

# Pharmaceutical aseptic preparation on-call duty period: setting up a training and accreditation program for pharmacists

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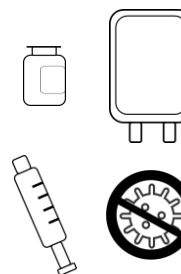
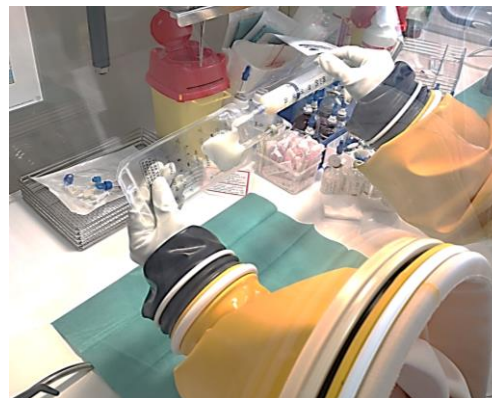
## Introduction

The performance of **aseptic preparations during on-call duty** meets the pharmaceutical permanence obligations of public health establishments. In the context of the re-authorisation of activities by the competent authorities and the enforceability of French Good Preparation Practices 2023, it is necessary to ensure that pharmacists participating in on-call pools have the **necessary skills**. This work will present the **training and accreditation program** implemented in our establishment.

## Material and Method

A **3-phase accreditation program** has been decided following consultation between training pharmacists

- **Phase 1** : making of 5 placebo preparations inside an isolator, under the supervision of a pharmacist. Objective : to determine the learner's skills based on his experience, review of basic aseptic handling techniques.
- **Phase 2** : training in the production of preparations, under the supervision of qualified preparers, with a set objective as to the nature of the preparations to be made.
- **Phase 3** : accreditation with 5 placebo preparations inside an isolator and aseptic filling test (AFT) under laminar flow hood with worst case (min 3 criteria, ex: inexperience of the actions to be adopted under PSM II, use of non-decontaminated devices).



A **review of the protocols** carried out on-call duty selected the nature of the **10 simulated preparations** (phases 1 and 3). For these, the following variation criteria were established: final container (bag, syringe), withdrawals/dilutions, drug presentation (lyophilisate, ready-to-use product, glass ampoule), use of specific medical devices (Spiros®, 0.22µm filters).

An **accreditation grid** (58 points divided into 13 categories) was drawn up. Pharmacist accreditation was based on validation of at least 50 points and compliance of the AFT after incubation.

## Results and discussion

- Since January 2024, **9 pharmacists** (out of 20) have been **re-certified** by this program (average score : 55,1/58 [53 ; 58], compliance of all AFT).
- Training and accreditation require a considerable amount of time (average of **6 hours** for phases 1 and 3, not including the preparation of equipment kits). Accreditation is validated for 3 years, but each pharmacist can come and train regularly.
- Using **placebo preparations** was based in particular on the **simulation of costly or exceptional preparations (antidotes)**.
- In the long term, this protocol could be improved to also vary the **excipient composition** of the placebos (foaming, viscous).
- From a subjective point of view, the re-accreditation helped to boost the **confidence of pharmacists**, particularly those who do not carry out their day-to-day work in a sterile preparation unit.

## Conclusion

The proposed programme meets a need to formalise training and accreditation in aseptic handling and has been fully integrated, in our hospital centre, into the wider training programme for pharmacists' on-call duties.