Academic Journal of Engineering and Technology Science
ISSN 2616-5767 Vol.7, Issue 3: 152-157, DOI: 10.25236/AJETS.2024.070321

Design and Implementation of Closed Loop Management System for GMP Workshop Cleanroom Garment

Xin Ke

Electronic Information Technology, Shanghai Jiabai Litong Technology Co., Ltd, Shanghai, China

Abstract: *In order to strengthen the management of cleanroom garments in GMP workshops to ensure its safety, compliance and legality, as well as to further control the pollution risk in the production chain, Shanghai Jiabo Litong Technology Co., Ltd. monitors the use process of cleanroom garments in GMP workshops based on RFID technology and the closed-loop management system of cleanroom garments. The application of science and technology allows a convenient electronic traceability management for the storage, distribution, use, recycling, scrapping, cleaning, sterilization, usage time and whole life process of cleanroom garments. One-key query can trace all the use information of cleanroom garments. The application of RFID technology on cleanroom garments can effectively reduce the statistical error possibility. From more than a dozen of customer feedback, it has achieved the purpose of the system design with a remarkable effect in improving personnel cleanroom garments management and risk control management of GMP workshop.*

Keywords: *GMP workshops; RFID; Cleanroom garments management; Traceability; Close-loop management*

1. Introduction

In the theory of total quality management[1], the personnel factor is the biggest difficulty, and all departments need to participate in the entire process in order to better manage quality; Meanwhile, in the pharmaceutical industry, personnel in GMP workshops are also the largest source of pollution in clean areas[2]. Mainly because currently, better metal wall panels are used for clean room decoration, and the amount of dust generated from the building surface is also low. The dust mainly comes from the human body itself. Clean clothing is an important protective barrier for personnel working in GMP workshops. Any slight negligence in management can lead to risks such as microbial contamination in the environment. The Ministry of Health of the People's Republic of China (Order No. 79) issued the Good Manufacturing Practice of Medical Products (GMP) (Revised in 2010). On April 23, 2020, the National Medical Products Administration issued a notice (No. 58 of 2020) on the revised draft of the appendix for biological products, in which Article 59 specifies the requirements for inputting relevant data into the information system. The management of clean clothing usage is receiving increasing attention from the industry. Therefore, designing a traceable closed-loop management system for clean clothing and optimizing the compliant use of protective equipment such as clean clothing is of great significance for improving management efficiency in the pharmaceutical industry.

To this end, Shanghai Jiabai Litong Technology Co., Ltd. has introduced the concept of closed-loop management of clean clothing and combined RFID technology[3] to provide real-time and comprehensive supervision and feedback on clean clothing and clean protective equipment in GMP workshops, while also winning good market feedback.

2. Management process

The GMP workshop clean clothing closed-loop management system is led by the concept of closed-loop management, introducing RFID technology, and combining with the industry and enterprise specific SOP (Standard Operating Procedure) to optimize and transform the management process of clean clothing, so that the distribution, use, recycling, scrapping and other links of protective equipment such as clean clothing are traceable, in order to achieve closed-loop management of clean clothing and protective equipment. The process is shown in Figure 1.

ISSN 2616-5767 Vol.7, Issue 3: 152-157, DOI: 10.25236/AJETS.2024.070321

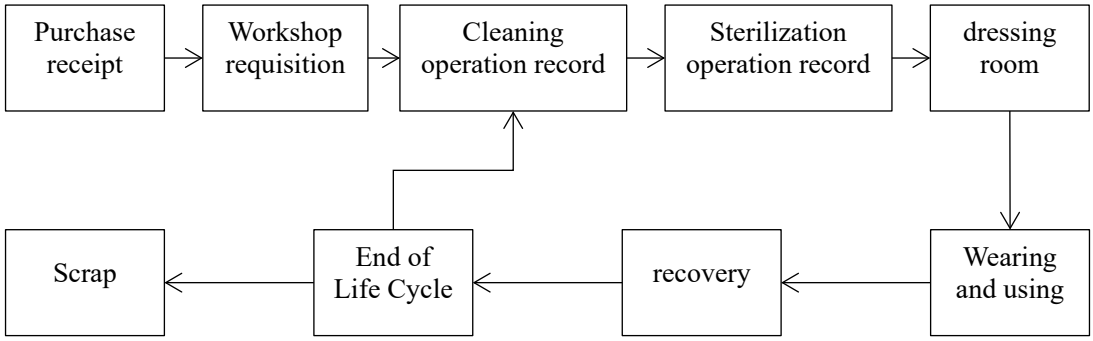

Figure 1: GMP workshop clean clothing uses a closed loop management system

2.1. Clean clothing manufacturer's RFID tag implantation and information initialization operation

In the process of digital technology transformation in clean clothing management, implanting an RFID tag into each clean clothing is the primary step. In this step, establish detailed identity information for each piece of clean clothing. Before leaving the factory, the clean clothing manufacturer needs to enter the following information: clean clothing production batch number, style, size, material, style number, quality inspector, and other basic information. At the same time, during the RFID tag implantation process, it is necessary to strictly follow the relevant requirements of the Good Manufacturing Practice for Drugs (revised in 2010), and the packaging material of the RFID tag must also meet the requirements of 121 degrees Celsius and 100 KPa for 30 minutes during the wet heat sterilization process[4]. The working performance of the RFID tag throughout the entire sterilization process and the dust generation during the high-temperature sterilization process must also be strictly controlled.

2.2. Procurement and warehousing by pharmaceutical companies

In the procurement and warehousing process of pharmaceutical companies, efficiency and accuracy are paramount. Warehouse administrators play a crucial role in ensuring that clean clothes, which often serve as protective equipment for employees, are properly managed. These administrators utilize advanced scanning technology, such as mobile scanning terminals or desktop scanning terminals, to streamline the process.

The warehouse administrators log into the system platform using their exclusive accounts, providing a secure and personalized environment for managing inventory. Once logged in, they scan the RFID tags affixed to the clean clothes. These tags contain vital information about the clothing, including the production batch number, style, size, material, style number, quality inspector's details, and quantity. By scanning these tags, the administrators can quickly verify that the received items match the order specifications.

Concurrently, the administrators enter the information regarding the warehouse location and specific shelves where the batch of clean clothes will be stored. This step is crucial for maintaining organized inventory and ensuring that the clothes are easily accessible when needed. The system then updates its database with the new information, reflecting the current stock levels and location of the items.

After the information is entered and verified, the physical goods are stored in the designated location. This process ensures that the clean clothes are securely stored and can be easily retrieved when required. The use of RFID technology and scanning terminals significantly reduces the chances of errors, improving overall efficiency and accuracy in the procurement and warehousing process.

2.3. Pharmaceutical workshop requisition

Within the pharmaceutical workshop, the management of protective equipment is a vital aspect of ensuring the safety of employees. The transfer personnel, who operate outside the main production area, play a crucial role in this process. Based on the regular usage patterns and requirements of the workshop, these personnel are responsible for reserving a certain amount of protective equipment within the workshop itself. This preemptive step ensures that when the need arises, the required equipment is readily available, minimizing disruptions to the production process.

ISSN 2616-5767 Vol.7, Issue 3: 152-157, DOI: 10.25236/AJETS.2024.070321

Once the protective equipment is received, the transfer personnel carefully store it in a designated temporary storage room. This space is typically equipped with the necessary conditions to maintain the equipment's integrity and functionality, such as proper ventilation, humidity control, and temperature regulation. When the workshop's inventory of protective equipment falls below a predetermined threshold, indicating the need for additional supplies, the transfer personnel proceed to the main warehouse to receive new stock. This process includes checking the availability of the warehouse, completing necessary paperwork, and transporting the equipment back to the workshop, which helps to ensure the smooth and efficient operation of the entire production process.

2.4. Management of cleaning protective equipment

In the production workshop, the internal transportation personnel plays a pivotal role in ensuring the efficient management of cleaning protective equipment. Their primary responsibility is to retrieve the protective equipment requiring cleaning from the temporary storage room and transport it to the designated cleaning operation room. Before commencing the cleaning process, the cleaning operator adheres strictly to a series of verification procedures. Utilizing their exclusive account on either a mobile RFID scanning terminal or a fixed scanning terminal, the operator logs into the system platform. They then scan the RFID tags attached to each batch of protective equipment, carefully verifying the quantity, ID number, style, size, and any other relevant information. This step ensures that the equipment is accurately identified and accounted for, minimizing the chances of misplacement or loss.

Once the scanning and verification process is complete, and the information is confirmed to be accurate, the operator proceeds with the laundry operation. This involves using appropriate cleaning methods and detergents to thoroughly clean the protective equipment, ensuring it is ready for reuse. Upon completion of the laundry operation, the operator takes on the responsibility of the subsequent garment and packaging procedures. This includes ensuring that the equipment is properly folded, packaged, and labeled for storage or redistribution. The entire process, from retrieval to packaging, is executed with precision and care, ensuring the protective equipment remains in optimal condition for its intended purpose.

2.5. Sterilization management of protective equipment

The internal transfer personnel in the production workshop plays a crucial role in the sterilization process of protective equipment. They ensure that the equipment is safely and efficiently transported from the temporary storage area of the laundry center to the designated sterilization operation area. Once the equipment is in the sterilization area, the sterilization operation personnel take charge.

Utilizing their exclusive accounts on either a mobile RFID scanning terminal or a fixed scanning terminal, the sterilization personnel logs into the system platform. They then scan the RFID tags attached to each batch of protective equipment, carefully verifying the quantity, ID number, style, size, and any other critical information. This verification process ensures that the equipment is accurately identified and tracked, minimizing the risk of errors or mismanagement. After the scanning and verification process is completed, and the information is confirmed to be accurate, the sterilization personnel proceeds with the sterilization operation. This process ensures that the protective equipment is thoroughly sanitized, making it safe for reuse in various applications. The entire process, from transfer to sterilization, is executed with precision and care, ensuring the highest level of hygiene and safety.

2.6. Management of Clean Clothes Distribution

The personnel in the internal transfer position determine the number of clean clothes that need to be transferred based on the recent demand in the workshop. Before transfer, they log in to the terminal software by entering their own exclusive account and password at the distribution terminal, scan the RFID electronic tags on the batch of clean clothes, and type or select the destination changing room for distribution. After the data is successfully scanned and entered, the system automatically records and calculates the distribution related data, which is displayed on the display screen of the distribution center. At the same time, the distribution center can display the real-time quantity of available clean clothes in each changing room, and the distribution personnel can dynamically adjust the quantity of clean clothes to be distributed through the data displayed on the information screen[5]. If the existing clean clothes in the changing room are used by production personnel or exceed the expiration date of the current cleaning or sterilization during long-term storage, the system will reduce and display the corresponding number of existing clean clothes at the distribution center.

ISSN 2616-5767 Vol.7, Issue 3: 152-157, DOI: 10.25236/AJETS.2024.070321

2.7. Changing Room Usage Steps

Before entering the workshop to change clothes, workshop staff should find a suitable size of clean clothes from the temporary storage area and scan the RFID electronic tag in the RFID electronic tag sensing area of the inquiry and use confirmation terminal. The software on the terminal will automatically retrieve the cleaning and sterilization status, expiration date, and other data of the clean clothes. After the relevant verification conditions are met, the system confirms the compliance status of the clean clothing and prompts a verification pass and a "✓" pattern display on the query terminal display screen. Feedback to the user that the clean clothing status is compliant. At the same time, the software system automatically records that the clean clothes have been used, and updates the real-time number of clean clothes in the changing room associated with the clean clothes management backend. On the distribution center display screen[6], the current number of compliant clean clothes in the changing room is correspondingly reduced by 1 piece.

2.8. Clean clothing recycling process after use

Once the workshop staff has completed their shift and is ready to relinquish their current clean clothes, they are responsible for returning them to the designated return and recycling area. This area is specifically designed to facilitate the efficient collection and management of used protective clothing. Once a sufficient number of clean clothes have been collected in the recycling area, the internal transfer personnel initiates the next step of the recycling process. They carefully gather the used clothes into batches, ensuring that they are properly sorted and accounted for. Then, the transfer personnel transports the batches of used clean clothes to the laundry room, where they will undergo the necessary cleaning and sanitization procedures.

The laundry room is equipped with state-of-the-art equipment and procedures to ensure that the clothes are thoroughly cleaned and sanitized, ready for reuse. After the cleaning and sanitization process is completed, the clean clothes are returned to the inventory and are ready to enter the next cycle of use. This entire recycling process ensures that the protective clothing is effectively managed, reducing waste and ensuring that it remains in optimal condition for continued use.

3. Management effectiveness

The application of RFID management technology for clean clothing in pharmaceutical production departments has achieved closed-loop management in a series of processes, including clean clothing storage, distribution, cleaning, sterilization, and usage confirmation. At the same time, information management based on RFID ensures the traceability of cleaning and cleaning services in various usage stages, reduces the risk of human error, and achieves good results in practical application, mainly manifested in the following aspects.

3.1. Effectively reducing the dust risk of paper labels and printing ink used for clothing labeling

In the pharmaceutical industry, labeling plays a crucial role in ensuring the traceability, validity, and sterility of clean clothing. However, traditional labeling methods, which often rely on self-adhesive paper labels with handwritten or printed information, can pose a significant dust risk in dust-free environments.

The use of paper labels and printing ink in labeling clean clothing introduces several potential hazards. The stylus used for handwriting can emit dust particles, contaminating the clean environment. Similarly, the ink used for printing can also release volatile compounds that can contaminate the air and surfaces in the cleanroom. To address these issues, the implementation of RFID (Radio Frequency Identification) electronic tags offers a viable solution. RFID tags are encapsulated with special materials that are designed to be dust-resistant and non-volatile. By implanting these tags inside clean clothing, we can effectively reduce or eliminate the dust risk posed by the tags themselves on the clean environment[7]. Not only do RFID tags minimize the dust risk, but they also enhance the efficiency and accuracy of labeling. Information such as cleaning date, cleaning validity period, sterilization date, and sterilization validity period can be electronically stored and retrieved, eliminating the need for handwritten or printed labels. This not only reduces the potential for human error but also speeds up the process of identifying and tracking clean clothing.

Based on this, it can be seen that,, the use of RFID electronic tags for clothing labeling in the pharmaceutical industry is a significant step towards reducing the dust risk associated with traditional

ISSN 2616-5767 Vol.7, Issue 3: 152-157, DOI: 10.25236/AJETS.2024.070321

labeling methods. By minimizing the potential for dust emission and enhancing the efficiency and accuracy of labeling, RFID tags contribute to maintaining a cleaner and safer production environment.

3.2. Effectively reducing identification and statistical errors caused by human factors

In the distribution and usage process of clean clothing in the pharmaceutical industry, human factors often play a significant role in causing identification and statistical errors. Traditionally, the identification of transfer personnel relies heavily on visually observing handwritten or printed information on clothing numbers and paper labels to determine the cleaning status, sterilization status, number of times cleaned, number of times sterilized, and other crucial details. However, when workloads increase, it becomes increasingly difficult to rely solely on human observation, leading to inevitable errors in identification and statistical data. To address this challenge, the implementation of RFID (Radio Frequency Identification) wireless scanning technology offers a significant advantage. The RFID antenna on the scanning terminal automatically senses and identifies the unique ID of the clean clothing, eliminating the need for human visual inspection. This technology automatically retrieves the cleaning and sterilization status information of the clean clothing, ensuring compliance and significantly improving the accuracy and efficiency of identification.

During the usage process, workshop staff no longer need to visually inspect written or printed information on paper labels to determine compliance. Instead, the system terminal automatically scans the RFID electronic labels, instantly verifying the authenticity and accuracy of the information. This not only saves staff valuable work time but also significantly improves recognition accuracy and efficiency. By relying on RFID technology, we can minimize the risk of identification errors caused by human factors, ensuring a more reliable and accurate process for clean clothing management. Overall, the introduction of RFID wireless scanning technology in clean clothing management represents a significant step forward in reducing human errors and improving the overall efficiency and accuracy of the distribution and usage process. By automating the identification process, we can ensure compliance, enhance traceability, and reduce the risk of contamination in dust-free environments.

3.3. Improve the work efficiency of operators in the distribution process and save human resources

In the traditional distribution process of clean clothing, operators face significant challenges in maintaining efficiency while ensuring accuracy. They need to personally visit each changing room, physically checking the remaining quantity of available clean clothing and requesting timely replenishment. This process is not only time-consuming but also prone to errors. Furthermore, when the laundry center (sterilization center) and changing room are of different cleanliness levels, distribution personnel must change clothes before entering higher-level changing rooms to avoid contaminating the environment. This additional step significantly increases the time required for each inspection. The introduction of RFID clean clothing automatic scanning technology has revolutionized this traditional process. By utilizing RFID tags and scanners, the system can automatically track and monitor the remaining quantity of clean clothing in each changing room. This allows distribution operators to remotely monitor the status of clean clothing, identifying any need for replenishment without physically visiting each changing room. The real-time dynamic update of clothing quantities ensures that operators can respond quickly and efficiently to any changes in demand.

The benefits of RFID technology in this context are significant. Firstly, it significantly improves the work efficiency of distribution operators, reducing the time and effort required for manual inspections. This not only saves valuable human resources but also allows operators to focus on more critical tasks. Secondly, the real-time update of clothing quantities reduces the risk of clothing shortages or overstocking, ensuring a smooth and efficient distribution process. Finally, by reducing the need for operators to enter different cleanliness levels, RFID technology helps maintain the integrity of the clean environment, reducing the risk of contamination. In summary, RFID clean clothing automatic scanning technology represents a significant advancement in improving the work efficiency of operators in the distribution process while saving on human resources. It not only reduces the time and effort required for manual inspections but also ensures a smooth and efficient distribution process by optimizing the utilization of clean clothing.

3.4. Real time monitoring of information, establishment of efficient traceability mechanism , reducing risks in the production process

A traceability mechanism has been established overseas in various links such as distribution, use,

ISSN 2616-5767 Vol.7, Issue 3: 152-157, DOI: 10.25236/AJETS.2024.070321

cleaning, sterilization, etc[8]., to implement the work responsibilities of operators in each link to their positions and individuals, and to reduce risks caused by human factors in the system and management system;

3.5. The management of clean clothing in the pharmaceutical industry has important promotional value

Due to the particularity of the industry, the technology mentioned in this article has not yet been widely used in the pharmaceutical industry. At the same time, this technology can bring great convenience to the existing clean clothing management. We believe that it will have important promotion value in the pharmaceutical industry in the future.

4. Conclusions

The use of RFID technology in clean clothing management has obvious advantages compared to traditional paper-based record management methods, but there are also some problems in practical application, such as the need for clean clothing manufacturers to increase the cost of the implantation process and the cost of RFID electronic labels; The completeness and diversity of protective equipment will also increase corresponding costs. In the purification workshop of the pharmaceutical industry, in addition to the main clean clothing that needs to be traced and managed, all supporting protective equipment such as masks, protective shoes, and eye masks will be included in RFID automatic identification management, which will increase the management investment cost. When RFID tags are damaged, it poses a challenge to managing data, and measures need to be taken during system design and labeling [9].

References

[1] Hu Jinglu, Guo Jidong. The Application of Total Quality Management Theory in Pharmaceutical Management Work [J]. China Health Industry, 2022, 19 (4): 94-96.
[2] Wang Sijin, Wang Baobang, Yu Meng, etc. Personnel management in domestic and foreign guidelines for sterile drug production regulations [J]. Chinese Journal of Pharmaceutical Industry, 2022, 53 (8): 1222-1226.
[3] Ma Chaoqiong, Wen Lin, Li Dengke, etc. Research on Integrated Management of High Value Medical Consumables Supply Chain [J]. Medical and Health Equipment, 2019,40 (7): 81-85.
[4] Li Ying, Han Zijian. Developing a humid heat sterilization process using the principle of sterile assurance [J]. Strait Pharmacy, 2021, 33 (8): 6-9.
[5] Wang Xiao, Wang Lu, Gao Yongbao, etc. Analysis of inspection defects in factories, facilities, and equipment in the global pharmaceutical industry [J]. Chinese Journal of Modern Applied Pharmacy, 2020,37 (10): 1241-1247.
[6] Cui Juxia, Zhao Zhihong. Clean room control for sterile drug production [J]. Electromechanical Information, 2010 (26): 21-23, 52
[7] Wang Xin, Yan Huahui, Wang Hao, etc. Design and Application of Electronic Batch Records in the Pharmaceutical Industry [J]. Industrial Control Computer, 2019, 32 (8): 156-157+160.
[8] National Health Commission of the People's Republic of China. Good Manufacturing Practice for Drugs (Revised in 2010) (Order No. 79 of the Ministry of Health) [S]. 2011
[9] Li Zhike, Liu Zhusong. RFID tag data verification and recovery based on cloud storage technology [J]. Journal of Guangdong University of Technology, 2014 (3): 137-142.