

PLANNING FOR ANNEX 1 WITH MICRONCLEAN

EudraLex vol 4 covers Good Manufacturing Practice (GMP) guidelines and Annex 1 is specific to the manufacture of medicinal products.

The latest revision for comment was issued in December 2020 and the key requirements are highlighted below alongside the products and services that Micronclean can provide to help you remain compliant.

Delta

Available in four easy to use product forms Trigger Spray, 5L RFU, Presaturated Wipe and Reusable Laundered Mop. Delta is Micronclean's highly effective neutral detergent that is fully compatible with our Alpha and Beta rotational disinfectant system.

Cleanroom Socks

We have polyester, disposable socks in our consumable range to help you become compliant with this additional requirement.

Sterile Goggles

Micronclean offer the only reusable goggle service in the UK that is decontaminated using a validated ISO4/EU GMP Grade B cleanroom barrier wash process (with the addition of a unique anti-fogging agent) and sterilised by gamma irradiation.

The goggles are supplied ready for use with all the other benefits of a Micronclean rental service and we welcome in-use trials.



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Pharmaceuticals

EU GMP Annex 1 Revision: Manufacture of Sterile Medicinal Products

Annex 1 Consultation Document December 2020

4 Premises

Disinfection

4.36 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

7.15 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.**

7.16 Every operator entering Grade B or A areas **should gown into clean, sterilized protective garments (including eye coverings and masks)** of an appropriate size at each entry.

