

## Japan strengthening biopharma capabilities

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**Asia's biopharma landscape is shifting rapidly toward innovation, with countries such as South Korea, Singapore, India, and Taiwan advancing R&D capabilities. Japan, after a period of slowing innovation, is repositioning biopharma as a strategic priority through regulatory reform, pricing policy changes, increased R&D funding, and startup support. Initiatives spanning regenerative medicine, digital transformation, and AI-driven drug discovery—backed by strong university–industry collaboration and venture funding—are revitalising Japan's ecosystem and positioning the country to re-emerge as a leading Asian biopharma innovation hub.**



The Asian biopharma landscape is evolving rapidly and undergoing major shifts, expanding focus beyond generics and contract manufacturing. Over the years, South Korea, Singapore, India, and Taiwan have made rapid strides in terms of biopharma R&D, establishing themselves as innovation hubs.

On the other hand, Japan was previously a global biopharma and life sciences innovation leader, but innovation has slowed down in recent years. The number of new drug launches has reduced significantly, and this is attributable to pricing pressures and a relatively weakly funded biotech startup network compared to other Asian countries. Japan's government and private sector are actively repositioning biopharma by increasing investment in biotech, supporting cross-border collaborations, and rolling out targeted incentives to attract high-value R&D and reshape the innovation ecosystem for the next decade.

Japan's pharmaceutical regulatory landscape is undergoing a significant transformation, which aims to mitigate the biopharma lag and enable Japan to remain competitive globally. It is reforming pricing policies and launching new funds and programmes to incentivise innovative drug discovery and support innovative drug discovery.

Japan's Bioeconomy Strategy (2024) aims to create a ¥100 trillion market (approximately \$644 billion) by 2030, focusing on biomanufacturing, sustainable production, biopharma/regenerative medicine, as well as health/digital health. The Japanese Ministry of Health, Labour and Welfare (MHLW) has included a ¥790 million (approximately \$5 million) budget to establish a global center for First-In-Human (FIH) trials, which would act as a one-stop shop for global biopharma trials, and also support international companies to carry out their trials in Japan.

To accelerate drug development, MHLW allows drugs already in early clinical development outside Japan to skip additional Phase I studies in Japanese participants, provided safety and tolerability at the proposed dose are well justified. Japan has also relaxed criteria for orphan drug designation and established the Consultation Center for Pediatrics and Orphan Drugs

Development (CCPODD) to support rare disease therapies. Orphan drugs can now be designated before completion of Phase III trials. Japan's NHI drug pricing system has been criticised for hindering innovation.

Although its primary goal is to provide universal health coverage and ensure the insurance system's long-term stability, the government has recently implemented tougher repricing rules and more frequent price cuts. Japan started reforming its pricing system in 2024 to better support innovation while keeping costs in check. The MHLW has pledged to increase prices for innovative medicines to encourage more investment in local research and development.

Another example of initiative to promote R&D and innovation is the Japan Entry Acceleration Program (JEAP) started by JETRO (Japan External Trade Organization). It encourages promising startups focused on regenerative medicine and cell and gene therapy, gain direct access to Japan's business ecosystem, including expert mentorship, market insights, and connections with top CDMOs, CROs, and pharmaceutical companies. This programme delivers the resources needed for rapid market entry and expansion.

Analysis of recent policies and initiatives makes Japan's intent clear: biopharma innovation and R&D are now strategic priorities. The government is actively pushing this agenda by nurturing startups, recalibrating drug pricing, increasing budgets for clinical trials, and streamlining regulatory pathways.

### **Top Biopharma Focus Areas: Building a Holistic Innovation Ecosystem**

With one of the world's fastest-aging populations, Japan is an attractive market for regenerative medicine and innovative biologic therapies targeting age-related diseases and improving health span. Chronic diseases such as cancer and cardiovascular diseases are associated with the ageing population, and advanced antibody therapies and CGT innovations are aimed at addressing these. Japan is well-positioned as a leader in regenerative medicine and has been strategically investing in iPSC-based cell therapies since the 2000s. It is focusing on developing infrastructure and strengthening R&D to build next-generation iPSC cell therapy products. Technologies such as genome editing and RNA engineering are being integrated to improve the safety and therapeutic efficacy of iPSC therapies.

Japan's leading biopharma companies, such as Chugai, Daiichi Sankyo, Astellas, Eisai, Otsuka, and others, are focused on internal innovation and building a well-diversified pipeline. Strategic collaborations to foster open innovation and accelerate R&D are also a growing priority. For instance, Chugai launched a US partnering office in December 2025 to collaborate with US startups and academia. In June 2025, Mitsubishi Research Institute, Inc., and Astellas Pharma Inc. signed an MoU to support drug-discovery startups in Japan and strengthen Japan's position as a global hub for drug discovery. Many partnerships are thriving on utilising cross-functional expertise, such as AI, antibody engineering, manufacturing, etc., to accelerate the pace of drug discovery.

Chugai's focus on next-generation antibody therapies will remain a key priority from an R&D and product development standpoint. In addition to internal R&D, the company has been actively exploring external partnerships to develop advanced antibody drugs. Recently, it entered a joint research and licensing agreement with Singapore-based biotechnology firm Gero to develop new antibody drug candidates for age-related diseases. This partnership will leverage Gero's AI platform and Chugai's antibody engineering technology.

From a modality standpoint, cell and gene therapy development is undergoing strategic shifts, with many companies moving away from in-house development while others are doubling down on this area. The high costs and uncertainties with CGT development have prompted Japanese biopharma companies to reconsider betting heavily in this space. Companies such as Takeda reprioritised their pipelines in 2025, where Takeda stepped back from CGT development. Astellas, on the other hand, redirected its focus on late-stage assets but remains committed to its focus on regenerative medicine and CGT for rare diseases. It is building an early-stage pipeline of differentiated cell and gene therapies for blindness and ophthalmological diseases, in addition to in vivo CAR-T therapies for oncology.

On the manufacturing front, the country is also focusing on building its capabilities both within Japan and globally. Fujifilm Biotechnologies, one of the largest CDMOs globally, has also been expanding its capacity at a global level and building on its partnership agreements with large biotech companies.

Japan is undergoing a rapid digital transformation in its biopharma sector. Chugai is at the forefront, driving CHUGAI DIGITAL VISION 2030. Digital is explicitly positioned as a growth engine in its TOP I 2030 strategy. Initiatives such as Digital Innovation Lab (DIL), Chugai Cloud Infrastructure (CCI), or using AI in drug discovery (for example, the proprietary antibody design platform MALEXA-LI) or integrating digital biomarkers and real-world data (RWD) for trial design and personalized therapies are helping it strengthen its digital backbone.

Astellas is developing tools, such as antibody language models with NVIDIA BioNeMo, to streamline the drug discovery workflow. It is also developing patient-facing, evidence-based digital health solutions for chronic disease. Takeda Japan Innovation Center (TJIC), as part of the global Innovation Capability Center network, is developing advanced AI and big data-based digital solutions, such as AI-driven demand forecasting, to strengthen the domestic pharmaceutical supply chain.

Fujifilm plans to integrate AI-based culture media optimisation technology in its biopharmaceutical manufacturing process to increase the output by approximately 40 per cent. It's also using AI in drug discovery by collaborating with MOLCURE Inc. to use MOLCURE's proprietary AI-powered drug discovery platform to advance peptide drug discovery technology.

Daiichi Sankyo's 2030 vision is to transform into an innovative global healthcare company, with digital at the core of that shift. Its Digital Transformation Planning Department is building platforms that fully leverage data and digital technology to speed decision-making, increasing business agility.

As leading players include digital technologies in their core strategies, Japan is positioning itself as a digitally sophisticated biopharma hub.

### **Innovation Pipeline: VC-Funded Startups and Active University Research Hubs**

Japan's biopharma sector, dominated by large pharmaceutical companies, is currently undergoing rapid transformation. The Japan government has initiated the Startup Development Five-Year Plan (2022), which aims to create 100,000 startups and 100 unicorns. This is backed by about ¥10 trillion (approximately US\$64 billion) in public-private investment, with life sciences and biopharma prioritised as core deep-tech sectors.

Japan is emerging as a regenerative medicine and iPS powerhouse, with startups like iHeart (allogeneic iPS-derived cardiac products), Cellusion (iPSC-derived corneal endothelial cells for bullous keratopathy), and SanBio (stem cell-based nerve tissue regeneration) targeting the needs of an aging population. There are startups targeting transfusion medicine, like Megakaryon Corporation (megakaryocytes from iPS cells), or for cancer therapy, like Shinobi Therapeutics's iPS-T cell programme targeting GPC3+ tumours.

Cell and gene therapy startups in Japan are attracting significant VC and public funding. Celaid Therapeutics has raised ¥1.2 billion (\$7.6 million). Typewriter Therapeutics secured \$30 million under the Japan Agency for Medical Research and Development (AMED) 2024 "Strengthening Program for Pharmaceutical Startup Ecosystem" to advance its mRNA-based gene therapy pipeline for severe genetic disorders. RegCell, developing a first-in-class epigenetic regulatory T-cell reprogramming platform, recently raised \$8.5 million in seed funding co-led by UTEC and FTI, plus \$37.3 million in non-dilutive funding from AMED. Japan's large pharmaceutical companies are increasingly engaging with the domestic startup ecosystem. For example, PeptiDream is partnering with pharma giants such as Astellas and Takeda to use its proprietary drug discovery platform, PDPS (Peptide Discovery Platform System), for the development of novel targeted protein degraders and peptide drug conjugates for central nervous system targets, respectively.

Japan's biopharma startup ecosystem is increasingly fueled by deliberate government initiatives; for example, JST's university startup programmes and AMED's "Strengthening Program for Pharmaceutical Startup Ecosystem" provide non-dilutive funding and VC-matching to drug discovery and cell/gene startups, university infrastructure, and corporate-led clusters. Universities have built their own spin-off machinery with tech-transfer offices, incubators, and venture arms, for example, The Office of Innovation and Entrepreneurship of the Division of University Corporate Relations (DUCR) at the University of Tokyo, or Kyoto University Innovation Capital (Kyoto-iCAP- venture capital firm to support startups and commercialise research outcomes from Kyoto University). This is how platform biotechs like PeptiDream (University of Tokyo spin-out) or Celaid Therapeutics (University of Tokyo and University of Tsukuba), or CUORiPS (Spin-off from Osaka University, supported by Kyoto University Innovation Capital) have emerged from academia and scaled big.

Corporate support through industry-academia clusters like Greater Tokyo Biocommunity (GTB) supports research, investments, infrastructure, and startups. Ciconia Bioventures is a joint venture company formed with investments from Takeda Pharmaceutical Company, Astellas Pharma Inc., and Sumitomo Mitsui Banking Corporation. Recently, Ciconia has entered into an incubation research agreement with Kyoto University to foster the creation of startups capable of global

expansion, based on drug discovery seeds originating from Kyoto University's research.

Japan's biopharma sector is rapidly transforming into a policy-backed, university research-driven, and big-pharma-connected innovation engine, with distinctive strengths in iPS/regenerative medicine and platform biologics. On this foundation, Japan is actively positioning itself as a leading Asian biopharma innovation hub.

### **The Road Ahead**

With combined efforts from both the private and public sectors, Japan is poised to regain its lost position in biopharma innovation. The growing pipeline of diversified biologics and advanced therapies across development phases, together with ongoing investments in Japan's clinical trial infrastructure, underscores a forward-looking priority to strengthen the country's biopharma capabilities.

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