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Sustainably Structured Process FMEA for Pharmaceutical Products

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Author Note: Carolin T. Schulz and Oliver Mannuß are engaged in quality and reliability management. Their field of research covers the elaboration and development of approaches and methods for product and process development - especially issues of risk analysis.

Abstract: Quality plays a crucial role in the pharmaceutical industry. A major challenge is to validate the conformity of production processes with regulatory requirements. The ICH Q9 guideline for Quality Risk Management defined by regulatory authorities of the European Union, Japan and the U.S. Food and Drug Administration (FDA) requires a continuous update of the risk documentation to reflect the current manufacturing process for a pharmaceutical product. This paper introduces a sustainable and modular approach for "Failure Modes and Effects Analysis" (FMEA) of manufacturing processes in the pharmaceutical industry. The modular design builds upon an expandable and adaptable core structure defined by matrices. The matrix approach covers three steps considering each product characteristic and process parameter in the entire production process. The first step is to identify the product characteristics in each process step and to analyze how they relate to other product characteristics in successive process steps including the quality characteristics of the final product. Secondly, the specific product characteristics are correlated with the defined test and detection actions. Considering the requirements of the ICH-Endorsed Guide for ICH Q8/Q9/Q10 Implementation, the linkage between Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs) has to be pointed out in the risk documentation. Therefore, step three links the process parameters provided by the particular process step with the control and disturbance variables. This makes it possible to outline the interdependencies between each process step parameter (CPPs) and the entire set of process attributes (CQAs) in a single structured Process FMEA. In case that process steps in an existing process get adapted or replaced, the dependence of the new or changed process steps can be derived from the matrices. This eliminates the necessity to create a completely new Process FMEA. All process steps can thus be substituted at minimum effort. In conclusion, this enables the user to substitute sub-process steps without ignoring the holistic view of the methodological approach of a Process FMEA.

Keywords: Process FMEA, Risk Analysis, Critical Quality Attributes

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