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INTEGRATED HACCP AND GMP SYSTEMS IN THE VETERINARY PHARMACEUTICAL INDUSTRY: A COMPARATIVE ANALYSIS AND THE ADVANTAGES OF USING THEM IN PARALLEL

SISTEMELE INTEGRATE HACCP ȘI GMP ÎN INDUSTRIA FARMACEUTICĂ VETERINARĂ: O ANALIZĂ COMPARATIVĂ ȘI AVANTAJELE UTILIZĂRII LOR ÎN PARALEL

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ABSTRACT | REZUMAT

This article aims to investigate the advantages of using the Hazard Analysis and Critical Control Points (HACCP) system in parallel with Good Manufacturing Practices (GMP) in the veterinary pharmaceutical industry. The paper explores the historical development of the industry, the emergence of HACCP and GMP systems, and highlights the similarities between them. By analysing the integration of these two systems, the paper demonstrates how their combined implementation can improve the safety, quality, and compliance of veterinary pharmaceuticals.

Keywords: HACCP, GMP, integrated system, veterinary pharmaceutical industry

Acest articol își propune să investigheze avantajele utilizării sistemului de Analiză a Riscurilor și Punctelor Critice de Control (HACCP) în paralel cu Bunele Practici de Fabricație (GMP) în industria farmaceutică veterinară. Lucrarea explorează dezvoltarea istorică a industriei, apariția sistemelor HACCP și GMP și evidențiază similitudinile dintre acestea. Prin analizarea integrării acestor două sisteme, lucrarea demonstrează cum implementarea lor combinată poate îmbunătăți siguranța, calitatea și conformitatea produselor farmaceutice veterinare.

Cuvinte cheie: HACCP, GMP, sistem integrat, industria farmaceutică veterinară

The pharmaceutical industry is a vital and ever-expanding economic sector dedicated to the development, production, and marketing of medicines and pharmaceutical products.

The pharmaceutical industry is essential for maintaining the health of populations and is divided into two distinct branches: the human and veterinary pharmaceutical industries.

In the pharmaceutical industry, both GMP (Good Manufacturing Practice) and HACCP (Hazard Analysis and Critical Control Points) play vital roles in managing the risks associated with drug production. GMP is a set of standards and rules that ensure quality and compliance in the pharmaceutical manufacturing process, while HACCP is a structured and comprehensive system for identifying, evaluating, and controlling critical risks in production. Even if GMP also addresses aspects of risk management, there are situations where it may be insufficient to effectively cover all the specific risks of the pharmaceutical industry. This is where the need to implement the HACCP system comes in, which focuses exclusively on risk management and ensuring the safety and quality of pharmaceutical products. By specifically approaching risks and implementing appropriate preventive measures,the HACCP system provides a robust and effective framework to guarantee the production of safe and high-quality drugs (14).

This article focuses on demonstrating the usefulness of HACCP (Hazard Analysis and Critical Control Points) system implementation in parallel with the implementation of GMP (Good Manufacturing Practice) standards. By comparing and analysing the two systems, the article explores how their simultaneous implementation in the pharmaceutical industry can contribute to ensuring the safety, quality, and compliance of veterinary pharmaceutical products. It highlights the synergies between HACCP and GMP and explores how they can be effectively integrated into the manufacturing process to minimise risks and ensure compliance with regulations and standards in the veterinary and human pharmaceutical industries.

The historical background of the two industries

The human and veterinary pharmaceutical industries have evolved in parallel but on distinct paths. The human pharmaceutical industry has a long history, with roots stretching back to antiquity and having evolved significantly during the industrial revolution and the 20th century with scientific discoveries and

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technological advancement. On the other hand, the veterinary pharmaceutical industry began its development in the 20th century, with increasing importance given to animal health (15).

While the human pharmaceutical industry has been focused on treating human diseases since the Middle Ages, the veterinary pharmaceutical industry developed in the context of industrial agriculture and intensive animal husbandry. This evolution has brought up the need to prevent and treat animal diseases by developing specific medicines for them. Regulations and standards for the veterinary pharmaceutical industry have been introduced to ensure the safety and efficacy of animal products and to prevent the spread of disease. Today, the veterinary pharmaceutical industry plays a crucial role in promoting the health and welfare of animals by providing drugs, vaccines, and other specialised pharmaceutical products (2). Although there are some areas of intersection between the two industries, such as the adaptation of human drugs for animal treatment, each industry has specific regulations and standards tailored to the needs and characteristics of human and animal patients (12).

There are many similarities between the veterinary pharmaceutical industry and the human pharmaceutical industry, as both aim to develop and commercialise drugs that improve the health and well-being of their respective populations. Both sectors are research-based, have a global footprint, are highly regulated, and need to be profitable in a highly competitive business environment (1, 3).

The development of the two systems

GMP (Good Manufacturing Practices) and HACCP (Hazard Analysis and Critical Control Points) emerged in the context of increasing concerns about the quality and safety of pharmaceutical products. GMP began to develop in the pharmaceutical industry in the second half of the 20th century with the rise of industrialization and large-scale drug production. As the pharmaceutical industry has become more complex and global, the need to establish standards and manufacturing practices that ensure the quality, safety, and efficacy of pharmaceutical products has become apparent. GMP has gradually evolved as a set of rules and principles, which include aspects such as hygiene, quality control, process validation, and adequate documentation (7, 8).

GMP standards are mandated by regulatory authorities and are widely applied in the pharmaceutical industry to ensure that products are manufactured in accordance with quality and safety standards (18).

On the other hand, HACCP was developed in the 1960s in the food industry, initially as a food risk management system for NASA. The success of HACCP implementation in the food industry has led to the expansion of its application in other areas, including the pharmaceutical industry. HACCP was adapted and implemented to address critical risks associated with drug manufacturing, such as labelling errors or microbial contamination. This system is based on the identification and assessment of risks, as well as the establishment of critical control points in the production process, so that appropriate preventive and corrective measures can be taken to ensure the safety and quality of pharmaceutical products (10, 15).

Thus, both GMP and HACCP emerged in response to the need to ensure the quality and safety of pharmaceutical products, each with its own specific focus on manufacturing practices and risk management. These systems have evolved over time and are currently used in the pharmaceutical industry to ensure that pharmaceutical products are manufactured under appropriate conditions and meet the highest quality and safety standards.

The HACCP system in the pharmaceutical industry

The main objective of implementing the HACCP system in veterinary medicine factories is to identify and effectively manage hazards and critical control points in the production process. By applying HACCP principles, veterinary drug factories can reduce the risk of contamination and ensure rigorous quality control at all stages of the production process (1, 6).

Compared to GMP, which focuses on good manufacturing practices in general, HACCP focuses more specifically on identifying and controlling risks critical to product safety. The implementation of both systems in veterinary drug factories brings significant benefits, including improving product quality, protecting animal health, and reducing risk to consumers (16).

The objectives of the HACCP System

Although originally developed for the food industry, its principles of risk prevention and control of critical processing points have been successfully adapted for use in pharmaceutical manufacturing.

In the pharmaceutical industry, the main objectives of HACCP implementation include:

Hazard Identification: One of the main objectives of HACCP is to identify potential hazards that may occur in the pharmaceutical production process. These may include biological, chemical, or physical contamination, processing or labelling errors, or other problems that may affect the safety or effectiveness of drugs.

Risk Assessment: After identifying the hazards, the HACCP system aims to assess the risks associated with them. This involves analysing the likelihood of a hazard occurring and the severity of possible consequences.

Identification of Critical Control Points (CCP): HACCP involves establishing points in the production process where control can be applied to prevent or minimise the risk of a hazard. These points are called Critical Control Points (CCPs).

Establishing Critical Limits and Monitoring Procedures: For each CCP, HACCP requires the establishment of critical limits that must not be exceeded to ensure safety. Monitoring procedures are also established to verify that the PCCs remain within established limits.

Development of Corrective and Verification Plans: If a CCP's critical limit is exceeded, the HACCP system requires a corrective plan to address the problem. A verification system is also required to ensure that the HACCP system is working as it should.

Documentation and Recording: All aspects of the HACCP system, from hazard identification and risk assessment to monitoring and corrections, must be documented and recorded. This enables rigorous process tracking and facilitates audits and reviews (6, 11, 17).

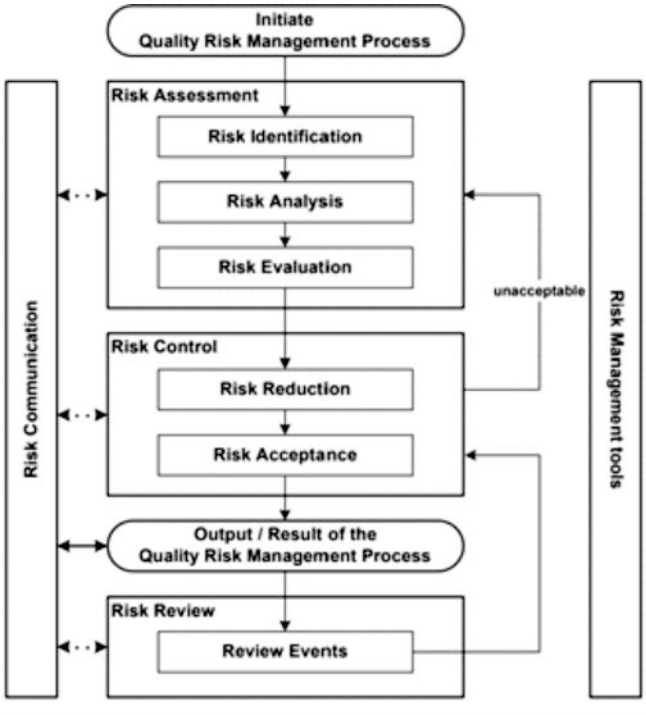

Fig. 1. Overview of a typical quality risk management process (source: Guide to Good Manufacturing Practice for Veterinary Medicinal Products – ICH Q9)

Good Manufacturing Practice (GMP) objectives

GMP pursues a wider range of objectives and activities, such as:

Quality Assurance: The main purpose of GMP is to ensure product quality. This is achieved by implementing rigorous quality control processes, which apply to all stages of production.

Contamination Prevention: GMP sets strict rules for personnel hygiene, cleanliness of equipment, and production facilities to prevent contamination of products.

Traceability: GMP requires detailed records of all processes and procedures, from the procurement of raw materials to the final distribution of products. This allows traceability, meaning that in the event of a problem, its source can be traced.

Regulatory Compliance: GMP is intended to ensure compliance with local, national, and international regulations. This is crucial to obtaining the necessary approvals for the production and marketing of medicines.

Process Control: GMP requires strict control of all production processes, from the selection and testing of raw materials to the production, packaging, and labelling of products.

Staff Training: GMP recognises the importance of well-trained staff. Therefore, an essential part of GMP is the constant training and updating of personnel to ensure that procedures are understood and followed (4, 5, 19).

Similarities and differences

Even though both have the role of ensuring product quality and safety, there are some notable differences in their origin, purpose, and methodology.

In terms of similarities, HACCP and GMP share several fundamental principles. First, both are prevention-focused; their goal is to prevent quality and safety problems before they occur rather than manage them after they have occurred. Second, both require rigorous documentation, from identifying potential risks and implementing control measures to monitoring their effectiveness. Third, both HACCP and GMP require management commitment, reflected in policies, procedures, and adequate staff training.

On the other hand, there are also important differences between HACCP and GMP. One of the most notable is their origin and applicability. GMP was developed specifically for the pharmaceutical industry and is mandatory in many countries, being regulated by agencies such as the FDA in the US or the EMA in Europe. GMP refers to the rules for manufacturing products in a way that ensures their quality and safety, taking into account all aspects of the production process, from raw materials to personnel, equipment, and the environment (13, 20). On the other side, HACCP is a preventive control system that identifies, evaluates, and controls significant hazards to food or drug safety. It focuses on the points in the production process where significant risks can occur and where control is essential to ensure product safety (9).

CONCLUSIONS

An integrated HACCP and GMP system combines these two approaches, providing a complete framework for quality and safety control.

It enables companies to ensure that their products are manufactured in accordance with best practices and that potential hazards are identified and managed effectively. Implementing such a system can help improve product quality, safety, and compliance, as well as increase operational efficiency by identifying and eliminating potential problems before they become safety incidents.

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