Research on the Future Development Direction and Management Model of Business Administration in Medical Device Enterprises

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Abstract: Medical devices, as a type of commodity closely related to human health, often cause medical accidents and significant economic losses and social impacts once quality problems occur. With the rapid expansion and development of the medical device industry and the continuous deepening of supervision and management work by supervisory departments, some problems in the production and operation of the medical device industry have gradually been exposed. This article analyzes the future development direction and management mode of business management in medical device enterprises, identifies existing problems, provides a basis for improving the supervision system, and ultimately integrates risk management into and becomes an indispensable part of the enterprise quality management system. For problems found during inspection, close tracking should be carried out to ensure product quality. The disinfection supply room should fully utilize existing equipment and human resources, achieve resource sharing, and centrally manage the washing, packaging, sterilization, and distribution of recycled medical devices, so that production enterprises and other personnel can establish a concept of full life cycle risk management.

1. Introduction

With the rapid development of modern medical and health technology, medical devices, as one of the symbol products of modern scientific and technological products, are widely used in disease prevention, diagnosis, treatment, health care and rehabilitation, and become an important part of modern medicine. Medical devices are a multi-disciplinary, knowledge-intensive and capital-intensive high-tech industry, in which medical devices cover 50 categories, more than 3,000 varieties and more than 12,000 specifications in various departments of hospitals. As a kind of commodity closely related to human health, medical devices often cause medical accidents once they have quality problems, resulting in great economic losses and social impact[1]. With the rapid expansion and development of medical device industry and the deepening of supervision and management by supervision departments, some problems in production and management of medical device industry are gradually exposed. At present, China's medical device manufacturers have some problems, such as small production scale, low management level, lax implementation standards and unstable quality of medical device products. Any medical device in its whole life cycle, such as design, research and development, clinic, manufacturing, sales, installation, use and maintenance, and even scrapping, will fail with a certain probability and bring risks. Therefore, risk management always runs through the whole process of the whole life cycle of medical devices[2-3]. In today's fierce competition, if we want to grow stronger and not be eliminated by the market, we must improve our own operation level and development efficiency. Therefore, doing a good job in business management of medical device enterprises has become an important requirement for enterprise development. Mastering the current situation of medical device manufacturing enterprises is an important prerequisite for effective supervision and formulation of laws and regulations. This paper analyzes the future development direction and management mode of industrial and commercial management of medical device enterprises, finds out the existing problems, provides the basis for improving the supervision system, and lays the foundation for the

basic construction of public health emergency response. All risks arising from procurement and production and post-production information are included in risk management, and finally risk management is integrated into and becomes an indispensable part of enterprise quality management system[4]. The business administration of medical device enterprises plays an important role in the sustainable development of enterprises. Therefore, the improvement of the quality of business administration plays an important role in promoting the successful transformation of enterprises, standardizing the development model of enterprises and promoting the sound and rapid development of enterprises.

2. Problems in Business Administration of Medical Device Enterprises

2.1 Lack of Professional Talents and Low Personnel Quality

Currently, most medical device enterprises in China still face problems such as production activities being blocked, production and marketing departments unable to coordinate in a timely manner, daily management still being chaotic, management mechanisms being too rigid, and organizational structures lacking flexibility, making it difficult for the entire medical device enterprise to achieve the development requirements of economic scale. There are a wide variety of medical device products that involve multiple disciplinary fields. The production and operation of different types of medical devices require practitioners to master different professional knowledge. Most of them are self cleaned, packaged, and sent to the disinfection supply room for sterilization by various departments[5]. The cleaning environment conditions are poor, and there are no dedicated cleaning facilities or equipment, no enzyme cleaning agents, and no dedicated instrument lubricants. There is no drying equipment, no cleaning workflow or quality standards, and there are still blood stains on the cleaned items. It should be reflected in the low level of understanding and mastery of medical device regulatory regulations and basic business knowledge by corporate legal representatives, technical leaders, quality management personnel, sales personnel, and after-sales service personnel[6]. There are still problems with the production planning and sales coordination of medical device enterprises, and there is still a significant gap between them and foreign enterprises. This indicates that our management level is still relatively backward, and the foundation of medical device enterprises is not solid enough, and the comprehensive economic benefits cannot reach the predetermined goals.

2.2 Shallow Legal Concept

After the planned economy entered the market economy and the concept of business administration was introduced, the guiding ideology of business administration in medical device enterprises began to change greatly. Maximizing the benefits brought by the increase of figures in financial statements can no longer meet the needs of modern enterprises, and more enterprises begin to formulate long-term goals or strategic development plans[7]. There is no special article loading rack or article box in the sterilization cabinet, and the biological monitoring package and chemical monitoring package do not meet the standards; The layout is not uniform. Poor transport and storage conditions after sterilization: there is no special transport equipment, the storage cabinet is made of ceramic tiles, and there is no dust-proof facility. Rational use of limited resources, put an end to excessive waste, and at the same time pay more attention to environmental protection, sponsor the development of education, provide training for better staff training, actively participate in and rebuild public welfare and a series of other issues.

2.3 Packaging Quality Does Not Meet Sterilization Requirements

Medical device manufacturing and operating enterprises only value economic benefits and neglect the study of relevant regulatory laws, regulations, and rules. Some practitioners cannot even recognize the authenticity of medical device registration certificates, making it difficult to consciously regulate management[8]. The bag cloth is repeatedly used without cleaning, with stains, hard texture, or even damage. There is no indicator card inside the bag, no indicator tape outside the

bag, no sterilization date and expiration date specified, and the size and weight of the bag exceed the standard; Sterilization cannot be carried out within 2 hours after packaging. Due to factors such as weak innovation awareness, lack of competitive products, low market share, and weak awareness of self pressure, the company's profits are thin, seriously affecting the development of the medical device industry.

3. Exploration and Analysis of Management Mode of Future Development Direction of Business Administration in Medical Device Enterprises

3.1 Strengthen the Management Training of Personnel.

According to the requirements, the personnel of each post shall be fully staffed, and the training system shall be established. Disinfection supply room staff should participate in continuing education courses and academic exchange activities related to disinfection supply, and disinfection supply room management personnel should have no less than 20 hours per year[9]. Improving the awareness level of risk management in production enterprises is the basic guarantee for implementing effective risk management. The first thing that needs to be changed is that production enterprises only regard risk management as the implementation procedure of registered products, or even an incorrect risk management concept of a risk management report. In the evaluation of quality inspection institutions and quality inspection ability, the outstanding problems for aseptic medical device manufacturers are “the environment of aseptic products and product testing ability” and “the facilities and product testing equipment of aseptic monitoring room”, which are quite different among manufacturers[10]. It is required to master various work quality standards and management requirements and special requirements such as washing and packaging of specialized instruments, and to have professional theoretical knowledge and operational skills.

3.2 Fully Utilize Disinfection Supply Room Functions

Strengthen the supervision of the medical device market, draw on the experience of foreign medical device management, increase the accountability and punishment of adverse events of medical devices, formulate laws or regulations related to medical devices, and incorporate adverse events of medical devices into the scope of legal management. Due to the unique nature of sterile medical device manufacturing enterprises, supervision should be strengthened, and problems found during inspections should be closely tracked to ensure product quality. The disinfection supply room should fully utilize existing equipment and human resources, achieve resource sharing, and centrally manage the washing, packaging, sterilization, and distribution of recycled medical devices.

3.2.1 Implementation Methods for Centralized Management

Conduct publicity and training based on the classification of medical devices to improve training effectiveness. Standardize the management of regenerative medical devices, including the basic workflow of storage, recycling, classification, cleaning, disinfection, inspection, maintenance, drying, packaging, sterilization, storage, and distribution of devices in the manuscript room after use, and develop quality standards and assessment rules for each link of work. In addition to daily supervision of production enterprises, the medical device regulatory department can implement targeted tracking and supervision, supervise enterprises to implement rectification, and enable enterprises to effectively fulfill their responsibilities as production entities. This article analyzes the countermeasures and measures to solve the problem, as shown in Figure 1.

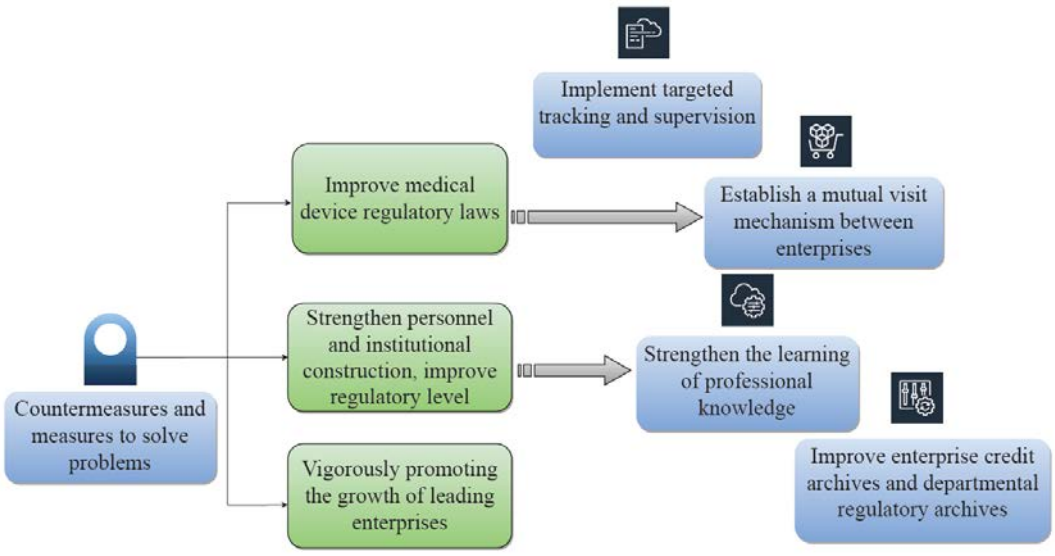

Fig.1 Countermeasures and Measures for Solving Problems

Strengthening the supervision of enterprise management systems can appropriately emphasize the importance of management systems in the training of enterprise management personnel, and combine various forces in daily supervision. The content can include corresponding categories of regulatory and standard requirements, as well as the implementation of guiding documents, to establish the concept of full life cycle risk management for production enterprises and other personnel.

3.2.2 Advantages of Centralized Management

In addition to strengthening targeted risk management training for technicians in production enterprises, we should also set up risk management majors in universities of science and engineering to train risk management talents with basic knowledge of medical devices. The person in charge of the medical device manufacturing enterprise should be strict with the enterprise itself and constantly improve the conditions of the enterprise. The medical device manufacturing enterprise should have higher requirements for the standards of the conditions of the enterprise itself. Through the investigation of 63 enterprises, 21 enterprises believe that the risk management process should run through the complete life cycle from the formation of product concept to the cessation of product use, and such enterprises account for 30% of the total number of investigations, as shown in Table 1.

Table 1 Cognition of The Surveyed Enterprises on Risk Management Time Period

Classify	Number of cases	Constituent ratio
From product design and development to post-marketing stage.	42	66.66
From product manufacturing to post-production stage.	15	23.81
Other	6	9.53

Among the enterprises surveyed, 35 enterprises believe that the risk management plan should be jointly drawn up by multiple departments, accounting for 51% of the total number of enterprises surveyed, as shown in Table 2.

Table 2 Understanding of The Surveyed Enterprises on the Way to Draw Up the Risk Management Plan

Classify	Number of cases	Constituent ratio
Should be drawn up by individual departments.	35	55.55
Should be jointly formulated by multiple departments.	28	44.45
Total	63	100

Centralized management mode can effectively guarantee the quality of sterile supplies, reduce the indirect nursing hours of clinical nurses, promote the overall nursing work and improve work

efficiency. It is beneficial to occupational safety protection and improves the quality of disinfection supply.

4. Conclusions

Regulatory authorities should provide specific guidance and assistance to enterprises in administrative approval, technology, and information services, and promptly coordinate and solve difficulties and problems encountered by enterprises in approval, system certification, and other aspects. In the evaluation of quality inspection institutions and quality inspection capabilities, the most prominent issues for sterile medical device production enterprises are “the environment and product testing capabilities of sterile products” and “the facilities and product testing equipment of sterile monitoring rooms”, with significant differences among production enterprises. There is still a gap between the level of understanding of risk management documents and indicators among the majority of enterprises surveyed in this article and the requirements of standards. The relevant documents and indicators of risk management are necessary documents to guide enterprises in risk management, and are also the focus of regulatory review. List the disinfection supply room as a key department for hospital infection management, ensure sufficient working space according to regulatory requirements, standardize process flow, and implement strict zoning management; Equip sufficient disinfection and cleaning facilities and medical equipment, and improve outdated sterilization equipment. Strive to promote the healthy and rapid development of enterprises, expand and strengthen small enterprises, and form a sustainable medical device industry chain, playing a positive role in promoting the scale, grouping, and industrialization development of medical device production and operation enterprises in Guiyang.

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