Sterilization of neoprene gloves for shielded preparation chambers & microbiological assessment in radiopharmacy

M. DEBARGE, A. LOMBARD, M. SACREZ, E. LOISON, F. BENOIT, Q. CITERNE, N. VERAN, B. DEMORE
Hospital pharmacy, CHRU Nancy, rue du Morvan, 54500 Vandoeuvre lès Nancy

COM24-29327

Introduction

Context : Preparation of **radiopharmaceuticals (RPs)** according to the 2023 **Good Manufacturing Practices (GMP) (LD1, LD4)**

Problem : Recurring **non-compliance** in the microbiological monitoring of gloves in a **grade A cleanroom**

Objective

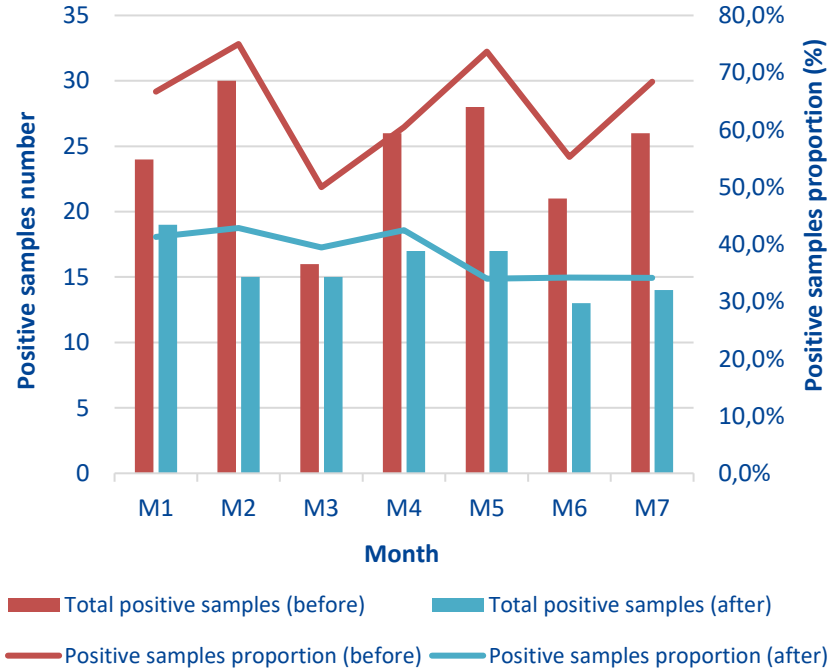
Application of **new hygiene practices on gloves**
Evaluation of their **impact** based on a **comparative microbiological assessment**

Methodology

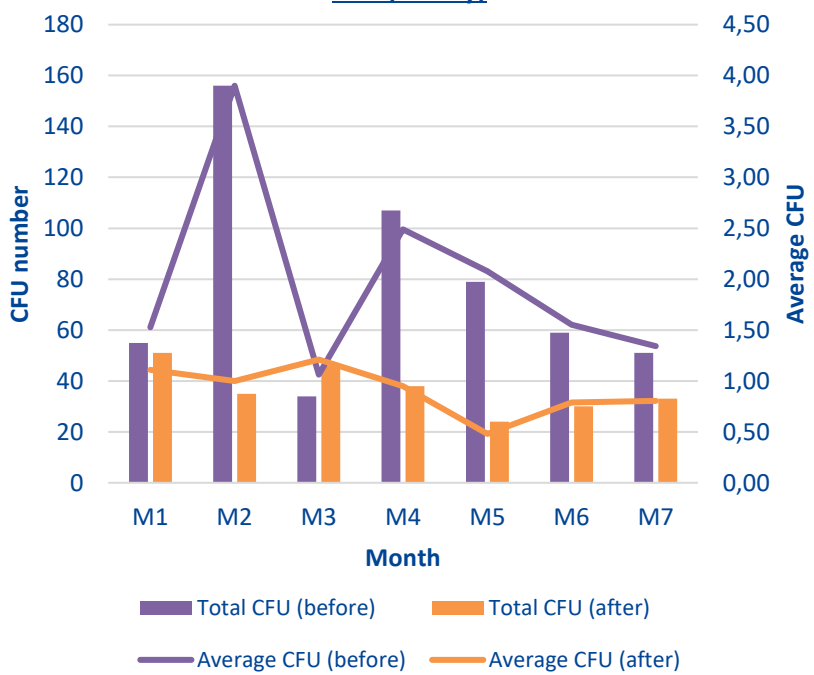
1. Glove hygiene
   - ❑ **Weekly sterilization :** washer-disinfector followed by autoclave (steam) at 134°C for 18 minutes
   - ❑ **Disinfection during operations** : hourly
2. Microbiological assessment over 7 months before and after adopting new hygiene measures
   + Identification of microorganisms

COMPARISON « BEFORE AND AFTER IMPLEMENTING GLOVE STERILIZATION »

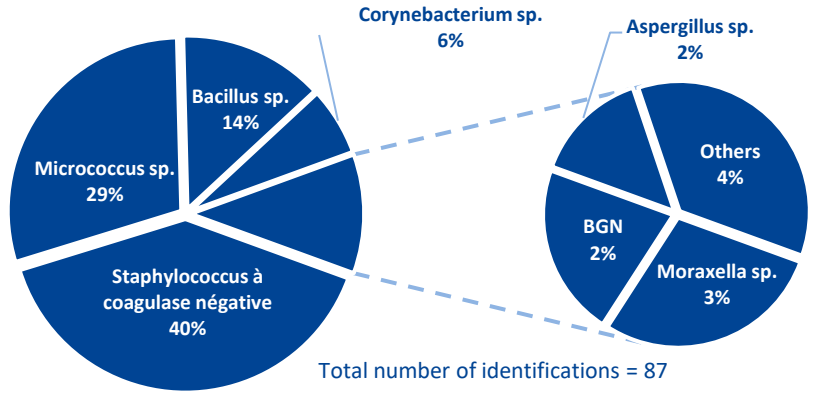
Positive samples



CFU (colony)



MICROORGANISMS IDENTIFIED IN SAMPLES



New Hygiene Protocol	BEFORE	AFTER
Positive samples	171 of 265 (64,5%)	110 of 288 (38,2%)
Innumerable samples	5	None
Average CFU	2	0,9

Discussion

Significant reduction in positive samples and the average CFU after implementing new practices

- Predominance of skin commensal bacteria
- *Bacillus sp.* : **sporulating** bacteria

What is the role of microbiological identification in cleanrooms ? → Adaptation of the detergent-disinfectant (sporicidal).

Conclusion

Importance of corrective measures (sterilization and bio-cleaning)
→ Compliance with GMP microbiological requirements for gloves in a grade A cleanroom.