Maintaining Aseptic Conditions in the Face of Unexpected Events: **Performance Qualification of a Modular Controlled Atmosphere Area Dedicated to ATMPs and Clinical Trials**

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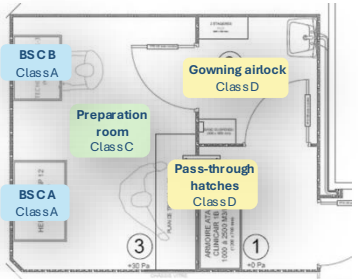
CONTEXT & INTRODUCTION:

The deployment of a **modular Controlled Atmosphere Area** (CAA) in 2025 at the hospital made it possible to meet the growing activity in reconstituting Advanced Therapy Medicinal Products (ATMPs) and medicinal products dedicated to clinical trials (CT).

The compounding of sterile preparations requires, following the **validation of the initial** and **operational qualifications**, the implementation of a **performance qualification (PQ)** meeting the **recommendations set out** by the **Good Preparation Practices (GPP)** guidelines of **2023**.

OBJECTIVE

Demonstrate the ability of the new modular CAA to meet the requirements of the performance qualification.



FLOOR PLAN OF THE MODULAR CAA

4 MAIN EVALUATION AREAS

Area 1 — In-operation air and surface microbiological monitoring

Use of **TSA agar** in the presence of **operators**

Sampling of **surfaces**

Air sampling by **Bio-collector**

Incubation **at 30°C** & **Reading** of plates on **day 7 (D7)**

RESULTS:

BSC A – BSC B	Class A	Compliant
Preparation room	Class C	Compliant
Other rooms	Class D	Compliant

✓ Compliant with the **recommendations of Common Guideline 1 (LD1) of the GPP**

✓ OK

Area 2 — Particle counts and aeraulic measurements

Performed by an external service provider

RESULTS:

✓ **Particle counts** and **aeraulic measurements** performed by the service provider **confirm the expected specifications at rest and in operation** throughout the CAA.

✓ OK

Area R — Test *Worst Case*: shutdown of the air handling unit (AHU)

AHU shutdown for 12h

Air and surface sampling at H+1 after restart

Observation of **aeraulic parameters**

Incubation **at 30°C** & **Reading** of plates on **D7**

RESULTS:

Microbiological sampling at 1h after restart:

✓ Still **compliant with the recommendations of Common Guideline 1** (LD1) of GPP 2023

✓ **Restoration of aeraulic parameters** (airflow rate and pressure cascade) **within a few minutes**

✓ OK

Area 3 — Evaluation of Disinfection of Surfaces by the Airborne Route (ASD)

Placement in the **preparation room** of:

- **Reactive strips** for H_2O_2
- Biological indicators **Tri-Scale®** with 3 concentration levels of ***G. Thermophilus***

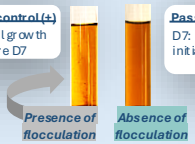
Initiation of a disinfection cycle with H_2O_2

Incubation at **60°C for the indicators** & **Reading** of broths on **D7**

EXAMPLE

Positive control (+)
Bacterial growth before D7

Pass-through hatch
D7: No growth for an initial concentration of 10^6



RESULTS:

✓ **Chemical efficacy demonstrated** on all strips

✓ **Reduction in the concentrations** of spores of ***G. Thermophilus*** **demonstrated at 10^5** throughout the room

✓ OK

CONCLUSION:

The **modular CAA met the objectives of the PQ**, with **in-operation microbiological controls compliant with the GPP** and **ASD with satisfactory sporicidal efficacy**. The rapid recovery of the cleanliness class following the prolonged shutdown of the AHU also confirms **the room's ability to secure sterile preparations** in the event of **technical hazards** .

OUTLOOK:

The results of the microbiological sampling in *Worst Case* will need to be **corroborated by particle counts** during a **future simulation.**

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