The Challenges in Floor Cleaning and Disinfection

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ABSTRACT

In cleanrooms, floors as a secondary surface are cleaned with the highest frequency. Proper cleaning and sanitization techniques are key in maintaining cleanroom surfaces. The buildup of residue on floors could lead to a risk of particulate in air, on equipment, or in products. A well-defined sequence of cleaning, residue removal, and sanitization can accommodate this risk.

Introduction

As an industry we face challenges to surface cleaning and sanitization. These include:

- Manpower shortages
- Consistency
- Management oversite
- Adequate time
- Cost of operations
- Safety
- Changes in regulations
- Proper use of disinfectants and rinsing

Understanding disinfectants selection

The most common disinfectants utilized are quaternary ammonia disinfectant and phenolic disinfectants. These products are well characterized in terms of performance against common bacteria, fungi and viruses.

Disinfectants are selected on the basis of performance of common environmental isolates. However, more than one product must be included in the disinfectant program. The spectrum should include routine disinfectants, sporicides and alcohols. Detergents should be considered for removal of residues.

Residue removal

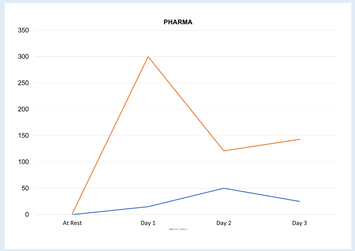
The removal of residue is a challenge today – when to remove the residue, frequency of removal and how to remove the residue. Many of the disinfectants and sporicidal agents are NOT compatible with each other. The chemical compatibility can result in significant visual residue. Removal of this type of residue is difficult and time consuming. When selecting a disinfectant and sporicide, the compatibility should be considered.

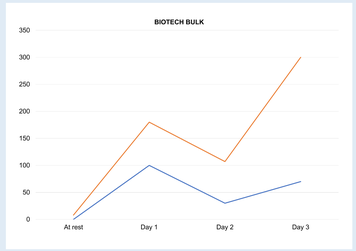
Over the last two years, there have been major concerns with floor cleaning. These issues have far surpassed the level of consequence in past cleanroom history. We have documented the common factors:

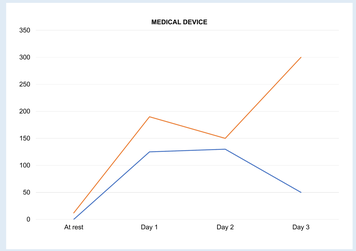
- Heavy residual
- Visible flaking
- Severe damage to floors
- Safety

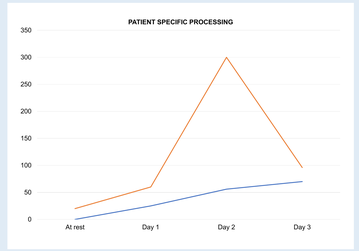
CASE STUDY

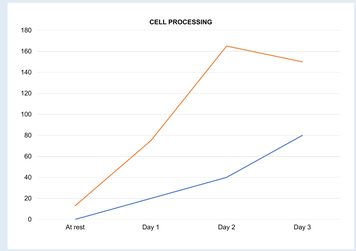
RINSE
NO RINSE











The case studies will demonstrate the impact of residue and removal on surfaces.

Over 150 sanitization events were reviewed and analyzed. The following factors were reviewed:

- Type of flooring
- Frequency of cleaning
- Tools for cleaning
- Disinfectants
- Environmental conditions – temperature and humidity

These cleaning events prompted the authors to find users that would perform testing under a protocol condition to determine why the issues were occurring and the impact of these events on the cleanroom marketplace. After months of efforts – 25 commercial manufacturing companies in 5 different sectors of the cleanroom marketplace agreed to perform testing.

Criteria background for the testing

- Floor surfaces were inspected for damage that could have an impact on cleaning and sanitization efficiency and potential EM risks. Floors selected were 97% aggregate – type 2 and type 3 finishes. One floor was welded sheet vinyl and one floor was a type 4 aggregate.
- All participants performed identical frequency.
- All mops were sterile and met cleanroom requirements for acceptable materials – microfiber. Buckets were either sterilized or sterile liners were used.
- All 25 case study participants followed IEST RP18 techniques – either pull-lift or modified figure “8”.
- All disinfectants were validated for efficacy. Contact times were appropriate to the specific site and validation.
- Temperature and humidity conditions were within similar ranges.

Location for testing

- ISO 8 material airlocks were selected for the testing
- Non-clean side of the airlock
- Airlock testing dimensions – 5 feet wide and 10 feet in length. Any participants with larger airlocks only tested in the center. This allowed for the same area to be tested in all case study participants.

Protocol #1

The purpose of this testing was to demonstrate the results on a floor following operations without a removal of the disinfectant residue (no rinse).

- Floors were mopped
- Floors were monitored after contact time (at rest condition)
- Operations as normal during a shift
- Testing was performed on the floor surfaces

Protocol #2

The purpose of this testing was to demonstrate the results on a floor following operations with the removal of the disinfectant residue by rinsing after the contact time.

- Floors were mopped and held for contact time. Floors were rinsed with WFI using sterile tools and techniques as identical to the mop step and allowed to dry. No admittance was allowed until the testing was performed.
- Floors were monitored (at rest condition)
- Operations as normal during a shift
- Testing was performed on the floor surfaces

Data

The data will be presented by the type of company represented in the study:

Client A Pharmaceutical
Client B Biotech (bulk)
Client C Medical Device
Client D Cell processing
Client E Patient specific processing

The DATA

The numbers are variable due to several factors:

- Numbers of transfers in the airlock
- Type and sizes of the transfers
- Number of personnel required to place an item on the non-clean side of the airlock

Summary

1. The difference between rinse and no rinse after sanitization and prior to reapplication of the disinfectant is evident – the effectiveness was no longer adequate to control contamination when the disinfectant was removed after contact time.
2. Residue is of significant concern if the application does not follow the proper techniques of application.
3. Training and proper tools are required to control contamination. Sanitization procedures must be supervised and audited to ensure consistency.
4. Airlocks are difficult to manage, and the amount of contamination risk is dependent on many factors. In these 25 examples, the protocols were correct, the techniques were appropriate, but the number of transfers could exceed the airlock’s ability to maintain the levels of control required. Users must review the sanitization frequency of these areas to determine if additional floor sanitization is needed.

References

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