Risk analysis by the FMECA method of the pharmaceutical circuit of injectable experimental drugs

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CONTEXT AND OBJECTIVES

- In our hospital pharmacy : **2 units are involved** in the injectable experimental drugs (EDs) circuit
  - **Pharmaceutical clinical trial unit (UPEC) :** pharmaceutical validation of the prescription
  - **Centralized pharmaceutical preparation unit (UPCP)** : preparation of injectable EDs

Increased risks

- Updating of the quality assurance system and preparation for ISO9001 certification of the UPEC unit

→ **Risk assessment, according to the FMECA method**

OBJECTIVES : To map the process of management, preparation and dispensation of injectable EDs, in order to assess possible risks and propose corrective actions (CAs) to optimize the injectable ED circuit.

MATERIAL AND METHOD

FMECA : Failure Mode, Effects and Criticality Analysis

5 sessions of multi-professional working group : UPEC/UPCP pharmacists, pharmacy resident, pharmacy technicians and their managers

- Process description
- Identification of failure modes (FM), causes and their effects
- Scoring of the frequency (F) of occurrence, severity (G) and detectability (D) for each FM, using scales from 3 to 5 levels[1]
- Assessment of criticality C = F*G*D

Assessment of criticality	
> 20	Major criticality
12 à 20	Moderate criticality
< 12	Low criticality

Table 2. Rating scale for criticality

Table 1. Rating scales (severity, frequency, detectability)

Scoring the severity of the effects	
G1	No impact
G2	Delay in the management of the clinical trial
G3	Delay in the dispensation of the clinical trial
G4	Quality impairment of the clinical trial or alteration of the ED
G5	Challenging patient safety
Scoring the frequency of occurrence of FMs	
F1	Appearance < 1 time a year
F2	Appearance 1 to 4 times a year
F3	Appearance 4 to 12 times a year
F4	Appearance > 12 times a year
Scoring the detectability of FMs	
D1	High detectability Existing and systematic checkpoint
D2	Partial detectability Occasional checkpoint
D3	Low detectability No control point or uncontrollable point

RESULTS

Identification of **50 risks**

- 40 of a low level (80%)
- 8 of a moderate level (16%)
- 2 of a major level (4%)

2 risks of major criticality

- **Specific training of UPCP staff in preparation of injectable EDs**
- **Preparation of EDs requiring volume removal**

Pharmaceutical validation: 1 moderate risk
- Non-detection of a dose error, calculation error

Preparation of fabrication forms for ME : 1 moderate risk
- Omission or error in the allocation of kit numbers in the IWRS (where allocation need to be done by the pharmacy)

Dispensation : 4 moderate risks
- Incorrect storage of preparations
- Dispensation of preparation without validation by UPEC pharmacist
- Dispensation for another patient included in the same clinical trial
- Lack of traceability

Management/organisation : 2 moderate risks
- Lack of coordination between UPEC/UPCP
- Failure to respect the storage conditions of the vials before preparation

Table 3. Number of risks for each steps of the process

Criticality / Step of the process	Low	Moderate	Major	Total
Setting up	4	0	0	4
Pharmaceutical validation	6	1	0	7
Preparation of fabrication forms	9	1	0	10
Vial selection	5	0	0	5
Fabrication	8	0	1	9
Dispensation	6	4	0	10
Management & organisation	2	2	1	5
Total	**40**	**8**	**2**	**50**

CONCLUSION

Identification of steps with highest risk → Corrective actions (CAs)

2 Risks of major criticality = Priority CAs must be carried out

- Improving the continuous training of all staff involved in preparation of injectable EDs
- Updating preparation forms (by emphasizing volume removal)
- Validation of preparation forms by UPCP technicians and pharmacists
- Reminder of ED specificities preparation by UPEC pharmacist before preparation for technicians when it is considered necessary

After the implementation of these CAs, a new FMECA will be conducted to assess their impact in the process.

[1] Analysis of the risks related to the circuit of management and dispensing of products in clinical trials by "FMECA" - Hurtrel & al., 2012