

# Cleanroom Proper Gowning Procedure

The way in which your personal protective equipment is donned prior to entering the cleanroom is critically important to prevent contamination and minimize dispersion of particles and microbes naturally carried on skin.



It is common to find 3 cleanroom zones:

- 1. Pre-Change Zone**
- 2. Changing Zone, and**
- 3. Cleanroom Entrance Zone**

## Prior to Arriving to the Cleanroom

Basic hygiene, like bathing and showering is performed. People with dry skin may wish to use skin lotion to replace the lost skin oils. Clothing below cleanroom garments are best made from artificial fibers because they disperse much fewer particles and fibers. Close-woven fabrics are also better as they are more effective in filtering and controlling particles and microbes from skin.

Personnel should consider the use of cosmetics, hair spray, etc, as well as jewelry because these items should be removed prior to entering the cleanroom.

## Changing into Cleanroom Garments

The best method of changing into cleanroom garments is one that minimizes contamination getting onto the outside of the garments. It should be noted that alternatives to this proposed method are successfully used in existing cleanrooms, as long as they give a level of contamination control appropriate to the standard of the cleanroom.

## Approaching Pre-Change Zone

Blow nose, as this cannot be done correctly once in a cleanroom. Visit bathroom to reduce back and forth, and having to change clothes unnecessarily. Use shoe cleaners if outdoor shoes are not removed or effectively cover shoes with shoe covers, often as high as the knees. Some examples below.

### 1. Pre-Change Zone (ISO 4 procedure)

Personnel should remove sufficient street clothing, and/or fully change into dedicated under-clothing if provided by company. All jewelry should be removed, with the exception of wedding rings that have a smooth surface and can be taped over. Remove makeup, and if required apply approved skin moisturizer. Don disposable hat or hairnet, as well as a beard cover if needed. Put on a pair of disposable footwear coverings or change into dedicated cleanroom shoes.

Handwashing Should Be Done At This Time, As Well As Hand Drying.



This is where Meritech CleanTech Automated Handwashing Systems are best utilized (optional Integrated Air

Curtain or optional D.I. model). And apply a suitable hand lotion if needed. It is best to wash hand within the change area just before putting on the clean garments. If gloves are used to put on cleanroom clothing, then handwashing can be done at this time.

In bioclean areas, it will be necessary to wash the hands in a suitable skin disinfectant. Hands can be dried with a non-linting towel or a hand drier. If a hand drier is used then the best type is one



that does not disturb the dirt on the floor.

Next, crossover from Pre-Change into Change Zone, however that is delineated at your facility.

### 2. Changing Zone

Garments to be worn are selected. A facemask and hood (or cap) is put on. If a hood is put on, the hair must be tucked in and the studs/snaps/ties at the back of the hood adjusted for comfort.

If handwashing did not occur in the Pre-Change Zone, this is the time to wash hands as clean garments will now be handled, and contaminated parts of the body, such as hair and face, should not be touched again. If “donning gloves” are

required, this is the time to put those on. Remove coverall or gown from packaging and unfold without it touching the floor. If a coverall is used, it should be unzipped and turned so that the zip is to the side away from the person. Whatever method you use to dress into coverall, it should not touch the floor whatsoever. One can gather the garment from the inside at waist level, and/or hold onto arm cuffs while being gathered up at the waist and placing one leg at a time into the garment and then releasing one cuff at a time.

### 3. Cleanroom Entrance Zone

If a crossover bench is available, it should be crossed now, and allows cleanroom footwear to be correctly put on. Personnel should sit on the bench. As one leg is raised and cleanroom footwear put on, the leg should then be transferred over the bench.



Repeat with the other foot/leg and stand up. If required, protective goggles can be put on. These also help prevent eyelashes and eyebrow hair from falling onto the product.

Garments should be checked in full-

length mirror to see that they are worn correctly — no gaps, and no hair showing.

If “donning gloves” were used, they can be dispensed on or kept on if clean working gloves are put on top. Two pairs of gloves can be used as a precaution against



punctures, although sensitivity of touch is lost. If deemed necessary, the hands can be washed again.

Gloves can also be washed. In a biocleanroom it is beneficial to decontaminate the hands by applying an alcohol solution containing a skin disinfectant.

Low particle and sterile working gloves should now be put on. Personnel may now proceed into the cleanroom. This may be over a cleanroom mat.

### Importance of Cleanroom Gowning and understanding the Minimum Apparel Recommendations

Gowning methods and materials are critical to minimize contamination and provide a barrier between the individual and the at risk product. Additionally – protect the cleanroom technician from the product. The minimum apparel is

Minimum Apparel Recommendations					
	ISO 8 (Class 100,00)	ISO 7 Class (10,000)	ISO 6 (Class 1,000)	ISO 5 (Class 100)	ISO 4 (Class 10)
Beard Cover	✓	✓	✓	✓	✓
Face Mask				✓	✓
Booties			✓	✓	✓
Coverall			✓	✓	✓
Gloves				✓	✓
Hair Cover	✓	✓	✓	✓	✓
Hood				✓	✓
Lab Coat	✓	✓			

dependent on the ISO Class. See chart.

Remember that garbing order is typically dirtiest to cleanest: Shoes/shoe covers, facial/hair covers, glasses – wash hands – non-shedding gown, gloves (sanitizer).

### Where does CleanTech Handwashing systems play a role in cleanroom cGMP?

Meritech’s Cleanroom specific Cleantech 2000SR is designed with all of these facts and current trends in mind. A part of our line of fully automated handwashing systems, the 2000SCR is compatible with 18 megohm DI water, is clinically tested and proven to remove up to 95% of particles (0.3 micron and larger) and most sodium chloride, and uses just .6 gallons of water per cycle. The 2000SCR is fully CIP, and employs trickle through plumbing features to prevent stagnant water.

### 3 log reduction in bioburden

Cleantech is clinically-validated to remove pathogens and particulates. In an independent study from one of our Fortune100 med device accounts in SLC

conducted a before and after study from using our fully-automated handwashing system and found a 3 log reduction in measurable bioburden.



### CleanTech 2000S CR – Deionized water

Ideal for cleanroom facilities where standardized glove washing is critical for removal of particulates like sodium and fibers. Clinically tested and proven to remove up to 95% of particles (0.3 micron or larger) and most sodium chloride.

**Contact one of Meritech’s Employee Hygiene Experts for more information.**

*Content for this paper adapted from C K Moorthy’s, “Good Cleanroom Practices: A Manual for Cleanroom Personnel”*