



# ROTATIONAL CLEANING

## INTRODUCTION

The upcoming revision to EudraLex vol 4 covers Good Manufacturing Practice (GMP) guidelines and Annex 1 is specific to the manufacture of medicinal products. This update comes after several years since its last revision and provides direction to the industry, reflecting best practice.

For in cleanroom cleaning and disinfection regimes the key part to note that the draft guidelines clearly separate the cleaning step from the subsequent disinfection.



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods  
Pharmaceuticals

**EudraLex**  
**The Rules Governing Medicinal Products in the European Union**  
**Volume 4**  
**EU Guidelines to**  
**Good Manufacturing Practice**  
**Medicinal Products for Human and Veterinary Use**  
**Annex 1**  
**Manufacture of Sterile Medicinal Products**

### **4 Personnel**

**4.10** | Changing and hand washing should follow a written procedure designed to minimize contamination of clean area clothing or carry-through of contaminants to the clean areas. Garments should be visually checked for cleanliness and integrity prior to entry to the clean room. **For sterilized garments, particular attention should be taken to ensure that garments and eye coverings have been sterilized** and that their packaging is integral before use.

**4.13** | Outdoor clothing should not be brought into changing rooms leading to grade B and C rooms. **It is recommended that facility suits, including dedicated socks be worn before entry to change rooms ...**

### **5 Premises**

#### **Disinfection**

**5.31** | The disinfection of clean areas is particularly important. They should be cleaned and disinfected thoroughly in accordance with a written programme **(for disinfection to be effective, cleaning to remove surface contamination must be performed first).**



## CLEANING AND ROTATIONAL DISINFECTION

### Delta Product

Micronclean has recently brought to market a brand-new product Delta which is a neutral detergent. Our Delta product has been developed to be fully compatible with our Alpha and Beta cleanroom disinfection regimes by having the following key features:



#### Low foaming formulation

this reduces the risk of streaks and staining when in use which could affect the subsequent disinfectant effectiveness.



#### Neutral (pH 6.5-7.5)

to ensure that it is non-corrosive and will not damage hard surfaces.



#### Supplied Pre-mixed

to ensure a homogenous distribution of the active ingredient.



#### Manufactured with WFI

to ensure maximum cleanroom compatibility with cleanroom environment.



**Gamma Irradiated** - to give a sterile product with a two-year shelf life.

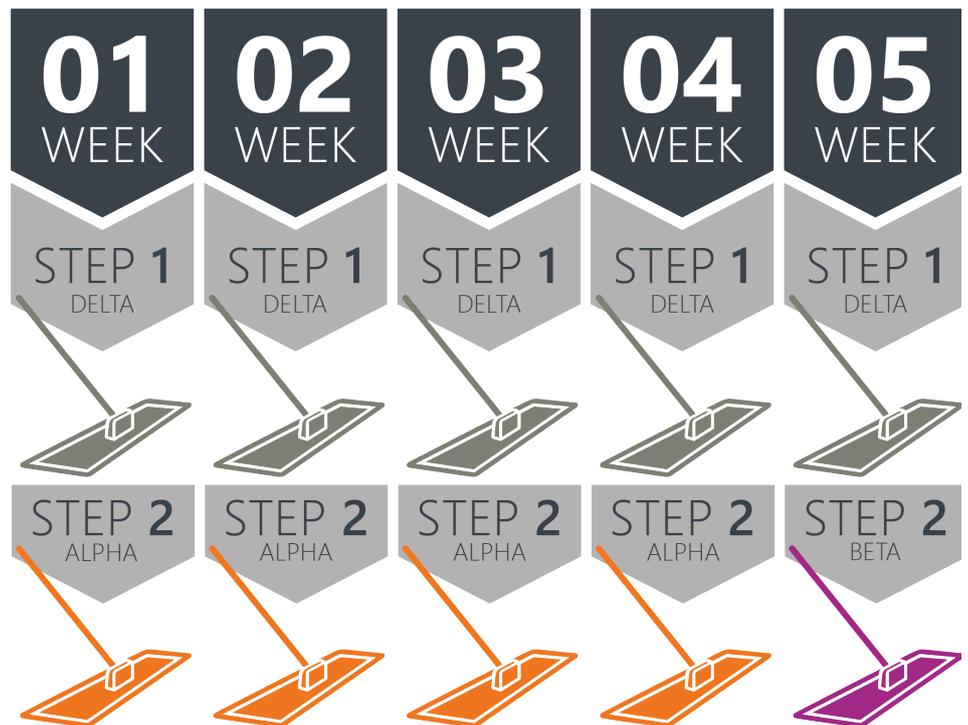
## HOW TO USE

With both of our Laundered Mopping Systems, we would advocate use the following regime alongside both of systems to ensure the maximum benefit from our specially formulated detergent and disinfectants.

**Week 1** | Clean the floor by using Delta Mops followed by disinfection by using Alpha Mops.

**Weeks 2 to 4** | As in Week 1 Clean the floor by using Delta Mops followed by disinfection using Alpha Mops

**Week 5** | As in the previous week clean the floor using Delta Mops but then use a Beta Mop as the rotational disinfection step to prevent the potential buildup of resistance within your environment



It is worth noting that as part of a Micronclean Laundered Mop contract the mops we supply to you will be in the correct order to match our proven regime without you having to worry.