Risk Analysis on the Automated Syringe Filling Process Using the Smartfiller® Filling Machine

Sahra MUHAMMAD[1,2], Bérangère QUITTE[1], Marion JOBARD[2], Marie-Laure BRANDELY-PIAT[1], Rui BATISTA[1,2]
Clinical Pharmacy Service, [1]Ophthalmology and Oncology Sterile Preparations Unit, and [2]Quality Assurance Unit, AP-HP Paris Cité University Center, Cochin Hospital, 27 rue du Faubourg St Jacques, 75014 Paris (France)

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Background

A Smartfiller® syringe filling machine (AddedPharma, Nederland) has been set up in our unit to ensure the centralized production of injectable drugs

The goal of this work was to conduct a risk analysis (RA) on the automated process to identify sensitive steps and determine possible improvement.

Methods

Risk Analysis

- based on the 5M method (Materials, Methods, Labor, Raw Materials, and Environment)
- conducted by the pharmaceutical team

Four 2-hour sessions, which has permit to :

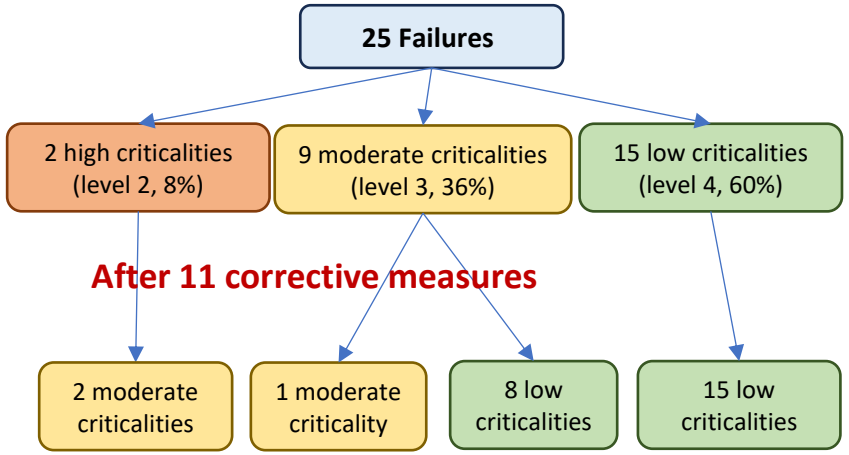
- list all possible failures and their effects
- Evaluate frequency, detectability and severity using a scale from 1 to 5 for each failure

→ Criticality (Cr) = Frequency (F) x Detectability (D) x Severity (S)

	Description	Interval (F*D*S)	Priority
C1	Extrem criticality	[75-125[	Absolute
C2	High criticality	[36-75[	High
C3	Moderate criticality	[12-36[	Moderate
C4	Low criticality	[1-12[	Low

Results

The RA identified 25 failures. In decreasing order of frequency, the identified failures were related to equipment (loss of calibration…), to method (loading error, non-compliant cleaning…), to labor (lack of staff…), to raw materials (stock shortage…), and to environment (equipment corrosion…).



	Material	Methods	Labor	Raw material	Environment
Failures examples **(High Cr)**	**Calibration loss (Cr=60),** no syringe recognition, carrousel jamming, improperly dipped cap, liquid leackage…	Loading error, forgetting to unclamp the tubulure, **non-compliant cleaning (Cr =50)**	Lack of formation/staff shortage, musculoskeletal disorders	Stock shortage	Equipment corrosion

Main corrective measures

- Implementing a maintenance contract
- Double-checking caps at the end of production
- Pre-start checklist
- Adequate training

Example

Corrective measures examples for the two failures with high criticality

→ **Calibration loss between 2 batches (Cr = 60)** → Calibration volume checking for each new batch (Cr=15)

→ **Non-compliant cleaning (Cr=50)** = cross contamination→ Validating the cleaning process and implementing an analytical method to detect chemical contamination (Cr=20)

Conclusion

The risk analysis identified the critical points of the automated process related to the SmartFiller® machine. By reducing the criticality through corrective actions, the risk analysis validates the routine use of Smartfiller® for the centralized production of injectable drugs.