

# Environmental microbiological surface non-conformities in clean areas : 2019 retrospective analysis

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## INTRODUCTION

- Context:**
- Within the drug production unit of the hospital's pharmacy, sterile pharmaceutical preparations are produced in controlled environment.
  - Monitoring micro-organisms ensures the **absence of biocontamination**.
- Objective:**
- **Analyze of microbiological non-conformities that occurred on the Sterile Production Area (SPA) in 2019.**

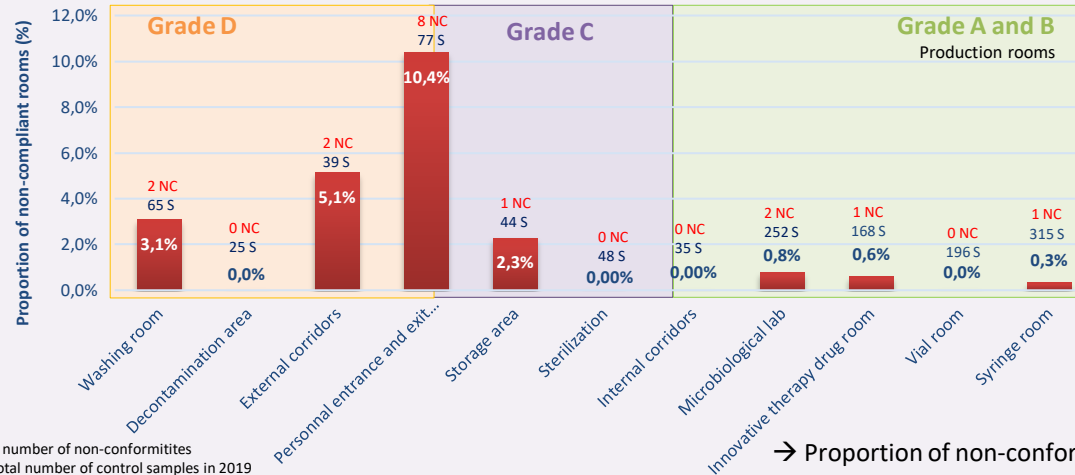
## MATERIEL ET METHODES

Collection of all the results of the 2019 environmental controls in SPA:

- Date
- Cleanroom concerned
- Number of compliant samples
- Number of non-compliant samples
- Surface area involved
- Microorganism
- Number of colony units

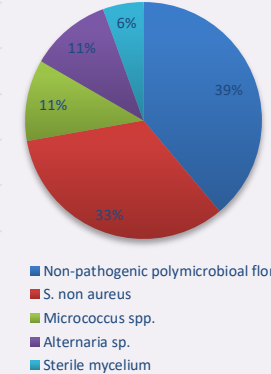
- Proportion of non-compliant results in each room and in each surface type
- Evolution of non-conformities over the year

## RESULTATS



NC : number of non-conformities  
S : total number of control samples in 2019

90 rooms  
1264 control samples



→ Proportion of non-conformities stable over the year

## DISCUSSION ET CONCLUSION

Biocontaminations in SPA = significant human risk (administration of préparations to patients)

- **Correctives actions:** Blanking and biocleaning
  - **Preventive measures:** Retraining agents about hygienic practices in controlled environment + ↗ biocleaning and monitoring frequency in involved rooms
- In 2019, low biocontamination in PSA provided the production unit of the pharmacy to ensure and secure the production of sterile preparations.**