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Analysis on Main Issues and Key Technologies of Real-time Monitoring of Veterinary Drug Production Process

Shanshan Cao¹, Guodong Cheng¹, Hongyu Zhang¹, Chen Shen¹ and Jifang Liu^{1*}

¹ Agricultural Information Institute, Chinese Academy of Agricultural Sciences/Key Laboratory of Agricultural Big Data, Ministry of Agriculture and Rural Affairs, Beijing, 100081, China

* Corresponding author's e-mail: liujifang@caas.cn

Corresponding author: Jifang Liu (liujifang@caas.cn).

Abstract. Veterinary drug quality and safety is the key to the healthy development of animal husbandry. Veterinary drug quality is directly related to the safety of animal products and human health. In recent years, the Chinese government has promulgated regulations Good Manufacturing Practice of veterinary drugs and other regulations on the supervision of veterinary drug production process. However, the manufacture and sale of fake and inferior veterinary drugs and the illegal use of veterinary drugs are still prominent. It is urgent to further strengthen the quality and safety supervision of veterinary drugs. In the process of veterinary drug production, the identification and monitoring technology of HACCP key control points in veterinary drug production is studied, the dynamic real-time perception technology equipment of GMP key points in veterinary drug production is developed, the video analysis method of production operation specification is explored, and the traceability coding of minimum sales unit of veterinary drug is optimized. All these methods can realize the dynamic information monitoring on the production process of veterinary drugs. The research and implementation of the above-stated methods can strengthen the effective supervision of the source of veterinary drug production, ensure safe use of animal drugs, further improve the quality of livestock products, ensure food safety of people, and have significant economic and social benefits.

1. Introduction

The correct use of qualified veterinary drugs can not only cure diseases of livestock, but also improve the quality of livestock. However, the use of substandard veterinary drugs cannot produce positive results, on the contrary, play a counterproductive role, which affects not only the production of livestock, but also the quality of livestock. Moreover, if veterinary drug residues, it may ultimately affect human life and health. Therefore, the correct use of qualified veterinary drugs in the production of animal husbandry is very significant, so the supervision on veterinary drug production is imperative.

In 1989, the Ministry of Agriculture promulgated "Good Manufacturing Practice" (GMP) for Veterinary Drug, which stipulates the raw materials, technology, storage and other links of veterinary drug production in detail. With the continuous development of science and technology, veterinary drug production technology has made tremendous progress; the national veterinary drug GMP standards are also constantly updated and developed. In 2001, the Ministry of Agriculture revised the veterinary drug GMP. On March 19, 2002, the Ministry of Agriculture issued a new edition of



Veterinary Drug Production GMP, which is the basic criterion for the production and quality management of veterinary drugs. It is suitable for the whole process of veterinary drug production and the key process affecting the quality of finished products in the production of raw materials. The new edition of GMP for veterinary drugs is described in detail from the aspects of organization and personnel, plant and facilities, equipment, materials, hygiene, certification, documents, production management, quality control, product sales and recovery, complaints and untoward effect reports, self-checking, etc. It is stipulated that enterprises that have not obtained the GMP certificate for veterinary drugs on and before January 1, 2006 shall not be allowed to produce veterinary drugs. On November 30, 2017, the Ministry of Agriculture issued Order, Document No. 8th 2017, the veterinary drug GMP was further revised.

Currently human society has already been in the era of informatization; the use of computers has penetrated into all levels of society. Similarly, if the production and management of veterinary drug production industry can make good use of computer systems, it will undoubtedly reverse the current backward management situation and fundamentally solve the problems in veterinary drug GMP production and management [1]. Luo Shunting, Tong Wei [2] and others have developed GMP information management system for veterinary drugs. Guided by GMP for veterinary drugs, the system adopts the means of combining intelligent electronic devices such as bar code and IC card with computer network technology to realize the whole process control of every link of GMP daily management for veterinary drug manufacturers. The whole process, including 12 prescriptions required by GMP documents for veterinary drugs, is computerized information management mode. Tan Zhijian, He Weixiong and others have developed "Veterinary Drug GMP Information Management System" to replace the traditional manual record management model for enterprise GMP management. The system fully conforms to GMP for Veterinary Drug Production of the Ministry of Agriculture and Law of Electronic Signature of the People's Republic of China. Guided by the GMP for veterinary drugs, the system adopts the means of combining the bar code, IC card and computer network technology, and realizes the daily management on GMP for veterinary drug enterprises through Internet or Intranet. The whole process is free of paper.

2. Analysis on major issues

Since the Ministry of Agriculture formally implemented GMP for veterinary drugs, the production of veterinary drugs in China has been optimized and integrated, and entered a virtuous circle, initially realizing the automation of veterinary drug production supervision, traceability of circulation and guaranteed use. However, there are still some issues in the production of veterinary drugs.

Some veterinary drug enterprises have weak awareness of safety in production, cannot correctly understand the importance of safety in production of veterinary drugs, as a result, GMP for veterinary drugs cannot be truly implemented in the production of veterinary drugs. Some enterprises only apply GMP in links of inspection and acceptance. After passing the GMP inspection and acceptance, the enterprises relax the safety control of veterinary drug production, and cannot effectively implement the GMP self-inspection of veterinary drugs. Some veterinary drug producers even do not carry out the production, transportation and storage of veterinary drugs in accordance with the provisions of GMP [3].

In order to uphold the concept of "one code for one drug, one code for one animal, one-to-one correspondence, the whole process traceability", the Ministry of Agriculture has compulsorily implemented the electronic traceability code (2-D code) marking system for veterinary drug products [4]. By printing 2-D label codes on the package of veterinary drug products, a Traceability Technology System for the whole process of veterinary drug production, circulation, storage and use is formed, which can effectively solve the problem that the flow direction information of veterinary drug does not match the actual production and marketing information. However, there are still some problems in the electronic traceability code (2-D code) marking system, which cannot meet the requirements of traceability of veterinary drugs. Firstly, 2-D code can store a large amount of information, but it is easy to print, easy to be counterfeited by illegal elements. Secondly, 2-D code

printing is not standardized and vulnerable, resulting in the failure to query the product name, approval number, production enterprise name, telephone and other basic information [5].

3. Exploration to key technology research path

3.1. Recognition technology of HACCP critical control points in veterinary drug production

The production link of veterinary drugs is the foundation and key to ensure the safety of livestock and poultry. Standardizing the production process of veterinary drugs, preventing various risks and ensuring the quality and safety of veterinary drugs from the source are important measures to prevent unqualified veterinary drugs from flowing to the market. The first is to establish a risk factor index system for veterinary drug production process. In the whole production process from raw materials entering the factory to veterinary drug products leaving the factory, the relevant links affecting the quality level of veterinary drug are screened out, the risk factors and their harmfulness extent existing in each link of veterinary drug production are defined, and the risk factor index system of veterinary drug production process is established in order to eliminate the potential safety hazards and reduce the quality risk of veterinary drug to the maximum extent. The second is to analyze and evaluate the critical control points of veterinary drug production. Based on the principle of HACCP and CCP decision tree, the risk factors of veterinary drug production process are analyzed, and the judgment matrix of risk factors is established by comprehensively applying analytic hierarchy process. The index weights of harmfulness extent of key points in veterinary drug production are calculated by expert scoring, and the key control points and general control points in veterinary drug production process are divided. The third is to study and determine the critical limits and monitoring frequencies of critical control points. The key limit table of control points in veterinary drug production links is studied and established, the reasonable fluctuation range is defined, and the control level is divided, so as to provide operation nodes for automatic perception and intelligent control. The monitoring data of different monitoring frequencies of key control points are collected and extracted, and the related factors such as harmfulness grade, occurrence frequency, emergency extent, monitoring difficulty and monitoring cost of key control points are comprehensively compared and analyzed. The monitoring frequency guide of key control points is formulated to provide a basis for scientific and reasonable monitoring of key control points.

3.2. Dynamic real-time perception technology of key points in veterinary drug production based on GMP

Effective control of key points in veterinary drug production is the primary condition to ensure the quality and safety of veterinary drugs. Dynamic real-time perception of key points is conducive to preventing the occurrence of veterinary drug quality and safety risk events. The first is to select sensors for critical control points. The risk factor index system based on veterinary drug production process, the performance indexes of different sensors, such as temperature, humidity, pressure and dust, under different application conditions such as plant, equipment, storage facilities and pipelines, such as accuracy, precision, maintenance-free working time, service life, etc., are tested to meet the requirements of screening, so as to find out the sensors. The second is to research and develop perception devices for critical control points. Based on the sensors selected at key control points, the integrated design of STC12 microcontroller, sensor, wireless communication module and other electronic components are carried out by using electronic circuit development and PCB board fabrication technology. The third is to study the simulation of sensing nodes. From the point of view of network performance such as package loss rate, average delay and received signal strength, ZigBee, NB-IoT, 433 MHz and other wireless transmission technologies are analyzed and compared. According to the geographical location, climate conditions, plant layout and equipment layout of different veterinary pharmacies, simulation and testing of the environment of veterinary drug production perception nodes to form the best layout. The scheme realizes the whole network coverage and seamless connection of production information in key areas.

3.3. Recognition technology of manufacturing operation practice based on video analysis

Good production operation practice is an important content of GMP, is the prerequisite for qualified veterinary drug production, and also the guarantee of preventing occurrence of veterinary drug quality and safety accidents. The first is to determine the video content of production operation. In view of the key control points which cannot be sensed by environmental sensors, the contents of video monitoring are analyzed and determined, including operation of equipment, storage location of goods, key operation and operation time nodes which affect the quality and safety of veterinary drugs. A video monitoring catalogue based on GMP is formed to cover the operation of veterinary drugs production in an all-round way. The second is to establish a knowledge base for veterinary drug production operation. Aiming at the difficulty recognizing GMP of veterinary drugs, this paper combs the standard operating procedures of staff at key control points of veterinary drugs production, focuses on the post operating procedures of contact products such as antigen preparation, distributing and packaging, and establishes the knowledge base of veterinary drugs production and operation process, so as to develop veterinary drugs production in a bid to lay foundation for intelligent recognition of operation practice for veterinary drugs. The third is to explore the image recognition algorithm based on transfer learning for veterinary drug production practice. VGG depth convolution neural network is used to extract the operation behavior features of video sequences. According to the image label information of knowledge base, a RCNN-based depth learning video image operation behavior specification recognition model is established. Combined with the monitoring data of the dynamic real-time perception platform of key points in veterinary drug production, the intelligent diagnosis workers' production operation is made. Make a timely warning if it is consistent with the standard knowledge base, and automatically generate post operation records to avoid human errors.

3.4. Design of traceability coding technology for minimum sales unit of veterinary drugs

The traceability carrier and coding of the minimal sales unit of veterinary drugs are the only identification of veterinary drugs, also the basis of their traceability dynamic information association, and the key and core of the whole process quality traceability of veterinary drugs. The first is to study the coding design of minimum sales unit of veterinary drugs. Based on the National Veterinary Drug Product Traceability System Standards for Traceability Code and Data Exchange Document, this paper analyzes the requirements of veterinary drug traceability information, summarizes the necessary key information such as traceability code, product name, approval number, manufacturer name and production date of the minimum sales unit of veterinary drug, and designs the minimum based on RS coding principle. The coding structure and rules of the sales unit optimize and enhance the effective information acquired by the QR barcode of the scanning veterinary drug traceability. The second is to study the anti-counterfeiting encryption technology of veterinary drugs. In order to curb the circulation of fake and inferior veterinary drugs and solve the problem of veterinary drug anti-counterfeiting, based on the electronic traceability code of veterinary drug products, the anti-counterfeiting and encryption technology of veterinary drug traceability code watermarking is studied. The emphasis is to break through the watermark embedding and extracting algorithm with high robustness, embed invisible watermark anti-counterfeiting information in traceability code, and establish an efficient and low-cost anti-counterfeiting system of veterinary drug traceability code, so as to realize the functions that veterinary drug traceability code cannot be duplicated, cannot be modified and cannot be counterfeited, and provides technical guarantee for cleaning veterinary drug market.

4. Conclusion

The supervision of veterinary drug production can effectively reduce circulation of substandard veterinary drugs in the market, reduce the use of counterfeit and inferior veterinary drugs, and further enhance the quality of animal husbandry products in China. Therefore, it has very important market value and application prospects. Intelligent real-time monitoring of veterinary drug production process is based on "recognition technology of HACCP key control points in veterinary drug production", "dynamic real-time perception technology of GMP key points in veterinary drug production",

"recognition technology of manufacturing operation practice based on video analysis" and "Design of traceability coding technology for minimal sales unit of veterinary drugs". What it mainly researches and realizes is as follows: analysis and evaluation of risk factors in veterinary drug production process, establishment of risk factor index system, identification and determination of key control points and their thresholds in veterinary drug production, research and establishment of control points and their control thresholds table in veterinary drug production, determination of monitoring frequency of key control points, screening of sensors meeting requirements of critical control point perception, development of sensing devices based on selected sensing sensors and the dynamic real-time monitoring of critical control points, establishment of layout of sensing devices with "pertinence, accuracy, personalization" characteristics, dynamic real-time perception on environment of veterinary drugs production such as temperature, humidity, air pressure, etc. and internal micro environment of veterinary drugs such as flow rate and moisture content, etc. establishment of knowledge base of veterinary drug production operation process based on the post operation process of contact products such as antigen preparation, making and packaging, construction and calculation of video analysis sample set of veterinary drug production operation, the application of video analysis algorithm based on machine vision and depth learning technology for veterinary drug production operation behaviour, the application of encoding design technology for minimal selling unit of veterinary drug and the application of watermarking anti-counterfeiting encryption technology for veterinary drug traceability code.

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