How to Choose the Right Cleanroom Gloves

Different gloves for different environments

The gloves needed for industrial manufacturing environments and cleanroom environments differ because of their particular purpose. In cleanroom environments, gloves are worn to protect the process or product from contamination and integrate with other cleanroom apparel such as masks and gowns. In industrial environments, gloves are worn to protect the worker from hazards such as chemicals, hot or frigid temperatures, or hand injuries caused by sharp surfaces.

Choosing the right gloves for the job can have either a negative or positive impact on completed project outcomes. When changing out or upgrading gloves, a wrong decision may be extremely costly if the wrong decision causes rework, recalls or rejects.

Contamination—it's only human

Humans have the ability to create contamination just because they're human. Analysis of the hazards and risks to the process or product, such as human contamination, are central to controlling the environment. Here's why -

- Stationary personnel generate about 100,000 particles of 0.3 microns or greater; when moving, the number increases to about 5 million
- The entire human body carries an average of 32 million bacteria
- Humans continually shed skin at a rate of about 30,000 to 40,000 dead skin cells every day
- One square inch of hand surface has an average of 10,000 microorganisms

What's the allowable threshold level?

The analysis of hazards and risks in sterile/aseptic cleanrooms should focus on both particulate and microbiological control. Depending on the manufacturing application, the allowable levels of particulates, extractables and nonvolatile residues (nVR) will differ.

iSo level 8 - medical device manufacturing - raw processing

iSo level 7 - assembly and packaging

iSo level 5 - aseptic assembly/QC testing for sterility

iSo level 5 - pharmaceutical manufacturing – sterile filtration and aseptic filling/stoppering

iSo level 7 - solid dose granulation, blending, compression and coating or aseptic compounding

iSo level 8 - solid dose packaging and cleaning, sterile materials staging, sterile capping, labeling and packaging.

Choose gloves according to the cleanroom classification shown on the labeling. You may see some gloves labelled as "critical" or "controlled" cleanroom gloves; however, no published standards designate gloves as "iSo 7/Class 10,000" or "iSo 5/Class 100" and exam gloves may actually be appropriate in less-clean rooms.

Hand in glove – it's a material choice

There are advantages and disadvantages to the material makeup of cleanroom gloves, which are usually made from vinyl, natural rubber latex, nitrile or chloroprene. You'll also find hybrid gloves combining nitrile and latex qualities.

Global Society for Contamination Control's outline of glove material pluses and minuses -

Vinyl
+ inexpensive, very clean and static dissipative
- retain heat, poor moisture vapor transmission

Natural rubber latex
+ highest cost/performance ratio of any of all available materials; durable; easy to manufacture
- no natural, static-dissipative features; potential for allergic reaction (rash) to natural latex proteins

Nitrile
+ puncture resistant; better resistance to chemicals then natural latex; good static-dissipative characteristics

Chloroprene
Not as commonly used in cleanroom industry; similar to nitrile

Other key considerations – durability, strength, comfort, etc.

Gloves also need to stand up to the strict, time-consuming process of gowning. Defective or torn gloves may cause personnel to have to re-gown.

Some cleanroom environments are sensitive to static electricity, therefore gloves with electrostatic discharge (ESD) resistance should be worn. Other cleanroom environments may need to be concerned with non-volatile residue (nVr) contamination which is not easily removed from surfaces through evaporation. Evaluate gloves for these environments to make sure they do not contain nVr.

Comfort is a major factor in choice of glove including hand-specific gloves, i.e. opposing thumb and ambidextrous types of gloves. Both offer user benefits and most sterile cleanroom gloves are hand-specific.

Also, tack level can be important in some instances. High-tack gloves make it easier to hold items without them slipping, while a glove with a slick grip makes it easier to double-don gloves, a common practice in aseptic environments. Texturing is also an important consideration and gloves can be found as fully textured or just fingertip-textured. Additionally, beaded cuffs on gloves make putting them on easier during gowning.

Gloves come in a variety of sizes including extra-large to extra-wide, as well as extra-small sizes. Glove length needs to be considered as well. Measurements should be taken from the tip of the middle finger to the cuff and lengths come in 10 inch and 12 inch sizes. Longer gloves will generally be used in more stringent cleanroom environments. The extra length can be used to prevent sleeves from billowing out, i.e., gown sleeves can be tucked into the glove to prevent skin exposure and risk of contamination.

Performance Certification

A cleanroom shutdown can cost upwards of $1.5 million per day, so make sure gloves are high quality. Understand Acceptable Quality level (aQl) data when buying gloves in lots. A low aQl number means a low probability of defective gloves in one given lot. The American Society for Testing and Materials sets an aQl at 2.5; however, some glove manufacturers choose to surpass the standard to ensure gloves have fewer pinholes and therefore greater barrier protection levels.

Suppliers can offer certificates of analysis (Coa) for sterile gloves with particle counts, extractable counts and other helpful data for each lot including trend data, technical specification sheets and certificates of irradiation (Coi). You can check the glove lot data online at several supplier websites.

Packaging and sterility

How cleanroom gloves are packaged and stored is also important. Packaging should be controlled from the beginning by the supplier, i.e. gloves should be packed in a cleanroom environment to prevent them from being tainted by the box or other contaminates. Additionally, gloves should be double-bagged with an additional case liner. Sterile gloves processed for cleanrooms (not surgical) ought to come packaged in poly wallets and pouches and should be sterilized using gamma irradiation or other methods to reduce potential bioburden.

**Sterilization completely removes and/or destroys viable organisms, making them unable to reproduce.*

Sterile gloves for aseptic cleanrooms must be packaged for aseptic donning (applying the gloves without breaking the sterile field) and donning should be made easier by packing them in poly pouches and wallets that are easy to open depending on whether workers are donning a left or right glove.

Sterile gloves are not the same as surgical sterile gloves. Cleanroom sterile gloves usually involve extra processing to reduce particulates and extractables in the final product. Additionally, cleanroom sterile gloves are manufactured to aSTM requirements, while surgical gloves aren't. Instead, they're cleared by the FDA as medical devices.

Managing the Process

A battery of people will have an interest in the selection and qualification process when introducing new glove products to the cleanroom including fab/production managers, contamination controllers, validation engineers, Qa/QC, cleanroom materials specialists and purchasing. Local safety officers ensure gloves don't violate any EPA or OSHA regulations or permits.

For aseptic cleanrooms, testing takes place on three glove lots before being validated, and once approved, the cleanroom standards of practice must be changed to reflect the new glove.