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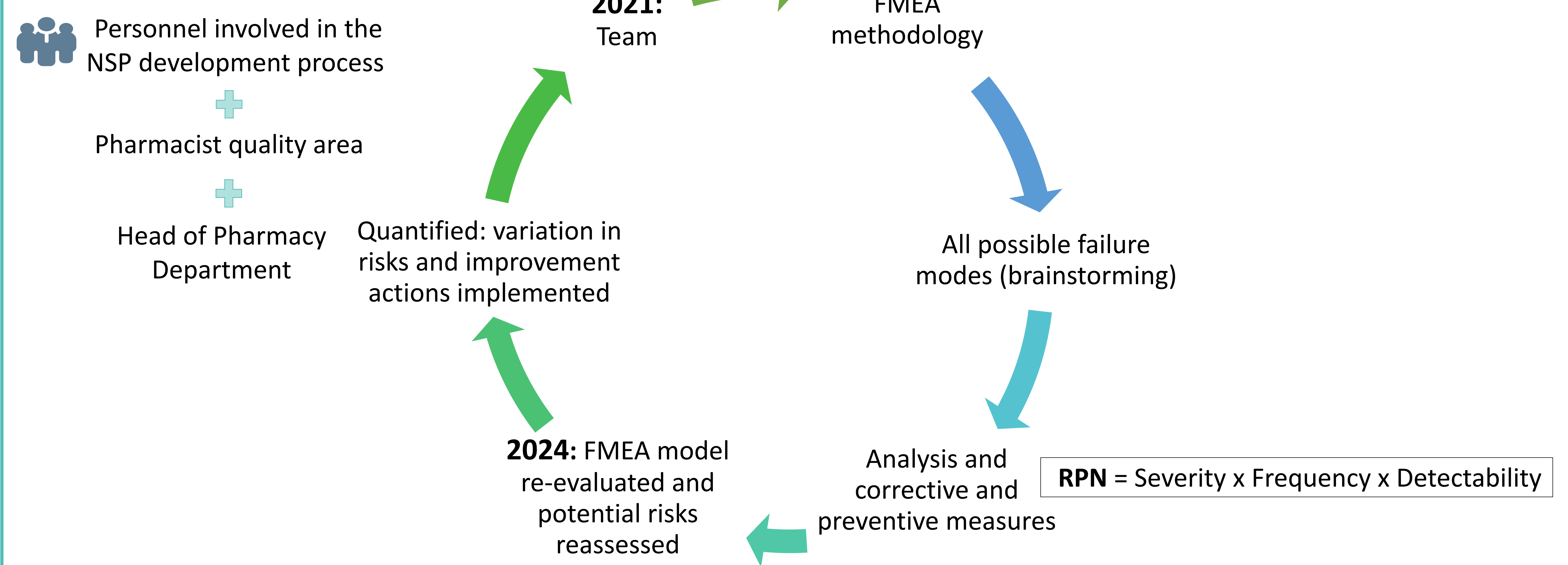
## BACKGROUND AND IMPORTANCE

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



## 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.

