



# Dress for Success:

## Products and Procedures for <797>-Compliant Gowning

A CRITICAL ASPECT IN THE ASSURANCE OF A STERILE compounded product is the proper selection and use of gowning materials, which protect the compounded sterile preparation (CSP) from contamination by the compounding personnel. According to an article in the May 2005 issue of *Pharmaceutical Technology* (“Aseptic processing: a vision of the future”), “microbial contamination in aseptic processing is mainly caused by personnel. It is estimated that more than 99% of all microorganisms detected in cleanrooms are of human origin.” With this idea in mind, it is important to choose gowning materials that are right for your compounding processes, and that decision may require some research. <797> requires the use of a knee-length lab coat, hair cover, mask, shoe covers, and beard/mustache covers.

### Reusable Versus Disposable Gowning

You should first determine whether disposable or reusable gowning materials are better suited for your facility. Both have their advantages and disadvantages; hence, the decision is usually based on cost effectiveness. However, it is important to note the following exception: When compounding hazardous drugs, specialized, coated, disposable gowns that have been tested for protection from hazardous drugs should be used, but not worn for longer than three hours. Double gloves, which have been tested at ASTM standard: D 6978-05-Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (2005), must also be worn.

The extent and choice of gowning materials will be dependent upon your compounding processes, primary and secondary engineering controls, and personnel. The product choices include dis-

posable or reusable coveralls (or a combination thereof), hoods, long boots, and accessories, such as gloves, masks, and goggles. Keep in mind that, for any reusable garments or parts, the washing and sterilization processes must be validated.

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### One Size Does Not Fit All

There should be appropriately sized gowning materials for all personnel. It is very



The gowning materials here are suitable, per <797>, for low-, medium-, and high-risk compounding.

is usually completed from dirtiest to cleanest, meaning that shoe and hair covers should be donned before items like masks. Gowning materials, such as gloves and coverall sleeves, should overlap to avoid exposure of skin and hair. The following can serve as a guideline for developing your own gowning procedure:

1. Tie loose hair back. Remove all makeup and jewelry, and wash and fully dry hands and arms to the elbows.
2. Don a hair net, and a mustache and beard cover, if necessary. Observe yourself in a mirror to assure all hair is contained.
3. Disinfect hands with a suitable agent, such as 70% isopropyl alcohol.

### Storage and Disposal

All gowning material must be stored in an organized manner to allow for easy access. This prevents personnel from rummaging through the materials to find the required garment in the right size. Garments should also be stored in a manner that does not compromise the integrity and sterility of the material. Gowning material must be removed from the shipping container and any outside packaging should be disinfected before it is stored in the anteroom. The shelving units for storing the material must be non-porous and easy to clean, as they should be cleaned on a regular basis. Waste containers should be large enough to hold at least one day’s supply of used gowns, and gowns used in the compounding of hazardous drugs should be kept in a separate sealed container, marked, handled, and disposed of as hazardous waste.

### Gowning Procedures

Personnel should meet certain requirements before they are allowed to gown and enter the cleanroom. All personnel need to be free from injury and illness, including allergies and sunburn. Any person exhibiting signs of injury or illness should report to their supervisor for alternative duties. Written procedures should describe what clothing is acceptable to gown over. The following should not be worn in the cleanroom:

- ▶ sweaters, jackets, fleeces, and tank tops
- ▶ high-heeled, open-toe, or sling-back shoes
- ▶ false nails and nail polish

No one gowning procedure will work for every facility; procedures will vary depending upon the materials used and the facility layout. However, every gowning procedure should have some basic commonalities. Gowning



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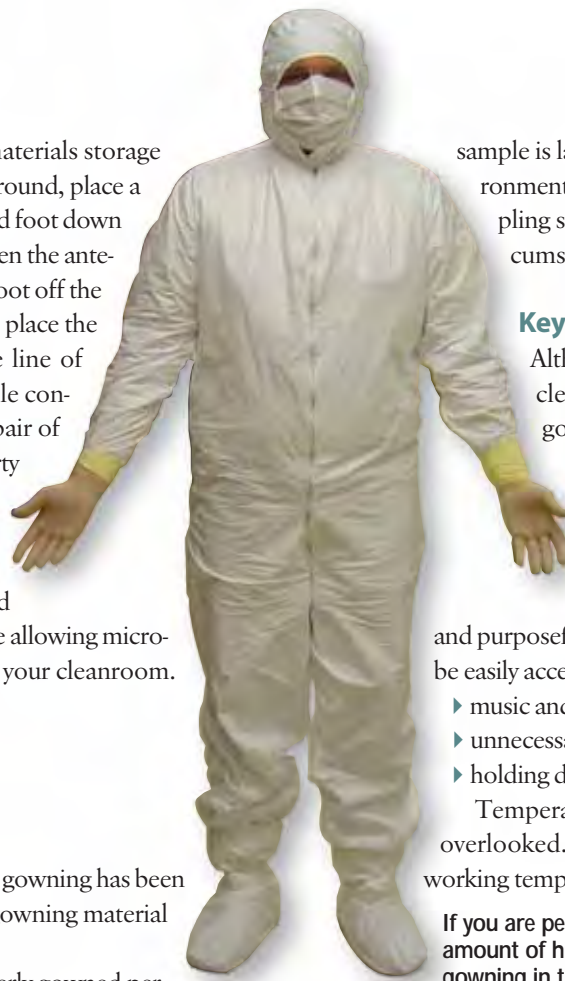
4. Obtain two shoe covers from the gowning materials storage area in the anteroom. Raise one foot off the ground, place a shoe cover over this shoe, and place the covered foot down on other side of the line of demarcation between the anteroom and cleanroom areas. Raise your other foot off the ground, place a shoe cover over this shoe, and place the second foot down on the other side of the line of demarcation. For a simple solution to possible contamination, use two sets of shoe covers or a pair of cleanroom-dedicated shoes. Shoes are very dirty and carry a very high level of microbial bioburden. Containing this bioburden with one shoe cover can be difficult. Furthermore, shoe covers can tear and tears may not be discovered until the covers are removed. Thus, you may be allowing microbials on your shoes to be tracked throughout your cleanroom.
5. Disinfect hands again with a suitable agent.
6. Don lab coat.
7. Disinfect hands again with a suitable agent.
8. Don gloves.
9. Disinfect gloves with a suitable agent.
10. Observe yourself in a mirror to assure proper gowning has been completed, no skin or hair is exposed, and gowning material has maintained its integrity (no holes or rips).

Consider posting a picture or drawing of a properly gowned person, accompanied by a description of the proper gowning procedure, on both sides of the line of demarcation as a helpful reminder for your personnel. It must be understood that materials touching the floor on the dirty side may not cross over to the clean side. If personnel are on the clean side of the line of demarcation and crossover to the dirty side, new shoe covers must be donned in order to cross back to the clean side.

Written procedures describing the order and method to aseptically don each gowning component must be drafted and followed by your personnel while gowning. These written procedures should also include the de-gowning procedure, as well as indicate how many people are allowed in the gown room at one time. This number will vary, but you need to have enough room for everyone to gown without touching or tripping over each other. An excess of people in the gowning area can also create an overload of particulate matter and microbial bioburden. The written procedures may also include measures for staff to follow when they encounter problems in the cleanroom, such as the compromised integrity of the gowning material (hole in glove or rip in gown).

### Training Procedures

All personnel entering the aseptic area — including certifiers as well as cleaning and maintenance staff — must have documented training in gowning and de-gowning procedures. While USP Chapter <797> does not require gowning qualifications, a thoughtfully established qualification process serves as a useful staff-training tool. Generally, cleanroom personnel should be qualified on a yearly basis by gowning according to their facility's standard operating procedure (SOP) while being observed by a second operator for compliance. Upon completion of the gowning process, the second operator samples the personnel's gowning material by touching a contact plate to the surface of the gowning material at predetermined points, and the personnel immediately de-gowns. The predetermined sampling points are the areas that are most prone to contamination while gowning, such as the chest area, gloves, and mask. The



sample is labeled, incubated, and counted in the same manner as environmental monitoring plates. An SOP describing the procedure, sampling sites, acceptance criteria, and failure and re-qualification circumstances must be drafted before implementing this process.

### Key Success Factors

Although often overlooked during the training process, proper cleanroom behavior is vital to maintaining the asepsis of the gowning material and product. Prohibit behaviors that contribute to gowning and/or product contamination, including:

- ▶ leaning against equipment or walls
- ▶ overcrowding the cleanroom
- ▶ unnecessary movements, such as crossing one's arms and touching one's face (Personnel should move in a slow and purposeful manner. As such, all of your cleanroom equipment should be easily accessed.)

Temperature maintenance is another important factor that is often overlooked. Depending upon the extent of the gowning, comfortable working temperatures usually fall between 65°F to 68°F. If these temperatures are not maintained, your personnel will become too warm, resulting in the expulsion of deeper skin flora into the cleanroom.

- ▶ music and singing
- ▶ unnecessary talking
- ▶ holding doors open

If you are performing a significant amount of high-risk compounding, consider gowning in the manner pictured here.

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### Conclusion

Proper gowning materials and procedures are vital pieces of any facility's plan for <797> compliance. Fortunately, paying close attention and thoughtfully adhering to an established set of procedures can ensure that your compounding operation is compliant with the rules set forth in USP Chapter <797> and that it positively impacts the safety of your patients. ■

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### WHERE TO FIND IT: Sources for Cleanroom Gowning Materials

Vendor	Reader Service	Website
Ansell Healthcare Products	83	www.ansell.com
Aramark	82	www.aramark.com
Berkshire Corp.	81	www.berkshire.com
Cintas Corporation	80	www.cintas.com
Conguard Contamination Control	75	www.conguard.com
Milliken & Company	74	www.milliken.com
Vidaro Corporation	73	www.vidaro.com
White Knight Engineered Products	72	www.wkep.com
Worklon/Superior Uniform Group	71	www.sug.biz