



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

As we all know, the new **EU GMP Annex 1 revision** became in force on **25th of August 2023**. But do you know, what kind of changes it brings for cleanroom 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

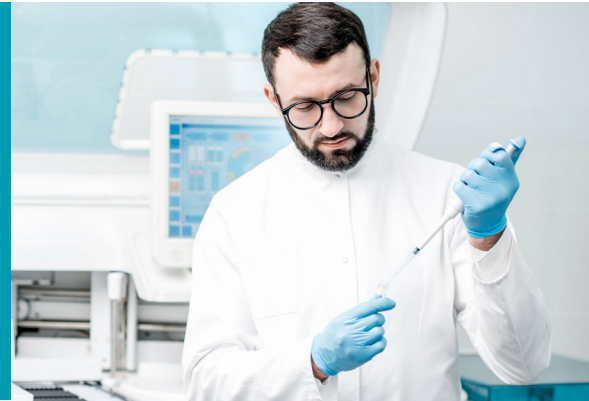
Additional gowning including gloves and facemask may be required in grade C and D areas when performing activities considered to be a contamination risk as defined by the CCS (Contamination Control Strategy)



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

Watch the video
on how
Lindström
cleanroom laundry
operates



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!

By choosing our cleanroom rental service, you no longer need to spend resources on updating your garment and laundry process according to the latest EU GMP Annex 1 update.

We offer a turn-key solution to cleanroom workwear needs, covering the whole process from the garment itself to washing, maintenance, allowable repairs, replacements, delivery and storage and garment lockers. Our cleanroom laundry process ensures a standardized decontamination process that meets all the pharma industry requirements, including Annex 1. Our garments, designed to meet IEST-RP-CC003 standards, shield your products from contamination, reducing cross-contamination risks and safeguarding against audit observations.

Stay compliant, save costs, and focus on your core competence.