

Emergency opening of sterile preparations unit during COVID-19 pandemic

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Context



April 2021, 3rd wave COVID-19 is coming !!



Intensive Care Unit (ICU) in difficult situation due to lack of staff and work overload



Shortage of many drugs including curare, lack of nurse time for syringe preparations



Call for immediate help to pharmacy unit to produce the syringes
→ availability of an unused Controlled Atmosphere Area (CAA) in our Pharmacy

Method



Crisis committee at D-0

Pharmacy unit :

- Evaluation of ICU needs and technical + operational feasibility
- Listing of needed materials for preparation under laminar flow ceiling
- Redaction of procedures and protocols (dressing, preparation, control, ...), manufacturing sheets, labels
- Training staff to manipulate under laminar flow ceiling
- Mobilize 1 extra manipulator to reinforce the staff
- Organize logistics (raw material, documents and preparations flows)
- Set in-process and final controls : double reading of volumes, batch numbers check , syringe and label check, microbiological (2 contact plates on gloves and settle plate for each batch prepared)
- Scheduler with traceability of produced batches

Objective : pharmaceutical quality!

Technical unit :

- Check the status of the unused CAA and laminar flow ceiling
- Change air pressures
- Find suitable furniture for CAA

Results



Our preparations

Beginning production at **D+1**

- 1 kind of preparation only : Atracurium syringes 50 mg/50 mL → better productivity
- 33 days of production including 4 Saturdays
- 2,126 syringes produced in 86 batches : 64 syringes/day (min: 9 - max: 126), 2,6 batches/day (min : 1 - max : 4)
- Controls : 4 nonconformity (0.2 %) 160 contact plates, 60 settle plates, 1 nonconformity (1.6 %)

Successful !!!



Our production staff

Conclusion

Involvement and reactivity of the pharmaceutical staff → Crucial support to ICU staff during this crisis
Importance of previous establishment of technical and operational feasibility