5PSQ-035

USING FAILURE MODE AND EFFECTS ANALYSIS TO IMPROVE PRODUCTION OF NON-STERILE PREPARATIONS

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BACKGROUND AND IMPORTANCE

The production of non-sterile preparations (NSP) is a critical task that requires **high levels of accuracy and safety. A risk management tool** is essential to ensure quality and minimise the risks associated with this process. Publications on this topic in the scientific literature are limited.

AIM AND OBJECTIVES

To identify **potential risks** in the NSP production process using a **Failure Mode and Effects Analysis (FMEA)** and to measure whether these risks decrease with the **implementation of improvement actions.**

MATERIALS AND METHODS

Personnel involved in the NSP development process
+
Pharmacist quality area
+
Head of Pharmacy Department

2021: Team

FMEA methodology

All possible failure modes (brainstorming)

Analysis and corrective and preventive measures

RPN = Severity x Frequency x Detectability

2024: FMEA model re-evaluated and potential risks reassessed

Quantified: variation in risks and improvement actions implemented

RESULTS

11 different phases: 26 failure modes

2021

- **1,929 RPN points** (range: 8-240).
- **RPN scores > 100: 7** of the failure modes, CRITICAL.
- Only 1 failure mode with **RPN > 200: inadequate raw material selection.**
- Phase with the most failure modes with RPN > 100 → **elaboration of the preparation**, 4 in total.

Prioritization and **improvement plan,** highlighted:

Implementation of specific software (CPFarma).

Establishing double checking by a qualified pharmacist.

Training of new residents in the Pharmacy Department.

2024

- **594 RPN points** (range: 6-180).
- Only 1 failure mode with **RPN > 100: incorrect measurement of raw materials.**

CONCLUSION AND RELEVANCE

The **FMEA methodology is a useful instrument** in the detection of potential risks in the production of NSP and in the implementation of improvement actions that have an impact on process quality and patient safety.