VALIDATION OF A MANUFACTURING PROCESS WITHIN A TEMPORARY CONTROLLED ATMOSPHERE AREA

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INTRODUCTION

Installation of a chemotherapy (CT) preparation robot (Apoteca®- Loccioni) in our controlled atmosphere area (ZAC)

Interruption of CT production within the ZAC

Alternative production during the 2 weeks of construction work

Outsourcing ? ✗

Other alternative ✓

Acquisition and installation of a temporary ZAC with positive pressure (class C) equipped with a material airlock (MAL)

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Two laminar flow production isolators in negative pressure (class A) equipped with a ventilated MAL

OBJECTIVE

In accordance with national guidelines → **Validate the new CT manufacturing process** + **Train staff in the new manufacturing process**

MATERIALS & METHODS

Implementation of a Media Fill Test (MFT) to validate the aseptic process
(2011 PIC/S PI 007-6 recommendations)

4 types of preparation representing our production were carried out per operator
(empty bag, pre-filled bag, syringe, infusor)

Computerization of MFT as part of our dematerialized manufacturing process

Equipment used :

Fertility test → kit EZ-ACCUSHOT (Microbiologics®)

MFT → kit KLERKIT (Shield Medicare®)

In practice - under pharmaceutical supervision :

1. Transfer of medical devices and raw materials via the MAL of the Stériroom-L after manual decontamination
2. Preparation of baskets and transfer to the ventilated MAL of the laminar flow production isolator
3. Spray biocide/disinfectant on medical devices and raw materials
4. MFT
5. 14-day incubation period

RESULTS

11 Operators
(10 preparers and 1 pharmacist)

→ A total of 11 MFTs
(i.e. 44 preparations)

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- ✓ No deviations observed in manufacturing steps
- ✓ Positivity of all fertility tests
- ✓ No contamination of MFT
- ✓ Validation of this new manufacturing process
- ✓ Enabling all operators to this new manufacturing process

CONCLUSION

The aseptic manufacturing process and the training of 11 operators were validated thanks to the MFTs.
No malfunctions were observed during the 2-week robot installation period.
This manufacturing process ensured the continuity of our production and therefore of patient care.