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OVERVIEW OF THE BIOLOGICS INDUSTRY

Biologics refer to medicinal products manufactured using biological technologies, starting from raw materials such as microorganisms, cells, animal or human tissues and body fluids, and intended for the prevention, treatment, and diagnosis of human diseases. Compared with chemical drugs, biologics typically feature more complex and heterogeneous structures, lower stability and greater sensitivity to external conditions, and potential immunogenicity, and are therefore highly dependent on the manufacturing process.

Biologics can be further divided into multiple categories, including antibody drugs, recombinant protein drugs, vaccines and cell therapy products. With advancements in genetic engineering, cell engineering, and protein engineering technologies, biologics have become one of the most dynamic sectors in innovative drug research and development as well as market growth.

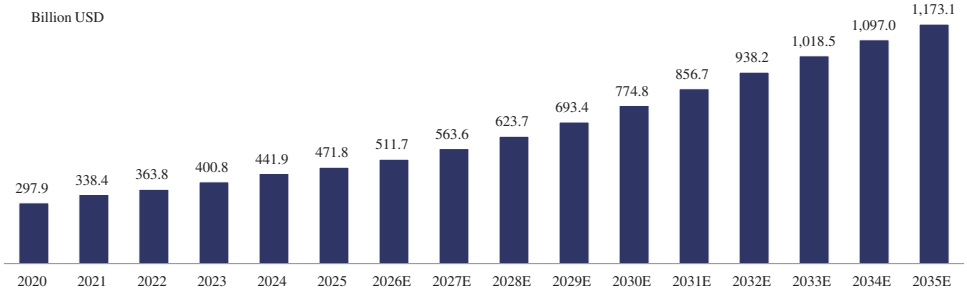
Overview of the Global Biologics Market

Driven mainly by population aging and longer life expectancy, increasing therapeutic applications, improving affordability and expanding patient access, the global biologics market has demonstrated consistent growth from 2020 to 2025 and is projected to continue expanding through 2035. The market size grew from US$297.9 billion in 2020 to US$471.8 billion in 2025, with a CAGR of approximately 9.6% during this historical period. Such growth is expected to continue, and the total market size is forecasted to reach US$774.8 billion by 2030, reflecting a CAGR of about 10.4% from 2025 to 2030, and further to US$1,173.1 billion by 2035, corresponding to a CAGR of roughly 8.6% from 2030 to 2035.

The following chart sets forth the global biologics market size by sales revenue.

Global Biologics Market Size and Forecast, 2020—2035E

Period	CAGR
2020–2025	9.6%
2025–2030E	10.4%
2030E–2035E	8.6%



Source: Frost & Sullivan

In addition to the growth in sales revenue, biologics' share in the global pharmaceutical market has also been rising. Biologics increased their share within the overall global pharmaceutical market from 22.9% in 2020 to 29.4% in 2025, and are projected to reach 46.2% by 2035, reflecting the growing role and expanding importance of biologics globally. Blockbuster product sales further highlight biologics' commercial importance. In 2025, the global top 10 drugs by sales revenue generated a combined US$180.0 billion. Among these top 10 drugs, seven were biologics. Key examples include Keytruda (US$31.7 billion) and Mounjaro (US$23.0 billion), alongside other major biologics such as Ozempic, Dupixent, Darzalex and Zepbound. These biologics span multiple therapeutic areas, including oncology, immune-mediated diseases and large chronic indications such as metabolic disorders (diabetes/obesity). The steady expansion of established biologic segments, together with the emergence of next-generation modalities, indicates that biologics are playing an increasingly important role in the global pharmaceutical market, both in terms of market share and product diversity.

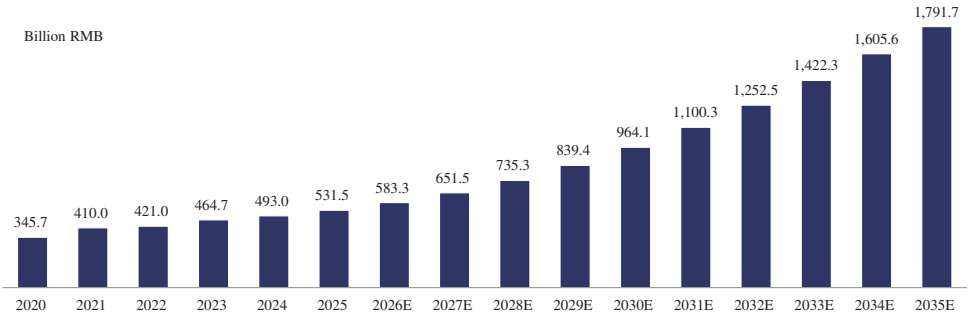
Overview of the China Biologics Market

China's biologics market has witnessed rapid growth in recent years, increasing from RMB345.7 billion in 2020 to RMB531.5 billion in 2025, achieving a CAGR of 9.0% during this period. Driven by expanding patient access, improving affordability, and continuous therapeutic innovation, the market is projected to reach RMB964.1 billion by 2030, representing a CAGR of 12.7% from 2025 to 2030. Further growth is anticipated, with the market expected to expand to RMB1,791.7 billion by 2035, corresponding to a CAGR of 13.2% during 2030 and 2035.

The following chart sets forth the China biologics market size by sales revenue.

China Biologics Market Size and Forecast, 2020—2035E

Period	CAGR
2020–2025	9.0%
2025–2030E	12.7%
2030E–2035E	13.2%



Source: Frost & Sullivan

China's biologics market growth is underpinned by multiple structural drivers and is expected to remain supported over the long term. On the demand side, accelerated population aging and the expanding patient pool for oncology and autoimmune diseases are driving sustained demand for long-term and effective therapies, with biologics increasingly replacing small-molecule drugs and becoming standard-of-care across multiple indications, while emerging biologics continue to address unmet clinical needs and broaden application scenarios. On the policy front, accelerated approval pathways, priority review mechanisms and increasing alignment with international regulatory systems are shortening time-to-market for innovative

biologics, and the maturing NRDL negotiation and dynamic adjustment mechanism is reducing the time from approval to launch and market expansion, due to commercialization predictability. In addition, a growing number of biologics are advancing into clinical and late-stage development, and novel and complex modalities such as bispecific antibodies and antibody-drug conjugates (ADCs) are becoming major incremental growth drivers as they demonstrate improved clinical efficacy and gain broader adoption. China's biologics sector is also rapidly internationalizing, with out-licensing activity accelerating in both volume and value, and an increasing number of leading biotech companies moving beyond single-asset licensing toward building independent global clinical development and commercialization capabilities. Meanwhile, the biologics industrial chain is becoming more complete, with specialized services such as contract development and manufacturing organizations (CDMOs) strengthening development and manufacturing efficiency and supporting greater scalability, cost efficiency and regulatory standardization.

Value Chain of the Biologics Industry

The biologics industry value chain is typically structured into three segments: upstream raw material supply and technology service platforms, midstream drug development and manufacturing companies, and downstream clinical application and commercialization.

- ***Upstream.*** The upstream segment of the biologics market comprises suppliers of cell culture media, reagent consumables, expression systems, bioreactor equipment, and preclinical model and tool platforms, which together form the foundational infrastructure supporting R&D and manufacturing efficiency.

- ***Midstream.*** The midstream segment of the biologics market includes companies developing and producing therapeutic biologics, as well as CDMOs providing integrated development and manufacturing services. With the commercial era of biologics, these companies' roles extend beyond discovery to cover chemistry, manufacturing and controls (CMC) process development, good manufacturing practice (GMP) production, and quality control — efficiently and compliantly translating potential candidates into commercial products. CDMOs offer scalable, quality-assured support from cell line development to commercial manufacturing, bridging discovery and production while improving efficiency and controlling costs.

- ***Downstream.*** The downstream segment mainly involves hospitals, physicians, and patients, serving as the interface between biologics manufacturing and real-world clinical use.

Within the midstream segment, CDMOs serve as an important integrator, linking upstream inputs and process technologies with downstream clinical, regulatory, and commercial requirements, thereby enabling more reliable translation of innovative discoveries into clinical outcomes and commercial products.

Evolution of Collaboration Models in the Biologics Industry

As the biologics industry evolves toward greater product complexity and a stronger emphasis on industrialization and commercialization, collaboration models across the value chain have become increasingly specialized and platform-driven. In particular, as manufacturing execution, quality systems and supply assurance become more central to value creation in biologics, the strategic importance of CDMOs has become increasingly pronounced. Against this

backdrop, division of labor across the biologics value chain has continued to deepen, with CDMOs and other specialized platforms supporting biologics developers across development, manufacturing and technology transfer, thereby improving overall efficiency and accelerating time-to-market.

As biologics projects progress from early-stage R&D to late-stage clinical development and commercialization, the need for integrated CMC, scalable GMP capacity, and robust technology transfer has increased. Compared with the in-house approach, CDMOs with established platforms can often deliver faster and more cost-effective solutions. Accordingly, CDMOs have increasingly been positioned as a key infrastructure within the midstream segment, providing integrated services across cell line development, process optimization, clinical manufacturing and commercial-scale production, and thereby reducing development timelines and execution barriers for developers.

In addition, for innovative biologics – particularly complex modalities such as monoclonal antibodies, bispecific antibodies, ADCs, and cell and gene therapies – CDMOs offer advanced capabilities in upstream process development, GMP manufacturing, and quality control that are difficult to replicate in-house. This enables biotech companies to focus resources on R&D and clinical execution, while leveraging external manufacturing expertise to improve efficiency and scalability.

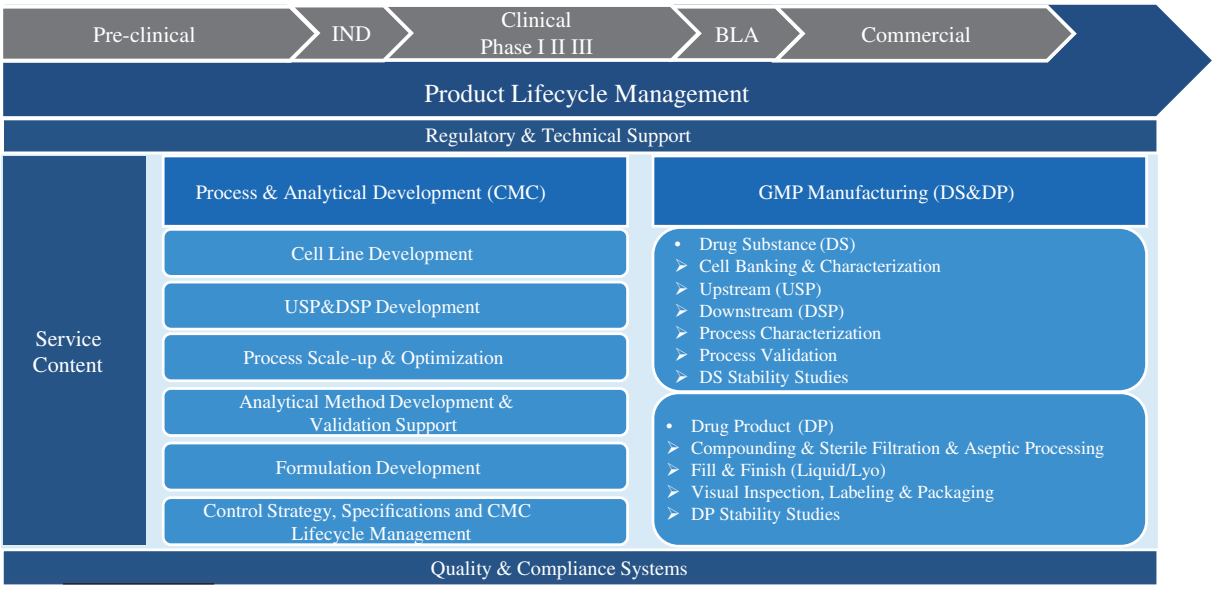
As biologics pipelines expand and product complexity increases, CDMOs have become a critical component of industrialization capabilities by enhancing capacity flexibility, cost efficiency, and regulatory compliance. Overall, the maturation of the CDMO ecosystem is a key enabler of high-quality growth in the biologics market, supporting faster innovation translation from laboratory to large-scale commercialization.

OVERVIEW OF THE BIOLOGICS CDMO INDUSTRY

Overview of Biologics CDMO Services

Within the division of labor across the biologics sector, pharmaceutical companies' core activities typically include disease/target selection, oversight of preclinical and clinical projects, regulatory submission management and commercialization activities, while biologics CDMOs can provide end-to-end, lifecycle services from preclinical to commercialization, including process development and scale-up (with validation and optimization), formulation development, quality studies and analytical/stability testing, clinical manufacturing, and post-launch commercial manufacturing with quality assurance and EHS support. Biologics CDMOs help pharmaceutical companies lower fixed investment and sunk-cost risk, fill capability gaps with specialized expertise and scalable capacity, and accelerate development through efficient workflows, thereby reducing the cost and time of drug development and manufacturing.

The following illustration shows the typical service offering of biologics CDMOs:



Source: Frost & Sullivan

Within the biologics sector, different modalities exhibit substantial differences in molecular complexity, manufacturing pathways, and regulatory requirements, leading to differentiated service demands on CDMO providers. As product development progresses from recombinant proteins and monoclonal antibodies toward more complex formats such as bispecific antibodies and ADCs, CDMO services are evolving from standardized manufacturing support toward integrated solutions encompassing complex process development, advanced facility capabilities, and global regulatory compliance.

- ***Recombinant proteins.*** Core service offerings include cell line construction and screening, upstream fermentation process development and scale-up, downstream purification process optimization, analysis of structural integrity and post-translational modification heterogeneity, as well as formulation development and long-term stability studies. At the commercial-stage, CDMOs are required to provide large-scale manufacturing capacity, validation of process consistency after scale-up, and routine regulatory filing support.

- ***Monoclonal antibodies.*** Key services include high-productivity cell line development and stability assessment, high-density upstream cell culture, multi-step chromatographic purification, control of glycosylation and charge heterogeneity, and validation of sterile filling and container-closure compatibility. During clinical and commercial manufacturing, emphasis is placed on process consistency, batch-to-batch comparability, process performance qualification, continued process verification (CPV), and global regulatory submission support.

- ***Bispecific antibodies.*** CDMO services focus on multi-chain co-expression or controlled chain-pairing process development, separation and removal of mispaired species and assembly-related byproducts, establishment of advanced structural and functional characterization methods, and stability evaluation of complex formulation

systems. At commercial scale, dedicated process platforms and high-selectivity chromatographic systems are required to support complex assembly pathways, together with more stringent process validation and customized regulatory support.

- ***ADCs.*** CDMO services cover antibody production, payload synthesis and supply, conjugation process development, control of drug-to-antibody ratio distribution, high-resolution purification, and removal of free payload and related impurities. Given the involvement of cytotoxic compounds, CDMOs must also provide high-containment manufacturing facilities, occupational safety and environmental control systems, and analytical platforms compliant with both biologic and high-potency small-molecule quality standards. At the commercial-stage, regulatory support must simultaneously meet global requirements for biologics and highly potent drug substances.

Core Value of Biologics CDMO Services

The core value of biologics CDMOs lies in leveraging their technological capabilities, manufacturing infrastructure and regulatory compliant quality systems to provide development and manufacturing support. Building in-house facilities and quality systems requires heavy capital expenditures, lengthy construction and validation timelines, and specialized compliance teams, with high execution risk and opportunity cost. Using established CDMO platforms reduces time and uncertainty, de-risks clinical supply and process consistency, and provides scalable, compliant capacity to support registration and commercial launch.

The stage-specific value of biologics CDMOs is as follows:

- ***IND stage.*** At the early development stage, sponsors rely on CDMO platform processes, analytical capabilities, and characterization systems to improve the probability of successful transition from laboratory-scale research to clinical trial material. Through established upstream and downstream process templates, validated analytical methods, and experienced development teams, CDMOs can shorten development timelines, reduce formulation and process iteration cycles, and improve the robustness of first-in-human material supply.

- ***Clinical development stage.*** During clinical development, the primary value of CDMO engagement lies in risk reduction across scale-up, manufacturing consistency, aseptic processing, and supply chain management. Compliant production facilities, validated manufacturing systems, and established quality management frameworks help mitigate risks associated with batch-to-batch variability, sterility assurance, and multi-site supply continuity. This enables sponsors to maintain stable clinical supply while controlling technical and regulatory uncertainties associated with process transfer and scale expansion.

- ***Registration and commercial supply stage.*** At the registration and commercialization stage, CDMOs provide access to scalable GMP-compliant manufacturing capacity, comprehensive documentation systems, and on-site regulatory inspection support. These capabilities improve the reliability of regulatory submissions and enhance supply assurance for launch and post-approval commercial production. Compared with self-operated manufacturing, outsourcing can also reduce labor, material, equipment, and time-related costs, contributing to lower unit manufacturing costs and improved capital efficiency.

Entry Barriers of the Biologics CDMO Industry

Given the complexity of biologics manufacturing and stringent compliance requirements, barriers to entry in the biologics CDMO industry are shaped by multiple capability dimensions:

- ***Manufacturing capacity and production flexibility.*** The scale of manufacturing capacity, manufacturing line configuration and facility compliance standards directly determine supply reliability and cost efficiency as client projects progress from clinical to commercial manufacturing. The ability to support long-term commercial supply under validated GMP conditions has become a fundamental entry requirement in the biologics CDMO market. Beyond absolute capacity, the ability to flexibly expand or contract production volumes has become an important competitive differentiator. CDMOs are required to adjust production schedules and line utilization in response to demand uncertainty, supporting rapid scale-up during periods of unexpected volume growth while retaining the capability to rebalance capacity when demand falls below expectations. This operational flexibility helps clients maintain supply continuity, avoid excessive inventory accumulation, and optimize resource utilization across development and commercial phases.

- ***Process development, scale-up and technology transfer capabilities.*** Control of process windows, critical quality attributes, and batch-to-batch consistency across development and commercial manufacturing remains a core technical barrier. CDMOs with standardized process development platforms, predictable scale-up strategies, and robust technology transfer systems are better positioned to shorten project timelines, improve development success rates, and limit post-scale-up change costs. These capabilities play a central role in ensuring manufacturing robustness, regulatory acceptability, and long-term product lifecycle stability.

- ***Advanced modality manufacturing capabilities.*** As complex modalities such as bispecific antibodies and ADCs continue to increase, competition is shifting from generic capacity provision toward integrated process and quality control capabilities for high-complexity products. For example, ADC manufacturing requires control of conjugation chemistry (including conjugation sites and drug-to-antibody ratio distributions), scale-up consistency, and specialized containment, isolation and EHS systems for handling highly potent compounds. The ability to operate compliant high-potency facilities and manage modality-specific manufacturing and control requirements has become a key factor distinguishing CDMO capability tiers.

- ***Quality systems and compliant delivery.*** Biologics CDMOs are required to maintain comprehensive quality and compliance systems covering regulatory inspections, data integrity management, deviation and change control, process validation, comparability studies and inspection support. The maturity and robustness of these systems directly affect regulatory acceptance, inspection outcomes and long-term supply reliability. The ability to consistently deliver compliant products under evolving regulatory expectations has therefore become a fundamental barrier to entry and a core determinant of client trust.

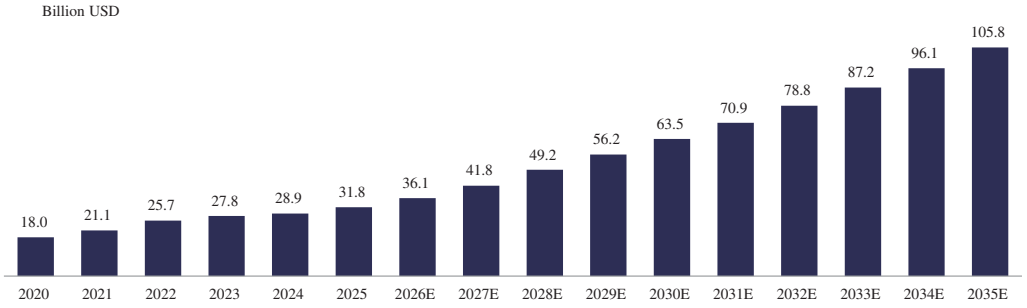
In addition to the above entry barriers, leading CDMOs may further differentiate themselves through a proven delivery track record across multiple stages and modalities, experienced and stable execution teams, resilient and well-controlled supply chains, responsive client service and customization capabilities, as well as multi-regulatory compliance experience and cross-border regulatory support.

Global and China Biologics CDMO Market

The global biologics CDMO market expanded from US$18.0 billion in 2020 to US$31.8 billion in 2025, representing a CAGR of 12.1% over the period. Looking ahead, the market is projected to reach US$63.5 billion by 2030, implying a CAGR of 14.8% from 2025 to 2030, and further grow to US$105.8 billion by 2035, corresponding to a CAGR of 10.8% from 2030 to 2035. The chart below provides details of the market size of global biologics CDMO market.

Global Biologics CDMO Market Size and Forecast, 2020—2035E

Period	CAGR
2020–2025	12.1%
2025–2030E	14.8%
2030E–2035E	10.8%

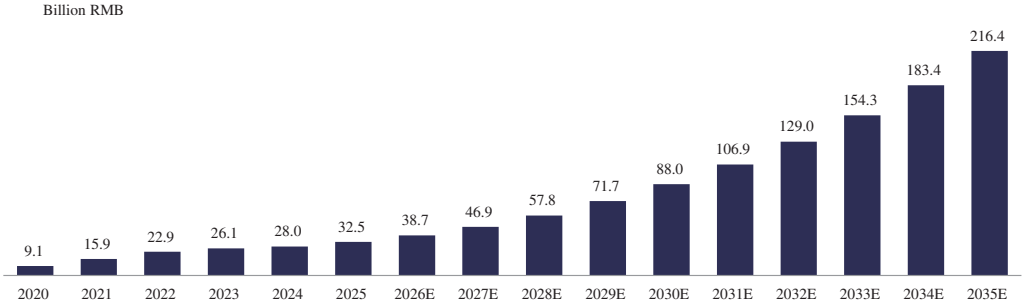


Source: Frost & Sullivan

In China, the biologics CDMO market expanded from RMB9.1 billion in 2020 to RMB32.5 billion in 2025, representing a CAGR of 28.9% over the period. Looking ahead, the market is projected to reach RMB88.0 billion by 2030, implying a CAGR of 22.1% from 2025 to 2030, and further grow to RMB216.4 billion by 2035, corresponding to a CAGR of 19.7% from 2030 to 2035. The chart below provides details of the market size of biologics CDMO market in China.

China Biologics CDMO Market Size and Forecast, 2020—2035E

Period	CAGR
2020–2025	28.9%
2025–2030E	22.1%
2030E–2035E	19.7%



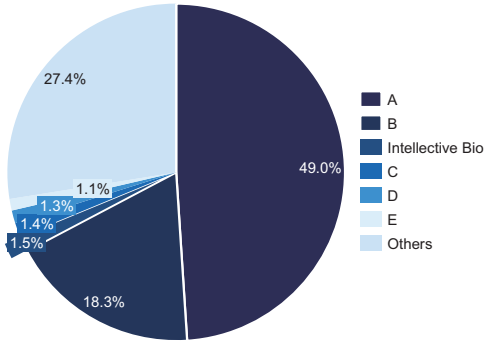
Source: Frost & Sullivan

Competitive Landscape of the Biologics CDMO Industry in China

The biologics CDMO industry in China is highly competitive and concentrated. There are at least 150 biologics CDMO companies worldwide, among which at least 25 are based in China. In 2025, the China biologics CDMO market reached a total of RMB32.5 billion. Among domestic biologics CDMOs primarily focused on antibody drugs, we ranked third in China's biologics CDMO market in terms of revenue in 2025. In addition, from a manufacturing-end service capability perspective, as of the Latest Practicable Date, we stood as one of only two biologics CDMO companies in China that are providing commercial supply for three or more approved products.

The following pie chart shows the revenue and ranking of top domestic players in China's biologics CDMO market that primarily focused on antibody drugs.

Competitive Landscape of China Biologics CDMO Market, 2025



Company	Revenue (Billion RMB)	Market Share
A	15.9	49.0%
B	5.9	18.3%
Intellective Bio	**0.5**	**1.5%**
C	0.4	1.4%
D	0.4	1.3%
E	0.4	1.1%
Others	8.9	27.4%

Notes:

(1) Only domestic CDMO companies whose core business (≥50%) focuses on contract development and manufacturing services for antibody drugs are included.

(2) To avoid double counting, where a CDMO platform or subsidiary is separately included in this ranking, its revenue has been excluded from the consolidated revenue of its parent company or controlling listed group.

Source: Frost & Sullivan

The following table sets forth a detailed comparison of financial and operational metrics of major players in biologics CDMO market in China in 2025:

Company	Background	Main Business Area	Revenue Generated from Biologics CDMO Services in 2025 (Billion RMB)	2025 Market Share	Venue of the Exchange
A	Founded in 2010, A is a leading global contract research, development, and manufacturing organization (CRDMO) providing integrated end-to-end biologics discovery, development, and manufacturing services. Through its open-access technology platform, the company supports partners from concept to commercial production, accelerating development timelines and improving efficiency. It operates multiple R&D and manufacturing facilities across China, the United States, Ireland, and Germany.	A provides integrated end-to-end CRDMO services covering biologics discovery, development, CMC, and commercial GMP manufacturing. Its core focus is on monoclonal antibodies, bispecific antibodies, antibody–drug conjugates (ADCs), fusion proteins and other biologics.	15.9	49.0%	The Stock Exchange
B	Founded in 2021, B is a leading CRDMO focused on the global ADC and broader bioconjugate market and is a pioneering CRDMO offering integrated, end-to-end services. Services are provided from proximately located, state-of-the-art laboratories and manufacturing facilities, allowing for a significant reduction in development timelines and costs.	B is a bioconjugate-focused CRDMO providing integrated services from discovery and process development to GMP manufacturing. Its capabilities span the ADC value chain, including antibody intermediates, linker and payload development and manufacturing, as well as conjugation and drug product fill-finish services.	5.9	18.3%	The Stock Exchange
Intellective Bio	Intellective Bio, founded in 2018, is a leading full-lifecycle CDMO company dedicated to large-molecule biologics. Intellective Bio offers integrated capabilities that span cell line development, process development, analytical development, and clinical to commercial-scale GMP manufacturing, empowering global biotechnology and pharmaceutical companies worldwide to advance their molecules from discovery through commercialization with a single trusted partner.	Intellective Bio provides end-to-end services for large-molecule biologics, including monoclonal antibodies, bispecific antibodies and polyclonal antibodies, bioconjugates and recombinant proteins, covering process development, analytical testing, clinical and commercial GMP manufacturing, and regulatory support.	0.5	1.5%	\
C	C, founded in 2013, is a professional CDMO serving global biopharmaceutical partners. Founded as a high-tech enterprise, C has established R&D and manufacturing sites in China and the United States. The company focuses on accelerating biologics development from early research to commercial production.	C provides end-to-end CDMO services for monoclonal antibodies, bispecific antibodies, fusion proteins, ADCs, recombinant proteins, and vaccines. Its capabilities cover cell line development, process and analytical method development, quality research, clinical and commercial GMP manufacturing and regulatory support.	0.4	1.4%	\
D	Founded in 2017, D is an independent CDMO focused exclusively on providing R&D and manufacturing services for biologics. The company supports global biopharmaceutical partners during clinical development and commercial production, leveraging industry experience and technical expertise to deliver tailored CMC solutions.	D provides end-to-end CDMO services for monoclonal antibodies, bispecific antibodies, fusion proteins, ADCs, etc. Its capabilities cover cell line development, process and analytical method development, pilot-scale production, clinical and commercial GMP manufacturing, and regulatory support for global submissions.	0.4	1.3%	\
E	Founded in 2017, E is an independent CDMO dedicated to providing biologics development and manufacturing services. Leveraging its proprietary cell line and process development platforms as well as extensive CMC expertise, E supports global biopharmaceutical partners across clinical development and commercial manufacturing, offering integrated end-to-end CMC solutions from DNA to commercial fill-finish.	E provides end-to-end CDMO services for large-molecule biologics, covering various modalities including monoclonal antibodies, bispecific antibodies, fusion proteins and ADCs. Its services cover drug and process development, manufacturing, quality control, stability studies, and global CMC regulatory support under GMP standards.	0.4	1.1%	\

Note: To avoid double counting, where a CDMO platform or subsidiary is separately included in this ranking, its revenue has been excluded from the consolidated revenue of its parent company or controlling listed group.

Source: Frost & Sullivan

In addition to revenue-based rankings, manufacturing capacity and scalable production infrastructure are critical competitive differentiators in the biologics CDMO industry, as they directly determine a CDMO's ability to support late-stage development, ensure stable commercial supply and respond efficiently to customers' evolving demand. As illustrated by the table below, as of the Latest Practicable Date, we ranked third in terms of manufacturing capacity among China-based biologics CDMOs, with a total capacity of 113,400 L.

Rank	Company	Modality					Reactor Type		Manufacturing Capacity	Maximum Bioreactor Size
		Unconjugated Antibody Drugs	ADC	Non-Antibody Protein Therapeutics	Peptides	CGT	Single-use	Stainless Steel		
1	A	√	√	√			√		255,700L	• 5,000L (SUB)
2	F	√	√	√		√	√	√	140,000L	• 2,000L (SUB) • 20,000L (SSB)
3	Intellective Bio	√	√	√	√		√	√	113,400L	• 2,000L (SUB) • 6,000L (SSB)
4	G	√	√	√	√	√	√	√	68,400L	• 2,000L (SUB) • 30,000L (SSB)
5	H	√	√	√		√	√	√	36,200L	• 2,000L (SUB) • 1,000L (SSB)

Note: Capacity reflects mammalian cell bioreactors only.

Source: Frost & Sullivan

Furthermore, from a manufacturing perspective, single-facility capacity is particularly important because it reflects the scale, integration and operational efficiency of a CDMO's production platform within an integrated GMP manufacturing facility. A higher single-facility capacity may enable more streamlined execution, facilitate flexible batch scheduling and capacity allocation, and support more consistent quality management and supply continuity.

In addition, for late-stage and commercial biologics projects, a larger integrated facility may provide greater potential for co-line design and flexible production scheduling under a robust GMP quality system. Compared with transferring a product across different sites or to another CDMO, maintaining production within the same facility may also reduce the technical transfer burden, regulatory complexity and additional validation requirements associated with manufacturing changes, thereby helping customers lower transition costs, shorten timelines and improve overall development-to-commercialization efficiency, while strengthening customer stickiness and enhancing a CDMO's ability to undertake development and manufacturing programs across various stages.

As illustrated in the table below, as of the Latest Practicable Date, we ranked first in China in terms of single-facility manufacturing capacity among China-based biologics CDMOs, with a total installed capacity of 85,300 L at our Changshu, Suzhou facility.

Rank	Company	Modality					Reactor Type		Single-facility Manufacturing Capacity	Maximum Bioreactor Size	Location
		Unconjugated Antibody Drugs	ADC	Non-Antibody Protein Therapeutics	Peptides	CGT	Single-use	Stainless Steel			
1	**Intellective Bio**	**√**	**√**	**√**	**√**		**√**	**√**	**85,300L**	• **6,000L (SSB)**	• **Suzhou**
2	F	√	√	√		√		√	80,000L	• 20,000L (SSB)	• Hangzhou
3	A	√	√	√			√		64,000L	• 4,000L (SUB)	• Wuxi
4	G	√	√	√	√	√	√	√	30,000L	• 30,000L (SSB)	• Shanghai
5	H	√	√	√		√	√		24,000L	• 2,000L (SUB)	• Beijing

Note: Capacity reflects mammalian cell bioreactors only.

Source: Frost & Sullivan

Growth Drivers of the Biologics CDMO Market

The following key drivers mainly contribute to the growth of the biologics CDMO market:

- ***Refinement of the regulatory environment.*** In recent years, the regulatory system governing the pharmaceutical industry has increasingly emphasized specialization and full life-cycle management. In China, in particular, the regulatory foundation for CDMO services has been increasingly strengthened by overarching legal framework and supporting regulations, providing clearer institutional arrangements for MAH-authorized contract manufacturing, allocation of quality responsibilities, regulatory inspections, and post-marketing supervision. These reforms have further enlarged the addressable demand for CDMO services.

- ***Growing scale and increasing complexity of the biologics market.*** As clinical adoption and market penetration of innovative biologics continue to rise, the demand for late-stage development, commercial supply, process development, quality control, and GMP-compliant manufacturing has grown. Increasing molecular complexity and scaling challenges increase the value proposition of CDMOs, with many clients integrating CDMOs' platform capabilities early to reduce risk and improve development certainty. In addition, the rapid expansion of the biosimilars market, driven by originator patent expirations and cost-containment pressures, is also creating a scalable, commercially attractive segment within biologics. By leveraging mature platforms, scalable GMP capacity, and validated quality systems, CDMOs help biosimilar developers shorten timelines, lower technical risk, and reduce costs, making biosimilars a sustainable driver of long-term outsourcing demand.

- ***Structural demand driven by asset-light strategies.*** The shift toward asset-light manufacturing models is becoming a structural trend in the pharmaceutical industry, driving sustained demand for CDMO services. By leveraging professional CDMO platforms, pharmaceutical companies gain access to ready-to-use GMP capacity, mature quality systems, and scalable production infrastructure without committing to long-term fixed assets. This industry-wide transition from in-house manufacturing toward outsourced production is accelerating the formation of a CDMO-centered manufacturing ecosystem and represents a key structural driver of long-term growth in the biologics CDMO market.

- ***Global pharmaceutical supply chain rebalancing creating external opportunities.*** Amid the ongoing relocation of the global pharmaceutical manufacturing value chain toward Asia and other emerging markets, China has become one of the preferred destinations for outsourced biopharmaceutical production. Supported by a well-established upstream and downstream supply chain, expanding manufacturing capacity, and a large pool of technically trained labor, Chinese CDMO providers offer competitive advantages in cost efficiency, capacity availability, and operational scalability.

Future Trends of the Biologics CDMO Market

The following is a summary of future trends of the biologics CDMO market:

- ***Toward more integrated services and long-term collaboration.*** Beyond providing clinical material supply and commercial manufacturing, biologics CDMOs will place greater emphasis on integrating process development, analytical methods and quality studies, GMP manufacturing, validation and batch release, and regulatory submission into a connected delivery chain from early-stage CMC to commercial supply. One-stop service providers are able to apply unified quality systems, methodologies and data chains across different stages, establish longer-term partnerships with clients, and are more likely to achieve market share concentration.

- ***Balancing scalable and flexible capacity configurations.*** An optimal capacity strategy combines both scalability and flexibility to support different scale-up pathways from clinical development to commercial manufacturing. Single-use systems enable parallel reactor scale-up, multi-line operations and disposable downstream processes, covering early-stage development through commercial ramp-up while supporting rapid product changeovers and shorter construction and validation cycles. In contrast, stainless steel systems offer advantages in ultra-large-scale production, stable and consistent operation and unit cost reduction. Leading CDMO companies are increasingly adopting hybrid and dynamically matched capacity configurations based on batch size, process characteristics and cost objectives.

- ***Deepening specialization and higher technical intensity.*** With increasing development activity in emerging therapies and rising process complexity, CDMOs will continue to strengthen their capabilities in biologics and related complex product formats. The development focus is expected to shift from capacity construction toward capacity supported by process development and engineering capabilities, with greater emphasis on the ability to stabilize complex systems, enable scalable manufacturing, and deliver compliant products. Technically advanced CDMOs are therefore likely to capture a larger share of orders in the ongoing expansion of the biologics market.

- ***Rising regulatory thresholds and increasing value of proven commercial track records.*** Regulatory developments are expected to place increasing emphasis not only on product quality and compliance, but also on demonstrated commercial manufacturing experience in the relevant dosage form. In January 2026, for instance, the National Medical Products Administration (NMPA) issued the Announcement on Strengthening the Supervision of Contract Drug Manufacturing (《關於加強藥品受託生產監督管理工作的公告》), which provides that, for sterile drug contract manufacturing, at least one party, whether the MAH or the contract manufacturer, must generally have no less than three years of commercial production experience in the same dosage form, subject to limited exceptions. Against this backdrop, CDMO providers completing their initial three-year commercial manufacturing cycle in or around 2027 are expected to be among the earlier beneficiaries of this trend, as market access increasingly favors service providers with established commercial track records, mature quality systems and stronger regulatory credibility.

- ***Strengthening supply chain resilience and cost control capabilities.*** Biopharmaceutical manufacturing is highly dependent on critical raw materials, single-use consumables, and key equipment, making delivery reliability and cost volatility important factors affecting clients' development timelines, supply continuity, and downstream gross margins. Going forward, CDMO providers are expected to place greater emphasis on strategic sourcing and inventory buffering of critical materials, the development of localized and diversified supply chains, and the gradual substitution of imported inputs with qualified domestic alternatives. In parallel, process optimization, scale-up efficiency and capacity utilization will be increasingly leveraged to reduce unit manufacturing costs. These measures are expected to enhance supply certainty, mitigate external supply risks, and improve long-term pricing competitiveness.

- ***Automation and intelligent manufacturing upgrades.*** Leading biologics CDMO companies are systematically enhancing their engineering capabilities, including higher levels of automation and digitalization, improved control of complex processes, and greater flexibility across different production scales. Standardization of manufacturing line design and operating procedures is being promoted to enable line replicability and backup capacity, strengthening manufacturing continuity and delivery reliability. CDMOs with advanced manufacturing capabilities are expected to demonstrate advantages in batch consistency, release efficiency, parallel project execution, commercial scale-up, and capacity allocation under fluctuating demand.

In addition to the above, the biologics CDMO market is expected to see further manufacturing site consolidation, and the continued build-out of globally compliant capabilities to support multi-jurisdictional development and commercial supply. CDMOs that are able to build and execute against these capabilities are expected to be better positioned to compete in the evolving market landscape.

Price Trends of Raw Materials

The raw materials used by biologics CDMOs primarily include cell culture media and supplements, buffer and process chemicals, chromatography resins, single-use components and consumables, filtration and separation materials, and primary packaging components, together with other materials used for cell banking and quality control, depending on the specific process and product type.

Similarly, our Company's key raw materials and consumables typically include cell culture media and feeds, chromatography resins, filtration membranes, single-use bioprocess components, buffer/process chemicals, and formulation excipients and primary packaging materials, with ADC projects additionally requiring linker/payload and related reagents. The prices of such raw materials have remained relatively stable overall in recent years, typically reflecting modest inflation.

SOURCE OF INFORMATION

Our Company has commissioned Frost & Sullivan, an independent market research company, to analyze the biologics CDMO market and compile a report. The information disclosed in this document regarding Frost & Sullivan is extracted from the Frost & Sullivan Report. We have agreed to pay Frost & Sullivan a fee of RMB500,000 for the preparation of the Frost & Sullivan Report. The payment of this fee is not contingent upon our successful **[REDACTED]** or the outcome of the report.

The Frost & Sullivan Report is based on both primary and secondary research obtained from various sources. Primary research includes interviews with key industry participants in the biologics CDMO market and other experts relevant to our business. Secondary research includes a review of company reports, independent research reports, and data from Frost & Sullivan's proprietary research database as well as government databases.

In compiling and preparing this report, Frost & Sullivan has made the following assumptions:

- During the forecast period, the social, economic, and political environments of the PRC, and other major global markets will remain stable, ensuring the continued and steady development of the biologics CDMO industry;
- Government policies on the biologics CDMO market will not undergo significant changes.

Frost & Sullivan believes that the fundamental assumptions used in preparing this report, including those for future projections, are factual, accurate, and not misleading. Frost & Sullivan has conducted an independent analysis of the data; however, the accuracy of its review conclusions largely depends on the accuracy of the collected information.