QUALIFICATION OF BIOCLEANING IN CLEANROOMS

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CONTEXT AND OBJECTIVES

During an audit of our sterile hospital preparations production unit, the auditor identified a major deviation: the lack of qualification for the bio-cleaning protocol. The objective of our work was therefore to qualify our bio-cleaning protocol.

MATERIALS AND METHODS

The bio-cleaning protocol involves sequentially applying a **detergent solution** *[Didécyldimethylammonium chloride (DDAC) 0.03 g/100 g + N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine) 0.06 g/100 g]* **followed by rinsing** *[Ethanol 70% (641 mg/g)]*, alternating with a **disinfectant solution** *[Hydrogen peroxide 1.5% (15 mg/g)]* **followed by rinsing** *[Ethanol 70% (641 mg/g)]*, on a 2-day/3-day cycle. The application by wet wiping or wet mopping is performed by impregnating a suitable polyester knitted fabric, used manually or mounted on an autoclaved mop, respectively. All the products are sterile

Figure 1 : Detergents, disinfectants, polyester knitted fabric and autoclavable mop.

Qualification is based on the comparison of microbiological contamination levels before and after cleaning, at critical points identified through a risk analysis, across four cleanrooms (90 m²; N = 81 samples). Post-cleaning contamination levels must be significantly lower (in case of contaminations detected in pre-cleaning samples) and remain within Grade B specifications. A visual inspection is carried out to ensure the absence of residues.

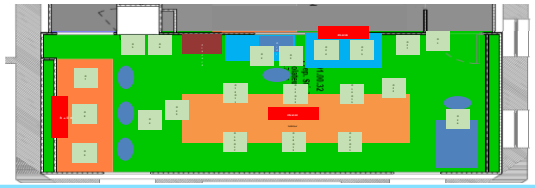

Figure 2 : Sampling plan for a room within the Controlled Access Zone (ZAC).

RESULTS

This protocols allows the conformity to the antimicrobiological norms EN 1040, EN 1276, EN 13697, EN 1276, EN 1275, EN 14348, EN 1650 and EN14476. All 81 post-cleaning samples complied with Grade B requirements (< 5 CFU/plate; 55 mm agar). No product residues were observed during visual inspections.

DISCUSSION AND CONCLUSION

These results confirm the effectiveness of the biocleaning protocol. The use of sterile products in alternation, combined with ethanol rinse, contributes to overall risk reduction in our operations.
The main limit of our study is the absence of applicability assay of the microbiological method. Even if the plate supplier has conducted neutralization tests on the disinfectants used in this study, the inspection may require confirmation of this effect under actual conditions.
This validation will be the subject of upcoming work in our unit.

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