The role of reliability research in ensuring the safety and effectiveness of medical equipment

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Abstract: The medical device industry is a multidisciplinary, knowledge-intensive, capital-intensive, rapidly developing high-tech industry, but also an important part of China's pharmaceutical industry. In recent years, China's medical device industry shows a trend of rapid development. With the development of economy, people pay more and more attention to health, and higher requirements are put forward for the safety and effectiveness of medical devices.

1. Introduction

China implements classified management of medical devices. The classification of medical devices I, II and III is based on the safety of products, and the distribution of management work completely depends on the requirements of product safety. Safety work is to be in the product life cycle (demonstration, design, production, use, retired) of all stages, through security design, quality control, management and technology, make the products get the best safety, reduce product when using the probability of accident, and as far as possible control accident can cause damage and loss. Basically, in order to realize the reliability is an important premise of medical equipment, need to work through a series of system, the reliability research correctly apply to the product design, production, planning, purposefully implement related organization, supervision and control of management, and adopt the appropriate reliability growth technology makes the original medical instrument design more mature, So as to guarantee the safety and effective medical equipment to provide technical support and premise guarantee[1].

2. the inevitable trend of the reliability requirements of medical devices

2.1 Requirements for reliability of medical devices in relevant regulations on medical devices

As a product of modern science and technology, with the rapid development of medical diagnosis and treatment technology, medical devices have been widely used in disease prevention, diagnosis, treatment, health care and rehabilitation. No matter it is high-end or low-end products, their reliability is the most core concern. From thermometer, disposable infusion set to monitor, ventilator, from cardiac pacemaker, artificial blood vessels to vascular stents, artificial joints, most of the medical work in hospitals need the assistance of medical devices. Not only that, many medical devices will be temporary or long-term implants in the human body, for medical personnel, the reliability of medical devices is impossible to avoid.

The low reliability of medical devices will not only cause economic losses, reduce the reputation of manufacturers, but also directly endanger the life safety of patients. For a long time, the quality of some medical devices in China is unstable, with high failure rate and low reliability. It is estimated that more than 40,000 adverse device events occur in China every year. In view of this, in 2000, the State Council issued the "Regulations on the Supervision and Administration of Medical Devices", the general provisions clearly stated that the safety and effectiveness of the medical devices implanted in the human body, used to support and maintain life and potentially dangerous to the human body must be strictly controlled; According to Article 32 of Chapter IV of the Regulations, the drug

regulatory department of the people's government at or above the provincial level shall revoke the product registration certificate for medical devices that cannot guarantee safety and effectiveness[2].

2.2 Requirements of national and industrial standards on the reliability of medical devices

To fundamentally ensure the safety of medical devices, it is limited to rely only on the supervision and management of product quality. Recently, a lot of products that have been tested and qualified appear problems in use. Although the probability of such adverse events of medical devices is very small, they directly threaten the life safety of patients. In 2000, the International Organization for Standardization promulgated the application standard of risk management in medical devices, standardizing the framework of effective management of medical device use risk for medical device manufacturers, and recommending the use of fault mode and impact analysis, fault tree analysis, hazard analysis, risk and operational analysis and other reliability work content. It provides a technical tool for the safety research of medical devices. This standard has been recognized and adopted in the United States and the European Union. At present, 80% of foreign medical device manufacturers use reliability method to study the safety and effectiveness of their products.

2.3 Requirements of medical device industry competitiveness on the reliability of medical devices

At present, medical device reliability has become an important factor affecting the market competitiveness of medical device industry. Although some advanced, sophisticated and sophisticated digital medical equipment such as nuclear magnetic field, CT and other industries in China's medical devices have started to take off, they still occupy a small share in the international market, and high-tech products are basically monopolized by the European Union, the United States and Japan. Compared with the medical device products of some advanced countries in the world, the gap in the reliability of the products of some domestic medical device manufacturers is much greater than the gap in the performance. After all, medical devices are special commodities, which have higher requirements in terms of safety and effectiveness. At present, it is urgent for China's medical device enterprises to realize the safety and effectiveness of products by improving the reliability of medical devices [3].

Although the word "reliability" is not clearly quoted, hospitals and manufacturing enterprises are paying more and more attention to the durability, life, stability, maintainability, safety and so on of products, which has actually used the concept of reliability. Once the medical device product leaves the reliability, not only is meaningless, even is the potential crisis. With the growth of the use of time, the performance of the product can be reduced, but it must be able to work reliably, advanced performance indicators, reliability is not high products of no value. Thus, reliability will become an important quality index of medical device products. After China's entry into the WTO, in order to participate in the competition of the international market, some domestic enterprises have begun to take the reliability of medical devices as a core work of product production, and gradually integrate the reliability work into the research and development, production and use of medical devices, and has achieved obvious results. In order to meet the international standards and participate in the competition in the international market, the medical device industry of our country can stand firm in the international market economy only by continuously improving the reliability level of the medical device. Therefore, it is an urgent task for medical device enterprises in China to study reliability deeply and continuously improve product reliability.

2.4 Government regulation and public safety requirements on the reliability of medical devices

In recent years, with the development of China's medical device adverse event monitoring system construction and monitoring work, more medical device injury incidents surfaced, these events endanger the quality of life and safety of users, and bring unstable factors to the society. In the face of more than 12000 medical device manufacturing enterprise in China (which need to take control of product risk measures of class ii and class iii production enterprises, 9000), each year more than 10000 registered products, how to improve the medical device manufacturing enterprise of emphasis

on product safety, efficacy, how to reduce the risk, the use of medical devices. To make the residual risk to an acceptable level, how to improve the comprehensive competitiveness of China's medical device manufacturing enterprises, how to make the government supervision work scientific, fair, timely and effective, a series of issues are objectively placed in front of China's medical device manufacturing enterprises and government supervision departments.

In the current phase of history, it is necessary to reposition the reliability research in the domestic medical equipment industry's position and role, will have been more mature reliability engineering concepts into medical equipment industry, gradually from the technical level to promote medical equipment reliability works carried out in our country, improve the relevant laws and regulations, the implementation of national standards and industry standards, To provide theoretical basis and technical support for the safety and effectiveness of public equipment. This is also the experience of developed countries in developing the medical device industry.

3. Content of medical device reliability engineering

Medical device reliability engineering is a series of work, including reliability design, test, production and management, in order to meet the reliability requirements of medical devices and their parts. It runs through the design, production, inspection, packaging, transportation, storage, use and maintenance of a medical device. It is a system engineering. Design is the most important part. On the one hand, in the design process to solve the reliability problem, the lowest cost, the minimum loss; On the other hand, injury incidents in recent years have revealed that it is almost impossible to achieve the desired reliability indicators through training, warning, and correction of problems if the design is not sound. Therefore, personnel engaged in the design and development of medical devices must fully understand and master the theory and method of reliability research, so that the products developed have clear and effective reliability indicators, the design can be predicted, the test can be tested, and the production can ensure the process and results. The performance of medical devices in use can be stable and controllable throughout the product life cycle. It is necessary to control the design, test, manufacture and use process of medical devices under a reliably-based management system on the basis of reliability research, and finally achieve the reliability goal and ensure the safety and effectiveness of public devices through reasonable use of management technology [4].

4. Reliability activities in the life cycle of medical devices

4.1 Reliability design stage of medical devices

According to the needs of medical activities, medical device manufacturers shall clearly put forward the requirements for the reliability of medical devices. At the same time, when enterprises study the reliability requirements of medical devices, they should fully consider the reliability status, existing technical level, cost, function, use environment and other factors of the existing medical devices. The main contents of medical device reliability design include: methods, approaches and organizational measures to achieve reliability indexes. Production enterprises need to formulate the corresponding implementation plan, quality control plan, reliability verification test plan, personnel training plan and reliability data management plan, and have the means to check the implementation of the plan.

4.2 Medical device development stage

On the basis of basic research and exploring the application of new technology, various alternative schemes are formed, effective measures are put forward, samples are designed and constructed, and samples are subjected to rigorous test and identification. Evaluate the cost of the manufacture and use of medical devices, provide the necessary data for the manufacture and use of medical devices, and comply with the provisions of the Regulations on Clinical Trials of Medical Devices.

4.3 Batch production stage of medical devices

The reliability control should be carried out in the production process to ensure the reliability and maintainability of the product to meet the design requirements. An effective and feasible inspection system and method should be established, and a standardized and effective tracking system should be established for Class II and Class III medical devices that have certain risks and need to take control measures.

4.4 Use stage of medical devices

The use stage of medical devices includes storage, transportation, regular inspection, preparation before use, use according to the specified purpose and maintenance activities. The basic task of this stage is to maintain the reliability of medical devices and improve the maintainability and safety of medical devices. It should be noted that the reliability of medical devices is designed, manufactured and managed. In the whole life cycle of medical devices, reliability engineering activities have two parallel processes: one is engineering technology process. In the product design and development stage, through reliability design and design improvement, improve the inherent reliability of medical device products; Another is reliability management. In the production stage, the use of a variety of quality tools, reduce the production of parameter variation, control product quality, to achieve product reliability formed in the design stage; During the use phase, the product is effectively managed and maintained to maintain its inherent reliability [5].

The ultimate goal of medical device reliability research is: medical devices can play the expected effect, have high reliability, high safety and easy maintenance within the service period promised by product registration, so as to lay a theoretical and technical foundation for the overall goal of safety and effectiveness of medical devices. The improvement of the reliability of medical devices is a systematic project, involving a lot of work. It requires China's medical enterprises, manufacturing enterprises and government regulators to continuously improve the understanding and application ability of the reliability of medical devices, so as to realize the increase of the reliability of medical devices in China and the improvement of the ability of government supervision and execution.In the future, the research on the reliability of medical devices will become a new research hotspot, and will play an important role in realizing the safety and effectiveness of medical devices.

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