



TM



TM

Choosing the Right Cleanroom Garment



Contents

Cleanroom Apparel		
Cleanroom Standard Guidelines		3
Guidelines Tables Non-Sterile		3
Sterile		4
Gowning for the Cleanroom		
What does gowning prevent?		5
Gowning Procedure		6
Choosing the Right Garments		
Disposable garments		7
SMS vs Microporous	7	
Permanent garments		8
Elasticated vs stud fittings		8
Garments styles and features	9-10	
Choosing the Right Headwear		
Caps	10	
Masks		11
Goggles		12
Choosing the Right Footwear		
Shoes		12
Shoe Covers	13	
Socks		13
Annex 1 Gowning Recommendations		
Grade A/B	14	
Grade C/D	14	

Cleanroom Apparel

Cleanroom Standard Guidelines

Individuals working in cleanrooms are required to follow strict protocols and wear special clothing such as coveralls, gloves, masks, and shoe covers. These garments are designed to prevent

shedding of particles and to protect the cleanroom environment from human generated contaminants.

Different cleanroom ISO classifications require different standards for gowning. Whether the cleanroom is sterile or non-sterile also changes what gowning items are required.

These guidelines should be strictly adhered to, to eliminate the risk of contamination. **Non-Sterile**

CLASS 1 ISO 3	CLASS 10 ISO 4	CLASS 100 ISO 5 GMP GRADE A/B
Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Integrated Suit (Optional) Boots Facial Cover Gloves Frequency of Change: Daily
CLASS 1,000 ISO 6	CLASS 10,000 ISO 7 GMP GRADE C	CLASS 100,000 ISO 8 GMP GRADE D
Hood, Cap or Hair Cover Coverall or Frock Boots or Footwear Boots Facial Cover (Optional) Gloves Frequency of Change: 3 Times/Week	Cap or Hair Cover Frock Boots or Footwear Boots Facial Cover (Optional) Gloves (Optional) Frequency of Change: 2 Times/Week	Cap or Hair Cover Frock Footwear Boots Facial Cover (Optional) Gloves (Optional) Frequency of Change: 2 Times/Week

Contd.

Sterile

CLASS 1 ISO 3	CLASS 10 ISO 4	CLASS 100 ISO 5 GMP GRADE A/B*
------------------	-------------------	--------------------------------------

Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Integrated Suit Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood Hair Cover Coverall Boots Facial Cover Gloves Frequency of Change: Per Entry
CLASS 1,000 ISO 6	CLASS 10,000 ISO 7 GMP GRADE C*	CLASS 100,000 ISO 8 GMP GRADE D
Hood Hair Cover Coverall Boots Facial Cover Gloves Frequency of Change: Per Entry	Hood (Optional) Hair Cover Coverall Boots Facial Cover Gloves Frequency of Change: Per Entry	<i>Garments in this environment are application specific.</i>

*Socks are required within GMP Grade A/B and C sterile cleanrooms where sterile medicinal products are being handled.

Gowning for the Cleanroom

What does gowning prevent?

Gowning helps prevent contamination in the cleanroom. From head to toe, there are plenty of areas where gowning is critical, however, even with gowning there can still be some risk.

Most of the airborne particles emitted from cleanroom personnel migrate up through their cleanroom garment collars or down their legs when walking.

Note: *Colognes, deodorants, lotions, makeup and perfumes are NOT allowed in cleanrooms.**



*For information on cleanroom guidelines, please check out Part 5 of our guides **Part 5 Preparing for the Cleanroom.**

Gowning Procedure

The following gowning procedure is for ISO 5. All products below are required to allow for full protection from contamination.

Choosing the Right Garments

Disposable Garments

Disposable garments are a cost effective solution to gowning within the cleanroom. Manufactured from lightweight low-linting materials, disposable garments provide comfort, breathability and high performance.

This style of garment is also easily sterilised for superior contamination control.

SMS vs microporous

SMS (spunbond/meltblown/spunbond) and microporous disposable cleanroom garments are widely used in cleanroom environments to protect both the wearer and the products being manufactured from contamination.

SMS garments:

- SMS garments are made up of multiple layers of spunbond and meltblown polypropylene, which are thermally bonded together.
- They provide an excellent balance of breathability and particle filtration, making them suitable for a wide range of cleanroom applications.
- They are more durable than microporous garments, as they are less prone to tearing and puncturing.
- They may be more suitable for cleanroom environments with lower contamination levels, as they are less effective at blocking smaller particles.

Microporous garments:

- Microporous garments are made of a thin film coated with a layer of microporous particles, such as polytetrafluoroethylene (PTFE).
- They provide excellent particle filtration, as the microporous particles are able to block particles as small as 0.1 microns in size.
- They are less breathable than SMS garments, as the microporous particles do not allow as much air to pass through.
- They are less durable than SMS garments, as they are more prone to tearing and puncturing.

The choice between SMS and microporous disposable cleanroom garments will depend on the specific needs and requirements of the cleanroom environment and the products being manufactured. It is important to carefully consider the trade-offs between breathability, particle filtration, and durability when selecting cleanroom garments.

Permanent Garments

The higher quality material of permanent garments means they have higher protection and can be used in cleanrooms with more stringent ISO levels. Permanent garments are specifically designed and manufactured from lightweight, non-linting, monofilament polyester materials, providing a combination of comfort and protection.

These garments are also bespoke, meaning they can be adjusted depending on the needs/requirements of your cleanroom and procedures.

Elasticated vs stud fittings

Permanent cleanroom garments are often designed to have either elasticated or stud fittings to help ensure that they fit properly and remain secure on the wearer.

Elasticated fittings:

- Elastic bands or bands with an adjustable clasp are used to hold the garment in place.
- Elasticated fittings allow for a more flexible and comfortable fit, as they can stretch and adjust to the shape of the wearer's body.
- They may not be as secure as stud fittings, as they may loosen over time or if the wearer moves around a lot.
- They may be more suitable for clean rooms with lower contamination levels, as they are less likely to shed particles compared to stud fittings.

Studded fittings:

- Studded fittings use small snaps to hold the garment in place.
- They provide a more secure fit, as they do not loosen easily and do not rely on elastic bands.
- They may be less comfortable than elasticated fittings, as they do not adjust to the shape of the wearer's body and may feel constricting.
- They may be more suitable for clean rooms with higher contamination levels, as they are more effective at preventing particles from entering or exiting the garment.

The choice between elasticated and stud fittings will depend on the specific needs and requirements of the clean room environment and the preferences of the wearer. It is important to carefully consider the trade-offs between comfort, security, and particle shedding when selecting clean room garments with either type of fitting.

Garments styles and features

Garments can come in a range of styles with a large variety of features included which aid increased productivity within certain workplace environments. These include:

Coverall

Gives full body protection to the user and should be used in more stringent ISO levels.

Lab Coat

Quick and easy to put on. Great for moderately stringent ISO levels.

Isolation Gown

Worn over coveralls to protect user from contamination in low risk patient situations.

EU GMP Annex 1 Gowning Recommendations

Grade A / B:

Grade A signifies a critical area for high-risk operations such as aseptic processing lines or for making aseptic connections by providing initial air protection. Its background, Grade B, represents its preparation area. The revision of Annex 1 stipulates the following requirements in these areas:

- Use dedicated garments worn under a sterilised suit
- A sterile headgear which must enclose all hair (including facial hair)
- Sterile face masks
- Sterile eye coverings such as goggles that should fit the around the face
- Powder-free rubber or plastic sterile gloves*, **
- Sterilised footwear, such as over boots, clogs and shoes
- Use dedicated cleanroom socks

Grade C / D:

Grade C/D signify cleanrooms used for less critical stages in the manufacture of aseptically filled sterile products though may be used for the preparation/filling of terminally sterilised products.

- Cover hair, beards and moustaches with a beard snood
- Operators must wear single or two-piece trousers and high collar tunics (in grade C) and general protective suit (in grade D)
- Use a dedicated cleanroom sock in a Grade C cleanroom

Our expertise and knowledge within the pharmaceutical industry have led our team to develop an extensive range of products to meet the requirements of Annex 1 and assist you with the challenges this new revision brings.