Risk analysis of the chemotherapy circuit produced in standard doses

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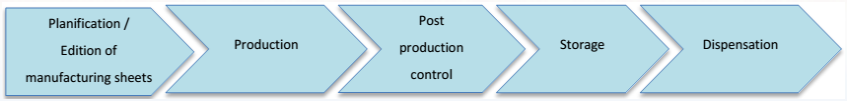
Background and Objective

Currently, more and more chemotherapy treatments are performed in day hospitalization. Faced with this strong demand, the cytotoxic preparation unit uses two manufacturing processes.
The first is to prepare extemporaneously for a given patient one or more chemotherapies. For the second, it is to prepare in series and in advance injectable cytotoxic, so-called « standard doses » (SD).

The manufacturing process of the SD respects the circuit below.



The objectives of the study were to define the failure modes of the system and to implement corrective actions.

Setting and Method

To perform this risk analysis we used **FMECA** (Failure Modes, Effects and Criticality Analysis) method :

- Scales of Frequency (F), Severity (G) and Detectability (D) (1)
- Calculation of Criticality Indices (CI) and CI = F x G x D
- Ranking of failure modes according to the calculated CI and identification of major risks
- Follow up the actions implemented and recalculate the CIs.

Results

- Over the entire process**, 47 failure modes were identified with a total CI of 2051**
- The most critical stages are the **dispensation** (average CI = 106) then the storage and the production
- Identification **of 11 priority failure modes** with an **average criticality of 124.**

Mise en place d'actions correctives

Dispensation :

✓ Double discharge control with « patient attribution » label

Storage :

✓ Storage reorganization

✓ Weekly stock inventory (batch number, expiry)

Production :

✓ Drafting of a procedure for the control of equipment and products before launching the sterilization chamber.

Residual criticality estimated at 39
for the 11 identified failure modes

Conclusion

This analysis shows that the dispensation and storage of these preparations are the most critical stages of the process. We favored simple, concrete measures that can be implement quickly in order to control risks. Moreover, this work made it possible to make the entire team aware of risk management.

(1) Williams E et al., The use of failure mode effect and criticality analysis in a medication error subcommittee, Hosp Pharm, 1994 avr;29(4):331-2, 334-6, 339.