

INTRODUCTION & OBJECTIVES

Context:

- Installation of **new isolators** in our Centralized Chemotherapy Reconstitution Unit (CCRU) in summer 2023
- Official release of new **Good Preparation Practices (GPP)** 2023

Objective:

- ✓ **Redefine a frequency of microbiological samples adapted to practice and consistent with recommendations**

MATERIEALS & METHODS

1st part

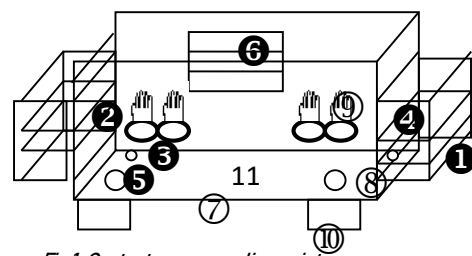
For 4 weeks: monitoring of samples according to the **GPP recommendations**

→ *Comparison of the two periods to February 2023 before the change of isolators*

2nd part

For 4 weeks (afterwards): **adjustment** of sampling according to the results obtained (not predetermined)

A C C O R D I N G G P P	Air by sedimentation agar at the work surface	→	DAILY
	Operator glove imprint on contact with the product	→	DAILY (end of work session)
	Contact samples within classified areas	→	WEEKLY
	Active air sampling for all classified areas	→	MONTHLY



The samples are taken according to the guidelines of the Association for Safety and Economy in Pharmacy (ASPEC) in class A overpressure isolators.

The mapping of risk points has been established with the insulator manufacturer.

RESULTS

CLASS	AIR SAMPLE cfu/m3	PETRI DISH cfu/4hours	CONTACT AGAR cfu/plaque	GLOVE IMPRINT cfu/glove
A	<1	<1	<1	<1

Tab. 1: GPP recommended limits for microbiological contamination

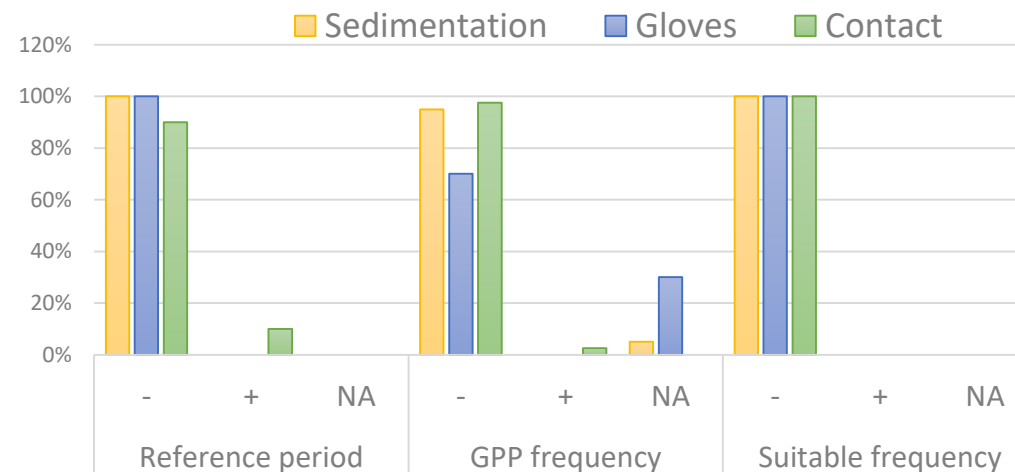


Fig. 2: results of the samples over the 3 periods

	Reference period	GPP frequency	Suitable frequency
Gloves	X	Daily (end of work session)	Daily (1 glove per day)
Contact	Weekly (2 points)	Weekly (10 points)	Weekly (2 points)
Sedimentation	Weekly	Daily	Daily
Impaction	X	Monthly	Monthly

Tab. 2: results of microbiological samples according to sampling frequencies

- Single positive sample during the "GPP frequency period"
- No positives during the "suitable frequency" period

DISCUSSION & CONCLUSION



Updating our GPP microbiological sampling practices



Implementation of aerobiocontamination on inside isolators



Spacing of samples while guaranteeing compliance with class A of the isolators



New collection schedule

- ✓ **Aerobiocontamination:** monthly
- ✓ **Contact agars:** 10 critical points of the isolator weekly
- ✓ **Gloves:** daily on each pair of gloves
- ✓ **Sedimentation:** daily sampling of maximum 4 hours at each station