



EU GMP Annex 1 revision - key takeaways for gowning and laundry processes



Hello! I'm Harshvardhan Galat, the head of Cleanroom at Lindström India. I believe we are all aware of the **EU GMP Annex 1 revision that will be valid from 25th of August 2023**. But do you know, what that means for pharma workwear and garment management? Well, we have taken care of that for you and prepared this document, including the key take-aways from Eu GMP Annex 1 regarding cleanroom gowning and laundry practices.

Garment requirements for grade B

Before gowning:

- Wear sterilized, non-powdered, rubber or plastic gloves while donning the sterilized garments
- Outdoor clothing (including socks, but excluding personal underwear) should not be brought into changing rooms leading directly to grade B and C areas.

Garment requirements:

- **Gown:** Clean, sterilised protective garments (including eye coverings and masks)
- **Headcover:** Sterile headgear to cover all hair (including facial hair). If separate from the rest of the gown, should be tucked into the neck of the sterile suit
- **Facemask and goggles:** Sterile facemask and sterile eye covering (e.g. goggles) to be worn to cover and enclose all facial skin to prevent the shedding of droplets and particles
- **Footwear:** Sterilised footwear (e.g. over-boots) to be worn. Trousers legs should be tucked inside the footwear.
- **Gloves:** Second pair of sterilised gloves to be worn over the pair worn while donning the gown. Garment sleeves to be tucked into the gloves



Garment requirements for grade C

Before gowning:

- Outdoor clothing (including socks, but excluding personal underwear) should not be brought into changing rooms leading directly to grade C areas.
- Single or two-piece facility trouser suits, covering the full length of the arms and the legs, and facility socks covering the

Garment requirements:

- **Gown:** A single or two-piece trouser suit gathered at the wrists and with high neck.
- **Footwear:** Appropriately disinfected shoes or overshoes.
- **Headcover:** Hair, beards and moustaches should be covered

Additional gowning including gloves and facemask may be required in grade C and D areas when performing activities considered to be a contamination risk as defined by the CCS (Contamination Control Strategy)



Garment requirements grade D

- A general protective suit
- Appropriately disinfected shoes or overshoes

Additional gowning including gloves and facemask may be required in grade C and D areas when performing activities considered to be a contamination risk as defined by the CCS (Contamination Control Strategy)



General garment handling requirements

- Garments should be packed and folded in such a way that they allow operators to don the gown without contacting the outer surface of the garment and to prevent the garment from touching the floor
- After washing and before packing, garments should be visually inspected for damage and visual cleanliness.
- Gloves should be regularly sanitized during operations
- Damaged garments and gloves should be changed immediately

Laundry requirements for reusable clean area clothing:

- Should be adequately segregated from production operations.
- Should use qualified process ensuring that the clothing is not damaged and/or contaminated by fibers or particles during the repeated laundry process.
- The laundry facilities should not introduce risk of contamination or cross-contamination.
- Inappropriate handling and use of clothing may damage fibers and increase the risk of shedding of particles.
- A maximum number of laundry and sterilisation cycles to be defined and evaluated as part of the garment qualification program.

Lindström cleanroom laundry service

Cleanroom workwear operations



1. SORTING & SCANNING:

All garments are scanned and sorted for washing. Damaged garments either go for repair or replacement and then for washing.



2. WASHING AND DRYING:

Soiled garments are loaded into a washing machine according to their washing programs. After washing, wet garments are taken out of the washing machine from the folding area and put into a drying machine in classified area.



3. PARTICLE TESTING:

The test is conducted on particles generated from the cleaned garment to keep it under the required limit.



4. INSPECTION AND FOLDING:

Each garment goes through a quality inspection after drying. Both washing and finishing quality is checked, as well as the wear and tear of the garment. The garments are folded according to requirements.



5. PACKING:

Folded garments are packed in a sterilized or plastic bag as per customer requirements, then further packed to a polyester bag.



6. DELIVERY:

All packed garments are transported on a roll container or a transport cart to the customer's premises as agreed with the customer.

Let us help!

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