Qualification of Pharmaceutical Staff for Handling Cytotoxic Safety Cabinets: Simulation at the Heart of Certification

L. Fourcaud[1], S. Hermann[1], G. Hily[1], D. Sankhare[1], N. Jourdan[1], I. Madelaine[1], M. Brault[1]
[1]Hôpital Saint-Louis (APHP), Pharmacy Department, Paris (75010)
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Introduction and context

Good Preparation Practices (GPP): Initial and ongoing training commensurate with the duties and responsibilities assigned

→ Healthcare **simulation program** on handling within a **cytotoxic safety cabinet** (biosafety cabinet, BSC)

→ Integration of an **media fill test (MFT)** in response to GPP requirements

Objective : To assess the impact of healthcare simulation on the qualification of pharmaceutical personnel for the handling of cytotoxic products in a CSC

Materials and methods

1

High-fidelity immersive simulation program SoFraSimS

2 Identification of **critical steps**

Input function: Opening of the CSC
- Biocleaning (initial and final)
- Aseptic practice and GPP within the CSC
- Microbiological monitoring

Output function: Closing of the CSC

3

MFT
Series of 4 preparations representative of routine daily production

4

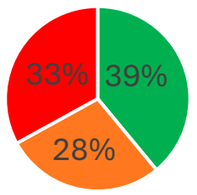
Visual certification:
observation by a trainer
Checklist inspired by the United States Pharmacopeia (USP), Chapter <797>

Habilitation = réussite TRA + certification après observation par un formateur

Results

36 participants (18 operators and 18 assistant operators)
- 10 pharmacy technicians, 13 residents, and 13 senior pharmacists
- **100%** success rate in Media Fill Tests

Manipulateurs (%)

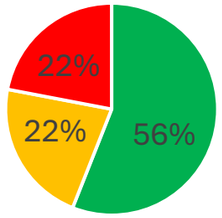


Qualifié ■ Qualifié sous réserves ■ Non qualifié

4 residents + 1 pharmacist

100% of failure causes = Poor practices within the CSC

Aide manipulateurs (%)



4 residents

Qualifié ■ Qualifié sous réserves ■ Non qualifié

Discussion and conclusion

Securing of preparations and **risk management**

Highlights the **need for continuous trainin** (pharmacy technicians and pharmacists) a initial training (residents)

Time constraints (2 one-hour sessions per trainee) and **organizational constraints** (CSC/BSC used for routine production)