UPDATING THE RISK CONTROL LEVEL OF THE RISK MAP FOR AN AUTOMATED DISPENSING PROCESS

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Background

To **secure and ensure** the traceability of the drug circuit, the acquisition of automated machines for producing single doses and doses to be administered has enabled the implementation of the **Automated Single-Dose Dispensing** (ASDD) process.

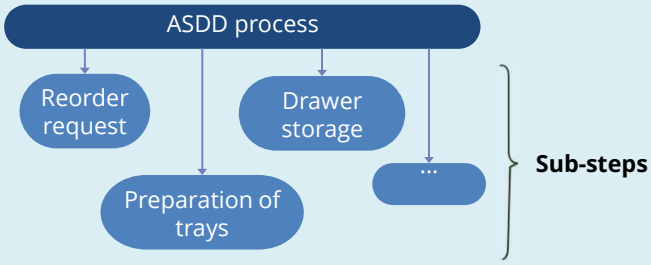
Supplier documentation → Risk map (RM) *initial version* → Development of tests for Operational Qualification (OQ) → **Technical validation of the equipment**

Validation requirements for automated systems

Objective : Verify the control level reported during the development of the RM

Material & Methods

1 Initial version of the RM



- ✓ Fourteen sub-steps identified
- ✓ Risk identification for each sub-step : **Ishikawa diagram and supplier documentation**
- ✓ Risk rating : Risk assessment grid based on French national guidelines
- ✓ Residual criticity = Gravity x Frequence x Level of control

→ First version of the RM obtained

2 Updating the risk control level

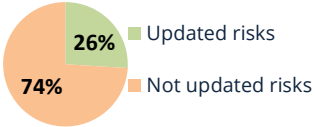
- ✓ OQ performed based on the initial RM
- ✓ **Control level scale** : adapted to the automated process

Control level scale	
Level 1	Blocking of action by software or equipment
Level 2	Non-blocking alert on software or equipment
Level 3	Situation controlled by a procedure
Level 4	Situation controlled by the internal organization of the sector
Level 5	Risk discovery

→ **Level control** of each risk has been updated
→ **Residual criticity** was recalculated

Results

Risk situation	Consequence(s)	Risk management system	Level of control	Residual criticity
Tray not cleared in the system before being filled with another medication	Non-compliant cutting of the blister	Procedure	3	**27**



Proportion of risks updated during the OQ

Risk management system	Level of control	Residual criticity
Blocking alert by the system software : "Is the tray empty ?"	1	**9**

OQ

✓ OQ led to systematic **improvement in risk control levels**

Conclusion & Perspectives

This process of updating the level of control of the RM should not be necessary during the OQ. It highlights the importance of the supplier providing **detailed technical documentation** on the behavior of the software and equipment. Close **collaboration** between the supplier and customer is essential in order to have a **complete risk analysis prior to the OQ phase**.

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