


# 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. This update comes after several years since its last revision and provides direction to the industry, reflecting best practice.

The key changes are highlighted below alongside the products and services that Micronclean can provide to help you remain compliant.



**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**).

## STERILE GOGGLES

Micronclean offer the only reusable goggle in the UK that is cleaned using a GMP Grade B washing process, and sterilised by gamma irradiation. The goggles are supplied ready for use with all the other benefits of a Micronclean rental service. With a new and improved anti-fogging agent, we welcome in-use trials.



## CLEANROOM SOCKS

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



## NEUTRAL DETERGENT

Micronclean have a brand new neutral detergent product range – Delta. Ask us how we can support you with Delta detergent mops, trigger sprays and wipes in addition to our normal rotational cleaning system utilising Alpha and Beta.



For more information on how we can help you remain compliant please contact Micronclean's UK Cleanroom Solutions Team on

Email | [SalesEnquiries@micronclean.co.uk](mailto:SalesEnquiries@micronclean.co.uk)  
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