



Glove Selection for Controlled Environments

Minimizing contamination risks in sterile gowning

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Changing or upgrading your cleanroom or controlled environment gloves is a process that requires time and due consideration. It is not to be undertaken quickly or lightly. Make the right decision and it could have a positive influence on both employee satisfaction and product/process yields. Make the wrong decision and you could be looking at hundreds, thousands, perhaps millions of dollars worth of rework, recalls and rejects if the gloves don't perform as expected.

Hazard Analysis & Risk Assessment

In "dirty" manufacturing environments, gloves are typically worn to protect the wearer from hazards in the environment such as chemicals, extreme heat/cold, and rough or sharp surfaces that could cause hand abrasions. In "clean" manufacturing settings such as cleanrooms and other controlled environments, gloves are typically worn to protect the product or process from contamination and are used along with cleanroom gowns, masks and other process protection apparel. Therefore, unlike in a dirty manufacturing environment, where users must identify hazards to human health and safety, in a cleanroom environment, it's important to analyze hazards and risks to the process or product – the critical control points for contamination by personnel.

Consider how dirty a "clean" environment might become due to human contamination:

- Even when stationary, people generate about 100,000 particles of 0.3 microns or greater. On the move, this rises to about 5 million.
- Every square inch of the human body has an average of 32 million bacteria on it.
- Every minute of the day, we lose about 30,000 to 40,000 dead skin cells off the surface of our skin.
- One square inch of hand surface area has an average of 10,000 microorganisms.

Part of the hazard analysis and risk assessment process is understanding the cleanroom environment and the allowable levels of particulates, extractables and non-volatile residues (NVR) allowed. For sterile/aseptic cleanrooms, the hazard analysis and risk assessment process should focus not only on particulate control but also on microbiological control.

Every cleanroom in every industry is different. Medical device manufacturers may operate at ISO Level 8 for raw material processing, ISO Level 7 for assembly and packaging and ISO Level 5 for aseptic assembly and QC testing for sterility. Pharmaceutical manufacturers may operate at ISO Level 5 for sterile filtration and aseptic filling/stoppering; ISO Level 7 for solid dose granulation, blending, compression, and coating or aseptic compounding; and ISO Level 8 for solid dose packaging and cleaning, sterile materials staging, and sterile capping, labeling and packaging.

Look for gloves labeled according to the cleanroom classification in which you operate to be sure that particulate levels, extractables and NVR levels are appropriate for the specific cleanroom class. Some manufacturers make it easy to tell which gloves are appropriate for different cleanroom classes. Other glove suppliers may label their gloves as “critical” or “controlled” cleanroom gloves. But keep in mind that there are no published standards that designate gloves as “ISO 7/Class 10,000” or “ISO 5/Class 100.” In less clean cleanrooms, as mentioned above, it may be appropriate to use exam gloves.

Glove Materials

Cleanroom gloves are typically made from vinyl, natural rubber latex, nitrile or chloroprene. The Global Society for Contamination Control outlines advantages and disadvantages of each:

- Vinyl – known for being very clean, inexpensive and static dissipative. However, vinyl gloves retain heat and have poor moisture vapor transmission.
- Natural Rubber Latex – has the best cost/performance ratio of any material available. It is durable and easy to manufacture. However, it has no inherent static dissipative features. Some people have allergies to the proteins found in natural latex, which can result in painful rashes.
- Nitrile – offers very good puncture resistance and exhibits broader chemical resistance than that of natural latex, especially with solvents. Nitrile also has very good static dissipative features not found in natural rubber latex.
- Chloroprene – is not widely used in the cleanroom industry, but has characteristics similar to those of nitrile.

A glove’s material can have a dramatic influence on its comfort. For example, latex gloves are typically viewed as being more comfortable, while vinyl gloves tend to be more uncomfortable due to the rigid nature of vinyl. Nitrile gloves are now becoming more comfortable, however. In fact, some suppliers are using new nitrile-based production technologies to combine the sensitivity of latex with the protection of nitrile for gloves that provide the best of both worlds – sometimes at a value price.

Key Performance Factors

There are a variety of factors that must be taken into account when selecting cleanroom gloves. Table 1 summarizes key considerations.

In cleanrooms, a glove’s particle and extractable counts are important and should be closely evaluated to match the cleanroom class. Refer to IEST RP-5 for material specifications as well as procedures for testing and evaluating cleanliness and other properties of cleanroom gloves. It also contains guidance for users to assist in choosing the proper glove type and test method according to application.

Compliance with AAMI, ASTM, and EN standards and regulations is also important, and some suppliers exceed the minimum performance standards set by these organizations. In the pharmacy industry, compliance with USP <797> is also important.

Because the cleanroom gowning process is so strict and time-intensive, it's important for gloves to stand up to the gowning process itself, as well as work tasks within the cleanroom to avoid having to exit the cleanroom for re-gowning if the glove tears or has defects. Therefore, durability and strength are two important factors to consider as is barrier integrity (freedom from pinholes), especially for sterile cleanroom gloves.

Some cleanroom environments are sensitive to static electricity, so gloves should be evaluated for electrostatic discharge (ESD) resistance properties. Other cleanroom environments are concerned with non-volatile residue (NVR), contamination that is not easily removed from surfaces through evaporation. Gloves for these environments should be evaluated to ensure they do not contain NVR.

Comfort is also part of the performance equation. It's common sense that when a glove is more comfortable (soft and stretchy like a "second skin"), users will be more likely to comply with wearing protocols. Some users may prefer the comfort of hand-specific gloves, which are made with an opposing thumb that minimizes hand fatigue, while others work well with ambidextrous gloves, which tend to be less expensive to manufacture. Most sterile cleanroom gloves are hand-specific.

The glove's tack level is also important. In some cases, high-tack gloves are preferred because they make it easier to hold items without the items slipping. In other cases, a slick grip is preferred for easier donning and double-donning, a common practice in aseptic environments. The amount of texturing on a glove can vary from fully textured to fingertip texture. Fully textured gloves are important with ambidextrous styles so that, no matter which glove is grabbed, the texture will be felt. Beaded cuffs are another important feature; they make the gloves easier to grip and pull up during donning.

Sizing is an important comfort factor. While most suppliers offer a range of glove sizes, some are tweaking the formula to fit a wider variety of hand sizes – for example, offering larger-size gloves, hand-specific gloves, gloves with extra-wide palms, or extra-small sizes.

The gloves' length is another sizing issue to consider. As measured from the tip of the middle finger to the cuff, cleanroom gloves are either 10 inches or 12 inches. Ten-inch gloves are typically used in less stringent cleanroom environments, while 12-inch gloves are used in more stringent cleanroom environments in conjunction with cleanroom gowns. The longer gloves allow the gown sleeves to be tucked into the gloves, thus eliminating problems with gown sleeves billowing out as air moves past their cuffs, which creates a potential contamination concern as skin becomes exposed.

Finally, while most cleanroom gloves are designed to protect the sensitive cleanroom environment from contamination by workers, workers themselves may need protection from chemicals, acids or other hazards in the environment such as biohazards. Don't forget to consider a glove's protective properties during your evaluation. Some cleanroom operators may find that one glove does **not** fit all and should make a variety of appropriate gloves available depending on the work task being conducted.

Performance Certification

Consistently superior performance is of utmost importance in the cleanroom environment. Shutting down a cleanroom can cost manufacturers up to \$1.5 million per day. Ensure the glove you choose is not only of the highest quality, but that it also stays within a reasonable variance of that level over time. Lot consistency should be ensured from raw materials through processing.

Acceptable Quality Level (AQL) is one piece of important data to consider. This refers to the probability of having defective gloves within a lot. The lower the AQL number, the lower the probability of defective gloves. While ASTM sets an AQL of 2.5, some glove suppliers exceed that standard to provide gloves with fewer pinholes and thus, a greater level of barrier protection.

Make sure your glove supplier can provide certificates of analysis (COA) with particle counts, extractable counts and other important data for *each lot* of product; trend data; technical specification sheets; and certificates of irradiation (COI) if purchasing sterile gloves. Some suppliers make this information easily accessible 24/7 on their web sites, after plugging in the glove's lot number. Actual data is better than average data, because it reflects consistency in quality manufacturing.

Packaging & Sterility

Cleanroom design, operator procedures, correct cleaning and sanitization are critical when it comes to cleanrooms, but if incoming items are not controlled, cleaned and monitored, the contamination will walk right in. So pay special attention to how and where gloves are packaged.

Are the gloves packaged in a cleanroom environment? Are they double-bagged with an additional case liner to ensure cleanliness? If you operate in an aseptic/sterile environment, look for sterile gloves that are processed for cleanrooms (not surgical), are packaged in poly wallets and pouches and are also sterilized through gamma irradiation or other methods to reduce potential bioburden. Sterilization completely removes and/or destroys viable organisms, rendering them unable to reproduce.

For aseptic cleanrooms, sterile gloves must be suitably packaged for aseptic donning (applying the gloves without breaking the sterile field). This is easier to do if the gloves come in packaging that opens properly. Sterile gloves should be packaged in poly pouches and wallets that open up so the left and right gloves are easily donnable.

It is important to note that there is a difference between cleanroom sterile gloves and surgical sterile gloves. Cleanroom sterile gloves typically undergo additional processing to reduce particulates and extractables from the finished product. They are packaged within a cleanroom before being sent on for sterilization. Moreover, cleanroom sterile gloves are manufactured consistent with ASTM requirements, while surgical gloves are not. Instead, they are cleared by the FDA as medical devices. Some glove manufacturers today produce cleanroom gloves to medical device standards but also process the gloves to cleanroom standards. This assures the user of the highest quality glove possible.

Managing the Process

As stated earlier, changing or upgrading your cleanroom gloves is a process that requires time and due consideration. Many people have a stake in the process of selecting and qualifying any new product to be used in a cleanroom. Fab/production managers, contamination control, validation engineers, QA/QC, cleanroom materials specialists and purchasing should all play a role.

In pharma and biotech cleanrooms, local safety officers must ensure that the glove will not violate any EPA or OSHA regulations or permits. Regulatory personnel will need to be involved as any changes to process may affect FDA licenses. Users will be able to provide important feedback on comfort and dexterity issues.

For aseptic cleanrooms, testing should be done on three lots of the glove before it can be validated. Once approved, it is important to change the standards of practice for that cleanroom to reflect the new glove.

Operator training is critical. Proper donning/doffing and when to change gloves must be covered when training employees on gowning procedures. Proper gowning (including gloving) should be evaluated on an ongoing basis, with fresher training conducted as needed.

Table 1

Compliance with Standards/norms	Barrier protection (chemical and biohazard)	Bio-compatibility	Traceability	Ergonomics/ Allergenicity
Personal protection: <ul style="list-style-type: none"> • CE Marking • 89/686/EEC • EN 420:2003 Process protection: <ul style="list-style-type: none"> • ISO 14644-1 • EC GMP • IEST-RP-CC005 • LAL Test (Kinetic Turbimetric Tech) • Low Pre-Sterilization Bioburden Level • Processed to reduce & control DNase, RNase, Protease 	Chemical protection: <ul style="list-style-type: none"> • EN374:2003 Cytotoxic Drugs protection: <ul style="list-style-type: none"> • EN374-3-2003 • ASTM F 739-99 a • ASTM 6978-05 Biohazard protection: <ul style="list-style-type: none"> • EN374-2-2003 • ISO 16604 Proc. B:2004 • AQL and Inspection Level 	Non-cytotoxic Non-pyrogenic Low-endotoxic Non-hemolytic	Product Quality Monitoring Plan cGMP Regulation FDA Regulation ISO Regulation ISO 9002 QSR Packaging	Ergonomics: <ul style="list-style-type: none"> • Double donning application • Tactile sensitivity and grip • Comfort and fit • Wearer health and safety Allergenicity: <ul style="list-style-type: none"> • Low in chemical residue • Low in protein • Low in endotoxin