

PLANNING FOR ANNEX 1 WITH MICRONCLEAN INDIA



ANNEX 1

Annex 1 of EU GMP provided specific guidance on the manufacture of sterile medicinal products. The latest version of the guidance was published and came into force on August 25th, 2023.

This new version is substantially different to the previous version and includes additional guidance on cleaning and disinfection processes, and cleanroom clothing.



EUROPEAN
COMMISSION

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GUIDELINES

The Rules Governing Medicinal Products in the European Union
Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for
Human and Veterinary Use

4 Premises

Disinfection

4.33 The disinfection of cleanrooms is particularly important. They should be cleaned and disinfected thoroughly in accordance with a written programme. **For disinfection to be effective, prior cleaning to remove surface contamination should be performed.**

7 Personnel

7.11 The clothing and its quality should be appropriate for the process and the grade of the working area. It should be worn in such a way as to protect the product from contamination. Reusable garments should be replaced if damage is identified, or at a set frequency that is determined **during qualification studies. The qualification of garments should consider any necessary garment testing requirements, including damage to garments that may not be identified by visual inspection alone.**

7.14 Outdoor clothing (other than personal underwear) should not be brought into changing rooms leading directly to Grade B and C cleanrooms. **Facility suits, covering the full length of the arms and the legs, and socks covering the feet, should be worn before entry to change rooms for Grades B and C.**

7.15 Every operator entering Grade B or A areas **should gown into clean, sterilized protective garments** of an appropriate size at each entry.



4.33 TWO STAGE CLEANING AND DISINFECTION

To aid this two-stage process Micronclean can offer its own reusable laundered sterile dry mop system. This allows you to dose on your own site with your own neutral detergent and disinfectants and return to us for complete decontamination. We then return then the mop to you in a clean dry sterile condition ready for immediate reuse without using your production capacity to decontaminate a large number of mops. Our mops can be supplied either singularly or in packs of five or ten depending on the size of your cleanroom.

Micronclean can also provide our Neutral Disinfectant, Delta, as a pre-mixed solution to run alongside the our rotational disinfectants Alpha and Beta.



7.11 CLEANROOM CLOTHING

Within India, Micronclean is unique in that it has committed a large amount of resource to undertake fundamental research into its cleanroom fabrics. As a result we have qualified our cleanroom garments to prove how the properties of the fabric, and the garment, are affected by the numerous decontamination and sterilisation cycles.

Our garment study describes how we have tested a variety of cleanroom fabrics to assess the effect of both decontamination and sterilisation cycles (covering both irradiation and autoclave process) on several fundamental properties including particle filtration, durability, tensile strength and abrasion resistance. In this way we have established a unique knowledge about the right fabrics to use and the performance of our garment systems made from these fabrics.

As a result, when you are looking to qualify your garments in use, we can advise you on the use/life cycle of your garments, using a vast amount of research data, cutting your own qualification process considerably.



7.14 CLEANROOM SOCKS

Annex 1 states that cleanroom socks should be worn before entry into cleanrooms. As a consequence Micronclean would recommend that you use our Cleanroom Laundered Reusable Sock service.

This service offers:

- A naturally foot shaped sock made from 100% synthetic fibre which is available in three sizes.
- Full traceability from integral RFID chip.
- Shipping alongside our existing cleanroom garment service.



"At Micronclean our passion is to be the first to develop new technological solutions that change the shape of the markets we serve, creating quality and efficiency for our customers."

Micronclean India has established a state-of-the art cleanroom laundry in Bangalore. These brand new facilities have been built by Micronclean, a family-owned UK company with over 40 years' experience in the provision of contamination control.

The plant is a first in India in that it has been specifically designed to process and deliver high quality, sterile ready for immediate use cleanroom garments to support the Indian Pharma/Biotech industry.

The plant has already begun to support Pharmaceutical and Biotech producers who are seeking to export products under increased regulatory scrutiny.

Designed from the outset to incorporate world best practices to ensure compliance with the industries highest cGMP garments.



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