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Insight into Development and Smart Transformation of Biopharmaceutical Industry in China



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Table of Contents

Overview 5

1 Definition and classification of biopharmaceutical industry 6

2 Current status of biopharmaceutical industry in China and analysis of market size 7

2.1 Prediction of future development trend of biopharmaceutical industry 7

2.1.1 Accelerated the cluster development of biopharmaceutical industry 7

2.1.2 Increasingly prominent digitalization trend 7

2.1.3 Gradual move towards the era of original drugs 9

2.2 Market size of biopharmaceutical industry and analysis of market segment 9

2.2.1 Biopharmaceutical market size and market segment dynamics 9

2.2.2 Analysis on key biopharmaceutical market 10

3 Analysis of biopharmaceutical industry chain 14

3.1 Overview of biopharmaceutical industry chain 14

3.1.1 Upstream of industry chain 14

3.1.2 Midstream of industry chain 14

3.1.3 Downstream of industry chain 16

3.2 Dynamic and trend analysis by CDMO 16

3.3 Summary of relevant developments in the biopharmaceutical industry 18

4 Current situation of biopharmaceutical equipment market in China and trend analysis 20

4.1 Analysis of biopharmaceutical core equipment market 20

4.1.1 Market status 20

4.1.2 Future development trend 20

4.2 Market analysis of general equipment for biopharmaceuticals 23

4.2.1 Pump market analysis 23

4.2.2 Valve market analysis 25

4.2.3 Introduction to typical companies 26

5 Biopharmaceutical production line design and integration and intelligent transformation in China 32

5.1 Current situation of intelligent transformation market 32

5.2 Intelligent manufacturing transformation program for Chinese biopharmaceutical plants 33

5.2.1 Content of intelligent manufacturing transformation program 33
5.2.2 Problems and challenges for intelligent manufacturing transformation in biopharmaceutical enterprises 35
5.3 Targets for intelligent transformation of biopharmaceutical enterprises 37
5.4 Trend and direction for intelligent transformation 38

Table of Figures

Figure 1 Forecast of biopharmaceutical market size in China 10
Figure 2 Global market size of CGT industry 12
Figure 3 Market size of CGT industry in China 13
Figure 4 Process flow from drug R&D to marketing 15
Figure 5 Industrial production process flow of biopharmaceuticals 16
Figure 6 Size of bioreactor market in China from 2017 to 2022 (100 million yuan) 21

Overview

This article makes an analysis and insight into the development and smart transformation of biopharmaceutical industry in China from the perspectives of industry status, industry chain, pharmaceutical equipment market, production line design and integration, and smart transformation. It focuses on the development status of hot markets such as antibody-drug conjugates (ADC) and cell & gene therapy (CGT) in terms of the industry status. In the industry chain analysis section, this article depicts the current status of biopharmaceutical industry chain and focuses on the annual development trend of CDMO industry market in recent years. As for the pharmaceutical equipment market, it focuses on the bioreactor market, the mainstream of biopharmaceutical industry, and briefly summarizes the current status of general biopharmaceutical equipment, and provides macro-market information for industrial equipment practitioners. In addition, the article continues to focus on the smart transformation of biopharmaceutical industry, presenting readers with the current status and evolving trend of the smart transformation market.

1 Definition and classification of biopharmaceutical industry

Biopharmaceuticals are preventive, therapeutic and diagnostic products manufactured from organisms and their components by using the research results in microbiology, biology, medicine and biochemistry. The treatment principle lies in stimulating the body's immune system and producing immune substances, such as humoral immunity and cellular immunity, so as to achieve treatment effects. Because the raw materials are mostly natural biological materials with high biological safety and relatively small side effects, biopharmaceuticals are of great significance to human life and health and are regarded as one of the industries with great development prospects in the 21st century.

There are many kinds of biopharmaceuticals, which can be divided into monoclonal antibodies, recombinant proteins, vaccines and cell and gene therapy drugs according to the product type, and can be used to treat tumors, AIDS, cardiovascular and cerebrovascular diseases, hepatitis, autoimmune diseases, metabolism-related diseases and so on. Due to the complex structures, the high technical requirements for R&D, production and purification processes, the biopharmaceutical market starts late but has great development potential. China's biopharmeceutical industry experienced since its inception in the 1980s and has entered an explosive growth stage in recent years.

2 Current status of biopharmaceutical industry in China and analysis of market size

2.1 Prediction of future development trend of biopharmaceutical industry

The biopharmaceutical industry is entering a new development stage, with its main development trend reflected in the following three aspects: accelerated industrial clustering, a significant stronger trend of digitalization, and a gradual move towards the era of original drugs.

2.1.1 Accelerated the cluster development of biopharmaceutical industry

In China, the construction of biomedical industrial parks mainly relies on high-tech zones. In this regard, China started about 30 years later compared with foreign countries, but a number of industry clusters have been formed sine the 1990s, including the Yangtze River Delta region, the Pearl River Delta region, the Bohai Rim region and the Northeast region. In addition, Henan and Hubei in the central region, and Sichuan and Chongqing in the western region have also shown a solid industrial foundation. China is gradually forming more perfect biomedical industry chains and industry clusters. In the future, driven by policies, the cluster development of biomedical industry will be further accelerated, and the advantages of clustering will be used to attract professionals and promote the deep integration of capitals and the biopharmaceutical industry, thus promoting the rapid development of the industry.

2.1.2 Increasingly prominent digitalization trend

The digital development of the biopharmaceutical industry is a major trend in the future. With breakthroughs in the artificial intelligence technology, the importance of data and intelligent technology in the development of biopharmaceutical industry has become increasingly prominent. Due to the special requirements of the biopharmaceutical industry for safety and quality, the industry in the primary stage of digitalization as a whole, a large number of pharmaceutical companies are still in the state of single-

point information coverage, with a low degree of integration between systems. Insiders point out that the pharmaceutical industry is under strong regulation with strict regulatory requirements, so they are cautious about the construction of digitalization and informationization. However, in the long run, the inherent demand for digitalization in the biopharmaceutical industry will continue to increase, and the requirements of related companies for refinement and automation degree of overall production will be increasingly higher. In particular, the promotion of industrial Internet will promote the innovation and transformation of the biopharmaceutical industry.

From the perspective of regulatory agencies, since 2015, the China Food and Drug Administration (CFDA, currently NMPA) and its affiliated institutions have successively built and put into use corresponding drug supervision data centers. The future drug supervision system will become an important means of drug supervision, to effectively guarantee the medication safety of patients. From the perspective of pharmaceutical manufacturers, digitalization can be applied to R&D, production and marketing. With digital R&D, the drug R&D model can be innovated, artificial intelligence and other technologies can be used in all aspects of new drug R&D to effectively reduce the risk of R&D failure and R&D cost, shorten the R&D cycle. Digital production can guarantee the stability of drug quality. With the advent of Industry 4.0 era, driven by automation, Internet of Things and information technology together, the pharmaceutical industry is also experiencing intelligent upgrade.

Digital marketing helps to realize multi-channel marketing. Digital marketing is designed to expand brand awareness, establish reputation, change consumer perception and increase drug sales under the premise of compliance. Pharmaceutical companies mostly adopt a combination of online and offline marketing. As the core channel of online drug sales, Internet healthcare plays a role of online portal for pharmaceutical companies in digital marketing, providing more direct and accurate patient education, realizing the transformation of drug consumption and providing pharmaceutical companies with a broader space for growth.

2.1.3 Gradual move towards the era of original drugs

The development of biopharmaceutical

industry in China can be divided into three stages: the first stage is the production of biosimilars, which have a price advantage due to elimination of huge R&D expenses and are able to meet the most fundamental medical needs. Since the implementation of a series of major reforms by the CFDA in 2015, the biopharmaceutical industry in China has rapidly stepped into the second stage, the fast-following stage, including the R&D of drugs such as Me-too, Me-better and Fast-follower. Driven by the reform of the listing system for biopharmaceutical companies in Hong Kong stocks in 2018 and the establishment of China's science and technology innovation board, the biopharmaceutical industry has ushered in rapid development. The year 2021 was another important turning point of the biopharmaceutical industry in China, which witnessed China's rapid development of innovative drugs, continual improvement of the independent R&D capabilities of local pharmaceutical companies, and new high achievement in the number of domestically marketed new drugs. In the future, the First-in-class new drug R&D companies with originator R&D capabilities and global intellectual property rights will become the leaders of the biopharmaceutical industry in China.

2.2 Market size of biopharmaceutical industry and analysis of market segment

2.2.1 Biopharmaceutical market size and market segment dynamics

Despite being in its initial stage of development, the biopharmaceutical market in China has strong growth potential. With the improvement of residents' affordability, the increase of patient population and the expansion of medical insurance coverage in the future, it is estimated that the biopharmaceutical market size in China will further expand to 957.7 billion yuan by 2026, with a compound annual growth rate of 14.5%, as shown in Figure 1.

Segmented by drug type, the main products in Chinese biopharmaceutical market include blood products, recombinant proteins, monoclonal antibodies, vaccines, immune serum, in

vitro immune reagents, and biological diagnostic reagents. Among them, blood products, recombinant proteins, monoclonal antibodies and vaccines occupy a large market share in the biopharmaceutical field, with the market size of their products accounting for more than 60% of the total market size in the biopharmaceutical field in 2021. It is noteworthy that vaccine is the fastest growing product in the biopharmaceutical industry in 2021, followed by monoclonal antibodies. The blood products and recombinant proteins feature a relatively mature market, stable market share of stock drugs, and relatively clear competition pattern.

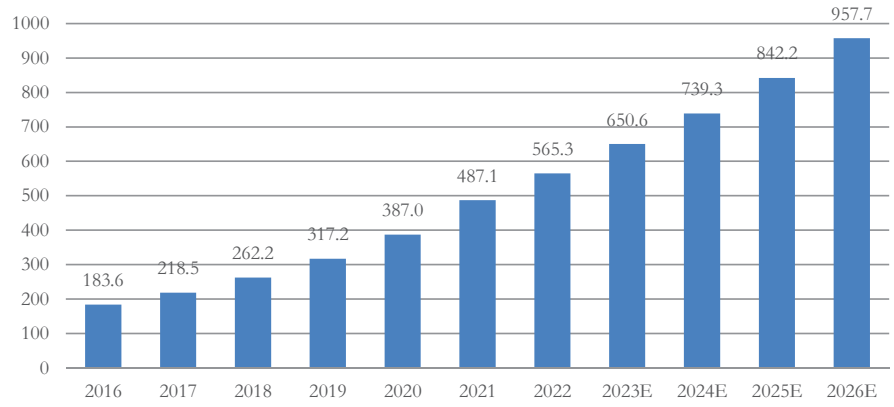
2.2.2 Analysis on key biopharmaceutical market

Antibody-drug conjugate (ADC) drugs

Antibody-drug conjugate (ADC) is a novel biological drug, which is formed by covalently coupling a highly selective antibody with a potent cytotoxic drug through a coupler. With the continuous progress of technology, the toxicity of ADC drugs is gradually controlled and the safety is gradually improved. In 2021, the global ADC drug market was about USD 5.25 billion (equivalent to about 36.732 billion yuan). The United States is the region with the fastest development and the largest market share of ADC drugs in the world, accounting for 37%; Europe, by virtue of

Figure 1

Forecast of biopharmaceutical market size in China



Biopharmaceutical market size and forecast in China (one billion yuan)

Data source: public dataset, M2 Consulting research & analysis.

its high R&D level, accounts for 29% of the global market share. In contrast, China starts late in ADC drugs, but the market still has a broad development space. In 2021, the market size of ADC drugs in China was about 2.204 billion yuan, accounting for about 6% of the global market share.

In recent years, ADC drugs have set off a R&D boom in the world and become the key layout field for many new drug R&D companies. At present, the main R&D mode of ADC drugs in China is joint R&D by local and overseas pharmaceutical companies, and the overall R&D level is still in the primary stage. China's ADC pharmaceutical industry has appeared obvious piling up phenomenon in the layout of targets and indications, with remarkable competition. In terms of indications, ADC drugs are mainly indicated for the treatment of tumor, and about 95.2% of pipeline layout indications being tumors, followed by autoimmune diseases. In terms of targets, HER2 targets account for the highest proportion, about 38.4%, with about 60 product items; EGFR targets account for about 11.9%, and other targets account for less than 10%. Homogeneous competition among many pharmaceutical companies may lead to the risk of wasting resources.

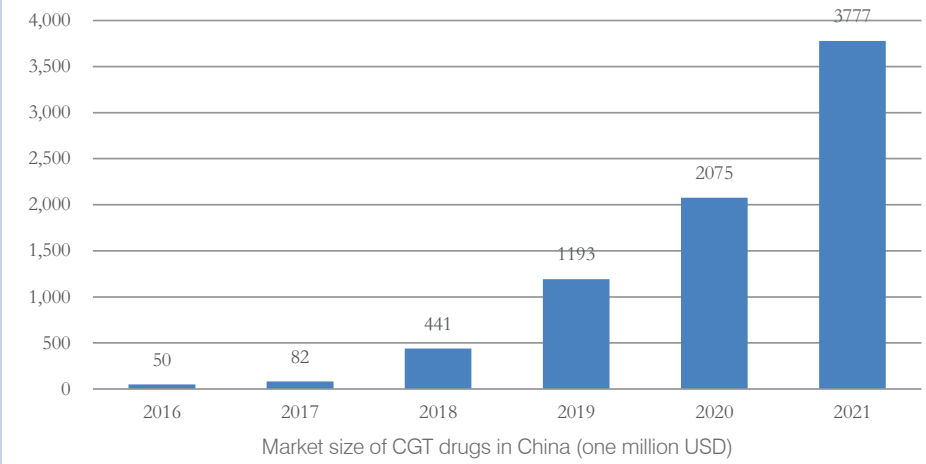
The R&D of ADC drugs have shown five major trends: the use of ADCs to target mutant protein, the use of dual-epitope or dual-target ADCs, the use of dual-payload ADCs with two different cytotoxic agents as payloads to reduce resistance, peptide-drug conjugate (PDC) and the development of non-internalized ADC.

Cell and gene therapy (CGT) drugs

Cell and gene therapy (CGT) industry is a new field which relies on cell and gene technology to provide fundamental treatment regimens for refractory diseases including tumors. This therapy is better than the traditional therapy and is an important force in medical innovation. Since 2016, the global market size of CGT has grown rapidly. From 2016 to 2020, the market size of CGT industry increased from USD 50 million to USD 2.08 billion, with a compound annual growth rate of 153%, as shown in Figure 2, which is mainly attributed to the successful marketing of CGT drugs after 2015, the growing demand for treatment, increasingly active investment and financing activities, and rising enthusiasm for CGT drug R&D around the world. The global market size of the CGT industry is forecast to continue to maintain a rapid growth trend and reach USD 30.539 billion by 2025.

Figure 2

Global market size of CGT industry



Data source: public dataset, M2 Consulting research & analysis.

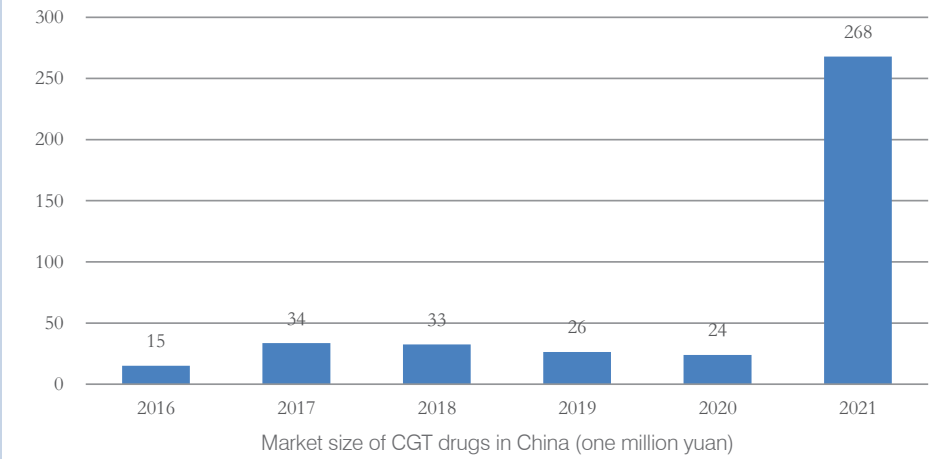
Despite the late start of CGT industry in China, the R&D enthusiasm is high. Since 2015, relevant support and regulatory policies have been intensively introduced, effectively promoting the development of the industry. With the favorable policies and the surge in market demand, the investment in R&D of CGT drugs has increased rapidly, and the R&D progress of new drugs ranks among the top in the world. Despite early prudent regulatory approval due to safety and efficacy problems caused by immature technology in the early stage, China's CGT industry is growing strongly with the increased R&D investment and the hot R&D pipeline. China is expected to usher in an explosive growth in CGT drug marketing in 2025. According to Frost & Sullivan, the market size of the CGT industry in China grew from 15 million yuan to 24 million yuan from 2016 to 2020, as shown in Figure 3.

The treatment field of CGT drugs is gradually expanding. At present, CGT mainly focuses on the treatment of rare diseases and tumors, and is expected to cover more diseases in the future. Gene therapy has many potential targets. The therapy in the future will no longer be limited to single gene defect, but realize the expression of multiple exogenous genes by constructing efficient transfer, which is of great significance to the treatment of multi-gene defective diseases.

The selection of CGT drug vectors tends to be diversified, with adeno-associated viral vectors and lentiviral vectors being

Figure3

Market size of CGT industry in China



Data source: public dataset, M2 Consulting research & analysis.

the most widely used, while oncolytic viruses such as herpes virus, poxvirus and adenovirus have become a hotspot for research. With the deepening of R&D, the type of virus vectors will be enriched, aiming at improving the efficiency, safety and stability of introduction. Meanwhile, non-viral vectors, such as naked DNA, liposomes and nanocarriers, have also become an important R&D direction due to their low cost, simple preparation, easy mass production and high safety.

The R&D cost of CGT drugs is gradually decreasing, and the existing products such as CAR-T cell therapy have demonstrated great market potential. With the optimization of viral vectors, the maturity of production technologies and the continuous progress of CAR-T cell technology, the cost of CGT treatment will be further reduced, benefiting more patients.

3 Analysis of biopharmaceutical industry chain

3.1 Overview of biopharmaceutical industry chain

3.1.1 Upstream of industry chain

The upstream of the biopharmaceutical industry chain mainly consists of raw materials and excipients, pharmaceutical equipment and consumables, and design and integration of production line. Raw materials include starting raw materials, biological raw materials and chemical raw materials, which are used for the production of biological products. Excipients refer to auxiliary materials in the formula of biological products. Pharmaceutical equipment include bioreactor, liquid preparation system, chromatography system, membrane filtration system, filling system, packaging equipment and lamp inspection machine, with the bioreactors as the core equipment.

While culture media, chromatographic packing/media, disposable bioreactors, microcarriers and filter membranes are key consumables. Cell culture medium is the core raw material of biopharmaceutical production, which simulates the nutritional environment of cell production in vivo and provides the material basis for cell nutrition and growth and proliferation. It is mainly classified into serum culture medium and serum-free cell culture medium.

The design and integration of production line is also an important part of the upstream industry chain, which affects the rationality of production and technology. The design process includes two stages: process package design and engineering design. The quality of process design directly affects production rationality, construction cost, drug production quality, product cost and labor intensity. The integration of production line is to combine multiple single devices into a complete production line in order to improve the efficiency, stability and reliability of production and bring more value to customers.

3.1.2 Midstream of industry chain

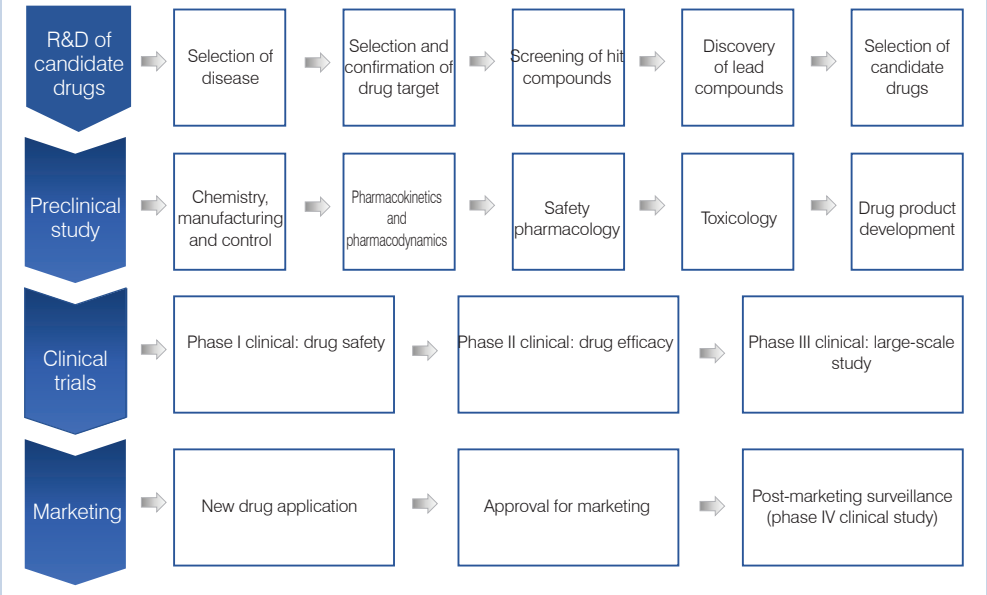
The R&D and production of biopharmaceuticals is the midstream of the industry chain, in which raw materials, pharmaceutical equipment and

consumables provided by the upstream are used to develop and produce biopharmaceuticals through biotechnology such as genetic engineering and enzyme engineering. From R&D to marketing, a new drug needs to go through four stages: candidate drug R&D, preclinical study, clinical trials (Phase I, II and III), and new drug application, marketing approval and post-marketing surveillance (phase IV clinical trial), with specific process flow as shown in Figure 4.

The production process flow of biopharmaceuticals is divided into two parts: drug substance (DS) preparation and drug product (DP) preparation, and drug substance preparation includes upstream fermentation and downstream

Figure 4

Process flow from drug R&D to marketing

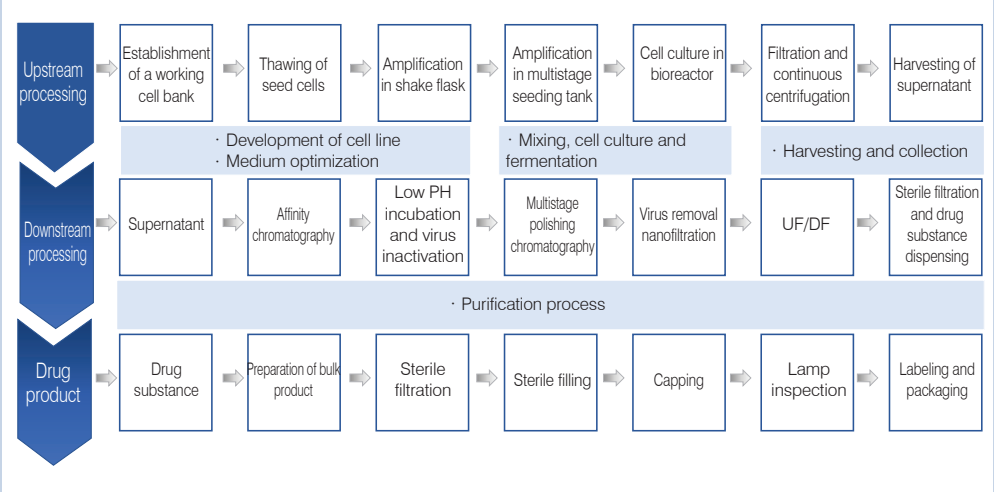


Data source: public dataset, M2 Consulting research & analysis.

purification. The specific process flow is shown in Figure 5. Upstream fermentation involves the thawing, culture, amplification and reproduction of seed cells, until the maximum cell density and the highest yield are reached, then the cells are transferred to the production tank to continue culture, and finally the cells are clarified by depth filtration or centrifugation. Downstream purification includes chromatography, virus inactivation, filtration and other steps to finally get the drug substance.

Figure 5

Industrial production process flow of biopharmaceuticals



Information source: China Securities, Sullivan

3.1.3 Downstream of industry chain

The downstream of the industry chain mainly includes drug sales and drug consumption. Pharmaceutical circulation is an intermediate sales circulation link among pharmaceutical manufacturers, medical institutions and pharmacies. At present, the mainstream operation mode in the industry is "two-invoice system", that is, only two invoices are allowed in the whole production chain, including one invoice directly issued by a manufacturer to a commercial company, and another invoice issued by the commercial company to a hospital, and the commercial company is responsible for returning the loans to the manufacturer.

3.2 Dynamic and trend analysis by CDMO

CDMO, the Contract Development Manufacturing Organization, is a new development and production outsourcing organization in the field of medicine and biotechnology, focusing on providing high-tech value-added services for pharmaceutical companies and biotechnology companies, including process development, preparation, optimization, registration, validation batch production and commercial customized R&D and production. Its core lies in the deep integration of the technological development capability of high-tech barriers with the large-scale production capacity. CDMO has multi-faceted services,

covering preclinical studies, clinical stage and commercial production stage. In terms of drug type, CDMO can be divided into small molecule CDMO, macromolecule CDMO and cell and gene therapy (CGT) CDMO.

In recent years, the CDMO industry witnessed significant market dynamics, with the implementation of the marketing authorization holder (MAH) for drugs being a key driver. The system realizes the separation of drug ownership and manufacturing right, allowing pharmaceutical companies, R&D institutions or scholars to become MAHs and entrust other pharmaceutical companies with production of drugs. This policy has promoted CDMO/CMO enterprises to undertake more drug R&D and manufacturing orders, and stimulated the motivation of innovative drug R&D institutions.

As an important area in the development of CDMO industry, ADC drugs are difficult to develop and have a high outsourcing rate. Many factors such as antibody selection, coupler type and stability, toxin and drug-antibody coupling ratio should be considered in the R&D and manufacturing of ADC drugs, together with complex biological analysis and characterization methods, so the development workload is huge. Therefore, the development and manufacturing of ADC drugs mostly rely on outsourcing, and only a few outsourcing companies have the ability to develop couplers and cytotoxins. Leading CDMO companies with the advantages of complex molecular R&D and manufacturing technology innovation are expected to benefit from the rapid development of ADC technology.

In addition, CAR-T therapy also brings new development opportunities for CDMO industry. The high R&D cost of CGT has prompted companies to outsource their R&D and manufacturing tasks to CGT CDMOs with relatively mature systems in order to control costs. CDMO companies usually have a large cell or vector libraries, which can help pharmaceutical companies to select and optimize suitable cells or vectors, thus improving the success rate of R&D and reducing the cost and time of commercial manufacturing. With the continuous maturity of CGT therapy, the CGT CDMO market will also usher in rapid growth.

Looking ahead, the CDMO industry will accelerate the integrated layout, improve the added value of overall services and the ability to obtain profits. CDMO

companies will provide integrated services to customers, improve R&D efficiency and enhance customer stickiness by expanding their business scope to cover the whole process of new drug R&D and manufacturing. At the same time, CDMO companies will also develop a one-stop service platform and enhance their core competitiveness by investing in self-construction or merging and integrating industry resources, so as to attract more downstream biopharmaceutical companies to cooperate. Specifically, horizontal layout of new business has become the main development trend of domestic CDMO industry, and small molecular CDMO is gradually expanding to macromolecular CDMO.

3.3 Summary of relevant developments in the biopharmaceutical industry

Merck acquired Erbi Biosystems to gain the leading manufacturing capacity of micro-perfusion bioreactor

On December 6, 2022, Merck acquired Erbi Biosystems, headquartered in Massachusetts, USA, which is well known in the industry for its 2 ml miniature multiplex perfusion bioreactor called BreezTM. With acquisition, Merck further expands its product capability in the upstream protein drug products, and provide scalable cell perfusion bioreactors with different working volumes (from 2 mL to 2,000 L).

GEMU helps China in COVID-19 vaccine construction projects

In 2021, in order to quickly respond to the COVID-19 epidemic, GEMU delivered more than 100,000 valves in just a few months, and participated in almost all COVID-19 vaccine projects under construction in China. GEMU manufactured the valve systems required for COVID-19 vaccine and drug R&D in the first time and delivered them in time. At the same time, GEMU cooperated with Sino Biopharm and other listed vaccine manufacturers to provide support for COVID-19 drug R&D and vaccine R&D projects.

Electrostatic spray dryer helps global R&D and manufacturing of live biotherapeutic products (LBPs).

SER-109, the world's first LBP, recently obtained the priority review qualification from the US FDA, driving the heat of LBP development. This is an oral microbiome therapy consisting of high-purity firmicute spores and is used to prevent recurrent clostridium difficile infection. PolarDry

electrostatic spray dryer is favored by domestic and foreign LBP enterprises for its low temperature, rapid drying and enhanced generation of probiotic powder microcapsules. In China, Spraying Systems cooperated with leading LBP manufacturers in R&D, and made a breakthrough in the drying and enteric protection of second-generation probiotics. In addition, , Spraying Systems has achieved breakthrough results in oligonucleotide and polypeptide product drying by partnering with domestic leading enterprises in R&D. In the future, Fluid Air will continue to support domestic biological companies to move toward the forefront of international bio-pharmaceutical manufacturing by means of advanced technology and equipment.

4 Current situation of biopharmaceutical equipment market in China and trend analysis

4.1 Analysis of biopharmaceutical core equipment market

4.1.1 Market status

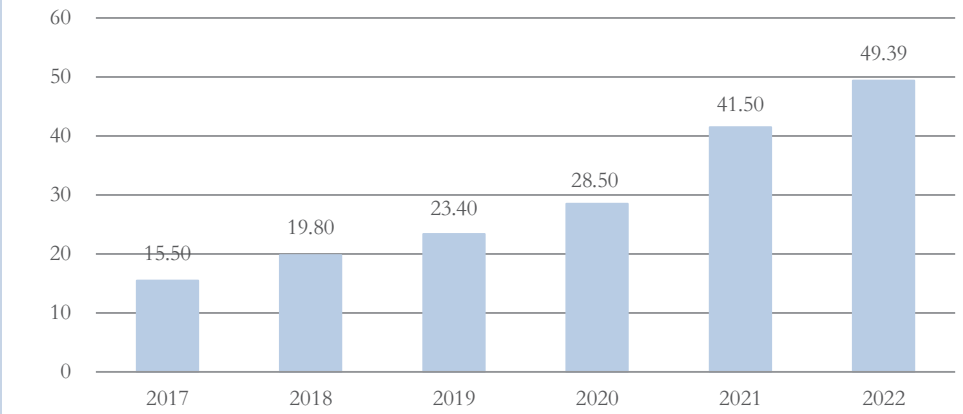
In recent years, the vigorous development of the biopharmaceutical industry has driven the sustained growth of related pharmaceutical equipment and consumables market. Especially driven by the epidemic, the biopharmaceutical equipment and consumables market surged in 2021. However, by 2022, due to the sluggish investment in the biopharmaceutical market, the capacity expansion projects for products such as monoclonal antibodies, recombinant proteins have significantly reduced, leading to a slowdown in the growth of the market size of related equipment and reagent consumables. According to statistics, the market size of biopharmaceutical equipment in China was about 20 billion yuan in 2022, and the market size of related reagents and consumables was about 22 billion yuan, with a year-on-year growth of about 20%.

Among the biopharmaceutical core equipment and consumables, bioreactor is one of the most core equipment, also known as fermentor, which is the place for biochemical reactions. Driven by the increasing demand for vaccines, the increasing use of disposable products, the development of therapeutic drugs and the technology development of bioreactor, the size of domestic bioreactor market has grown steadily. In 2021, due to the surge in demand for COVID-19 vaccines, the size of bioreactor market in China reached 4.15 billion yuan, up by 46% year-on-year, as shown in Figure 6. By 2022, despite of sluggish investment in biopharmaceuticals, the size of bioreactor market was still about 4.94 billion yuan, with a year-on-year growth of about 19%.

In terms of segmented product category, bioreactors can be categorized into

Figure 6

Size of bioreactor market in China from 2017 to 2022 (100 million yuan).



Size of bioreactor market in China from 2017 to 2022 (100 million yuan).

Data source: public dataset, M2 Consulting research & analysis.

stainless steel bioreactors and disposable bioreactors. Stainless steel bioreactors have a mature technology and are more suitable for commercial large-scale manufacturing with a higher degree of localization. Disposable bioreactors are more suitable for small batch manufacturing from R&D to pilot stage, with low initial investment cost and fast launch in production, and the cleaning and related validation steps are eliminated. However, as domestic disposable bioreactors are limited by raw materials and manufacturing process, domestic substitution still has a long way to go. In particular, as the highest technical barrier in disposable bioreactor, the membrane material is difficult to develop and manufacture, and the domestic related technology is immature, so foreign companies still take a dominant position in this market in China.

In addition to bioreactors, other equipment and consumables such as chromatographic medium also have high technical content and low localization rate. The chromatographic medium is a microsphere material with nano-pore structure, which has high requirement for manufacturing process, and the products need to meet GMP requirements. Due to low stability of products made by domestic manufacturers, the downstream manufacturers have a low acceptance degree of domestic products. However, in recent years, in order to reduce the cost, some domestic biopharmaceutical

companies began to manufacture or purchase related subjects, or ask sister companies to contract the subjects, which promoted the localization progress of chromatographic media to some extent. According to statistics, in 2021, the chromatographic packing market in China reached USD 670 million, up by 10.6% year-on-year.

4.1.2 Future development trend

In the future, automation, digitalization and intelligence will be the mainstream development trend of biopharmaceutical equipment. It has been clearly put forward in the 14th Five-Year Plan period that the pharmaceutical equipment industry should innovate and develop pharmaceutical equipment with high efficiency, low energy consumption, low carbon emission, automation and smart by focusing on the "deep integration of informatization and pharmaceutical equipment". At present, China's pharmaceutical equipment is still in its infancy in terms of automation, digitalization and smart, but more and more pharmaceutical equipment companies have begun to strengthen the R&D of smart pharmaceutical equipment.

In addition, with the gradual enhancement of the product competitiveness of domestic equipment suppliers and the obvious manifestation of price advantages, the internationalization progress of domestic pharmaceutical equipment is also accelerating. According to statistics, the export delivery value of special pharmaceutical equipment manufacturing industry in China has increased year by year in recent years. The domestic pharmaceutical equipment are mainly exported to India, Southeast Asia, Russia and other countries, which indicates that China's pharmaceutical equipment industry is gradually moving towards the world stage and showing more and more competitiveness in the international market.

4.2 Market analysis of general equipment for biopharmaceuticals

4.2.1 Pump market analysis

Pump, as the key machinery for conveying and pressurizing fluids, plays an indispensable role in the biopharmaceutical sector. It is responsible for pushing fluids such as buffers, media, and water for injection (WFI) through the pipelines to ensure that they are accurately delivered to the process equipment. The biopharmaceutical processes are extremely demanding on pumping systems, as its top priority is to prevent cross-contamination, while avoid potential damage to biologics by shear forces. To meet these needs, peristaltic pumps, diaphragm pumps, rotary lobe pumps and gear pumps are usually used in biopharmaceutical processes.

In hygiene and biopharmaceutical applications, the pumps must be contamination-resistant and rigorously validated. In the design of pump, disposable components can be considered or it should be ensured that the pump is easy to clean if it can be used multiple times to comply with biopharmaceutical process standards such as Bioprocessing Equipment (BPE) standards of the American Society of Mechanical Engineers (ASME).

In recent years, the scale of pump market is expanding gradually with the continuous growth of downstream market demands. The global production capacity of pharmaceutical pumps is mainly concentrated in countries such as China, USA, Germany and Japan. The pump manufacturers from the Europe, USA and Japan dominate the global high-end pump market with their advanced technology, quality products and brand effect. In contrast, the peristaltic pump manufacturers in China are generally small in scale, with relatively low level of technology, and mainly engaged in the mid-range and low-end market.

However, with the sustained and steady economic growth in China, the demands of pump market continue to be released, coupled with scientific progress and downstream demand for upgrading, the pump industry is driven to develop towards high-end, diversification, branding and integration. Although China is a large producer of pumps, but the relevant enterprises are still mainly small and

medium-sized, with less competitiveness in the high-end market. Therefore, China's peristaltic pump manufacturers need to improve their product quality and upgrade technologies actively to enhance their competitiveness and compete for their shares in the high-end market.

The R&D of core technologies substituting the imported ones has become the main innovation direction for the Chinese pump industry. With the development of industrial technology and manufacturing, R&D of core technologies related to the import substitutions has become an inevitable demand for the development of pump industry. In recent years, thanks to computer technology, the Internet and the development of emerging business models, the pump technologies have made significant progress, together with expanded application field and developed business model. Leading foreign companies focus on building a new innovation model, i.e. the integration of the latest computer technology and the Internet, while the domestic pump enterprises are mainly making technological innovations in import substitution, energy saving and environmental protection, as well as technological upgrading.

Improving product performance, energy saving and environmental protection are the focus of the development of pumping equipment technology. As important pharmaceutical manufacturing equipment, the pump equipment is demanding highly for stand-alone power, reliability and cleanliness. Therefore, the development of high-performance pumping equipment is an important demand of the pharmaceutical industry. In addition, with the improvement of informatization and intelligence, the new generation of information technologies, such as artificial intelligence, the Internet of Things and big data, are widely and deeply penetrating into all areas of the economy and society, and cross integrating with bioengineering and other emerging technologies, leading to significant changes in green and intelligent areas. The relevant policy points out that by 2025, the networking rate of digital production equipment will continue to increase, the intelligent manufacturing model will be constantly enriched and improved, cultivating a number of advanced enterprises, demonstration platforms and typical projects of service-oriented manufacturing in the machinery industry. This will further promote the technological innovation and development of the pumping equipment market.

4.2.2 Valve market analysis

Valves, as key components for fluid control, are widely used in various fields, especially in the pharmaceutical industry with particularly strict requirements. The pharmaceutical industry has high standards for the cleanliness, material and performance of valves. The types of valves commonly used include diaphragm valves, wafer-type ball valves and non-retention ball valves.

Diaphragm valve is favored for its unique design in clean pipework systems in the pharmaceutical industry. It ensures that pipeline medium do not come into contact with other fittings than the gasket, effectively preventing stagnant water. The wafer-type ball valves, on the other hand, are popular for their high level of cleanliness inside the valve body, especially the fully encapsulated, three-piece ball valve with no dead space, despite its higher cost. Non-retention ball valves, also known as non-dead-space ball valves, are designed with smooth inner walls of high cleanliness, effectively preventing bacterial growth. Therefore, they have become an indispensable type of valve for the pharmaceutical industry.

In recent years, China's valve production has been growing steadily; the annual output value has exceeded 210 billion yuan. The growth rate of the industry is more than 6%, indicating that China's valve industry is in a steady development stage. However, compared with foreign valves, the domestic valve industry is featured in low concentration, generally small enterprise scale, capital and technical strengths insufficient to compete with internationally renowned enterprises.

In the global valve market, the United States, Germany, Japan and France are in the first echelon of comprehensive strength, dominating the industry's high-end market. China's valve enterprises are mainly engaged in the mid-range and low-end markets under the background of low overall level of R&D, serious product homogeneity and intense competition. Although China's valve exports accounted for 25% of global production, the transaction amount was less than 10% of that of the world, showing that China's valve industry is still in a low-end position in the global value chain. However, in recent years, China's high-end valve imports showed a declining trend in both the number and amount, indicating that China's valves are rising at accelerated pace, gradually replacing the imported products.

With the rapid development of

biopharmaceuticals, CMO/CDMO and other pharmaceutical companies, as well as the sustainable growth of output value and fixed asset investment in the pharmaceutical industry, pharmaceutical equipment industry is ushering in a new development opportunity, and the valve market is expected to expand further. Especially during the epidemic, many companies increased their capacity of vaccines and COVID-19 related drugs, promoting the rapid growth of the scale of sanitary valve market.

Driven by the rapid development of the pharmaceutical industry, the size of pharmaceutical valve market is expected to grow rapidly, and the competition among enterprises will be more intense. With the accelerated restructuring pace of pharmaceutical valve industry, the product quality, safety and brand will become the main factors for competition. In the future, the valve products will develop towards high technology, high specifications, strong corrosion resistance and long service life. The overall level and grade is expected to improve further.

In addition, with the promotion of 'Made in China 2025' strategy, smart manufacturing will be an inevitable trend in the development of pharmaceutical industry. Artificial Intelligence (AI) is increasingly used in the pharmaceutical R&D and market, aiming at improving the success rate of new drug development, reducing manufacturing costs and shortening the development cycle. In this context, valve products will also develop towards smart. For example, GEMÜ CONEXO is an smart product that has been innovated continuously in practice. With advantages such as the ability to identify information about the valve body, actuator and diaphragm, it enhances the process reliability through information traceability, and helps to create job-specific electronic documents, etc, with its degree of smart at the forefront of the industry.

4.2.3 Introduction to typical companies

GEMÜ

(1)Company profile

GEMÜ Group was founded in 1964 in Ingelfingen town, southern Germany. It is one of the world's leading manufacturers of valves, measurement and control systems, and also a leader in sanitary valves for biopharmaceutical market. It employs more than 2,400 members of staff worldwide and has business partners all over the world. GEMÜ has always been customer-

oriented, committed to the practical application of valves and providing customers with individual system solutions. GEMÜ's products include diaphragm valves, butterfly valves, globe valves, ball valves, solenoid valves, various system measurement and control components and digital solutions, and are widely used in biopharmaceutical, food and beverage, general machinery, chemistry & metallurgy, industrial fluids, microelectronics semiconductor and other industries.

GEMÜ Valve (China) Co., Ltd. (GEMÜ China) was established in 1998, headquartered in Shanghai, which is one of the six production sites of GEMÜ Group and the butterfly valve production center. As the R&D, production, sales and logistics center of GEMÜ Group in the Asia-Pacific region, GEMÜ China is committed to providing high-quality products and services for customers in China and around the world. At the same time, GEMÜ China is also a well-known company in the industrial valve industry in the Chinese market, which is highly favored by the industry. In recent years, GEMÜ China is engaged in promoting sustainable development, lean production and digital transformation, focusing on high-quality development, growing together with partners, and serving global customers in a better way under the driven by innovation and change.

(2)Core strengths

GEMÜ has a wide range of products, including sanitary diaphragm valves and high-efficiency multi-port valves, which have technological advantages in the industry and have won a lot of reputation, and are the "invisible champions" in the field of sanitary valves. They occupy more than half of shares in China's biopharmaceutical market, and are widely used in monoclonal antibody drugs, insulin, blood products industry, vaccines, nucleic acid drugs, CDMO and other industries.

GEMÜ focuses on the investments in product optimization, new product development and technological innovation, spending more than 5% of its annual sales on R&D and innovation. In addition, GEMÜ's production process is controlled from top to bottom, ensuring high performance and quality of products. In addition, GEMÜ has efficient stocking, assembly and delivery capabilities to ensure timely delivery of products.

GEMÜ is a trendsetter and industry leader with a wide range of products: from multi-port valves satisfying complex specialized needs, to one-off process products for small batch research and production, and

award-winning PD technology. Currently, GEMÜ is focusing on green development and implementing sustainability in the whole chain to empower a green future.

(3)Introduction to typical products

① Intelligent information system - CONEXO

CONEXO is an information traceability and maintenance support system. CONEXO equips radio frequency identification (RFID) chips on various valve components, including valve bodies, actuators and diaphragms or valves as a whole, which enables electronic traceability of each component of the valve and enhances the level of digital maintenance.

All valve or component information can be imported via an RFID reader - the CONEXO Pen, and viewed via the CONEXO App on a tablet. The customers can digitally access the equipment component documents of the plant and manufacturing plant certificates via the App at any time.

In addition, the CONEXO system offers the options for digital maintenance job support. During the maintenance, the technicians are guided by throughout the sequence of maintenance processes and customized maintenance reports are generated with the App. With the help of CONEXO system, the customer maintenance logs will no longer be entered manually, and technicians can evaluate wear parts electronically on site for systematic analysis. The assignment of entire part management and maintenance jobs will be carried out through the program. The maintenance work orders will be assigned electronically to the technicians' tablets, allowing them to identify the corresponding valves and carry out the maintenance work.

CONEXO is also an open system and through which, all components equipped with RFID chips can be managed. In addition, it is possible to create interfaces for all common enterprise resource planning (ERP), supervisory control and data acquisition (SCADA) and the maintenance system. In this way, CONEXO can support maintenance, equipment management, and purchasing with data to help the plant make scientific maintenance decisions, keeping the plant running at optimum performance. CONEXO has already been applied to several systems.

② GEMÜ SUMONDO single-use diaphragm valve

The new single-use diaphragm valves of GEMÜ can fulfill the needs for quick, easy and safe replacement of disposable consumables or valve bodies, and open

up new opportunities in plant design. The single-use diaphragm valve consists of an actuator unit, which can be easily integrated into disposable equipment, and a single-use body with a welded diaphragm, which is used to convey the medium. SUMONDO single-use diaphragm valves are used for mixing, dispensing and dosing of medium, flow control, fast and high-frequency opening and closing, with good switching safety and excellent working pressures, and can achieve automatic control.

Based on the principles of SUMONDO, GEMÜ has developed single-use multi-port valves, including a customer-specific single-use multi-port body design and a multi-actuator integration module. The diaphragm valves enable diversified flow path control in a compact size in addition to its easy installation and low dead volume, adding more possibilities for plant design.

Spraying Systems

(1)Company profile

Spraying Systems was founded in 1937 and headquartered in Illinois, USA. In 1994, Spraying Systems entered China and began to cultivate the Chinese market, developing rapidly in its businesses. In 2003, Spraying Systems established a subsidiary company, Spraying Systems (Shanghai) Co., Ltd., and invested in the establishment of production base in Shanghai.

Spraying Systems is a spray nozzle manufacturer specializing in the R&D, design, manufacture and sale of spray nozzles and spray systems, providing efficient spray technology solutions for customers in various industries. Spraying Systems has been specializing in industrial spray technology for over 80 years and its products have been used in a wide range of industrial applications, including steel, flue gas desulphurization, industrial dust removal, precision electronic processing, large scale integrated circuits, chip manufacturing and many more.

For the pharmaceutical industry, Spraying Systems has established the FLuidAir division to specialize in the design, manufacture and production of pharmaceutical equipment. FLuidAir's products, such as fluidized bed, wet granulator and granulator, have obtained recognition from the market in the pharmaceutical equipment field.

In 2016, Spraying Systems made a major breakthrough in the field of rapid drying at ambient temperature with the launch of its innovative product PolarDry. By use of the principle of electric field drying, the technology creatively

combines electrostatic field technology with spray drying technology to reduce the temperature of traditional spray drying by nearly half, making rapid drying of temperature-sensitive products at room temperature possible. At present, PolarDry has already been applied in the manufacture of LBPs, mRNA products, peptide and oligonucleotide products. With the further expansion of the demand for solid product forms in the pharmaceutical industry in the future, PolarDry, as a gentle, rapid and efficient drying technology, will be applied in a broader space.

(2)Core strengths

With 12 manufacturing plants in North and South America, Europe and Asia, and more than 200 sales offices in 57 countries and regions, Spraying Systems' global sales and service network provides timely technical support, training, maintenance and optimization services. Spraying Systems has a localized plant in Shanghai to meet customized manufacturing and design needs. In addition, Spraying Systems has established a comprehensive product and sales and service network in major cities throughout China, committing to 24-hour response and 48-hour on-site service.

Spraying Systems' plants utilize state-of-the-art manufacturing equipment and quality management systems, and are certified by ISO 9001 and ISO 14001, as well as a number of Chinese and international industry standards and accreditations. The completed PolarDry electrostatic spray drying laboratory is equipped with 0.1 kg and 1 kg class laboratory equipment and industry advanced SEM scanning electron microscope, DSC thermal difference analyzer, laser particle size analyzer, etc, which is established in accordance with the global standard to serve the Chinese biologics customers.

(3)Introduction to typical products

① PolayDry electrostatic spray dryer

By creatively utilizing electrostatic-assisted drying technology, PolayDry electrostatic spray dryercan instantly dry the material into powder when it is at a temperature of about 40℃, effectively maintaining the biological activity of the product and improving production efficiency. The particles produced by electrostatic action are fine and uniform, which helps to reduce the "bridging" phenomenon after pressing, and at the same time creates conditions for large-scale and continuous mass bio-manufacturing. The pulsed controlled electric field can assist in adjusting the

properties of the finished particles. In addition, the whole machine is designed to meet the requirements of the ASME BPE standard.

② TankJet cleaning guns

TankJet series cleaning guns can be applied to cleaning in various sizes, under various conditions and with different requirements, and can be customized according to the customer's equipment for different cleaning.

5 Biopharmaceutical production line design and integration and smart transformation in China

5.1 Current situation of smart transformation market

Biopharmaceuticals is one of the fastest growing areas of digitalization and smart in the life science industry, and is also the focus of the National Pharmaceutical Industry's 14th Five-Year Plan. Despite a late start in integration and smart manufacturing, China's biopharmaceutical production line has achieved initial results now.

At present, China's biopharmaceutical enterprises are generally at a lower degree of automation, informatization, smart. Most companies are still in the single automation stage of equipment control, therefore there is an urgent need for automation in overall biopharmaceutical production process. The production process information is mainly collected manually, difficult to grasp the dynamics of the production site in real time. There is an urgent need for informatization and upgrading through sensors and software systems.

In order to cope with the competition in domestic and international markets and legal and regulatory supervision, and to enhance competitiveness, the domestic pharmaceutical companies are actively promoting digital transformation to achieve cost reduction and efficiency enhancement. Although informatization means are mostly limited to individual equipment or equipment groups and lacks unified management, some large and medium-sized enterprises have achieved initial results in digital transformation. In the future, China's biopharmaceutical production lines will continue to develop towards integration and smart to improve production efficiency and product quality.

5.2 Smart manufacturing transformation program for Chinese biopharmaceutical plants

5.2.1 Content of smart manufacturing transformation program

(1)Construction of digital system

Smart manufacturing can comprehensively optimize the management of drug R&D, manufacturing, quality, logistics, etc. throughout the life cycle, and promote the continuous optimization of the operation and management of pharmaceutical enterprises. To this end, pharmaceutical companies need to build a digital system, promote the integration of systems, equipment and various links, and set up an organizational system and project management mechanism directly led by the senior management.

① Building a digital foundation

Most traditional Chinese pharmaceutical companies, especially small and medium-sized enterprises (SMEs), are at the stage of building a digital foundation. Enterprises should focus on their core needs, assess the current situation, deploy software and hardware, and carry out digitalization pilots for key business areas, realizing the interconnection and integration of some business segments. Innovative R&D enterprises should focus on deploying LIMS, CTMS and corresponding control layer and equipment layer applications; while enterprises focusing on mature varieties need to prioritize the configuration of MES, WMS and other systems to cope with price pressures and lean production needs. Enterprises can gradually adapt to the construction thoughts of smart manufacturing through the pilot projects.

② Enabling interconnected empowerment

Interconnected empowerment requires the pharmaceutical companies to expand the scope of business, deepen the application level and enhance the management level. The change at this stage is complex, and requires more management involvement and the setting of clear visions and goals. Enterprises need to sort out plant-wide business processes, go online, tap

system functions, achieve cluster-level automatic control in some business areas, and try to open up the business systems, such as R&D, production, quality and logistics. To solve the problem of insufficient dialog between systems, enterprises should cultivate an integrated management culture and solve problems from a digital and interconnected perspective.

③ Practicing the vision of smart

For pharmaceutical companies that already have the foundation of digitalization and automation, practicing the vision of smart is the key to transformation. In addition to improving the integration of all levels and systems, enterprises need to explore a digital governance model that meets their own characteristics and gradually shift to a digital-oriented system.

(2)Smart plant management

The docking of equipment with the central system makes the plant production process transparent. Relevant personnel can arrange their work according to the completion of the process, and managers can efficiently and comprehensively manage production, reduce redundant steps, and make the management of production plan, process routes, materials, containers, production process control and real-time data analysis.

(3)Production line automation

The automation of biopharmaceutical production process can enhance production capacity, reduce operators and improve efficiency. Taking the preparation process as an example, smart liquid dispensing, washing, filling and sealing, sterilization and light inspection system can achieve online weighing, washing, sterilization and fully-automated production operation, covering a range of processes such as bottle washing and drying, filling and sealing, sterilization, drying, light inspection, leakage detection and printing.

(4)Continuous batch production

Traditional drug production involves separate steps, while continuous production allows continuous sample loading of batches, eliminating the pause phase in batch production. In addition, it enables real-time quality monitoring, removal of non-conforming intermediate products, with reduced costs and human errors, and accelerated production process.

The continuous, flexible production proposed in smart manufacturing reduces both worker stress and error rates, which is the greatest benefit of technological advancement. The industrial development trend requires the designers to take into account the needs of employees and visitors to make the production setup more flexible.

In recent years, in order to promote the smart transformation of the biopharmaceutical industry, biopharmaceutical equipment companies have increased the digital product development efforts, from smart systems (e.g., GEMÜ CONEXO information traceability and Thermo FisherTM , Chromeleon Chromatography Data System) to smart plant solutions (e.g., Bio4CTM biopharmaceutical digital plant solutions from Merck), the new products are popping up all the time, promoting the smart development of biopharmaceuticals.

5.2.2 Problems and challenges for smart manufacturing transformation in biopharmaceutical enterprises

The pharmaceutical industry is related to the national economy and people's livelihood, and is therefore regulated by strict laws and regulations, especially in terms of drug quality. Each aspect of the whole life cycle, from R&D, manufacturing to logistics and use, must comply with relevant regulations and standards. For example, equipment and processes need to undergo complex procedures such as Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) in order to ensure that the quality of drug products is up to standard and consistent from batch to batch in manufacturing. The transformation towards smart manufacturing often involves the adjustments of equipment or processes, which require complex changes and risk reassessments, and revalidation of manufacturing processes and registration with regulatory authorities. As a result, pharmaceutical companies are taking a prudent approach to advancing smart manufacturing, avoiding potential quality risks.

Long return on investment cycle is the main reason why pharmaceutical companies are hesitant towards digital transformation. Digital transformation is a project with large investment and long

cycle, characterized by importance, complexity, arduousness and long-term nature. A large amount of investment in the short term without significant outputs makes most pharmaceutical companies take a wait-and-see attitude. Even if some enterprises have invested first, the lack of overall planning and a longer run-in period between the system and the actual production further increase the uncertainty of investment.

The weak foundation of informatization is also a serious constraint to the digital transformation of biopharmaceutical companies. A high level of informatization and process automation is the basis for ensuring safe, reliable and information-traceable manufacturing of biopharmaceuticals and medical devices. However, according to the statistics, 70% of China's biopharmaceutical enterprises are still at Industry 2.0 stage, with 20% at the stage Industry 3.0, and the rest 10% still at Industry 1.0. This status quo of insufficient informatization has seriously hindered the digitalization process of biopharmaceutical enterprises.

In addition, the low degree of localization of core equipment is also a big challenge faced by biopharmaceutical enterprises in the transformation towards smart manufacturing. Most of the core equipment used by Chinese biopharmaceutical enterprises are imported, demonstrating that domestic pharmaceutical machinery enterprises are experiencing a significant shortage in production capacity of high-end equipment. This increases procurement costs, and makes maintenance highly dependent on foreign manufacturers. During the epidemic, global public health events such as COVID-19 may lead to disruptions in the distribution of equipment and parts, further affecting the production.

Finally, the shortage of talents required for transformation towards smart manufacturing is also an issue that cannot be ignored. The digital transformation of biopharmaceutical enterprises involves the expertise in a number of fields, ranging from pharmaceutical processes, biotechnology, chemical machinery, automation control, and computer use to cutting-edge technologies such as artificial intelligence and smart manufacturing. This requires the technical personnel to understand

both technology and business, while the management personnel need to develop management objectives and performance assessment indicators that match the digital transformation. The fact is that there is still a large gap in the reserve of such composite talents in China. At the same time, the common problems of enterprises focusing on production rather than research, introducing rather than digesting and learning, imitating rather than innovating, as well as focusing on the present rather than the long term, have also led to insufficient motivation for and a low level of innovation.

5.3 Targets for smart transformation of biopharmaceutical enterprises

The core objective of intelligent transformation of biopharmaceutical enterprises is to promote pharmaceutical R&D and innovation, which are the key driving forces for the development of the industry. Currently, China's pharmaceutical industry is transforming from a high-speed development to a high-quality development. Flexible use of new digital technologies (e.g. AI, big data, platform technologies, etc.) in key aspects such as R&D design and clinical data collection can significantly improve the success rate of drug R&D and shorten the R&D cycle.

Meanwhile, smart transformation is also committed to guaranteeing stable drug quality, which is the cornerstone of the biopharmaceutical industry. By building smart plants and utilizing digital software and automation systems, real-time data collection and analysis can be achieved, thereby bridging all aspects of product R&D, process, manufacturing, quality and internal logistics. This not only improves production efficiency and reduces manufacturing costs, but also builds a modular, transparent and smart production quality process control flow through the four modules of materials, production, quality and equipment, achieving comprehensive quality management.

In addition, smart transformation can significantly reduce production costs and improve production efficiency. By use of digital tools, biopharmaceutical companies can streamline the business

processes among various departments and personnel to achieve a rapid flow of information and improve the overall efficiency of business operations. At the same time, digital tools can also reshape the customer experience, respond positively to the diverse needs of business scenarios, and capture new growth opportunities for enterprises.

5.4 Trend and direction for smart transformation

Smart plants have become the benchmark for construction of new projects of biopharmaceutical companies. Against the backdrop of the expanding scope of centralized drug procurement and the drastic compression of drug profit margins, establishment of digital plants has become an effective way to improve production efficiency and reduce production costs. At present, leading enterprises such as Johnson & Johnson, United Imaging and Pfizer have taken the lead in realizing the digitalization of production, experiments, energy management, etc. Digital plants will become the new standard for new plants.

Networked collaboration has also become a new drive for the development of biopharmaceutical industry. With the specialization of industrial division of labor, some specialized, refined, special and innovative small enterprises continue to emerge. The various links of the industry chain begin to disperse into different organizations. As the biopharmaceutical industry is featured by a long R&D cycle, high risks and rapid changes, it has become an inevitable trend for the industry to develop towards networked collaboration. Through large-scale, on-demand, dynamic allocation of resources, online transactions, services and collaboration between upstream and downstream of the industry chain, the organizational margins between enterprises in the same industry chain are blurring, which will greatly improve R&D and production efficiency and increase the overall competitiveness of the industry chain.

With the improvement of informatization level, digital regulation has become an important means to adapt to the new situation of technological integration.

Currently, drug regulation is centered on clinical trials, but the development of informatization provides a more efficient and cost-effective means for regulation. The regulation authorities can improve the review and approval efficiency through real-time data collection and analysis; build a digital file management system for tractability; build a risk monitoring and early warning system and a public opinion supervision system to keep abreast of the side effects and violations of the law in biopharmaceutical products, safeguarding the lives and health of patients in a better way.

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