombinant, Conjugate	Diphtheria, pertussis, tetanus, hepatitis B, Haemophilus influenzae type B, measles, rubella, Japanese encephalitis, typhoid
CanSino Biologics, China	280 million (Tianjin) + 100 million planned (Shanghai, mRNA facility)	Conjugate, recombinant, viral vector, mRNA	Meningitis, pneumonia, pertussis, diphtheria, tetanus, COVID-19, tuberculosis, shingles, Ebola virus
CNBG – Sinopharm, China	7 billion	Conjugate, recombinanant, Inactivated	Smallpox, cholera, typhoid, and rabies vaccine
Sinovac Biotech, China	150 million	Inactvated, recombinant, viral vector	hand-foot-mouth disease, hepatitis A (Healive®), influenza (Panflu® and Panflu.1®), varicella, poliomyelitis (Sabin-strain inactivated polio vaccine, sIPV), and pneumococcal disease.
CSL Seqirus, Australia	150 million	adjuvant technology, sa-mRNA	Influenza vaccine
GC Biopharma, South Korea	300 million	mRNA	seasonal influenza vaccines
Chongqing Zhifei Biological Products, China	1 billion	Conjugate, recombinant, Adjuvant, mRNA	TB fusion protein (Ekear), Hib vaccine, meningococcal polysaccharide, conjugate vaccines, Gardasil, Rotateq, Pneumovax, Vaqta and Shingrix.

GC Biopharma (South Korea)
Manufacturing Capacity:
300 million doses annually
at Ochang facility

GC Biopharma is a leading South Korean biopharmaceutical company with a global footprint in vaccine and biotherapeutic production. The company operates South Korea's largest filling and finishing facility in Ochang, established in 2019, with a capacity to produce up to 300 million doses annually. This WHO-prequalified plant is fully automated, leveraging isolator technology and a single-use system to minimise contamination and ensure streamlined, GMP-compliant manufacturing for both vaccine and non-vaccine drug products (sterile vials and prefilled syringes). GC Biopharma is a major supplier of seasonal influenza vaccines through global health agencies, including PAHO and UNICEF, delivering over 50 million doses annually even during the peak of the COVID-19 pandemic. The company's facility in Hwasun complements its global vaccine efforts and has recently expanded to include a new mRNA production pilot plant, completed in late 2023. This "all-in-one" GMP facility covers the entire mRNA production process, incorporating single-use technology to enable rapid, flexible, and contamination-free manufacturing across multiple products. GC Biopharma also achieved a major milestone with BARYTHRAX, the world's first recombinant anthrax vaccine, approved by the Korean

Ministry of Food and Drug Safety in April 2025.

Emerging markets beyond India and China

Following COVID-19, there have been increased efforts to develop and expand regional manufacturing so that each region has local manufacturers that can supply vaccines, in service of equitable access, regional supply security and economic development.

Dr N Erlyani said, "Pre-COVID-19, countries like India, China, & Indonesia had already built strong vaccine manufacturing footprints, driven by domestic demand & public health goals. India, in particular, was recognised as the largest global supplier of WHO prequalified vaccines. Post-COVID, the pandemic catalysed massive public & private investments across the region: mRNA capabilities were introduced in countries like Singapore, South Korea, Thailand, & Australia. Fill-finish capacity expanded significantly in countries such as Indonesia, Vietnam, & the Philippines to reduce reliance on imported vaccines. Regional institutions began developing platform-based R&D ecosystems to complement manufacturing, enabling faster response to emerging threats."

Other players like South Korea, Singapore, and Australia are emerging—not yet major exporters by volume, but leaders in biotech innovation and contract manufacturing. Prior to COVID-19, Singapore did not have a single facility for vaccines. Over the past few years, however, the country has seen an outpouring of interest from pharma giants to set up manufacturing sites. Vaccine-maker Hilleman opened a $27 million plant in Singapore in November 2024. In the same month, pharma giant Sanofi inaugurated a $595 million vaccine facility, aimed at preparing for potential pandemics. Earlier, other vaccine makers—BioNTech and GSK had also announced plans to build manufacturing plants in the country. Altogether, these facilities will produce millions, if not billions, of doses annually.

Australia is also taking significant steps to scale up its vaccine manufacturing capabilities, with a clear ambition to become a powerhouse in mRNA vaccine production. In December 2024, global vaccine leader Moderna opened its state-of-the-art facility in Victoria. Beyond domestic capacity building, the Australian government is forging regional partnerships to boost manufacturing across Asia. As part of its Biomedical Manufacturing Programme , Australian scientists are collaborating with Thailand and Malaysia to strengthen their local vaccine and medicine production capabilities.

South Korea is another country ramping up its vaccine game, with a strong push to enhance both domestic capabilities and global partnerships. The Korea Disease Control and Prevention Agency (KDCA) is building a robust vaccination infrastructure aimed at enabling faster response in developing and producing vaccines. In April 2025, vaccine maker EuBiologics was chosen to spearhead a major government initiative to establish a domestic mRNA vaccine platform, targeting future pandemics and emerging infectious diseases. Meanwhile, another firm SK Bioscience is expanding its vaccine manufacturing plant and scaling up exports—most recently extending its influenza vaccine reach to the Southern Hemisphere. The company is also teaming up with Sanofi to distribute RSV and Hepatitis A vaccines within Korea, reinforcing South Korea's growing footprint in global vaccine supply chains.

Korean firms are playing a key role in strengthening vaccine capacity across the region. SK Bioscience signed an MoU with Thailand's state-run Government Pharmaceutical Organization (GPO) to bolster the country's vaccine infrastructure. In the Philippines, Glovax Biotech and Korea's EuBiologics are collaborating to build the nation's first vaccine manufacturing facility, an investment of PHP 7.5 billion ($132 million) under the banner of Glovax Lifescience Corporation.

Malaysia, which currently relies entirely on vaccine imports, has outlined plans to advance its vaccine manufacturing capabilities. The country's National Vaccine Development Roadmap aims to build domestic production capacity, including the development of Halal-certified vaccines to serve both national and regional demands. Supporting this initiative, the National Institutes of Biotechnology Malaysia (NIBM) is setting up a pilot-scale vaccine manufacturing facility at the Malaysia Genome and Vaccine Institute (MGVI).

Overall, we are seeing a shift from contract manufacturing to end-to-end vaccine development, with Asia-Pacific increasingly positioning itself as a self-reliant and globally competitive vaccine hub.

"Behind these advances is an industrial maturing to conduct world-class clinical trials and increasingly robust compliance processes. We are witnessing greater harmonisation of regulatory standards across the region, which helps speed up access to life-saving vaccines. Similarly, strong technical knowledge, scalability, and a highly skilled workforce are the other factors that will continue to set advanced production standards in the region. We are just seeing the beginnings. Ten years from now, this decade will be the foundation of Asia-Pacific's leadership in global vaccine innovation and production," signs off Dr Harshavardhan. BS

Ayesha Siddiqui

“Asia-Pacific region has firmly established itself as a global vaccine export powerhouse”

« **Suchitra Ella,** Managing Director of Bharat Biotech, India

Suchitra Ella, Managing Director of Bharat Biotech, India delves into the evolution of vaccine manufacturing capacity in the Asia-Pacific region over the past decade and explores key lessons learned from the COVID-19 pandemic that will shape the future of vaccine production and distribution. ***Edited excerpts:***

How has vaccine manufacturing capacity evolved in the Asia-Pacific region over the past decade?

Over the past decade, vaccine manufacturing capacity in the Asia-Pacific region has expanded significantly, driven by rising demand, strategic investments, and public health priorities. The region now produces 46 per cent of global preventive vaccines and 31 per cent of therapeutic vaccines, according to industry estimates. India has led this transformation, with companies like Bharat Biotech scaling up operations to produce billions of doses annually across vaccines for Rotavirus, Typhoid, Cholera, Hepatitis, Rabies, Japanese Encephalitis and more. Indian manufacturers now supply over 60 per cent of the global vaccine demand for national immunisation programmes. China, backed by substantial state investment and export-led policies, has emerged as another major player, contributing significantly to the global COVID-19 vaccine supply. Meanwhile, South Korea has positioned itself as a premier contract manufacturer, especially in advanced platforms like mRNA and recombinant technologies. The COVID-19 pandemic acted as a powerful catalyst, pushing governments and industries to enhance agility, invest in R&D, and build resilient supply chains. As a result, the Asia-Pacific region is now a critical hub for global vaccine supply—technologically advanced, increasingly self-reliant, and better prepared to tackle future public health crises.

Which Asia-Pacific countries are the biggest vaccine exporters, and what are their key markets?

As of 2024, the Asia-Pacific region has firmly established itself as a global vaccine export powerhouse, driven by a blend of manufacturing scale, innovation, and strategic outreach. Leading the charge is India, the world’s largest vaccine supplier, accounting for over 60 per cent of global vaccine exports used in national immunisation programmes. Bharat Biotech has supplied vaccines for rotavirus, typhoid, polio, and COVID to more than 150 countries, with key markets spanning Africa, Latin America, Southeast Asia, CIS, and the Middle East. India’s COVID-19 response alone saw the export of over 282 million vaccine doses under initiatives like Vaccine Maitri, reinforcing its reputation as the "Pharmacy of the World." China follows closely, with massive production capacity—producing over 5 billion COVID-19 vaccine doses during the pandemic—and a growing export footprint in Asia, Africa, and South America.

While smaller in volume, South Korea has carved out a critical niche in the high-quality contract manufacturing space, exporting recombinant hepatitis and influenza vaccines primarily to North America, Europe, and regional Asian markets. The country attracted over $1.5 billion in biomanufacturing investments between 2022 and 2024, signalling its ambition to be a global hub for next-generation platforms like mRNA. Japan, traditionally focused on domestic vaccine needs, is beginning to expand exports of select vaccines such as dengue and influenza, supported by a $1.7 billion investment in advanced manufacturing infrastructure. Indonesia also has

large scale vaccine manufacturing companies mostly focused on domestic markets with some exports.

Together, these nations are shaping the global vaccine trade and reinforcing the Asia-Pacific region's role in global health security. Their growing influence enhances supply chain resilience, ensures equitable access to life-saving vaccines, and strengthens the region's standing as a dependable, innovation-driven contributor to global public health.

What lessons have vaccine manufacturers learned from the COVID-19 pandemic that will shape future vaccine production and distribution?

The COVID-19 pandemic was a watershed moment for vaccine manufacturers, offering invaluable lessons that continue to redefine production and distribution strategies across the Asia-Pacific region. Chief among them was the urgent need for speed and scalability. The global race to develop vaccines underscored how flexible R&D pipelines and adaptable manufacturing platforms could drastically compress traditional timelines—what once took 5–10 years was achieved in under 12 months. Several manufacturers in the region, including those in India and China, scaled up to produce billions of doses, collectively supplying more than 4.5 billion COVID-19 vaccines globally by 2022.

Another lesson was the importance of supply chain self-reliance. The pandemic exposed vulnerabilities in global logistics and raw material dependencies, prompting a shift toward localised, end-to-end manufacturing ecosystems. Governments and private players in countries like India, South Korea, and Singapore responded by investing heavily in domestic bioproduction, API manufacturing, and cold-chain infrastructure. For instance, India's government-backed initiatives helped expand local production capacity to over 5 billion doses per year, reducing import reliance.

Regulatory agility also came to the fore. Emergency use authorisations, accelerated clinical trials, and rolling reviews demonstrated that safety and speed need not be mutually exclusive. This has pushed regulatory bodies in the region to modernise protocols and build frameworks for future emergencies. Moreover, public-private partnerships and global collaborations—including technology transfers and co-development deals—were pivotal in expanding access and ensuring equitable distribution, especially in low- and middle-income countries.

As of 2024, the Asia-Pacific region has firmly established itself as a global vaccine export powerhouse, driven by a blend of manufacturing scale, innovation, and strategic outreach. Leading the charge is India, the world's largest vaccine supplier, accounting for over 60 per cent of global vaccine exports used in national immunisation programmes. China follows closely, with massive production capacity—producing over 5 billion COVID-19 vaccine doses during the pandemic—and a growing export footprint in Asia, Africa, and South America. The lessons learnt during COVID period are now shaping a more resilient, responsive, and inclusive vaccine ecosystem, positioning the Asia-Pacific not just as a global supplier, but as a dynamic leader in the next era of immunisation.

Bharat Biotech (BBIL) has built robust, end-to-end capabilities spanning R&D, clinical trials, and large-scale manufacturing, ensuring rapid response to emerging health threats. Bharat Biotech was one of the few companies to develop and commercialise COVID-19 vaccines without technology transfers from foreign entities. With a proven track record in developing indigenous vaccines like Covaxin, BBIL remains committed to global pandemic preparedness through innovation, agility, and strategic partnerships.

Finally, the pandemic catalysed a wave of innovation. Asia-Pacific firms are now actively developing next-generation vaccine platforms, including mRNA, intranasal, and thermostable formulations, designed for greater efficacy, ease of use, and wider reach, particularly in remote or resource-limited settings. South Korea and Japan have together committed over $3 billion toward advanced vaccine technologies and manufacturing innovation since 2021.

These lessons are now shaping a more resilient, responsive, and inclusive vaccine ecosystem, positioning the Asia-Pacific not just as a global supplier, but as a dynamic leader in the next era of immunisation. BS

Ayesha Siddiqui

Medtech education in APAC keeping pace with innovation

As medical devices grow smarter and more interconnected using AI, robotics and virtual reality, the need to train professionals is growing urgently. To position itself as a global powerhouse for medical technology, Asia Pacific (APAC) countries such as China, Japan, Korea, India, Singapore, Vietnam, Thailand, Taiwan are ramping up medtech education initiatives, recognising the critical role that talent pipelines, partnerships, and digital innovation play in advancing their healthcare economies. Let's take a closer look at the new initiatives being taken up by the APAC region for strengthening the medtech education sector amidst many challenges and opportunities.

From artificial intelligence (AI)-powered diagnostics in China to surgical robotics in Japan and wearable technologies emerging from South Korea, the Asia Pacific region is home to some of the world's most ambitious medical technology breakthroughs. Yet behind the scenes, an urgent challenge persists regarding a widening medtech talent gap at the academic level.

Despite world-class research institutions and strong government investment, universities in the APAC region are grappling with this challenge of how to produce enough industry-ready graduates who can navigate the increasingly interdisciplinary, globalised, and rapidly evolving medtech landscape.

Thus, solving the medtech talent gap at the university level is not just about introducing more programmes and degrees, it is also about making the medtech education system smarter and integrated, to reflect the realities of a fast-moving, tech-driven global ecosystem.

With this global ambition in mind, APAC countries are gradually carving out novel paths in the form of new medtech education courses, partnerships with the industry, support from the government, to supply talent to the global medtech industry and leading the next wave of transformation.

Key Initiatives and Trends Across Japan, China, Korea & Taiwan

In South Korea, a leader in robotics technology, universities like Pohang University of Science and Technology are offering specialised courses in robotic surgery. These programmes combine theory with hands-on training, allowing students to work with state-of-the-art robotic surgical tools. Korea University and Korea Advanced Institute of Science and Technology (KAIST) have rolled out interdisciplinary programmes that combine bioengineering with computational sciences, supported by funding from the Ministry of Science and ICT. Also, under the Digital Health Education Consortium, a collaboration between universities and leading firms like Samsung Medison and Lunit, immersive training in AI-driven imaging and wearable diagnostics is being offered.

Another leader in technology, Japan is deepening its integration of medtech into education with the government recently launching a national initiative under its Society 5.0 vision, focusing on embedding AI, robotics, and data science into medical and technical university curricula.

University of Tokyo and Osaka University have introduced interdisciplinary programmes combining biomedical engineering, computer science, and clinical exposure, in partnerships with leading medtech companies such as Hitachi, Olympus, and Canon Medical, which provide equipment, real-world case studies, and research opportunities.

Adding on, universities in China such as Tsinghua University and Peking University are leading the charge by offering AI-focused programmes tailored to the healthcare sector. 'Agent Hospital', an AI-powered virtual healthcare platform developed by Tsinghua University researchers, is preparing for a public pilot launching in 2025. This initiative features autonomous AI doctors trained through dynamic simulations of real-world clinical workflows.

Very recently, Hong Kong University of Science and Technology (HKUST) has launched a Digital Health and AI Innovation Lab, where students work on applications in medical imaging, predictive diagnostics, and virtual health assistants. HKUST has also partnered with Microsoft a few months

ago, for pioneering innovative medical pedagogies utilising cutting-edge technology to nurture the next generation of medical talent.

"The emergence of AI has brought unprecedented changes for our future. Integration of AI and biomedicine will pioneer innovative medical education and advance cutting-edge medical research, leading to improved prevention, diagnosis, and treatment", said ***Prof. Nancy IP, President, Hong Kong University of Science and Technology.***

In China, the Ministry of Education and National Health Commission have launched a multi-tiered national framework for medtech talent development, covering vocational training, university education, and continuing professional education. In fact, as a bold move to secure its place as a global leader in artificial intelligence, China has announced mandatory AI education for all primary and secondary school students, starting September 1, 2025.

Carving out a niche in high-precision medical devices and digital health, Taiwan's Ministry of Education and Ministry of Health and Welfare are aligning medtech education reforms with the broader Biomedical Industry Innovation Programme, aiming to make the country a global biomedtech hub by 2030. Also, National Taiwan University (NTU), Taipei Medical University (TMU), and National Cheng Kung University (NCKU) are integrating medtech into engineering and biomedical curriculums at an unprecedented pace.

South East Asia addressing talent bottleneck

As South East Asia races to embrace medical innovation and digital health transformation, one major constraint that comes into sharp focus is the growing medtech talent gap. According to ASEAN Development Outlook reports, the south east Asian region could face a shortfall of over 150,000 medtech-related professionals by 2030, spanning R&D, regulatory affairs, digital health, and advanced manufacturing.

As a result, in countries like Singapore, AI-powered diagnostic platforms are being integrated into medical curricula to teach students how AI algorithms can assist in disease detection. For example, Lee Kong Chian School of Medicine at the Nanyang Technological University (NTU) is deploying latest tech-enabled teaching tools, enriched with new courses in data science and artificial intelligence, among other enhancements, for producing doctors who will shape the landscape of healthcare delivery. The school has also teamed up with the Department of Cardiology in Tan Tock Seng Hospital (TTSH) to develop the Graduate Diploma in Cardiovascular Medicine Programme targeted at upskilling family doctors in cardiovascular medicine.

"The rapid advancement of AI is reshaping healthcare, creating new opportunities and challenges. Traditionally, medical education has focused heavily on basic sciences and clinical practice. However, as AI technology continues to evolve, it's clear that this approach must adapt. The healthcare professionals of tomorrow will need skills that prepare them to work effectively alongside AI, using it to enhance patient outcomes and drive innovation in care delivery", said ***Professor Joseph Sung, Dean, Lee Kong Chian School of Medicine, Nanyang Technological University (NTU).***

Striking a balance between medical education and technology, the Ministry of Education and Enterprise Singapore is launching programmes to integrate engineering, data science, and clinical exposure into medtech curricula at institutions like National University of Singapore (NUS) and NTU, to provide hands-on experience with emerging technologies such as digital therapeutics, AI diagnostics, and robotic surgery.

Further, Malaysia is positioning itself as a regional medtech hub by investing heavily in workforce upskilling and public-private partnerships. In 2024, the Ministry of Higher Education launched a nationwide initiative aimed at training over 5,000 professionals in areas such as medical device design, and digital therapeutics by 2026.

Also, Universiti Malaya is offering microcredentials and professional diplomas in medtech innovation and entrepreneurship, as telemedicine and AI-powered diagnostics have become focal points in Malaysia's national health technology education framework.

Keeping up pace with the technological advancements, the Vietnamese Ministry of Science and Technology has partnered with international agencies to develop curriculum modernisation programmes for technical universities in Hanoi and Ho Chi Minh City. These programmes emphasise AI in medical imaging, software development for health platforms, and smart hospital technologies.

Vietnam is also developing a national medtech incubator in partnership with Korea and Japan, to offer embedded training components for students and professionals.

Another notable development is taking place at the Thailand Medtech Academy, a government-backed consortium offering certifications in medical device quality control and manufacturing, to ensure that graduates meet international standards, making them competitive not just locally, but globally.

Mahidol University and Chulalongkorn University, two of Thailand's leading institutions, have expanded their faculties of biomedical science and medical engineering with new curricula, supported by Thailand's Board of Investment (BOI) incentives for medtech companies to collaborate with universities.

Joining this list is Indonesia where the Ministry of Health and Ministry of Education have jointly launched the Medtech Indonesia 2024 initiative, aimed at creating 10,000 new medtech professionals by 2027. This includes revamping technical vocational education and training (TVET) centres with upgraded labs, simulation equipment, and standardised curricula developed in collaboration with Germany's Fraunhofer Society and Singapore's Agency for Science, Technology and Research (A*STAR).

India & Australia shaping up new tech skills

Government initiatives and collaborations between academia and industry in India are promoting the development of AI-focused medtech curricula. Investments in Centres of Excellence for skilling in AI, such as the one announced in India's Union Budget 2025-26, aim to enhance skill development and promote digital inclusivity in the healthcare sector.

Moreover, institutes and universities within India are announcing new partnerships and investments in the medical education sector. For instance, International Institute of Information Technology Hyderabad (IIIT-H) has launched an online course on 'AI for Medical Professionals', in collaboration with National Academy of Medical Sciences (NAMS), an autonomous organisation under the Ministry of Health & Family Welfare, Government of India, and IHub-Data. The course is directed towards equipping medical professionals and students with the requisite skills needed to understand, evaluate, and apply AI technologies in clinical settings.

On the other hand, the Centre for Biomedical Engineering (CBME) at the Indian Institute of Technology (IIT) Delhi has launched an exclusive Master of Science (Research) programme in 'Healthcare Technology', specifically designed for medical students and professionals, integrating the principles of medicine with cutting-edge engineering disciplines to foster deep-tech innovations in healthcare. Further, Tata Group is making a contribution of Rs 500 crore to support the establishment of a medical school at the Indian Institute of Science, enabling students to acquire global expertise, technical knowledge and practices.

Similar initiatives are being taken up by Australia where universities are moving away from purely academic instruction and embracing work-integrated learning models. Giving a few examples, University of Melbourne has created executive education courses in medtech commercialisation and IP strategy; University of Sydney has introduced new units combining biomedical engineering with data analytics and AI in healthcare; University of Queensland has expanded its partnerships with medtech firms to provide semester-long internships within startups and hospital innovation units.

Closing the Gap

According to ***Dr Marc D. Succi, Associate Chair of Innovation & Commercialisation, Harvard Medical School,*** "Medical schools of the future must thoughtfully integrate AI technologies, using them to enhance both education and patient care. Medical education must evolve to teach students not only how to use AI tools effectively but also how to critically assess and integrate AI-generated outputs into patient care."

As APAC positions itself as the next global hub for medtech innovation, it becomes imperative for the academic sector to modernise the courses and programmes, with inputs from the industry and by keeping pace with new developments. Additionally, it requires investment in faculty development, recruitment professionals with commercial and clinical experience, and creating regional medtech academies and hubs for efficient training and practice, keeping the ethical guidelines in mind. With these steps being taken in the right direction, the APAC region will not only become a medtech talent leader, but also an exporter of medtech innovation for the world. BS

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The Rise of K-Biotech

After K-pop, K-dramas, and K-beauty, South Korea is now turning its focus to biotechnology. Through a series of government initiatives and industry investments, the country is working to position itself as a major player in the global biotech sector. From manufacturing capacity to research and development, Korea is laying the groundwork to become a significant force in the biotech industry.

South Korea's biopharma market, at $22 billion, ranks as the thirteenth largest globally, reports Intralink Korea. The country has made notable strides in biosimilars, contract manufacturing etc. More recently, it has emerged as a growing hub for biopharma innovation, now ranking third worldwide for new drug discoveries. According to Citeline's Pharmaprojects database, South Korean companies have developed over 1,300 new drug candidates in the past three years, representing 10 per cent of the global total. This puts the country ahead of established R&D leaders like the UK, Switzerland, and Japan, with innovation driven by more than 320 pharmaceutical and biotech firms.

In clinical research, too, South Korea continues to gain ground. In 2023, it ranked fourth globally for clinical trial activity, with Seoul maintaining its position as the world's top clinical trial city. While global clinical trial activity declined by 5.5 per cent that year, South Korea recorded a 9 per cent increase, according to the Korean National Enterprise for Clinical Trials (KoNECT).

Now, South Korea is setting its sights even higher, with a concerted effort to become the world's leading biotech and pharmaceutical innovation hub.

"The South Korean government is actively working to establish the country as a global biotech hub by 2030," said ***Jurie Hwang, Director of Public & International Relations Division at KoreaBIO.*** "This includes a $19 billion R&D budget to fuel biotech startups and innovation, regulatory reforms to speed up approvals and IPOs, expanded infrastructure in key clusters like Songdo and Pangyo, and deeper global partnerships to drive licensing, M&A, and international growth."

Let's take a closer look at how South Korea is putting this ambitious vision into action.

Creating an innovative ecosystem

South Korea is taking various steps to strengthen its position in the global biotech landscape. In January 2025, the country launched the National Bio Committee, a presidential advisory body tasked with overseeing national strategies for biotechnology and the life sciences industry. This initiative reflects Korea's intent to remain competitive amid the global race to develop novel drugs and advanced biopharmaceutical technologies. This development builds on a series of ongoing government initiatives to promote the biotech sector. In November 2024, the Ministry of Science and ICT (MSIT) announced the launch of the National Synthetic Biology Initiative. This initiative is designed to foster innovation in biomanufacturing and strengthen Korea's capabilities in synthetic biology—one of the 12 key technologies identified under the National Strategic Technology Nurture Plan.

The country has also set bold targets for the sector's growth. In March 2024, the government announced plans to increase the country's biotechnology output nearly fivefold, from $43 billion in 2020 to $149 billion by 2035. This projection spans biopharmaceuticals, medical devices, supplements, biomass, and biotech services. The administration also plans to expand the number of biotech venture firms significantly, from around 400 annually to over 1,000 by 2035—by boosting investment in R&D.

Government backing has been central to Korea's biopharma progress. In 2023, the government introduced the Third Five-Year Comprehensive Plan for the Development and Support of the Bio-Pharmaceutical Industry, with a clear aim to place Korea among the world's top six pharmaceutical powerhouses.

By 2027, the plan envisions:

- Development of two blockbuster drugs, each generating (annuals sales of KRW 1 trillion or more) in annual revenue
- Establishment of three companies in the global top 50 pharmaceutical rankings
- Doubling of pharmaceutical exports to $16 billion

- Creation of 150,000 high-quality jobs
- Elevation to the third-highest ranking globally in clinical trials

Talking about other initiatives, ***Joonho Choi, General Manager Commercial, Cytiva Korea*** said, "South Korea is implementing several key strategies to develop its bio cluster and position itself as a global biotech powerhouse by 2030. The Bio Economy 2.0 Initiative aims to transform South Korea into a global leader in bio-medical products, new materials, bio energy, and digital bio innovation. The Songdo Bio Cluster in the Incheon Free Economic Zone (IFEZ) is home to not only major world organisations but also global biotech companies like Samsung Biologics and Celltrion. This cluster is expanding its infrastructure and ecosystem to attract more foreign investment and enhance global competitiveness."

He added, "The government is actively supporting contract development and manufacturing organisation (CDMO) companies through a recently proposed Biopharmaceutical CDMO Support Act. This law aims to reduce regulatory hurdles for biopharmaceutical exports by allowing businesses to register as export manufacturers without needing pharmaceutical manufacturing licenses for exports. Additionally, it seeks to codify good manufacturing practice (GMP) guidelines, ensuring safety, efficacy, and consistent quality. This would bolster the credibility and marketability of Korean CDMO companies internationally."

How pharma giants see Korea

Global pharmaceutical and life sciences companies are increasingly turning their attention to South Korea.

"The country is home to a large number of public and private research institutions performing cutting-edge and innovative research, in areas including biotechnology, mRNA and gene therapy," said ***Emrae Jung, Program Management Director, Merck Korea.***

In April 2025, GSK signed a £2 billion licensing deal with Korean startup ABL Bio to co-develop treatments for neurodegenerative diseases, marking one of the largest cross-border deals involving a Korean biotech. In the same month, Prazer Therapeutics secured a $29 million Series B funding round led by Johnson & Johnson Innovation and other international investors.

Multinational suppliers and technology partners are also deepening their footprint in the country. Sartorius has announced plans to open a cell culture media facility by 2027, while Taiwan's Formosa Group has committed $12.5 million to establish a biomedical research centre in Korea. Merck has also invested €300 million in a new Bioprocessing Production Center in Daejeon, its largest life sciences investment in the region to date.

"This is a major step in realising our 'in-region, for-region' manufacturing strategy and will strengthen the resilience of our supply chain in the fastest-growing region of the world," said Jung.

Cytiva, another major player in life sciences, has identified South Korea as a strategic growth market due to the rapid expansion of its biopharma sector, fueled by CDMO and biosimilar leaders such as Samsung Biologics and Celltrion, and rising players like SK Bioscience and Lotte Biologics.

Speaking about Cytiva's commitment to the region, Choi said, "Cytiva has established its first Innovation Hub in Korea, located in the Songdo Bio-cluster, which includes a manufacturing unit expected to begin local production from 2026, and a customer experience lab aimed at driving advancements in biopharmaceutical manufacturing. Cytiva focuses on supply excellence through local manufacturing, ensuring the security of supply for Korean customers. Due to higher customer demand, Cytiva has been contributing to customers' improved productivity with advanced hardware solutions equipped with automation functions. The company is also expected to release new innovative products, including consumables like resin and cell culture media, that offer better efficiency and cost-effectiveness to better meet Korean customers' various needs."

Cytiva is also investing in talent and capability development. Through collaborations with institutions like K-NIBRT at Yonsei University and its own Fast Track Center, it offers hands-on training programmes for professionals in biomanufacturing.

Korean firms stepping up the game

Some of the leading innovative firms in South Korea's biopharma and biotech space:

Orum Therapeutics, a rising star in South Korea's biotech sector, debuted on the Korea Exchange in 2025, raising ₩50 billion in what marked the nation's first biopharma IPO of the year. Specialising in targeted protein degraders

(TPD) for cancer treatment, the company is rapidly positioning itself at the forefront of oncology innovation, with a transformative approach that is capturing the attention of the global biopharma industry. Orum Therapeutics is at the forefront of the Degrader-Antibody Conjugate (DAC) approach to TPD, a transformative approach in the field. Advancing this technology presents exciting opportunities to refine selectivity and expand the potential of protein degraders beyond conventional approaches. One of the key areas of innovation is achieving precise tissue specificity, ensuring that small-molecule degraders effectively target tumours while minimising impact on healthy tissues. Additionally, Orum is overcoming the limitations of traditional antibody-drug conjugates (ADCs) by leveraging novel TPD payloads that go beyond DNA-damaging agents and tubulin inhibitors. Its pipeline is rich with promising candidates, focusing on areas of high unmet need in both oncology and non-oncology. It is particularly excited about its preclinical assets ORM-1153, leveraging its innovative TPD² approach.

Alteogen Inc. specialises in novel biologics including antibody-drug conjugates (ADCs), biobetters, and biosimilars. Its pipeline features clinical-stage long-acting therapeutic proteins and next-generation ADCs developed using its proprietary NexP-fusion and NexMab platforms. Alteogen has also developed ALT-B4, a recombinant human hyaluronidase enzyme based on its Hybrozyme technology, which enables subcutaneous delivery of drugs traditionally given via IV infusion. This innovation has attracted major pharma partnerships. In March 2025, AstraZeneca signed a license agreement with Alteogen to develop subcutaneous formulations of multiple oncology drugs. In November 2024, Daiichi Sankyo entered an exclusive global licensing deal to use ALT-B4 to develop a subcutaneous version of ENHERTU, a HER2-directed ADC co-developed with AstraZeneca for $1.7 billion. Both companies will collaborate during the ongoing phase 1/2 trial, with Janssen taking over full development and commercialisation upon option exercise.

J INTS BIO is pioneering the development of personalised cancer therapies and orphan drugs by integrating artificial intelligence with multi-omics technologies. This approach—combining genomics, transcriptomics, metabolomics, and proteomics—aims to improve drug efficacy prediction and reduce toxicity in cancer treatment. J INTS BIO's pipeline includes targeted therapies for NSCLC such as 4th-gen EGFR-TKIs (JIN-A02, JIN-A04) and inhibitors for HER2/EGFR mutations. It also features candidates like JIN-001 and JIN-002 for glioblastoma, solid tumors, and Parkinson's disease. In 2024, the company launched a major AI-supercomputing alliance for precision oncology, partnering with Yuhan Corporation, KAIST, and policymakers to transform lung cancer therapy through next-gen computational tools.

Top pharma companies in South Korea

- SK Bioscience
- Yuhan Corp
- Hanmi Pharmaceuticals
- LigaChem Biosciences Inc
- Sam Chun Dang Pharm Co Ltd
- Medytox Inc
- HK inno.N Corp
- HanAll Biopharma Co Ltd
- GC Biopharma Corp

Source: Global Data

Oncocross is harnessing artificial intelligence to revolutionise drug discovery and development. At the heart of Oncocross's innovation is its proprietary AI platform, which analyses gene expression patterns to accurately identify optimal indications for new drug candidates, particularly in the areas of cancer, rare diseases, and intractable conditions. The platform's high predictive accuracy enables faster progression into clinical trials, reducing the risk of late-stage failures and accelerating the path to market. In 2024, the company made headlines with its successful IPO on the Korea Exchange, raising ₩85.56 billion ($59.5 million) by offering approximately 11.85 million shares at ₩7,300 each.

With a blend of strong government backing, global partnerships, and a wave of homegrown innovation, South Korea is on track to establish itself as a global biotechnology powerhouse. BS

Ayesha Siddiqui

"South Korea is rapidly emerging as a global biotech powerhouse"

« **S J Lee,**
CEO,
Orum Therapeutics,
South Korea

Orum Therapeutics debuted on the Korea Exchange (KOSDAQ) on February 14, 2025, raising ₩50 billion in South Korea's first biopharma IPO of the year. With a focus on targeted protein degraders for cancer treatment, CEO S J Lee outlines how Orum is advancing and positioning itself at the forefront of oncology innovation. ***Edited excerpts;***

How do you see this milestone positioning the company in the biotech landscape, and what are your immediate priorities post-IPO?

We believe Orum's recent milestone reinforces our leadership in targeted protein degradation through our Dual-Precision Targeted Protein Degradation (TPD²) approach, which combines antibody precision with targeted protein degraders to address critical unmet needs in oncology and beyond. Post-IPO, we are advancing our pipeline, including ORM-1153 for hematologic cancers, while also actively developing new targeted protein degrader (TPD) payloads to expand the potential of our platform.

Orum is pioneering the development of TPD, which is an exciting area in cancer treatment. What unique challenges do you face in advancing this technology?

Orum Therapeutics is at the forefront of the DAC approach to TPD, a transformative approach in the field. Advancing this technology presents exciting opportunities to refine selectivity and expand the potential of protein degraders beyond conventional approaches. One of the key areas of innovation is achieving precise tissue specificity, ensuring that small-molecule degraders effectively target tumors while minimising impact on healthy tissues. Additionally, Orum is overcoming the limitations of traditional antibody-drug conjugates (ADCs) by leveraging novel TPD payloads that go beyond DNA-damaging agents and tubulin inhibitors.

Can you share more details about Orum's pipeline? Are there any specific drug candidates or therapeutic areas that you're particularly excited about in the near future?

Our pipeline is rich with promising candidates, focusing on areas of high unmet need in both oncology and non-oncology. We're particularly excited about our preclinical assets ORM-1153, leveraging our innovative TPD² approach. ORM-1153 is a GSPT1-based TPD² candidate in preclinical development. While the specific antibody target remains undisclosed, we anticipate this candidate will provide a novel approach to treating acute myeloid leukemia (AML), an area where new therapeutic options are critically needed. We are planning to release preclinical data for ORM-1153 by the end of this year, which will provide critical insights into its potential as a novel treatment. Following this, we intend to submit an Investigational New Drug (IND) application to the U.S. FDA in the latter part of next year to initiate clinical trials. In addition to oncology, we are exploring opportunities in other therapeutic areas, where protein degradation can unlock transformative treatments for patients across multiple disease areas.

Could you share some of the key strategies and steps that South Korea is taking to develop its bio clusters and strengthen its position in the global biotech landscape? As a company having presence in both South Korea and the U.S., how do you foresee the growth in the coming years?

South Korea is rapidly emerging as a global biotech powerhouse, driven by a supportive public market, strong government support, investment in innovation, and expanding biotech hubs, like the one in Daejeon. We aim to leverage the best of both worlds – favorable ecosystems in the U.S. and South Korea – to foster our growth. BS

Ayesha Siddiqui

"The biosimilar developers are eagerly awaiting revised CDSCO regulations that might lead to simplification of the development pathway for biosimilars"

In an interaction with BioSpectrum, ***Dr Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC), India*** *reflects on the evolution of India's biosimilars sector and shares his insights on the country's growing role in the global biosimilars landscape over the next decade.*

How has India's biosimilars landscape evolved over the past 25 years, and what have been the most significant milestones? Can you share insights into the number of biosimilars approved for domestic use vs. exports?

India approved its first biosimilar, Biovac-B for hepatitis B in 2000 which was launched by Wockhardt Limited. Since then, several biosimilars have been developed and marketed in India by various biopharmaceutical companies. Department of Biotechnology (DBT), India announced the release of regulatory guidelines for 'similar biologics' on 19 June 2012 and these guidelines were implemented on September 15, 2012. The guidelines outline a simple abridged procedure for evaluation of 'similar biologics' which have been approved and marketed in India, Europe or USA for more than four years. These guidelines were then revised and updated, with new guidelines, which came into effect in August 2016.

Apart from the streamlined regulations, DBT and its public sector enterprise Biotechnology Industry Research Assistance Council (BIRAC) have made sustained efforts through funding, policy advocacy, new initiatives, capacity building, and promoting innovation and infrastructure creation in research institutions, small and medium size companies, and large firms. The schemes of BIRAC like the Biotechnology Industry Partnership Program (BIPP), Small Business Innovation Research Initiative (SBIRI) and Promoting Academic Research Conversion to Enterprise (PACE) launched between 2008 and 2012 are to assist small and medium-sized biotech firms in the creation of biosimilars.

In 2017, the Government of India, DBT with co-funding from World Bank, launched the National Biopharma Mission (NBM), an Industry-Academia Collaborative Mission for accelerating discovery research to early development for Biopharmaceuticals, implemented by BIRAC. One of the focused mandates of the Mission is to accelerate the biosimilar development to bring them closer to market.

Under these schemes, BIRAC has supported several biosimilars including Trastuzumab, Insulin Glargine, Insulin Lispro, Bevacizumab, Ramicirumab, Liraglutide, Aflibercept, Pertuzumab, Romiplastim, Ustekinumab, Insulin Aspart, Pembrolizumab, Golimumab, and Pegloticase. Many of these biosimilars are also developed by startups. Of these, Biosimilar Liraglutide for type 2 diabetes was developed by Levim Biotech LLP, and launched in the market by Glenmark (Levim's marketing partner) in January 2024 under the brand name "Lirafit", and is the first biosimilar of Liraglutide in market and introduced at ~65 per cent discount over the innovator's price. Many other biosimilars supported by NBM and BIPP and other schemes of BIRAC will be ready for market launch in the next 1-2 years.

The NBM has also contributed in establishing regulatory-compliant, accessible facilities to cater to services for bio-analytical and functional testing, immunogenicity testing and cGMP manufacturing of clinical trial lots, to support domestic industry and startups to accelerate the development of biosimilars to improve accessibility and affordability. In addition, NBM also supported indigenous production of raw materials such as culture media, resins and Single-Use Bioreactors which will further reduce the manufacturing costs of biosimilars and other biologics.

The biosimilar landscape in India is characterised by a multitude of bio-pharmaceutical entities actively involved in the production and distribution of biosimilar products. Prominent players include Intas Biologicals, Biocon, Dr. Reddy's Laboratories, Zydus Lifesciences, Reliance Life Sciences, Lupin Pharma, Cipla, Wockhardt Ltd. Apart from these, Gennova Biopharmaceuticals, Enzene Biosciences, Hetero Biopharma, Torrent Pharmaceuticals also

The biosimilar domestic market is projected to grow to ~$40 billion by 2030. Till date there are > 100 biosimilars for ~ 40 Reference Products (RP) approved from India, for oncology, hematological, immunological, toxicology, musculoskeletal and metabolic, hormonal, neurological disorders, ophthalmic diseases, infectious diseases, cardiovascular and respiratory diseases, and women health. Out of these ~ 20 (RP) biosimilars are exported to developed and emerging markets, mostly to USA, Europe, Brazil, Belgium, Netherlands, and Africa mostly by the Indian companies Biocon, Dr. Reddy's, Intas, Hetero and Lupin.

have several approved biosimilar products for Indian and some for global markets. The startups who have ventured into biosimilars space include Levim Lifetech, Genext Genomics Pvt. Ltd, Lamark Biotech, Bycus Therapeutics, etc. The biosimilar domestic market is projected to grow to ~$40 billion by 2030. Till date there are > 100 biosimilars for ~ 40 Reference Products (RP) approved from India, for oncology, hematological, immunological, toxicology, musculoskeletal and metabolic, hormonal, neurological disorders, ophthalmic diseases, infectious diseases, cardiovascular and respiratory diseases, and women health. Out of these ~ 20 (RP) biosimilars are exported to developed and emerging markets, mostly to USA, Europe, Brazil, Belgium, Netherlands, and Africa mostly by the Indian companies Biocon, Dr. Reddy's, Intas, Hetero and Lupin.

Which therapeutic areas have seen the most approvals?

Oncology has seen the most approvals, followed by haematological and immunological disorders.

How do you see India's role in the global biosimilars industry in the next 10–15 years?

Indian companies currently hold less than 5 per cent of the global biosimilars market, but with increasing R&D investments and an expanded product pipeline, biosimilar exports are expected to grow from $0.8 billion now, to $4.2 billion (£3.3 billion) by 2030, and $30-35 billion by 2047. Over the next seven years, about 100 drug patents valued at a total of $180 billion are expected to expire, creating a good opportunity for Indian companies.

As per the landscaping exercise done by BIRAC, large companies in India are trying to be vertically integrated in-house – i.e. Clone development to Manufacturing and aiming at the global markets from conceptualisation stage. The companies are also licensing tie-ups at an early stage or taking the co-development route. On August 31, 2024, Science &Technology Minister Dr. Jitendra Singh released the BioE3 Policy. The policy, which is jointly implemented by DBT and BIRAC, aims to foster high-performance biomanufacturing in India. It seeks to develop and commercialise bio-based products through the establishment of BioEnablers like Bio-AI Hubs, Biofoundries, and Biomanufacturing Hubs, which will give a major boost to the biosimilars sector.

India's biotech ecosystem includes more than 800 core biotech companies, over 100 bio-incubators, and ~ 10,000 biotech startups. This investment, along with the focus on innovation, will encourage the growth of Indian biopharma capabilities. The 2024 Indian Bioeconomy Report prepared by the Make in India Facilitation Cell of BIRAC with research support from the Association of Biotechnology Led Enterprises (ABLE), highlights that India's BioEconomy achieved a landmark value of $151 billion in 2023, reflecting impressive double-digit growth. The report also gives hope that India is in the right direction to cross the $300 billion mark by 2030. On the regulations side, on April 10, 2025, the FDA announced the plans to phase out animal testing requirements for monoclonal antibodies and other drugs. The biosimilar developers are eagerly awaiting revised CDSCO regulations which might lead to simplification of the development pathway for biosimilars with improved accessibility and affordability. The BioSecure Act is also expected to benefit India. All of this will support the growth of smaller Indian companies into key players in the global biosimilar industry and help establish India as a leading contributor to the international biosimilar market over the next 10 to 15 years. BS

Ayesha Siddiqui

Biomarkers in Kidney Health: Enhancing Early Detection and Treatments

Emerging biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL) and kidney injury molecule-1 (KIM-1) have shown great potential in the early diagnosis of kidney injury. These biomarkers are extremely sensitive indicators of tubular injury, and they can detect renal damage at stages when conventional markers are still within normal ranges. While these novel biomarkers have high sensitivity and specificity, incorporating them into ordinary clinical practice raises several problems. Despite its potential, more study is needed to validate these biomarkers in large-scale, long-term clinical studies.

« **Dr Ajay A Phadke,**
Pathologist,
Agilus Diagnostics,
India

Doctors rely on assessing kidney function to diagnose and manage kidney disease. For years, medical professionals have used traditional indicators such as serum creatinine, blood urea nitrogen (BUN), and the calculated estimated glomerular filtration rate (eGFR) to check and track kidney health. These tests are widely accessible and useful for monitoring the gradual loss of kidney function. However, they have a significant limitation: they often fail to detect problems until substantial kidney damage has already occurred. This is particularly concerning in glomerular diseases, where early damage may go unnoticed until the kidneys are severely impaired.

For patients at high risk of kidney problems—such as those with diabetes, high blood pressure, or a family history of kidney disease—the urinary microalbumin-to-creatinine ratio has become an important tool. This measurement can detect early kidney damage, even when blood creatinine levels appear normal by identifying small increases in albumin excretion in the urine. Early detection allows doctors to begin treatment sooner, potentially slowing the progression of chronic kidney disease (CKD) and reducing the risk of cardiovascular complications.

Cystatin C, a low molecular weight protein produced by all nucleated cells, has also gained attention as a biomarker for kidney function that may be more accurate than creatinine. Unlike creatinine, cystatin C levels are less influenced by factors such as muscle mass, age, or diet. This makes it especially valuable in populations where serum creatinine may be unreliable, such as the elderly or individuals with low muscle mass. Despite its advantages, cystatin C has yet to become a routine part of clinical practice due to higher testing costs, variability in laboratory measurements, and the lack of standardised reference ranges.

In recent years, research has increasingly focused on discovering and validating novel biomarkers to overcome the limitations of traditional tests. Emerging biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL) and kidney injury molecule-1 (KIM-1) have shown significant promise for the early detection of kidney injury. These biomarkers are particularly sensitive indicators of tubular injury and are capable of detecting renal damage at stages when conventional markers remain within normal limits.

NGAL is produced by renal tubular cells when they are damaged by factors such as ischemia (lack of blood flow) or exposure to harmful substances. Its levels in urine and blood can rise dramatically within hours of kidney injury, allowing for earlier detection than serum creatinine. Similarly, KIM-1, a protein minimally expressed in healthy kidneys, becomes highly elevated in the urine following

Future research may also focus on identifying additional biomarkers that reflect other key aspects of kidney disease, such as inflammation, fibrosis, or cellular damage. Combining biomarkers that indicate different pathogenic mechanisms could provide a more comprehensive assessment of renal health and help identify patients at risk of rapid disease progression. For example, integrating markers of inflammation such as interleukin-6 (IL-6) or tumour necrosis factor-alpha (TNF-α) with NGAL and KIM-1 could offer deeper insights into the role of inflammation in kidney injury.

injury to proximal tubular cells. Monitoring KIM-1 levels provides valuable insights into acute kidney injury (AKI) and the severity of renal damage.

While these novel biomarkers demonstrate excellent sensitivity and specificity, integrating them into routine clinical practice presents several challenges. Standardising assay methods and establishing universally accepted reference ranges are essential to ensure consistency across laboratories. Additionally, kidney diseases are complex and can arise from various causes, meaning no single biomarker can provide a complete picture of renal health. A more effective approach may be to combine traditional tests with newer biomarkers such as NGAL, KIM-1, and cystatin C. This combination could enable earlier detection and more accurate risk stratification.

There is also great potential for these biomarkers to play a key role in personalised medicine. As our understanding of the molecular pathways involved in kidney diseases improves, targeted therapies could be developed for specific types of renal injury. For example, elevated NGAL levels might indicate the need for immediate interventions aimed at protecting the renal tubules, while increased albuminuria might prompt strategies to preserve glomerular function. By incorporating a panel of biomarkers into individualised treatment plans, healthcare providers could slow disease progression and reduce the risk of complications such as cardiovascular disease.

In addition to aiding diagnosis, novel biomarkers can serve as valuable tools for monitoring treatment effectiveness. Traditional markers like serum creatinine typically do not change until significant kidney function has been lost, potentially delaying critical treatment decisions. In contrast, biomarkers such as NGAL and KIM-1 can reflect improvements or worsening of kidney injury much earlier. This timely feedback allows clinicians to adjust therapies proactively, optimising outcomes and potentially preventing permanent kidney damage.

Despite their potential, further research is needed to validate these biomarkers in large-scale, long-term clinical trials. Studies must assess their utility across diverse patient populations and determine whether they can reliably predict adverse outcomes such as end-stage renal disease (ESRD) or cardiovascular events. Additionally, strategies for integrating these markers into existing clinical workflows, especially complex decision-making processes, must be explored.

Future research may also focus on identifying additional biomarkers that reflect other key aspects of kidney disease, such as inflammation, fibrosis, or cellular damage. Combining biomarkers that indicate different pathogenic mechanisms could provide a more comprehensive assessment of renal health and help identify patients at risk of rapid disease progression. For example, integrating markers of inflammation such as interleukin-6 (IL-6) or tumour necrosis factor-alpha (TNF-α) with NGAL and KIM-1 could offer deeper insights into the role of inflammation in kidney injury.

Moreover, advances in fields such as genomics, proteomics, and metabolomics offer exciting new opportunities for biomarker discovery. These cutting-edge approaches may reveal novel molecular signatures associated with kidney damage and help clarify the underlying causes of disease. As these technologies become more accessible and cost-effective, they could help bridge the gap between laboratory research and clinical practice, enabling highly personalised and effective treatments for kidney disease.

While traditional markers like serum creatinine, BUN, and eGFR have long been the mainstays of kidney health assessment, they are limited in their ability to detect early disease. Emerging biomarkers, such as microalbumin-to-creatinine ratio, NGAL, KIM-1, and cystatin C, represent a promising frontier in nephrology. By incorporating these tools into clinical practice, healthcare providers can improve early detection, refine risk stratification, and enhance treatment strategies—ultimately offering better outcomes for patients with kidney disease. BS

Medical Device Classification and FDA Approval: What Startups Need to Know

For many innovators, the United States represents a key market, being the world's largest for medical devices. However, entering the US market requires navigating the US Food and Drug Administration's (FDA) stringent regulatory landscape, where accurate device classification is crucial. To assist innovators, the Regulatory Information and Facilitation Center (RIFC) at Venture Center, Pune has released a whitepaper early this year that offers practical insights, featuring examples of devices developed by Venture Center-supported startups to illustrate how medical devices are categorised based on risk.

« **Aishwarya Varpe,** Associate-Regulatory Services, Venture Center, India

Under the FDA, the Center for Devices and Radiological Health (CDRH) oversees the regulation of medical devices. It ensures that patients and healthcare providers have timely and sustained access to safe, effective, and high-quality medical devices, including radiation-emitting products.

To assist innovators, the Regulatory Information and Facilitation Center (RIFC) at Venture Center has released a whitepaper titled "Classification of Medical Devices in the US", providing a simplified step-by-step guide in the form of a flowchart on determining device classification (Class I, II, III), regulatory pathways (510(k), De Novo, PMA), and key compliance requirements with examples. The whitepaper also offers practical insights, featuring examples of devices developed by Venture Center-supported startups to illustrate how medical devices are categorised based on risk.

Determining whether a product qualifies as a medical device and identifying its risk classification become important when navigating the FDA approval process. A product is classified as a medical device only if it meets the FDA's definition, which can be ambiguous and often requires further evaluation. This is because medical devices may closely resemble drugs, combination products, or wellness products, each following distinct regulatory pathways. Accurately classifying a device is crucial as it determines the level of regulatory scrutiny and the appropriate market approval process.

Fallout of Misclassification

Misclassifying a medical device can lead to additional efforts, increased costs of rework and delays in the approval process. A clear example provided by the CDRH is the distinction between infant diapers and adult diapers. An adult diaper is designed for individuals with incontinence, a medical condition that affects bladder or bowel control. Since it is intended to manage a health issue, the FDA classifies it as a medical device. In contrast, an infant diaper is a standard part of baby care, as infants naturally lack bladder or bowel control. Because it does not treat a medical condition, it is not classified as a medical device. In fact, according to FDA regulation 21 CFR 876.5920, adult diapers fall under the category of "protective garments for incontinence"—designed to protect clothing from leaks. The regulation even makes it clear that this does not include infant diapers. The whitepaper further explores similar examples, demonstrating how a product's intended use and the manufacturer's claims can impact its classification as a medical device.

The US FDA Classification System employs a risk-based approach to classify medical devices into three categories: Class I, Class II, and Class III, with Class I (Low risk) having the least regulatory requirements and Class III (High risk) undergoing the most rigorous review through the Premarket Approval (PMA) pathway. Devices may require a 510(k) clearance, a De Novo request, or PMA submission, depending on their novelty and risk. The classification is determined by the intended use of the device, its indications for use, and the potential risks it poses to patients and users. FDA applies regulatory controls (general controls and special controls), which are essential for ensuring the safety, effectiveness, and quality of medical devices.

Once the product is confirmed to be a medical device, the next step is to identify similar devices.

Medical devices are categorised into three classes based on risk

FDA Class	Risk Level	Examples*
Class I	Low	- Noninvasive traction component - Dental hand instrument - Specimen transport and storage container - Limb orthosis
Class II	Moderate	- Resorbable calcium salt bone void filler device - Creatinine test system - Interactive rehabilitation exercise device - Low-energy DC-defibrillator (including paddles)
Class III	High	- High-energy DC-defibrillator (including paddles) - Intraocular lens - Intravascular occluding catheter - Resurfacing cemented prosthesis

*Examples given are the devices developed by the Venture Center supported startups.

FDA's medical device reclassification

- Section 513(e) of the FD&C Act allows the FDA to reclassify a device type that is already classified based on new information by the Commissioner. The FDA commissioner may initiate the reclassification or respond to the petition of an interested person to reclassify the device.
- Section 513(f)(1) of the FD&C Act automatically classifies medical devices into class III that were not available for commercial distribution before May 28, 1976.
- Section 513(f)(2) of the FD&C Act allows an alternative pathway to classify medical devices automatically placed in class III after a "not substantially equivalent" (NSE) to De Novo classification without first being required to submit a 510(k).
- Section 513(f)(3) allows the FDA, manufacturer, or importer to initiate a reclassification. If the FDA receives a petition, it may request that the device classification panel to review the information and provide a recommendation. The FDA will then issue an order that either approves or denies the petition.

The FDA product classification database, an online tool, allows manufacturers to search for devices by name, intended use, or Product Code. This database provides information on the class of a device, applicable regulations, and any predicate devices already cleared by the FDA to confirm the risk-based classification. Venture Center's whitepaper serves as a guide for innovators, offering insights on how to navigate these pathways effectively.

Reclassification of Medical Device

Classifying a medical device and obtaining approvals is not the final step. A device may be reclassified in case of updates that affect its safety and performance. The change in classification depends upon the updated risk profiles due to technological, non-technical modifications and the recent clinical data concerning the subject device. Reclassification ensures that the modified device remains subject to appropriate regulatory controls and continues to meet safety and effectiveness standards. If the FDA receives a petition for reclassification, it may refer the request to a device classification panel for review. After evaluating all relevant information, the FDA will issue an order either approving or denying the petition. Before 2012, if a medical device received a "not substantially equivalent" (NSE) decision, it was automatically placed in Class III. However, after section 513(f)(2) of the FD&C Act was amended by Section 607, an alternative reclassification process allows such devices to be classified under De Novo, and this process does not require a 510(k) submission first. Between 2020 and 2024, the FDA has reclassified seven medical devices through this alternate process.

With evolving technologies like Software as a Medical Device (SaMD) and AI-driven healthcare tools, regulatory landscapes are continuously adapting. New regulatory frameworks and flexible approaches to reclassification will continue to play an important role in fostering innovation. Manufacturers must stay informed about FDA guidance and classification databases to navigate compliance efficiently and align with the latest regulatory expectations.

As regulatory pathways evolve to accommodate emerging technologies, they are expected to become more streamlined and tailored, enabling faster market entry while maintaining patient safety, device quality and efficiency. Understanding these evolving trends will be critical for manufacturers as they navigate the future regulatory landscape. BS

(With inputs from Akash R Dhade, Chetna Dharmawat-Dabi and Dr Pinky Raychaudhuri at Venture Center)

Rise of Chinese companies in global medtech sector

The global medical technology (medtech) sector is undergoing a profound transformation, driven significantly by the rapid and strategic ascent of Chinese companies. The long-held narrative of China solely as a manufacturer of low-cost goods is dangerously outdated. Today, Chinese medtech firms are not merely competing on the global stage; they are increasingly setting the pace in innovation, enhancing product quality, and expanding their international reach. This shift necessitates a strategic reassessment by established players and presents both significant opportunities and complex challenges for the entire healthcare ecosystem. This article dissects the key drivers behind China's medtech surge, analyses their global expansion strategies, evaluates their competitive positioning, and provides an outlook on the future landscape.

« **Ayush Singh,**
Practice Member, Healthcare & Lifesciences, Praxis Global Alliance, India

China's impact on the global medtech trade is undeniable. From accounting for less than 3 per cent of global trade in medtech products in 2000, China's share exploded to 12.4 per cent by 2021, representing nearly $40 billion in exports. This surge coincides with a decline in the market share of traditional leaders like the United States. Domestically, China's medical device market has become the world's second-largest, supported by over 32,000 medical device manufacturers generating approximately $160 billion by the end of 2023. This phenomenal growth isn't accidental; it's the result of a deliberate national strategy coupled with dynamic market forces.

Key drivers fueling China's medtech rise

Several interconnected factors are propelling Chinese medtech companies onto the global stage:

1. Strategic government orchestration: The Chinese government plays a pivotal role through ambitious industrial policies like "Made in China 2025", which explicitly prioritises the medtech sector. This policy aims for high levels of domestic production (70 per cent for mid-to-high-end devices by 2025) and seeks to cultivate globally competitive champions. Support mechanisms are extensive, including substantial financial incentives (direct subsidies, tax breaks – like the 100 per cent super tax deduction for R&D costs, below-market loans), preferential procurement policies ("Buy China" initiatives potentially offering price advantages for domestic goods), streamlined regulatory pathways for innovative devices, and active export promotion. Government support for listed medtech firms, as a percentage of revenue, significantly outpaces that in Organisation for Economic Co-operation and Development (OECD) countries.

2. Aggressive R&D investment and innovation: Spurred by government incentives and fierce domestic competition, Chinese medtech firms are investing heavily in Research and Development. Leading companies now allocate 11-14 per cent of their revenue to R&D, often surpassing the 6-8 per cent average of their western counterparts. This investment signifies a strategic shift beyond cost competition towards technological advancement and improved product quality, further emphasised by initiatives like the 14th Medical Equipment 5-Year Plan.

3. Vast domestic market dynamics: China's enormous domestic market provides a critical launchpad, allowing companies to achieve significant production volumes and economies of scale. Growing domestic demand, fueled by an ageing population, rising incomes, and expanding healthcare infrastructure, creates a substantial base. However, this market is also characterised by intense competition and significant price pressure, exacerbated by Volume-Based Procurement (VBP) policies. VBP has led to drastic price reductions (e.g., over 90 per cent for coronary stents), eroding domestic margins and acting as a powerful catalyst for companies to seek more profitable growth overseas.

4. Compelling cost-performance advantage: Chinese manufacturers retain a significant edge by offering products of improving quality at substantially lower costs compared to Western equivalents. This is achieved through a combination of affordable labour, proximity to local

suppliers, scale efficiencies, investment in advanced technologies, and access to global talent. This strong value proposition is highly effective, particularly in price-sensitive emerging markets and commoditised segments within developed economies.

Global expansion playbook

• **Mergers & Acquisitions (M&A):** This has become a cornerstone strategy, especially for larger firms seeking rapid global scale-up. Acquisitions provide immediate market access, advanced technology and IP, established brands, regulatory expertise, and portfolio diversification. High-profile examples include Mindray's acquisition of HyTest Invest Oy, MicroPort's acquisitions of Wright Medical's OrthoRecon and LivaNova's CRM business, Venus MedTech's acquisitions of Keystone Heart and Cardiovalve, AK Medical's purchase of JRI Orthopaedics, and Weigao's acquisition of Argon Medical Devices.

• **Other key strategies:** Beyond M&A, firms utilise traditional exports and Original Equipment Manufacturing (OEM) agreements; strategic partnerships and alliances for co-development, distribution, or accessing local expertise; direct investment in overseas subsidiaries, R&D centres, and manufacturing facilities; and phased regulatory strategies, often targeting approvals in less stringent markets first before tackling the EU (CE Mark) and US (FDA).

Technological capabilities and competitive positioning

• **Strengths:** Chinese firms excel as "fast followers," adept at absorbing, adapting, and efficiently scaling existing technologies. Product quality and performance have demonstrably improved, evidenced by growing success in obtaining stringent regulatory approvals like CE Mark and FDA clearance, including breakthrough device designations. A particular strength lies in integrating digital technologies like AI and IoT connectivity.

• **Weaknesses:** A gap often remains compared to Western R&D powerhouses concerning foundational, breakthrough innovation, particularly in areas like cutting-edge imaging, advanced surgical robotics, and novel implantable devices. Reliance on imported critical components persists in some high-end segments. Furthermore, global brand recognition and trust generally lag behind established Western incumbents, and despite improvements in domestic IP enforcement, international perceptions can still pose challenges. Many firms are also still developing comprehensive global commercial infrastructure.

Industry impact and evolving dynamics

Concerns about state subsidies, market access (fueled by policies like "Buy China"), and fair competition have led to trade barriers, such as US tariffs and the EU's investigation under the International Procurement Instrument (IPI) targeting China's MedTech procurement practices. This adds a layer of complexity and risk to international expansion efforts.

Navigating challenges & seizing opportunities

• **Challenges:** Navigating complex and diverse international regulatory requirements (FDA, CE Mark/MDR/IVDR, etc.) remains costly and resource-intensive. Overcoming lingering quality perceptions and building global brand trust requires sustained effort. Managing IP risks and geopolitical tensions/trade barriers is increasingly critical. The domestic VBP policy, while driving efficiency, squeezes margins, potentially limiting funds for global R&D and expansion. Building effective global market access and commercialisation infrastructure is also a major undertaking.

• **Opportunities:** Emerging markets in Asia, Latin America, and Africa represent vast growth potential, aligning well with Chinese firms' cost advantages. Leveraging strengths in digital health (AI, remote monitoring) offers differentiation pathways. Aligning cost-effective solutions with the global shift towards value-based healthcare is another significant opportunity. Strategic partnerships (with MNCs, local distributors, and research institutions) remain crucial for technology access, market entry, and navigating local complexities. Continuous portfolio upgrading into higher-value niches is also key.

Strategic outlook and conclusion

The emergence of China as a global medtech powerhouse is irreversible and signifies a fundamental industry shift. Chinese companies are no longer just low-cost manufacturers but increasingly sophisticated and globally ambitious competitors moving rapidly up the value chain.

The future success of Chinese medtech companies in the world stage will depend on their ability to transition from "fast followers" to true pioneers of foundational innovation, build enduring global brand trust and credibility, and skillfully navigate an increasingly complex and politicised international regulatory and trade environment. Proactive engagement, strategic agility, and a deep understanding of this evolving ecosystem are essential for all stakeholders seeking to thrive in the future of global healthcare technology. BS

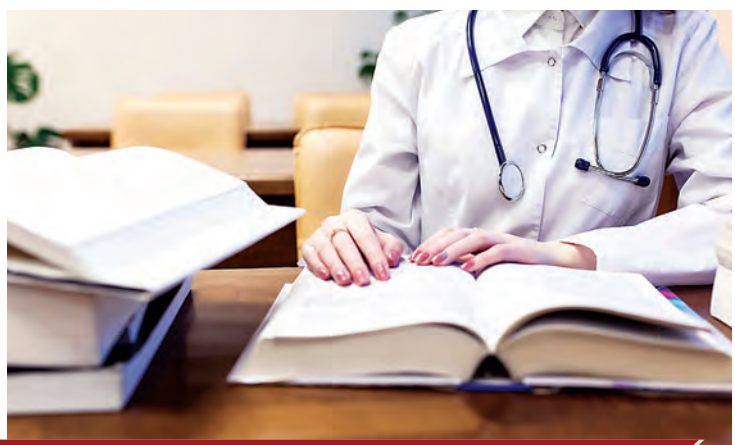
University of Hyderabad and Flinders University cement partnership in healthcare

The University of Hyderabad (UoH), India and Australia's Flinders University have entered into a landmark strategic partnership, formalised through the signing of a Memorandum of Understanding (MoU). The partnership deepens collaboration in healthcare management, digital health, and business education while enhancing faculty and student exchange, joint research, and professional development opportunities. The

MoU was signed by Professor B.J. Rao, Vice-Chancellor of UoH and Flinders University Vice-Chancellor Professor Colin Stirling. Key focus areas of the MoU include joint postgraduate twinning programmes in business and healthcare management; co-designed certificate programmes and short-term executive training; collaborative research in health workforce, digital health, aged care, operations, and leadership; faculty exchange, co-teaching modules, and student mobility; engagement with industry sectors in Telangana and South Australia; jointly hosted seminars, workshops, and innovation forums.

PolyU plans to establish Hong Kong's third medical school

The Hong Kong Polytechnic University (PolyU) has submitted a proposal to the Hong Kong Special Administrative Region (HKSAR) Government for the establishment of Hong Kong's third medical school, aiming to train more outstanding doctors to meet the healthcare needs of Hong Kong and the Greater Bay Area (GBA). The proposal was prepared based on the 10 key parameters set out by the HKSAR Government's Task Group on New Medical School, covering innovative strategic positioning, staffing, campus and teaching facilities, clinical exposure and learning resources, curriculum structure and assessment methodologies, student admission arrangements, funding arrangements, implementation plan, teaching and learning quality as well as research excellence. PolyU plans to offer a four-year bachelor's degree programme in medicine, targeting undergraduate degree holders. The first intake will admit 50 local and non-local students and will gradually increase the admission quota based on demand.



PSB Academy unveils third city campus in Singapore to train more paramedicine professionals

PSB Academy (PSBA), Singapore's leading private education institution (PEI), has officially launched its third campus at The Cathay, alongside the signing of a tripartite collaboration to enhance paramedicine education in Singapore. This new collaboration with Coventry University and COSEM, a cooperative of Singapore Civil Defence Force (SCDF), aims to introduce specialised paramedicine courses to address the nation's rising emergency call volumes and workforce shortages. This third campus complements PSB Academy's City Campus and STEM Wing at Marina Square, expanding its learning infrastructure with advanced classrooms equipped with cutting-edge audiovisual systems designed to enhance hybrid learning that simulate in-person interactions for distance learners.

Dr Seema Pai takes charge as President of Indian Society for Clinical Research

The Indian Society for Clinical Research (ISCR), an association of clinical research professionals, has announced the appointment of Dr Seema Pai as its President for the term 2025-2028. Dr Seema takes over from Dr Sanish Davis, who served as President from 2021 to 2025. Alongside Dr Seema, Anirban Roychowdhury has been appointed as General Secretary, and Amita Bhave as Treasurer for the new term. Dr Seema Pai has over 20 years of experience in clinical research and currently leads the Global Site & Study Operations for the India Cluster (India, South Africa & Sub-Saharan Africa) at Pfizer. Before Pfizer, Dr Seema was heading the development division of Daiichi Sankyo India Pharma where she was responsible for India Strategy, Clinical Development, Clinical Operations, collaboration with key acquisitions in India for synergies.

Hebe Biotechnology appoints Dr Hannes Hentze as Chief Development Officer

Hebe Biotechnology, a Singapore-based innovator in metabolic health therapeutics, has announced the appointment of Hannes Hentze, PhD, MBA as Chief Development Officer (CDO), effective April 1, 2025. Dr Hentze will lead the global development strategy for the company's next-generation GLP-1 receptor agonist (GLP-1 RA), a cutting-edge weight loss therapy designed to enhance efficacy and tolerability, addressing the global obesity challenge. Dr Hentze brings over two decades of experience in pharmaceutical development, specialising in oncology, metabolic disorders, and biologics. His background spans academic research (IMCB, NTU), biotech ventures (S*BIO, ES Cell International, ASLAN), and large pharmaceutical players (Schering-Plough, MSD). Most recently, he served as Associate Director of Translational Sciences at EDDC (A*STAR). At Hebe Bio, Dr Hentze will spearhead preclinical and translational development, guiding clinical trial readiness, regulatory strategy, and strategic partnerships to accelerate the GLP-1 RA programme's global commercialisation.

Prof. Patrick Tan steps in as Duke-NUS Dean to lead next era of medical innovation

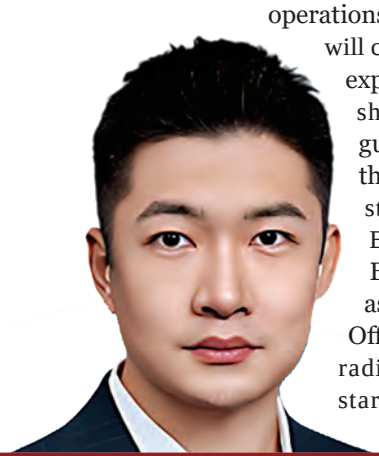
Duke-NUS Medical School in Singapore has appointed Professor Patrick Tan as its next and fourth Dean, effective January 1, 2026, marking a new chapter for the School as it builds on its legacy of medical education, research and innovation. Prof. Tan will serve as Dean-designate from July 1, 2025, succeeding Professor Thomas Coffman, the School's longest-serving Dean since 2015. An internationally recognised cancer geneticist and clinician-scientist, Prof. Tan is currently Senior Vice-Dean for Research at Duke-NUS, where he leads transformative research initiatives in genomics, precision medicine and biomedical innovation. He was one of the School's pioneer faculty members and has been involved in advancing its research strategy. Prof. Tan has also been an active contributor in Singapore's research landscape, taking on roles including Executive Director of Precision Health Research Singapore (PRECISE), Senior Scientific Advisor at SingHealth, and former Executive Director of the Genome Institute of Singapore. His leadership in integrating cutting-edge science with clinical applications has placed him at the forefront of Singapore's biomedical ecosystem.

Duality Bio appoints Dr Hua Mu as Global Chief Medical Officer

Chinese startup DualityBio has announced that Dr Hua Mu has joined the company as Global Chief Medical Officer (CMO). In this role, Dr Mu will oversee the strategic planning, meticulous design, efficient execution, and comprehensive regulatory compliance of the company's global clinical development efforts, ensuring adherence to the most stringent international regulatory standards. With decades of global experience in drug research, translational medicine, and clinical development, he has held leadership roles at top multinational pharmaceutical companies, biotech firms, and top-tier capital, successfully advancing multiple drug candidates from preclinical stages through commercialisation. As a seasoned biotech executive and drug developer, Dr Mu's extensive expertise and global vision will provide strategic leadership in driving clinical development programmes and navigating regulatory landscapes.

Harbour BioMed names Youchen Chen as Chief Financial Officer

Harbour BioMed, a global biopharmaceutical company with presence in China and the US, has announced the appointment of Youchen Chen as Chief Financial Officer. Chen will be based in Shanghai and Hong Kong SAR, and report directly to Dr Jingsong Wang, Founder, Chairman, and CEO of Harbour BioMed. Since joining Harbour BioMed in 2023, Chen has taken on increasing responsibilities across Investor Relations, Corporate Development, Business Development, and Finance. His strategic vision and collaborative leadership have significantly contributed to key strategic transactions, global partnerships and alliances, as well as global financial management and operations. In his new role, Chen will continue to leverage his expertise to further enhance shareholder value and guide Harbour BioMed through its next phase of strategic development. Before joining Harbour BioMed, Chen served as Chief Financial Officer at a clinical-stage radiopharmaceutical startup.

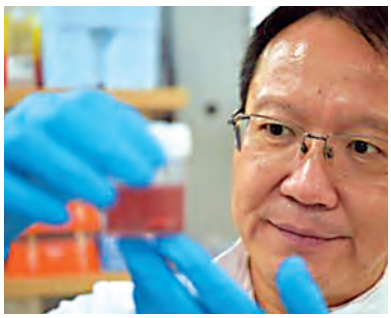


Telix Pharma ropes in Paul Schaffer as Chief Technology Officer

Australia's Telix Pharmaceuticals has appointed Dr Paul Schaffer to the newly created role of Chief Technology Officer (CTO). Dr Schaffer has been the CTO at ARTMS Inc. (acquired by Telix in 2024) for the past seven years, as well as Director, Life Science at TRIUMF, Canada's particle accelerator research centre, since 2012. Based in Vancouver, Canada, Dr Schaffer is widely recognised for his role in the buildout and transformation of the TRIUMF Life Sciences programme, which included design and construction of a major multi-cyclotron radiochemistry facility and the development of the ARTMS QUANTM Irradiation System (QIS) for large-scale isotope production, which was commercialised and later acquired by Telix. As Telix CTO, Dr Schaffer will be responsible for harnessing the power of technology to advance Telix's capabilities in radiopharmaceutical research, development, and clinical applications. Dr Schaffer will cover areas including chemistry, physics, artificial intelligence (AI), dosimetry, and data analytics, complementing the work of Telix's Chief Scientist, Dr Michael Wheatcroft, and his team in driving cutting-edge research and development (R&D).

Australia lays focus on nanotechnology to improve odds in treating aggressive breast cancers

Australia's University of Queensland researchers are designing nanotechnology they believe could improve how we treat the most aggressive form of breast cancer. Professor Chengzhong Yu and his team are developing novel nanoparticles that could dramatically increase the effectiveness of immunotherapies when treating triple-negative breast cancer (TNBC). TNBC is aggressive, fast-growing and accounts for 30 per cent of all breast cancer deaths



in Australia each year, despite making up only 10 to 15 per cent of new cases. Aided by a $3 million Investigator grant from the National Health and Medical Research Council (NHMRC), Professor Yu aims to design a nanoparticle to bolster TNBC patients' immune response to treatments. This 'nano-adjuvant' would work at a sub-microscopic scale to boost the performance of T-cells, the white blood cells used by the immune system to fight disease. The 5-year research project would hopefully kickstart clinical translation to fill a critical gap in the treatment of serious cancers.

Scientists assemble world's first immune cell atlas from diverse Asian populations

Researchers from the A*STAR Genome Institute of Singapore (A*STAR GIS), together with collaborators from South Korea, Japan, Thailand, and India, have assembled the world's first Asian Immune Diversity Atlas (AIDA)—a multi-national survey of human blood at single-cell resolution. The landmark study has the potential to advance Precision Medicine and empower the development of next-generation diagnostics and therapeutics tailored specifically for Asian populations. The A*STAR GIS-led AIDA consortium profiled the healthy immune systems of diverse Asian populations. Using advanced single-cell genomics methods, the researchers analysed over 1.2 million immune cells from blood samples of 625 healthy donors across five Asian countries. AIDA is a flagship project of the Asia network of the international Human Cell Atlas (HCA) consortium, which aims to create comprehensive reference maps of human cells to enhance disease diagnosis, monitoring, and treatment.

Hong Kong develops multiple smart devices to advance medical innovation

A research team at the Hong Kong University of Science and Technology (HKUST) has developed three innovative smart medical devices- AI Hand-Centric Tactile Interaction System (PhyTac); A portable wireless spirometer device and World's Smallest Multifunctional Surgical Robot, for health monitoring, surgical assistance and rehabilitation. Integrating artificial intelligence (AI) with robotics technology, the devices seek to help doctors address challenges in treatment and diagnostics, improve medical procedures and enhance efficiency. PhyTac is a cone-shaped AI hand-centric tactile interaction system fitted with a maximum of 368 sensing elements that could correspond to the exact points of force exertion in the hand. On the other hand, the portable wireless spirometer allows users to conveniently perform exhalation tests and perform breathing training at home. It can help ease the burden of frequent hospital visits for spirometry tests. Further, the micro-robot integrates imaging and precise navigation functions, and can assist medical professionals in sampling tissues, delivering drugs, and performing laser thermal therapy within the human body.

Hebrew University in Jerusalem develops rapid blood test for Parkinson's Disease

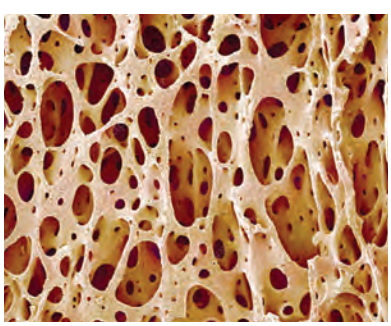
US-based ATED Therapeutics has announced a new diagnostic test for Parkinson's Disease, developed at Hebrew University in Jerusalem, Israel. The test measures transfer RNA fragments (tRF's) from nucleated red blood cells. Currently, there is no reliable blood test for Parkinson's Disease. Instead, physicians diagnose the disease by observing a patient's movements. Such qualitative tests have an error rate of 20-25 per cent, and can only be used once the disease has progressed and significant symptoms appear. Another test relies on a spinal tap, which cannot measure progression and involves significant discomfort and expense for the patient. Hebrew University and ATED have developed a simple, reliable, cost-effective blood test that will change the way Parkinson's is diagnosed and will allow clinicians to accurately identify and follow how the disease is progressing. In addition, ATED's test can measure the effects of deep brain stimulation (DBS), which is often used to treat Parkinson's disease.

Singapore uses microneedle technology to accelerate diabetic wound healing

Diabetic wounds often lead to severe complications that can result in amputations. These chronic and non-healing wounds are marked by persistent inflammation, affecting more than six per cent of the global population. To address this challenge of great national and global importance, researchers from the National University of Singapore (NUS) have developed two microneedle technologies that have shown efficacy in accelerating diabetic wound healing in preclinical models by preserving the functions of proteins called growth factors, and removing undesirable inflammatory compounds. In the first approach developed by the NUS research team, instead of delivering the growth factors directly, they first increased the production of growth factors within the wound. They achieved this by developing sucralfate microneedles (SUC-MN) to deliver an important immunomodulatory protein, interleukin-4 (IL-4), to stimulate the production of growth factors in diabetic tissues. The research team screened different materials and eventually used heparin-coated porous microneedles (HPMN) to address the issue of persistent inflammation in skin wounds at the source.

India designs natural bio-ink for 3D bioprinting of bone tissue

A team of researchers at the National Institute of Technology (NIT) Rourkela, India has developed a bioink made from natural materials for 3D bioprinting of bone-like structures. This bioink is designed to address challenges in bone grafting and implants, which are commonly used to treat bone defects caused by injury or disease. The research focuses on improving existing bone repair techniques by developing a bioink that is biocompatible, easy to use,



and supports bone regeneration. The newly developed bioink is composed of chitosan, gelatin, and nanohydroxyapatite, all of which are biocompatible and commonly used in biomedical applications. Supported by funding from the Department of Health Research (DHR), Government of India, this bioink has potential applications in a range of clinical settings. It can be used to treat large bone defects caused by accidents, infections, or surgeries by supporting natural bone growth. It is particularly useful in reconstructive surgeries for the skull and face, where precise bone repair is necessary.

Alamar Biosciences expands commercial support in APAC

Alamar Biosciences, a US-based company powering precision proteomics to enable the earliest detection of disease, has announced the signing of five new distribution partners to expand its global presence. The company has partnered with established industry leaders across key international markets to enhance access to its innovative proteomics technologies. The newly signed distribution partners include GeneWorks – Australia and New Zealand; Genomax – Singapore; PhileKorea – South Korea; Scrum Inc. – Japan; and Spinco – India. Alamar's technology empowers scientists to achieve groundbreaking insights in biomarker discovery, drug development, and disease research. Through these new partnerships, researchers in Asia-Pacific (APAC) will now have enhanced access to Alamar's cutting-edge platforms and technical support. The company's proprietary NULISA Platform along with the ARGO HT System work seamlessly with the latest advances in genomics to achieve single digit attomolar detection sensitivity, greatly surpassing the most sensitive protein detection technology on the market today.

Shimadzu Scientific Korea strengthens cooperation between industry & academia

Shimadzu Scientific Korea Corporation (SSK), a subsidiary of Japan-headquartered firm Shimadzu in South Korea, and Chungnam National University, have signed a Memorandum of Understanding (MoU) with the objectives of strengthening the development of technology and research equipment, and promoting collaborative research between industry and academia. The Shimadzu Group and Chungnam National University have a long-standing business relationship involving analytical and measuring instruments and medical systems. In recent years, SSK has provided the university with research and development equipment primarily in the fields of healthcare and green transformation. By signing this MoU, both parties are beginning cooperation between industry and academia with a view to collaborative research and collaborative development, and are taking collaborative initiatives for the development of programmes for human resource training for researchers as well as participation in international collaborative research projects.

BiomatiQ Group inaugurates world-class manufacturing facility in India

BiomatiQ Group has announced the inauguration of its state-of-the-art fully automated manufacturing facility in Hyderabad, a significant milestone in the Group's mission to build a self-reliant and innovation-led life science business ecosystem in India. This new unit reinforces BiomatiQ's commitment to the Make in India initiative by offering locally manufactured, globally benchmarked products for the pharmaceutical, biotechnology, and research sectors. Strategically designed to support high standards of quality, compliance, and scalability, the new facility will focus on the manufacturing of Ready-to-Use (RTU) microbiological media plates and Laboratory essential products tailored for regulated environments. The facility is equipped with fully automated Grade A aseptic filling line for high-precision, contamination-free RTU media; GMP-compliant manufacturing zones with ISO-certified operations; In-house microbiology and quality control laboratories, designed to support 21 CFR Part 11 compliance; and scalable and sustainable production infrastructure with a focus on data-driven operations and minimal human intervention.

Thermo Fisher Scientific introduces Krios 5 Cryo-Transmission Electron Microscope

Thermo Fisher Scientific has introduced the Thermo Scientific Krios 5 Cryo-Transmission Electron Microscope (TEM). This next-generation, atomic-resolution platform leverages enhanced optics and AI-enabled automation to study molecular structures and interactions at a throughput and fidelity that was previously unattainable. In the rapidly evolving field of structural biology, single particle analysis (SPA) and cryo-electron tomography (cryo-ET) are powerful techniques that allow scientists to better understand the intricacies of biology, providing atomic-level insights that reveal how viruses, proteins and cells work. The Krios 5 Cryo-TEM optimises productivity and performance to enhance these techniques. With a throughput improvement of up to 25 per cent compared to previously released models, the Krios 5 enables 3D visualisation of proteins, as well as their interactions and dynamics within the biological cell. Other Krios 5 advantages include AI-powered experimental set-up and upgraded data acquisition. For the cryo-ET workflow, the innovative vacuum capsule transfer helps prevent contamination of samples.

Sphere Bio extends distribution network to strengthen presence in APAC

UK-based Sphere Bio, a leading provider of picodroplet-based microfluidics for functional single-cell analysis and isolation, has announced a significant expansion of its Asia Pacific (APAC) distributor network. This development marks a key milestone in the company's global commercial strategy to meet growing demand for its next-generation single-cell analysis platforms. The expansion enhances Sphere Bio's footprint across key Asian and Pacific markets, improving regional access to its innovative technologies, local support, and technical expertise. The company has formed partnerships with five new distributors: 1st PhileKorea (South Korea), AS ONE Corporation (Japan), Decode Science (Australia and New Zealand), Everlife Research Instruments (Singapore), and Premas Life Sciences (India and Bangladesh). These new partnerships join an already robust network, including Bang Trading (Thailand), Cold Spring Biotech (Taiwan), and Gene Company (China and Hong Kong).

Waters expands Alliance iS Bio HPLC product line with photodiode array detector

Waters Corporation has announced the expansion of the Alliance iS Bio HPLC product line with integrated photodiode array (PDA) detection, advancing the capabilities of the next-generation intelligent HPLC platform designed for development and Quality Control (QC) laboratories. The Alliance iS HPLC Platform has been purposefully designed to simplify laboratory workflows by reducing the risk of out-of-specification results and the need for troubleshooting. Default system parameters provide over threefold improvement in day-to-day reproducibility and reduce carryover by up to two orders of magnitude, compared to other systems on the market. Additionally, with MaxPeak Premier columns, the Alliance iS Bio HPLC System enhances out-of-the-box sensitivity by up to 80 times compared to traditional systems and columns. Waters now offers four configurations of the Alliance iS HPLC Platform to support routine quantitative analysis and expanded spectral analysis of small and large molecules in development and QC.

Enhancing Safe Drug Development sans Animals

The U.S. Food and Drug Administration (FDA) made a historic move on April 10 to promote public health by substituting more efficient, human-relevant techniques for animal testing in the creation of monoclonal antibody (mAb) treatments and other medications. The new strategy, according to a statement from the US FDA, is intended to decrease animal testing, minimise research and development (R&D) expenses, and eventually, drug costs while also enhancing drug safety and expediting the evaluation process.

Several strategies, such as AI-based computer models of toxicity and cell lines and organoid toxicity testing in a laboratory setting (so-called New Approach Methodologies (NAMs data)), will be used to lessen, improve, or maybe replace the FDA's requirement for animal testing. For investigational new drug (IND) applications, where the inclusion of NAMs data is encouraged and is described in a roadmap, the FDA noted that the scheme will be implemented immediately. Efficacy assessments will be based on current, real-world safety data from other nations with similar regulatory criteria where the medicine has been evaluated in humans, the agency said.

The roadmap, also released on April 10, outlines a strategic, stepwise approach for the FDA to reduce animal testing in preclinical safety studies with scientifically validated NAMs, such as organ-on-a-chip systems, computational modelling, and advanced in vitro assays. By partnering with federal agencies, the FDA can accelerate the validation and adoption of these human-relevant methods, improving predictive accuracy while reducing animal use. This transition will enhance public health by streamlining drug development and ensuring safer therapies reach patients faster, while positioning the FDA as a global leader in modern regulatory science and innovation.

The US FDA pointed out that there is growing scientific recognition that animals do not provide adequate models of human health and disease. Over 90 per cent of drugs that appear safe and effective in animals do not go on to receive FDA approval in humans, predominantly due to safety and/or efficacy issues. Animal-based data have been particularly poor predictors of drug success for multiple common diseases, including cancer, Alzheimer's and inflammatory diseases. Some medications, which are generally recognised as safe in humans, such as aspirin, may have never passed animal testing. Conversely, some compounds which have appeared safe in animal models have been lethal in human trials. These examples highlight basic physiologic differences between humans and other animal species.

Due to the limitations of animal testing as well as ethical concerns about animals testing, there has been increased focus within the scientific community on NAMs that encompass in vitro human-based systems, in silico modeling, and other innovative platforms that can collectively evaluate immunogenicity, toxicity, and pharmacodynamics in humans and provide an opportunity to improve the predictive relevance of preclinical drug testing while reducing or replacing animal use. NAMs also have enormous cost-saving potential. The global market for animals used in research and testing, valued at $3,243.3 million in 2025, is projected to experience robust growth, driven by the increasing demand for preclinical drug development and the expansion of the pharmaceutical and biotechnology industries, according to a report from Market Research Forecast.

North America now holds a sizeable market share, according to the report published on April 25. This is because of the region's large pharmaceutical businesses, strong research infrastructure, and relatively greater research funding. Particularly, the US is a significant market participant. Europe is a significant market as well, with a well-established regulatory framework for animal research, a large number of biotechnology and pharmaceutical companies, and renowned research institutes. Rising healthcare costs, increased investments in biomedical research and development, and a growing pharmaceutical and biotechnology industry—particularly in nations like China and Japan—are all contributing to the Asia-Pacific region's rapid growth. The US, under the Trump Administration, which has increased tariffs on goods from across industries, including the pharmaceutical sector, is largely reliant on the import of generic medications for its patient population. The USFDA's decision to replace animal testing will greatly benefit the local sector as well as the global pharmaceutical business, since the US is the world's largest pharmaceutical market and all other nations closely follow its lead. BS

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