

CLEAN ROOM : MAPPING OF MICROBIOLOGICAL SAMPLES OF THE ENVIRONMENT USING A FAILURE MODE AN EFFECT ANALYSIS (FMEA) METHOD

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COM22-84271

Introduction

Environmental microbiological controls in Clean Rooms (CR) are key elements for monitoring the compliance of an aseptic production process. Upcoming work and changes to the layout of our CRs have led us to review the relevance of our sampling plans.

Objective

To map the areas at risk of microbiological contamination of CRs with isolators and, thus, to adapt our sampling plans accordingly.



Method

- 1 • Delimit two CRs into **17 areas**
- 2 • Use a **FMEA method**
- 3 • List the **risks of contamination** for the 17 areas
- 4 • Rate risks according to numerical scales of **severity (S), probability (P), non-detectability (D)** and **risk priority number (C = P x S x D)**.



Conclusion

✗ Reinforced controls and cleaning will have to be put in place for several areas.

- ✓ Relevance of control points in relation to microbiological contamination observed routinely
- Application of this method when changing equipment or CRs layout

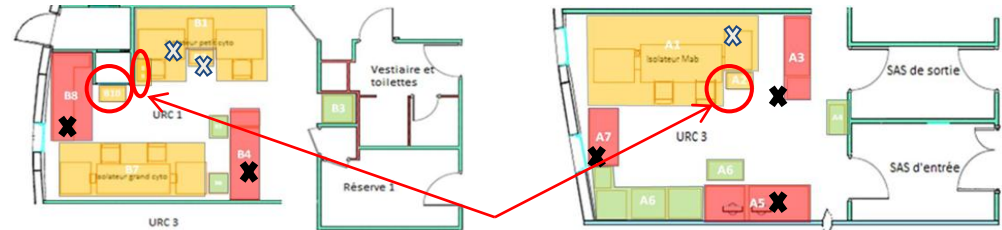
Results

The **risk priority number (RPN)** for each risk range from 2 to 80 points:



Classification of the 17 areas and comparison to our current sampling plan:

- 5 areas with a **high risk** of microbiological contamination : areas with **≥ 2 risks** with a **C3 RPN** (The results of the microbiological samples taken over the year 2021 identified these areas as those where the contaminations were the highest (6 CFU/week on average))
- 7 areas with a **moderate risk** of microbiological contamination: areas with **1 risk** with a **C3 RPN**
- 5 areas with a **low risk** of microbiological contamination: areas **without risk** with a **C3 RPN**



Types of samples currently carried out

- ✗ Sedimentation and contact-plate
- ⊗ Sedimentation or contact-plate

3 areas for which samples are missing