

Risk analysis of the chemotherapy production process: what changes after the deployment of the Drugcam® control tool?

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Context and objectives

Risk analysis of the chemotherapy production process in 2015

Main corrective action : Drugcam®



Identification of **33 failure modes (FM)** among which 5 were unacceptable



Assessment of the impact of the deployment of Drugcam® in June 2018

Methods

A Failure Mode and Effects Analysis (FMEA) was conducted **before and after** the deployment of Drugcam®



33 failure modes were identified among **6 stages of the process**

The **criticality index** of each FM was determined by a multi-professional team

Criticality index = Gravity x Frequency x Detectability



Initial criticality was weighted by **existing risk management means** → Residual criticality

acceptable ✓

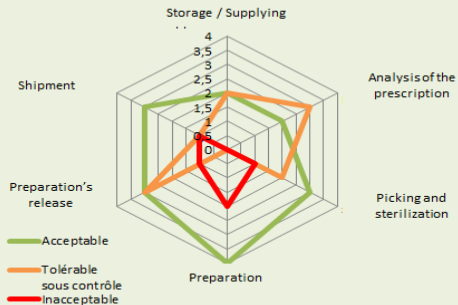
FM were classified in **3 risk categories**: **tolerable under control** ⚡

unacceptable ✗

Criticality difference between the 2 FMEA → evaluation of the **risk evolution** of each FM

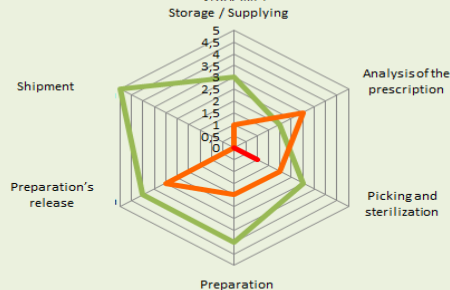
Results

Criticality index distribution in 2015



5 unacceptable
11 tolerable under control
17 acceptable

Criticality index distribution in 2019



1 unacceptable
11 tolerable under control
21 acceptable

Discussion

Drugcam®, like any automated system, induces **specific risks** that need to be **identified and managed**. The increased criticality of some FM is linked to the emergence of a **new profile of errors** characterised by an **excessive confidence** in the tool that can lead to control failures regarding certain key elements (operating mode, batch number) during the preparation. This new risk is **managed** thanks to **training** and **improvements of the system** with the publisher.

Drugcam® has however a **major impact** on the **risk management** of chemotherapy preparation by **reducing the overall criticality** et decreasing the amount of unacceptable FM. This tool therefore enables a **significant improvement** of the process by **detecting errors** and allowing their **analysis**. This risk analysis has led to **developing improvements of the system** with the publisher (ex: picking control) and **continuous training** of the users.