Equipment failure in a Controlled Atmosphere Zone (CAZ) : maintaining sterile drug preparations manufacturing

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Introduction

- An equipment failure in a Controlled Atmosphere Zone **can lead to a total blockage of sterile drug production**

  → **No compliance guaranteed** with particulate and microbiological classes (French Good Preparation Practices-BPP V.2023)

  → **Direct impact on the patient :** left without his medication
- **Aim = maintaining continuity and organization** of sterile preparations production whilst respecting particulate and microbiological classes (according to the BPP)

Materials/Methods

1. Inventory of equipment used in our CAZ focusing on which preparations are made under which laminar flow cabinet
2. Screening of BPP : identification of requirements in terms of microbiological and particulate contamination on the various sterile preparations produced
3. Inventory of equipment available in other pharmacy units complying with particulate and microbiological classes we need
4. Assessment of the possibility of degraded solutions that would still comply with BPP
5. Validation of the solutions provided by the unit's pharmacists
6. Flowcharts establishment

Conclusion

- ✓ Anticipation is key when faced with an equipment breakdown in a CAZ for sterile preparations
- ✓ Drafting of a **degraded procedure** → **securing activity and enabling continuity of care**
- ✓ **Saves time** in responding to unexpected equipment breakdowns
- ✓ Other options were studied but not considered: additional back-up equipment, problems for which there are no solutions.

Results

→ **Medical assessment** of the benefit/risk associated with a possible postponement, **based on various parameters (possible alternative, whether in stock or not, degree of urgency).**

→ Degraded solutions designed according to the risk of contamination specific to each preparation: **methods of manufacturing and obtaining sterility for a preparation, type of equipment used, closed/open system.**

→ **3 flowcharts were designed**

6 sterile prepartions concerned	Atropin Eye Drops	Ciclosporin Eye Drops	Antibiotic Eye Drops	Autologous Serum Eye Drops	Clinical Trials	Parenteral Nutrition
3 types of equipments that can break down	Air Handling Unit	Microbiological Safety Cabinet (MSC)	Horizontal Laminar Flow Cabinet			
2 back-up equipements identified	Depression isolator used for antibodies only in Anticancer Drug Production Unit (ADPU)	MSC that is not used for cytotoxics in the ADPU				
5 degraded solutions found	Production transfered to the ADPU **with dedicated time slots**	Postpone	Manual manufacturing	Subcontracting request	Production under the cabinet that is not down	

Flowchart Sample : Air Handling Unit failure or both stations at the same time?