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Effect of AI on GMP-Taking Quality Control in GMP as an Example

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Abstract: The Good Manufacturing Practice for Pharmaceutical Production (GMP) is a set of mandatory standards for pharmaceutical industries. GMP requires pharmaceutical manufacturers to strictly improve the quality management and verification system in accordance with the relevant national regulations, ensure the reliable process of pharmaceutical equipment, and realize the safe production of drugs. Under such a strict system, the excellence of GMP quality management system enables the small differences in all links of drug production to be found and corrected by the system, so as to ensure the quality, safety and effectiveness of drugs [1]. At present, modern science and technology has increasingly become an important basis for the research and development of new drugs. Among them, artificial intelligence (artificiAI intelligence, AI), as an advanced technological means, is bringing great promotion and change to many fields in GMP. Wikipedia's definition of artificial intelligence [2]: "Artificial intelligence, also called machine intelligence, is different from the natural intelligence of human beings themselves, which refers to the intelligence expressed by machines made by human beings". In recent years, AI technology has been widely used in various aspects of GMP, such as data processing, production line efficiency, and quality control, to improve the detection accuracy, efficiency, and management level. This paper will illustrate the impact of AI technology on GMP from the application, advantages, challenges and its future development prospects.

1. Application of AI in GMP quality control

At present, the application of AI in GMP quality control mainly focuses on the following aspects:

1.1 Product Testing, Accurate Control of the online Testing Equipment, to ensure the Accuracy and Stability of the Test Results

In GMP quality control, a variety of quality tests are required for the drugs produced, such as drug composition testing, microbiological quantitative testing, pharmacology and toxicology testing, etc. Traditional detection methods require a lot of manpower and material resources, and the

detection accuracy is sometimes not high enough. The application of AI technology can improve the detection accuracy and efficiency through deep learning and analysis of product data. For example, use "image recognition" technology to identify the drug quality standard [1] and "natural language processing" technology to analyze the drug instructions to improve the detection efficiency.

1.2 Quality Control, Identify Defective Drugs in the Image, and Ensure the Reliability and Stability of Online Detection in Extreme Cases of Drug Production

In the GMP quality control, a larger content is the quality control link. The traditional quality control method is manually verification by experience, which is very inefficient and not accurate. Now, with the application of AI technology, quality control can identify some non-compliance conditions faster, and it can also automatically identify and process abnormal signals during the production process. For example, using machine learning technology and digital imaging technology, surveillance video can be used to detect and judge the abnormal conditions during the production process, and to remind people to intervene to control [3-4].

1.3 Processing of the Safety Data

Drug safety and monitoring data are an important part of drug certification. Processing large amounts of data during monitoring is a tedious and complex task during monitoring. At this time, AI technology is widely used in the management and processing of security data. For example, "information mining" technology is used to find potential drug safety risks and give early warning [5], as shown in Figure 1, it is a drug risk monitoring index system based on data mining; "data mining" technology is used to find key data of related drugs and conduct comprehensive statistical analysis [6-7].

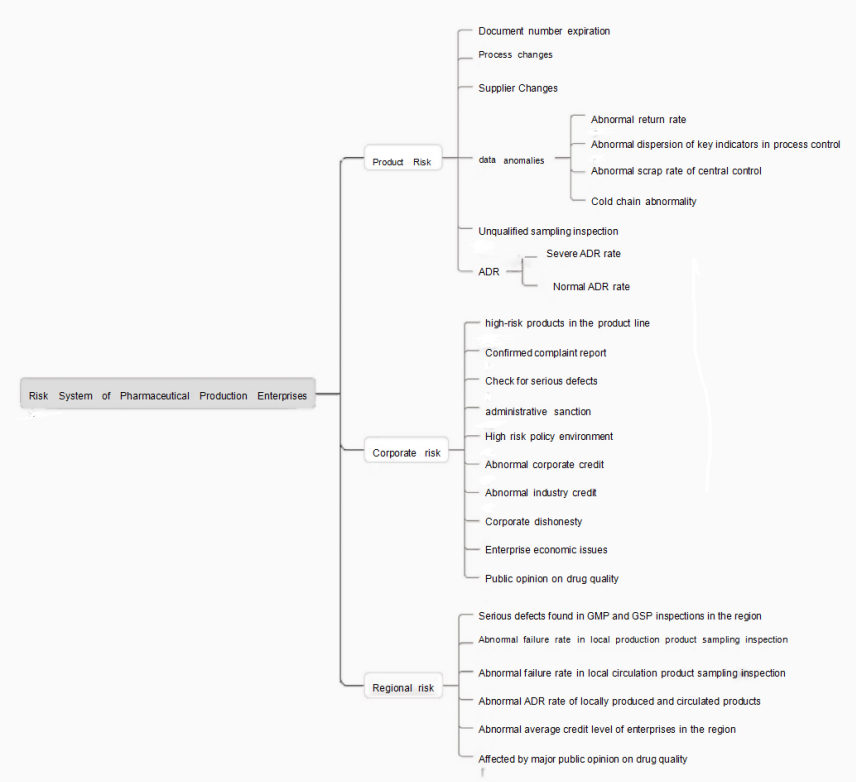

Figure 1: Drug risk monitoring index system [5] based on data mining

1.4 Accurate Quality Control, Analyze Drug Batch Data, Improve the Quality of Drug Production, and Reduce the Quality Difference between Batches of Drugs

Product quality traceability is an important task to ensure the safety and compliance of GMP quality control. Traditional traceability and management methods require a lot of manpower and material resources, and it is difficult to trace. The application of AI technology, product quality traceability can be conducted relatively automatically. For example, the application of Internet of Things system technology to track and monitor the whole process of drug production, and collect and record the data of each link, and provide comprehensive data support [8] in product quality traceability.

2. Advantages of AI Technology for GMP Quality Control

In GMP quality control, AI technology mainly operates in the following ways: data collection, AI technology can mine and collect a large number of production data, including production status, drug inspection data, instrument data, so as to generate a comprehensive and accurate database. Data processing, through machine learning and other technical means, AI technology can process and optimize all kinds of data generated in the process of drug production, data screening, classification, analysis, so as to realize automatic monitoring of the production link. Quality inspection, AI technology can also quickly carry out large-scale inspection work, and efficient analysis and comparison of the inspection results, so as to quickly eliminate the possible quality problems in the production process [9]

Compared with the traditional quality control methods, AI has incomparable advantages in quality testing:

2.1 High Efficiency

The traditional drug production process requires a large number of people to control the production process, while AI can fully automate the drug production life cycle, reducing the human burden to the greatest extent. Often seen in domestic pharmaceutical production is some independent and unit PID control or program control mode, in the ideal case in accordance with the requirements of GMP management specification, using the combination of automation and information, as far as possible in the maximum range, specification, constraints and replace the human behavior and operation, realize the whole process automation batch control (Batch Control) and batch management, as shown in Figure 2 [10].

Figure 2: Pharmaceutical automation part of the device

2.2 Precision

In the process of drug production, the error of each link will cause differences in drug quality. And AI can carefully monitor and control every production process to minimize human intervention.

2.3 Real-time

AI technology monitors the whole production process in real time to find potential problems in real time, which can better guarantee the safety, effectiveness and quality of drugs.

2.4 Statistical Analysis

AI technology can conduct statistical analysis of a large amount of data, quickly and accurately find out the regularity and problem points of the data of each batch of drug, and further optimize the pharmaceutical process and control quality, as shown in Figure 3.

Taking the adverse drug event signal using data mining as an example, in 2006, Ana Szarfman et al. used the adverse event data database of the United States to deeply explore the reports of hyperprolactinemia, galactorrhea and pituitary tumor of seven widely used antipsychotics, and found the drug risk [11] of risperidone. In 2008, Eric Colman et al., by combining data mining with other types of studies, confirmed the association [12] of statins with ALS. In 2010, Rivkees ScottA et al. used multiple gamma-Poisson shrinkage estimation method (multi-item gamma passion shrinker, MGPS) to find a serious hepatotoxicity risk of prothiouracil in children [13]. In 2018, Madigan et al, using the reported odds ratio method, showed that oral contraceptives containing drospirenone may produce more risk of VTE [14] than levonorgestrel-containing oral contraceptives.

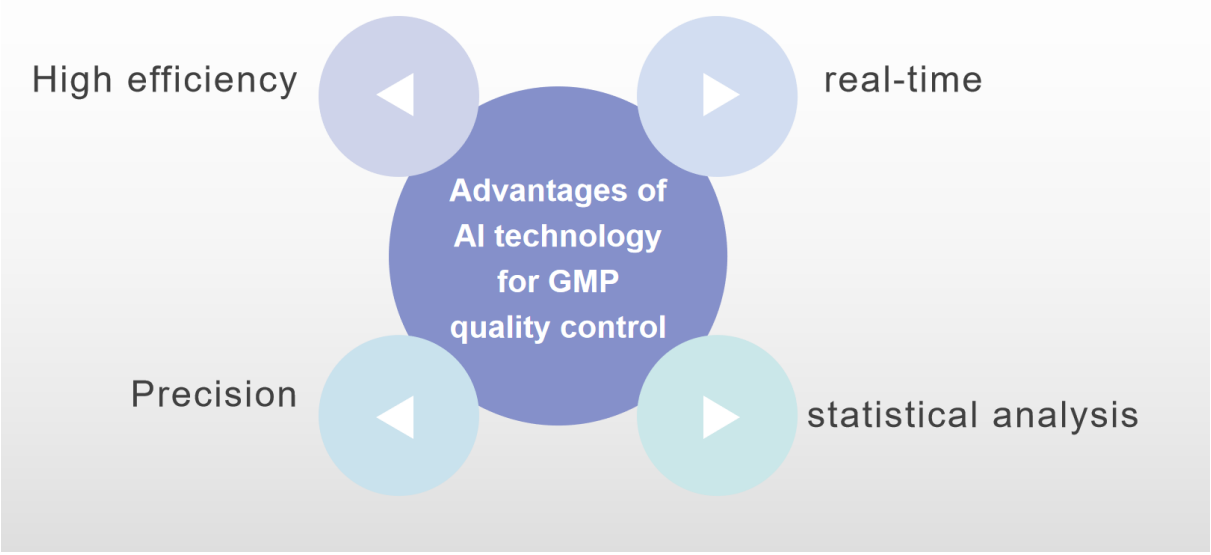

Figure 3: Advantages of AI technology for GMP quality control

3. AI challenges in GMP Quality Control

Despite the unparalleled superiority of AI in GMP quality control, multiple challenges remain

3.1 Insufficient Data and of Low Quality

The advantage of AI algorithms is the ability to analyze large amounts of data and make discoveries from them to improve quality and efficiency. However, in the pharmaceutical process, the quantity and quality of the data are problematic, which may lead to the failure of the AI algorithms. For example, outdated and poorly consistent data can lead to algorithmically erroneous predictions. In addition, data involves many processing steps and human records, with problems with errors and misoperations. Therefore, collecting and maintaining high-quality data remains difficult and will be a long-term challenge.

3.2 Lack of Standardized Process Data

Standardized process data is a crucial part of the biopharmaceutical quality control process. However, due to the different data collection methods and formats of pharmaceutical manufacturers, the lack of standardized process data becomes a major challenge for biopharmaceutical quality control. If such data is missing, the application of AI algorithms will be limited, resulting in a poor understanding of pharmaceutical manufacturers about their processes and production.

3.3 The Complexity of the AI Models

Biopharmaceutical production usually involves a large number of biochemical reactions and chemical protection, which may lead to pharmaceutical manufacturers facing complex data collections and models. Artificial intelligence algorithm is no exception. If the algorithm is too complex, it may lead to uninterpretation and increased uncertainty, resulting in false prediction. Therefore, good data analysis and collation are crucial.

3.4 Data Protection Issues

Medical data itself is very sensitive, and the protection and privacy issues of specific data have attracted widespread attention. The widespread application of artificial intelligence technology makes this problem even more prominent, and pharmaceutical companies need to establish safe data storage and management measures to ensure that data is complete, available and protected, and effectively avoid data leakage and protect privacy.

3.5 Compatibility and Ease of use Issues

Since different pharmaceutical companies use different GMP quality control systems, different data platforms and data standards, the AI algorithms must adapt to different environments, otherwise applicability issues will arise. Moreover, this complexity also involves the design of the user interface and application, improving the ease of use to ensure that the users can properly ate and interpret the results correctly.

3.6 Cost Problem

Quality control using AI technology requires a large amount of computing resources and state-of-the-art technology, where quality control tends to be costly, as shown in Figure 4. This can be an unbearable cost for many smaller pharmaceutical companies, nonprofit organizations, and medical institutions.

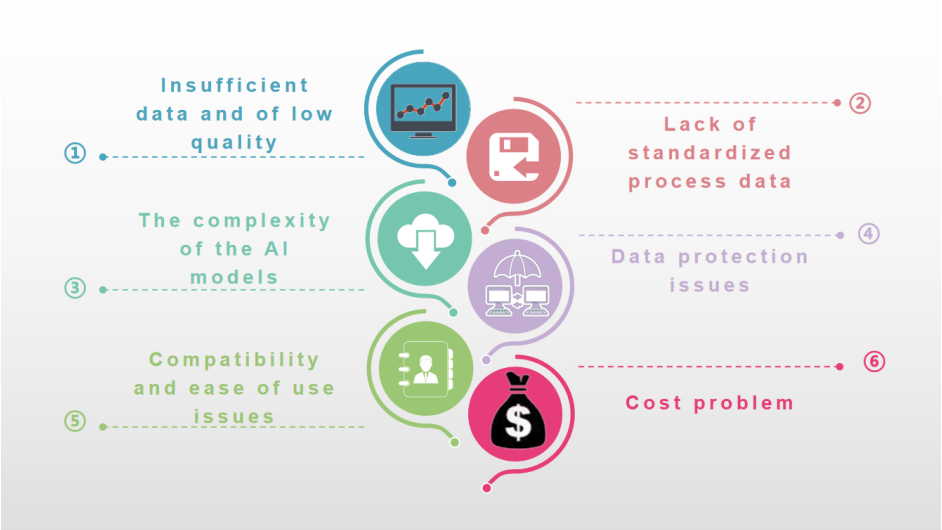

Figure 4: AI challenges in GMP quality control

4. Future Applications of AI in GMP Quality Control

The application of artificial intelligence technology in GMP quality control will undoubtedly gradually deepen, and there are the following application prospects in the future:

1. Accelerate drug research and development: AI technology can quickly analyze genes, metabolites, proteins, and metabolic pathways under different conditions, and assist pharmaceutical enterprises to quickly develop new drugs.

2. Accelerate drug source search: The intelligent drug traceability system based on AI technology will be able to realize the comprehensive analysis and traceability of the whole chain of drugs in the production and circulation, so as to ensure the credibility and availability of drugs to the maximum extent.

3. Realize quality innovation: Although quality standards have always been an important issue of pharmaceutical enterprises in pharmaceutical production, the improvement of quality standards is still very challenging. With the wide application of AI technology in specific fields, pharmaceutical production will have more opportunities to achieve quality innovation.

4. Reduce pharmaceutical production cost: The application of AI technology can reduce labor cost, and a series of favorable factors, such as shorten pharmaceutical production cycle and reduce production risk, which will greatly reduce the cost of pharmaceutical production.

5. Conclusion

At present, artificial intelligence (AI) is still in the initial stage in the field of drug quality control, but its future development potential is unlimited. AI technology will become an important means to ensure the quality and safety of drugs, bringing more development opportunities for China's pharmaceutical production industry.

The application of AI technology in the pharmaceutical industry can effectively improve the safety of pharmaceutical factories. First, AI technology can assist pharmaceutical factories to track the compliance of raw materials and finished products, monitor various environmental parameters in real time, and remind production personnel to adjust and control the production process in time. Secondly, through the monitoring and management of the production automation system, AI can help pharmaceutical factories to achieve industry standard process control, reduce the risks brought

by human operation, greatly reduce the error rate in drug production, and reduce the compensation risk in front of manufacturers.

In addition, the application of AI technology can also help pharmaceutical factories improve production efficiency and reduce production costs. In terms of production scheduling, raw material distribution, finished product testing and other aspects, AI automation technology will greatly reduce human intervention, reduce human operation risks, and improve production efficiency. At the same time, AI technology can optimize the pharmaceutical process, reduce human intervention, reduce production costs, and bring about higher quality and lower price products.

However, the adoption of AI technology also requires attention to protecting privacy and data security. Therefore, in the process of applying AI technology, pharmaceutical companies must show a high degree of sensitivity and understanding to ensure the protection and respect of privacy and data security.

In short, the medical industry will face great changes in the future, and AI technology will undoubtedly become one of the core forces driving the development of this field. Through investment, innovation and building an ecosystem, AI can improve the quality and safety of drugs and reduce the risk of compensation before manufacturers, while improving production efficiency and reducing production costs, which will also promote the deep reform of China's drug management system and open an era of deep intelligence.

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