Trend analysis of microbiological contamination within a pharmaceutical compounding unit : towards a risk-based revision of the environmental monitoring sampling plan

COM26-37472

P. Boute[1], D Goulley[1], P Gueneau[1], C. Pernot[1]
[1]Unité de Pharmacotechnie, CHU Dijon Bourgogne, Dijon, France

INTRODUCTION

- The French Good Preparation Practices (BPP 2023) require a documented microbiological sampling plan (SP) for cleanrooms, incorporating monitoring points, frequencies and action limits.
- Implementation of this PP represents a substantial burden in terms of sampling time and consumables.
- Its relevance therefore needs to be assessed to consider a revision.

OBJECTIVE

Assess the relevance of the SP through a 12-month trend analysis covering 2025.

MONITORED SITES

Class C cleanroom and airlock	4 isolators
Active air and surfaces	Active air, surfaces, gloves and settle plates

MATERIALS & METHODS

The SP complies with the sampling frequencies, sample types and limits recommended by the BPP 2023, as well as the number of monitoring points defined according to standard NF EN ISO 14644.
All sampling was performed under operational conditions ('in operation').

TREND ANALYSIS APPROACH

- Sampling plan compliant with BPP 2023
- Samples : active air, gloves, settle plates, surfaces
- Data collection in Lyra®
- 12-month trend analysis

KEY FIGURES

2,921 Samples analyzed

99.3% Overall compliance rate

RESULTS

CLASS C CLEANROOM AND AIRLOCK

0 OOS

Out of 73 samples

- Active air (n = 33)
- Surfaces (n = 40)

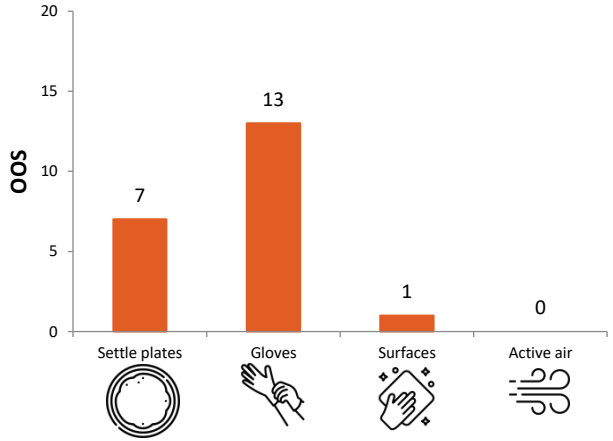
ISOLATORS (n = 2,848)

21 OOS

0.74% of samples

• Settle plates (n = 904)	7 OOS (0.77%)
• Gloves (n = 1457)	13 OOS (0.89%)
• Surfaces (n = 437)	1 OOS (0.23%)
• Active air (n = 48)	0 OOS (0%)

DISTRIBUTION OF OOS WITHIN THE ISOLATORS



DISCUSSION

CLASS C CLEANROOM AND AIRLOCK

- No OOS results ; mean active air contamination : 22 CFU/m^3, corresponding to 44% of the BPP action threshold (50CFU/m^3)

Reduction in sampling frequency

- Active air : monthly → quarterly
- Surfaces : weekly → monthly

ISOLATORS

- 21 OOS with no clinical significance and no unfavorable trend
- Predominance in glove samples (62% of OOS)

Action plan

- Reinforcing decontamination procedures rather than intensifying monitoring
- Class A active air : consistently negative → monthly-to-quarterly sampling may be considered

CONCLUSION

99,3% Compliance rate across 2,921 samples → Class C contamination levels well below action limits → Revision of the SP based on ICH Q9 and annual review → Reduction of the monitoring burden without compromising the microbiological safety of preparations