

DESIGNATION OF A HACCP LIKE MODEL FOR FOOT AND MOUTH DISEASE VACCINE PRODUCTION

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ABSTRACT

The Veterinary Serum and Vaccine Research Institute (VSVRI) was constructed to meet a specific aim – protection of animal health and welfare. Disease prevention and control calls for programs and projects that, depending on the characteristics of each disease, may involve all aspects from the laboratory to field activities. The purpose of this work , apply the Hazard Analysis and Critical Control Points method to the preparation of foot and mouth disease(FMD) vaccine. To identify critical control points and to propose control measures and corrective actions to manage these processes. The Hazard Analysis and Critical Control Points (HACCP) models were used as a basis for the generation of the model used in this study. The process steps as indicated in the flow diagram are then performed. According to HACCP method, a team is formed. listed all of the critical points and then defined monitoring, control measures and corrective actions for each identified risk. Tcated that, 13 steps in Controlled stage of foot and mouth disease vaccine preparation process and 31 hazzard as shown in tables (3a-3g) . The HACCP plan has helped to significantly reduce risks in the production process.The present study demonstrates the interest of the application of the HACCP method in the preparation of foot and mouth disease vaccine. The efficiency of the HACCP method is relevant when this method is used to target a specific process. Critical points were identified and led to improvement of our process. This method helped us to focus on the production steps, which can have a critical influence on product quality, and led us to improve our process. Recommendation :using a checklist that simplifies the task. HACCAP system that is developed can also serve as a guide for internal or external program audits.

Keywords: Hazard Analysis and Critical Control Point – HACCP – Good practice –Disease control – FMD – Foot and mouth disease – Vaccination.

INTRODUCTION

The Hazard Analysis and Critical Control Point (HACCP) methodology has been considered to be a product safety management system. It aims to prevent known hazards and to reduce the risks that

they will occur at specific points in the vaccine production process. The same principles are also increasingly being applied, in other industries, such as the chemical industry. This text provides general guidance on the use of the HACCP system to ensure the quality of products, Hazards affecting quality are controlled to a certain extent through the validation of critical operations and processes in the manufacture of vaccine products in accordance with Good Manufacturing Practices (GMP). However, GMP do not cover the safety of the personnel engaged in manufacture, while both aspects are covered by HACCP.

International trade in animals and animal products is facilitated by the adoption of international standards that are in line with the provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures, this agreement with the World Trade Organization (**WTO 2013**) .(**OIE 2015a**) stipulates that Veterinary Services should be able to demonstrate that they have appropriate legislation and an effective organizational structure; they must also be able to demonstrate that they have the human and financial resources that are needed to establish and apply the animal health, animal welfare and food safety measures that will enable them to issue international veterinary certificates of undisputed technical quality. To do this, it is essential that activities and processes, including the notification of diseases and/or health events, are regulated in a way that makes it possible to check that they are being carried out correctly.

This article provides details of checklists that have been developed by the authors to make it easier to verify that the established procedures are properly applied and that supporting documentation is available to carry out self-assessment and improvement procedures so that assessments of certification procedures can be handled more effectively and so that auditors can systematize and simplify their task. The procedures include animal disease prevention and control programs and good health practices applicable to the origin of the inputs, to the producer and processing establishments, and to the verification of the results obtained, primarily those regarding epidemiological surveillance.

FMD prevention and control programs with vaccination have three main elements: vaccination, including the inputs used and the manufacturing, control and shipping processes; vaccination of susceptible animals, including product transfer, application and registration and , lastly post-vaccination activities, including clinical and serological surveillance designed to demonstrate the effectiveness of vaccination, i.e. its ability to achieve or maintain official status. All these activities are regulated and detailed in **OIE (2015a)**. Thus, a full analysis of the system enables us to identify the main components, which are as follows: Vaccine, Vaccination and Surveillance.

HACCP is a tool to assess hazards and establish, control systems that focus on prevention rather than relying on corrective action based on endproduct testing. All HACCP systems are capable of accommodating changes, such as advances in equipment design and processing procedures or technological developments .

The present guidelines are aimed at assisting industry to develop and implement effective HACCP plans covering activities such as research and development, sourcing of materials, specific stages of production ,manufacturing, packaging, testing and distribution .

MATERIAL AND METHODS

According to (**Sueli et al. 2012**) , applying the seven HACCP principles make up the major steps to writing a HACCP plan. They are:

1. Conduct a hazard analysis.
2. Identify critical control points (CCPs).
3. Establish critical limits for each critical control point.
4. Establish monitoring procedures.
- 5 Establish corrective actions.
6. Establish record keeping procedures.
7. Establish verification procedures.

Material

This model is made according to the data of the production records of the batch number 01/2017 of trivalent foot and mouth disease vaccine produced in VSVRI in Egypt.

Method

This model is designed according to title 21, part 120 of the Code of Federal Regulations (**CFR 2017**). Personal protective equipment (PPE) follow up checklist , Staff training checklist Trainee ,Air control and ventilation follow-up checklist , Equipment calibration certificates checklist and Chemicals and packaging materials traceability to the source Certificates of supplier laboratory analysis checklist according to Code of Federal Regulations (**CFR 2015**). Also Production facility checklist (Based on 7 CFR 331; 9 CFR 121; 42 CFR 73; NIH Guidelines)

RESULTS

Hazard Analysis and Critical Control Point (HACCP) is important at different stages of a process. The HACCP system starts from the initial stage of Raw material dispensing through the method of product processing adopted and finally dispatch of the product. The designed model of HACCP for production of trivalent foot and mouth disease vaccine produced in VSVRI in Egypt could be demonstrated in the following tables (1a:1g), the detailed analysis of the vaccine manufacturing process takes into consideration aspects such as the origin of the ingredients used to manufacture the vaccine, tests for the potency, purity and safety of the final product, and cold chain integrity throughout the process.

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DISCUSSION

The present study of risk analysis using the HACCP method to a foot and mouth disease vaccine preparation process is done for the first time. The HACCP plan has helped to significantly reduce risks in the production process and enhance product quality. The HACCP method used for protect workers and product The present economic situation and global market conditions have led companies to look for ways to increase competitiveness by improving production processes, reducing production costs, and improving product quality. In terms of the vaccine industry, two other factors should also be included: the need to ensure safety and ensure quality. Therefore, the existence of a system that ensures vaccine safety is crucial to preserve a vaccine production company's image and reputation and to increase local and international market shares.

Safety has become a common concern worldwide, making public health agencies and governments of several countries look for more efficient ways to monitor production chains (**Makiya and Rotondaro 2002**). The hazard analysis and critical control points (HACCP) system is widely recognized as a management tool capable of ensuring safety. The keyword of the system is "prevention" (**Mortimore and Wallace 1998**), by means of the identification of possible contaminations before they occur, and of the definition of control measures to maximize safety in every step of the process (**Cullor 1997 ; Leitão 1993**).

The HACCP concept was originally proposed for the food processing industry, but has been successfully applied to medical products (**Glory et al., 2013**). Better trained employees and monitored procedures are responsible for this benefit, it faster way that troubles are controlled without delay and preventing errors and losses during the process. To guarantee vaccine safety and quality, the analysis assesses to what extent these aspects comply with good manufacturing practices and with the international regulations laid down in (**OIE 2014**). It should be noted that the official product and process controls are included.

The HACCP team using the same template as **Swanson and Anderson (2000)** and **Ljungqvist and Reinmuller (1995)** . During the study period, no microbial contamination is reported. We can also

consider another issue highlighted of critical control points have been highlighted by the HACCP which shown in tables (1a-g). HACCP contributes to the reduction of losses in all steps of the process. The use of high-quality raw materials, obtained from reliable companies and stored in adequate conditions, is an indispensable requisite for the quality of the final product (**Góes et al. 2001 ; Ehiri et al. 1995**) . Many of the raw materials delivered to the vaccine industry come directly from primary production, where levels of contamination, mainly chemical, contamination, may pose serious risks (**Forsythe 2002**)and (**Hulebak and Schlosser2002**) Thus, this CCP requires critical limits for the presence of chemical contaminants, ensuring quality control of raw material.

Ehiri et al. (1995) and **Mortimore and Wallace (1998)** showed that auditing suppliers is an important element in monitoring this CCP, because it prevents many problems that would only be identified at the moment of reception of the materials and enables the evaluation of quality standards of the suppliers.

The HACCP is a method that highlights issues and explains a complex process in detail. This method is helpful for focusing on the production steps, which may have a critical influence on the quality of the product. With the HACCP method, we can concentrate our limited resources on the identified critical points. Finally, the hazard analysis also provides a revision of the documented data such as standard operating procedures, production and check-up protocols. On the other hand, the HACCP method is extremely demanding on time and human resources.

CONCLUSION

The present study demonstrates the interest of the application of the HACCP method in the preparation of foot and mouth disease vaccine. The efficiency of the HACCP method is relevant when this method is used to target a specific process. Critical points were identified and led to improvement of our process. Following the implementation of the corrective actions, a reassessment of our process is planned in view of the future.

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