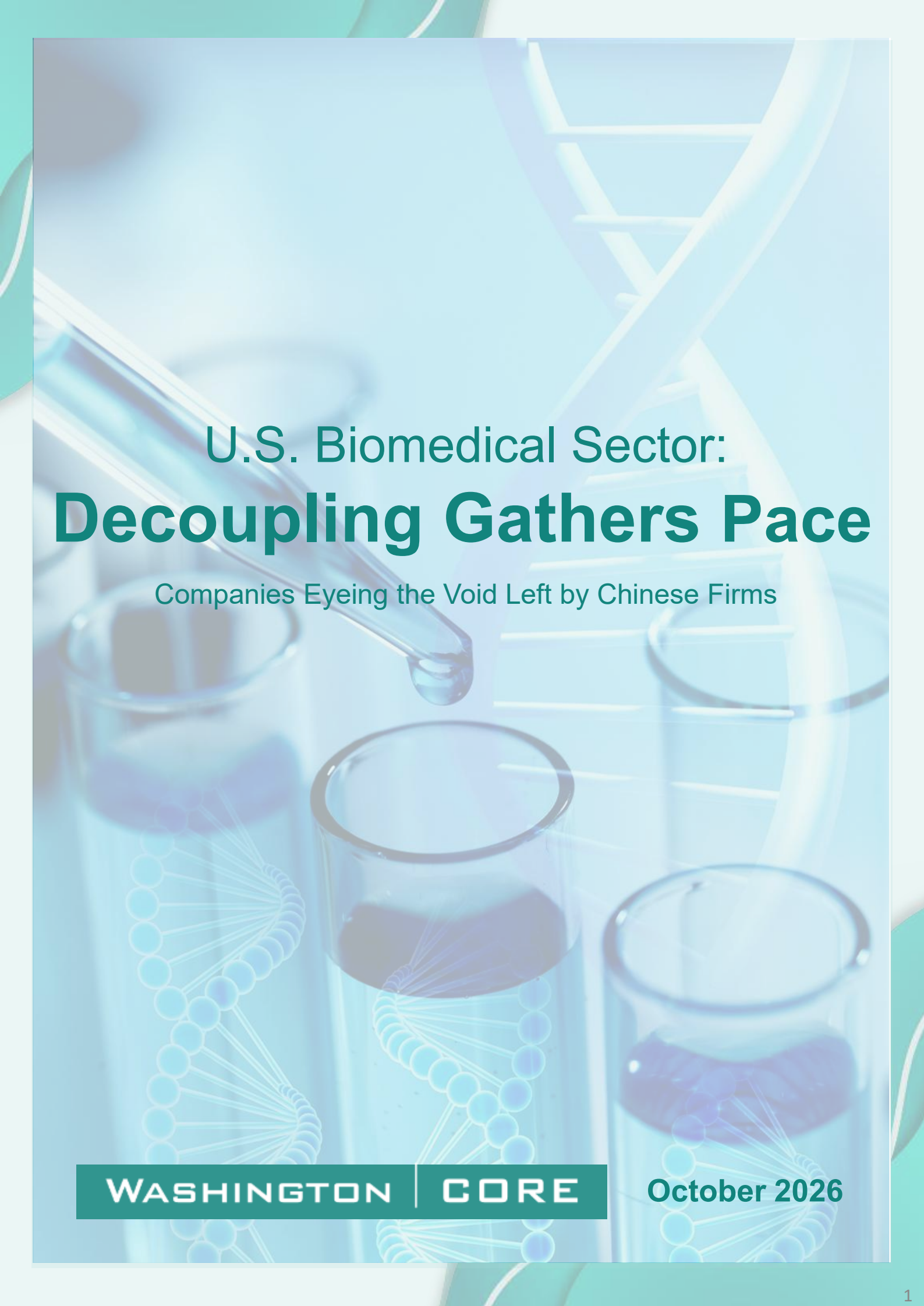


The background of the cover features a light blue and teal color palette. It includes several overlapping images: a large DNA double helix structure in the upper right, a pipette with a single drop of liquid falling into a beaker in the center, and other laboratory glassware like beakers and test tubes in the foreground and background. The overall aesthetic is clean and scientific.

U.S. Biomedical Sector: **Decoupling Gathers Pace**

Companies Eyeing the Void Left by Chinese Firms

WASHINGTON | CORE

October 2026

The U.S. federal government is moving to exclude Chinese biomedical technology companies from the U.S. market. It is using a mix of longstanding and newer tools—including export controls, designation on the Department of Defense's list of companies of military concern, and legislation enacted by Congress—to increase pressure on Chinese companies operating in the United States. Most recently, the Department of Defense added seven Chinese biomedical companies to that list. Chinese companies play an important role in U.S. drug development and manufacturing, and the exclusion measures have prompted criticism that they could damage U.S. industry. At the same time, tighter regulation is widely seen as unavoidable, and the void created by the exclusion of Chinese companies is being read as a business opportunity for companies in the United States and in allied countries.

Nearly 80% of U.S. Biotech Companies Work with Chinese Contract Manufacturers

The U.S. biomedical industry is closely intertwined with China. It is no exaggeration to say that the U.S. biomedical sector could not function without the involvement of Chinese companies. Chinese companies have business relationships with U.S. companies across a wide range of fields, supplying high value-added services and deepening those ties. In the biopharmaceutical industry, they have expanded into areas such as cell production, genetic analysis and cell storage, and the services they provide are growing more sophisticated.

According to the U.S.-China Economic and Security

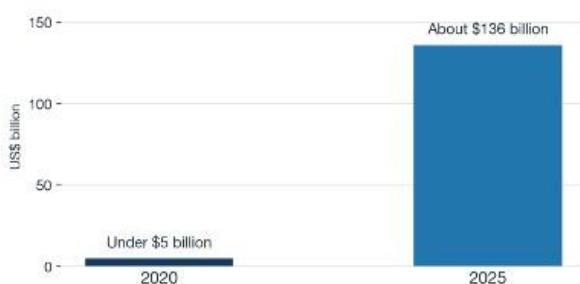
Review Commission (USCC), for example, the WuXi group of contract manufacturers is estimated to have been involved in developing one-quarter of the drugs currently used in the United States¹.

At the 2026 J.P. Morgan Healthcare Conference, WuXi AppTec said it had supported the development of 8 of the 30 small-molecule drugs approved by the U.S. Food and Drug Administration (FDA) in 2025². In a survey published in May 2024 by the Biotechnology Innovation Organization (BIO), 79% of the 124 U.S. biotechnology companies surveyed had at least one contract or product with a contract development and manufacturing organization (CDMO) or contract manufacturing organization (CMO) based in or owned by China³. WuXi AppTec voluntarily withdrew from BIO the day before the organization announced its support for the BIOSECURE Act, which bars federal agencies from procuring from, or using federal funds for contracts with, designated biotechnology companies of concern, primarily Chinese ones.

Dependence is also deepening rapidly in the drug discovery pipeline. Licensing deals between Chinese companies and U.S. and European pharmaceutical companies were worth less than \$5 billion in 2020 but reached \$136 billion in 2025⁴.

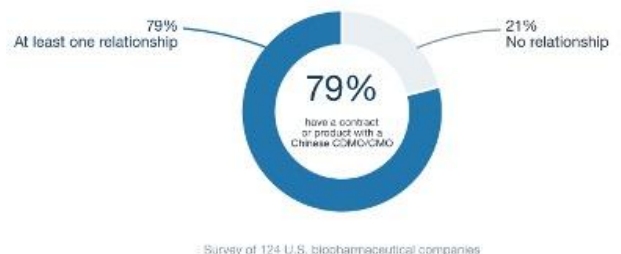


Value of Licensing Deals between Chinese Biomedical Companies and U.S. and European Pharmaceutical Companies



Source: U.S. House Select Committee on the Chinese Communist Party⁴

U.S. Biomedical Companies' Dependence on Chinese CDMOs and CMOs

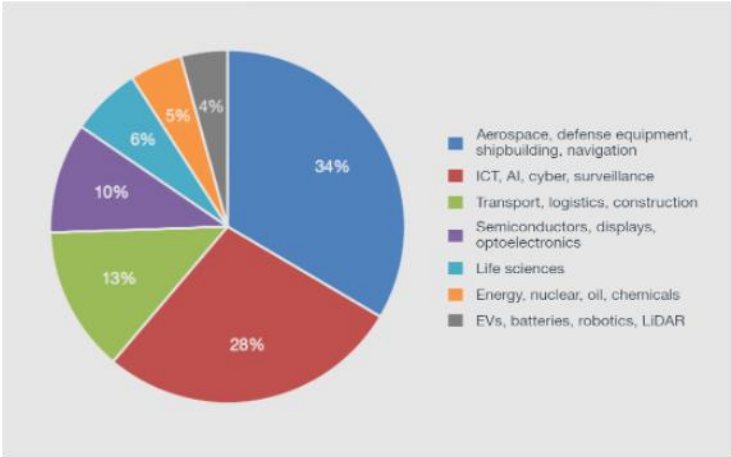


Source: BIO³

Seven Life-Science Entities Added to the “Chinese Military Companies” List

The U.S. government has long viewed this dependence on China as a concern and has pursued policies to curb it; those efforts are now intensifying. On June 8, 2026, for example, the Department of Defense updated the “Section 1260H list,” on which companies are designated on the basis of ties to the Chinese military or defense industry, or of involvement in military-civil fusion. The list is the department's published roster of “Chinese military companies operating directly or indirectly in the United States” and is updated at least once a year. A designation remains in force unless the entity is removed from the list. The list currently names 188 entities across industries including aerospace, information and communications, logistics and semiconductors. Among life-science companies, seven were newly added in this update, bringing the total to 12 entities.

Section 1260H Designated Entities by Industry



Source: Federal Register⁵

Note: The Department of Defense notice itself does not publish an industry classification. Section 1260H Designated Entities by Industry was prepared by Washington CORE on the basis of the principal business of each designated entity's parent company or group.

The 12 Life-Science Entities on the Section 1260H List (updated June 8, 2026)

★New indicates the seven entities added on June 8, 2026. The “Field” column is Washington CORE’s own classification. CRDMO stands for contract research, development and manufacturing organization — a provider that takes on the whole chain from drug discovery through manufacturing.

Entity / Country	Status	Line of business (not given in the notice; confirmed on company websites and other sources)	Grounds for designation as stated in the notice	Field
BGI Group (华大基因集团) / China	Continued	Group parent of BGI Genomics and other subsidiaries	Direct ties to the PLA; indirect ties to MIIT and the PLA	Genomics
BGI Genomics / China	Continued	Contract genome sequencing and clinical testing	Listed as a subsidiary of BGI Group	Genomics
Forensic Genomics Interational (FGI)	Continued	Could not be confirmed (the notice lists the name only, with no country or line of business)	Listed as a subsidiary of BGI Group	—
BGI Americas Corporation	★New	Could not be confirmed (same as above)	Listed as a subsidiary of BGI Group	—
Complete Genomics /United States	★New	Sells sequencers in the U.S. market	Listed as a subsidiary of BGI Group	Genomics (instruments)
GBI Diagnostics, Inc.	★New	Could not be confirmed (same as above)	Listed as a subsidiary of BGI Group	—
Innomics, Inc.	★New	Contract multi-omics analysis and sequencing	Listed as a subsidiary of BGI Group	Genomics
STomics Americas, Ltd.	★New	Spatial transcriptomics (Stereo-seq)	Listed as a subsidiary of BGI Group	Genomics
MGI Tech (华大智造) / China	Continued	Manufactures sequencers and related instruments	Direct ties to MIIT; indirect ties to SASTIND and the PLA	Genomics (instruments)
Novogene (诺禾致源) / China	★New	Contract sequencing services	Indirectly held by SASAC; indirect ties to MIIT and the PLA	Genomics
Origincell Technology / China	Continued	Cell banking, automated biospecimen storage equipment and related products	Indirect ties to MIIT, SASAC, SASTIND and the PLA	Cell storage
WuXi AppTec (药明康德) / China	★New	CRDMO centered on small-molecule drugs	Indirectly held by SASAC; indirect ties to SASTIND and the PLA	CRDMO

Source: Compiled by Washington CORE from multiple sources

Note: PLA = People’s Liberation Army; MIIT = Ministry of Industry and Information Technology; SASAC = State-owned Assets Supervision and Administration Commission; SASTIND = State Administration of Science, Technology and Industry for National Defense.

The Chinese biomedical companies identified as being of military concern operate in three broad business areas: contract research, development and manufacturing organizations (CRDMOs), genomic analysis, and cell storage and cell therapy.

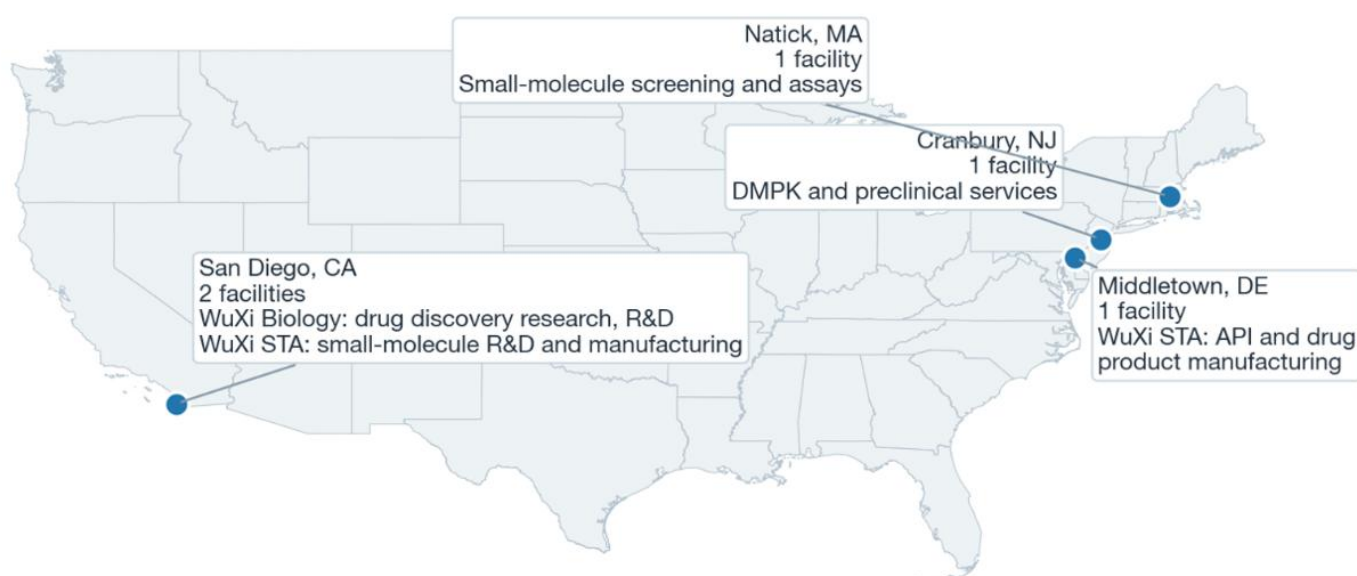


CRDMOs

The U.S. market for contract drug development and manufacturing is expected to roughly double over the next decade, to about \$83 billion, making it a field with strong growth prospects⁶. U.S. drugmakers are deeply dependent on Chinese CDMOs and CRDMOs, and WuXi AppTec — reported to have been involved in about 20% of the small-molecule new drugs approved by the FDA over the past five years — was designated for the first time in this update². The company is a central player in CRDMO work in the United States, taking on everything from drug discovery through development and manufacturing, mainly for small-molecule drugs.

The United States is WuXi AppTec's largest market. According to a statement filed with the court in the company's suit seeking to halt its Section 1260H designation, U.S. customers accounted for about 70% of its 2025 revenue, far ahead of China at 15% and Europe at 11%. The court's opinion in the same case states that the company employs roughly 450 people in the United States, serves more than 1,000 U.S. customers, and expects to complete a manufacturing site in Delaware, built at a cost of about \$600 million, during 2026⁷. According to the company's locations page, it has five sites in the United States including the Delaware facility. The other four are two sites in San Diego, California (drug discovery research, and small-molecule R&D and manufacturing), Cranbury, New Jersey (drug metabolism and pharmacokinetics, and preclinical services), and Natick, Massachusetts (small-molecule screening). In China, meanwhile, a new small-molecule API plant in Taixing began operating in May 2026, and a second small-molecule plant is due to start operations by the end of the year. Two additional plants for nucleic acids, peptides and similar products are expected to come on line in 2027, and the company is planning a new API site in Changzhou.

WuXi AppTec's Sites in the United States



Source: WuXi AppTec, Global Locations; U.S. Census Bureau, 2024 Cartographic Boundary File

In that litigation, the U.S. District Court for the District of Columbia found that the rationales given by the Department of Defense did not match the sources it relied on, and that the designation was likely to be held unlawful. The designation is therefore preliminarily enjoined while the case continues⁷.

Genomic Diagnostics

Genomic diagnostics is another field expected to grow. In 2019, the Federal Trade Commission noted that Illumina held more than 90% of the U.S. next-generation sequencing market and that China's BGI had refrained from entering the U.S. market in the face of Illumina's patent infringement claims⁸. Security concerns, however, are not limited to sequencers and other instruments: they also extend to the analytical data those systems produce. Indeed, most of the 12 designated entities belong to this field. In a February 2021 fact sheet, the National Counterintelligence and Security Center (NCSC) noted that the Chinese government regards collections of personal data, including health and genomic data, as a strategic asset.

Cell Storage (Biobanking)

Biobanks collect, preserve and manage biological specimens for use in research and medicine. The market includes not only contract storage services but also storage equipment, specimen management systems and



cold-chain logistics. The global biobanking market was estimated at \$89.7 billion in 2025 and is forecast to grow by an average of 8.02% a year through 2035⁹. Origincell Technology, designated in this update, runs a third-party cell bank and makes automated biospecimen storage equipment; its indirect ties to MIIT, SASAC, SASTIND and the PLA were cited as the grounds for designation⁵. The Justice Department's bulk data rule, which bars the transfer of large volumes of human omics data and biological specimens to China and other countries of concern, is expected to leave the company in an increasingly vulnerable position.

U.S. and Allied Companies Targeting the Market Left by Chinese Firms

Some see business opportunities opening for U.S. and allied companies as Chinese firms face tighter restrictions. Much of the activity centers on CDMOs with large-scale production capacity inside the United States as an alternative to China, and European, U.S., South Korean and Japanese players are already acting. Lonza (Switzerland), for example, acquired a plant in California in 2024, securing a site in the United States that ranks among the world's largest for biologics manufacturing.

U.S.-based Catalent, which operates just under 40 sites worldwide also has a substantial manufacturing network. In December 2024, Novo Holdings of Denmark acquired

the company in a transaction with a total enterprise value of about \$16.5 billion. Novo Holdings notes that Catalent “has assisted in 50% of all FDA approvals” over the past decade and helps its partners “launch over 150 new products every year”. Its existing manufacturing network inside the United States is a strength as production moves back onshore.

Samsung Biologics (South Korea) is also growing strongly, with full-year 2025 revenue up 30.3% and operating profit up 56.6% year on year. On March 31, 2026, it announced that it had completed the acquisition of GSK's (U.K.) plant in Rockville, Maryland — its first manufacturing site in the United States. The company says it works with more than 145 pharmaceutical and biotechnology companies worldwide and counts 17 of the global top 20, including AstraZeneca, Eli Lilly and Pfizer, among its customers.



The Debate over Excluding Chinese Companies from the U.S. Market

Views in the United States are divided over the policy of excluding Chinese companies from the U.S. market. U.S. drugmakers worry about dependence on China, but they also face potential losses in development capacity, the cost of switching providers and a lack of alternatives. The early stages of the drug development pipeline are seen as especially difficult to replace: losing access to WuXi AppTec, described as one of the world's largest engines of discovery and early development, could be a significant blow. The company's offering spans medicinal chemistry, screening, intermediates, building blocks and raw materials — all far upstream of manufacturing under Good Manufacturing Practice (GMP). At the front end of the pipeline, individual projects are small and have the least capacity to absorb a break in supply¹⁰.



Cell and gene therapy is expected to feel the effects of regulation most strongly, because the field relies heavily on university spinouts that have limited funding and staff that cannot afford facilities of their own¹⁰. There is also the argument that if exclusion is a U.S.-only policy, countries that do not decouple will continue to enjoy the efficiencies Chinese companies offer, potentially leaving U.S. companies alone at a disadvantage. Others warn that cutting ties could backfire by accelerating China's own innovation.

Breaking Away from China Will Be Painful

Japanese companies are also moving into the U.S. market at an accelerating pace. Fujifilm has invested in large-scale mammalian cell culture capacity in North Carolina, Ajinomoto has acquired a gene therapy CDMO in Ohio, and Kyowa Kirin has decided to build its own plant in North Carolina — part of a broader wave of Japanese investment, acquisitions and plant construction in the United States.

One analysis argues that these Japanese investments are driven less by U.S. restrictions on China than by broader supply-chain pressures: “Since the Covid-19 pandemic, mounting pressure to reassess supply chains has quietly given Japanese companies time to prepare for—and commit to—investment in the United States.” Japan, like the United States, also depends on China and other countries for pharmaceutical ingredients, and is therefore strengthening joint research, standard-setting and supply-chain rebuilding with partner countries including the United States⁶.

Conclusion

Concern about excluding Chinese companies runs deep in the U.S. biomedical industry. For research institutions and start-ups with limited funding and staff in particular, finding and moving to alternative contractors is a heavy burden. Some also warn that if regulation of China remains limited in markets outside the United States, subjecting only the U.S. market to it will erode the competitiveness of U.S. companies.

Even so, there is no denying that the pressure on China keeps building. Regulation now extends beyond drug development capacity to the handling of medical data, which is increasingly treated as a serious security matter. Against this backdrop, U.S. and allied companies are watching closely for opportunities to enter the U.S. market.

The moves of U.S. biomedical manufacturers and research institutions seeking to preserve their edge in development capability — and the moves of the domestic and allied companies that support them — are worth watching.

Sources

- ¹https://www.uscc.gov/sites/default/files/2024-11/Chapter_3--U.S.-China_Competition_in_Emerging_Technologies.pdf; p. 221
- ²<https://www.pharmaceutical-technology.com/analyst-comment/jpm26-wuxi-apptec-drives-growth/>
- ³<https://www.bio.org/bio-news/bio-survey-reveals-dependence-chinese-biomanufacturing>
- ⁴<https://chinaselectcommittee.house.gov/media/press-releases/moolenaar-dingell-introduce-legislation-to-prevent-offshoring-biotech-industry-to-china>
- ⁵<https://www.federalregister.gov/documents/2026/06/10/2026-11571/notice-of-availability-of-designation-of-chinese-military-companies>
- ⁶<https://www.csis.org/analysis/leveraging-japans-appetite-us-investment-and-partnership-pharmaceuticals-and-biotechnology>
- ⁷<https://storage.courtlistener.com/recap/gov.uscourts.dcd.293402/gov.uscourts.dcd.293402.25.0.pdf>; p.6
- ⁸https://www.ftc.gov/system/files/documents/cases/d9387_illumina_pacbio_administrative_part_3_complaint_public.pdf
- ⁹<https://www.precedenceresearch.com/biobanking-market>
- ¹⁰<https://cen.acs.org/business/outourcing/pentagon-ruling-hits-chinas-wuxi/104/web/2026/06>

Author Washington CORE, L.L.C.



Sawako Muguruma Research Analyst

Since joining Washington CORE as a research analyst in 2012, she has worked on numerous research projects commissioned by government and public-sector organizations, major electronics manufacturers, financial institutions, think tanks, and information security companies. In recent years, her work has focused on energy and environmental policy, as well as circular economy initiatives such as Extended Producer Responsibility (EPR) programs and California's zero-waste plans. She has also handled projects in cybersecurity, generative AI, digital health, and economic security. She is a graduate of Waseda University.

WASHINGTON | CORE

Washington CORE is an independent research and consulting firm headquartered in Washington, D.C. In an environment of constant change in politics, economics, business and technology, we deliver high-quality research, analysis and advisory services, drawing on our own network of experts around the world to provide the best solutions for our clients.

<https://www.wcore.com>

Inquiries about this report are also accepted in Japanese:

<https://www.wcore.com/home/contact-jp/#form-jp>