F-PCT-22

Implementation of an in-process control environmental monitoring tool for aseptic and sterile production at the CHUV pharmacy

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Background

- The CHUV produces **30,000** aseptic compound preparations annually in a class A environment, requiring strict **environmental monitoring** (Appendix 1 of GMP).
- The current control plate management system is no longer suitable and complicates the compilation of non-compliance statistics.
- A **new tool** is needed to record in-process control plates, manage non-conformities, make trending more visual and generate statistics quickly.

Objective

To **develop** and **validate** a user-friendly and reliable tool based on the SharePoint platform by integrating security features such as audit trail, coding of sessions and plates.

To improve operator **compliance** with environmental monitoring in cleanrooms

To be able to generate **precise, visual and usable statistics** for environmental monitoring of IPC in Grade A environment.

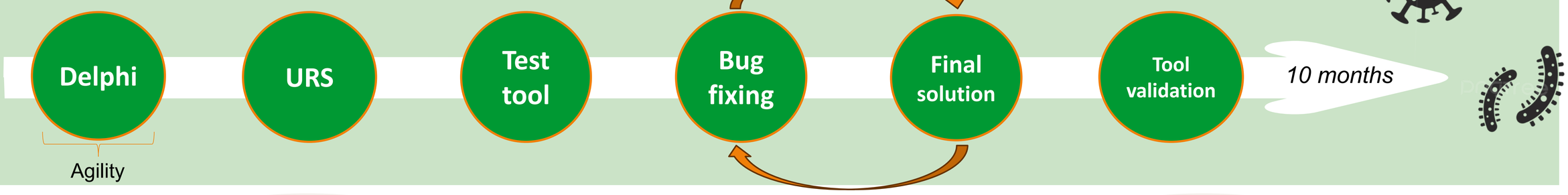
Conclusion

The validation step enabled us to perfect the tool.

The developed tool is ergonomic, built on the basis of a Delphi system which has allowed an increase in compliance.

Trend analysis encompasses operators and equipment contamination monitoring to ensure the control of the aseptic manufacturing processes.

Approach & Results



1

Method:
- Writing of validation documents
- Process of validation

Results:
- Validation protocol reviewed approx. **20** times
- Protocol execution by **6** people
- **4** documentary and **1** critical deviations

2

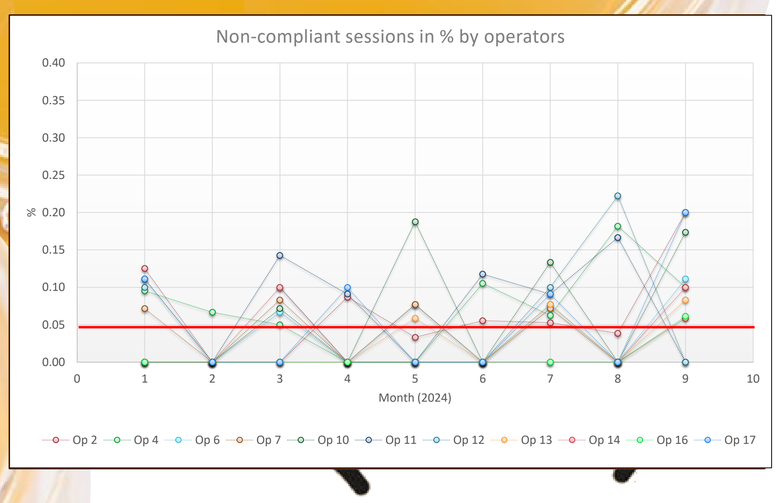
Method:
User survey before and after the project

Results:
- **+ 125%:** the increase in daily settle plate entries recorded in 2024 compared to 2023
- **80%** satisfaction within the production team (20 operators)

3

Method:
Interview with the QC manager before and after the project

Results:
- Statistics can now be extracted and analyzed in 30 minutes, previously 4 hours.
- Statistics are more visual, and trends are semi-automated



INNOVATION:
- **User considered at all stages**
- **Integrated system**
- **Automation**
- **Tool validation**

Reference: 1. Appendix 1 of Good Manufacturing Practices (GMP)

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