Donning by Design: Sterile Cleanroom Gowning Evolves to Help Minimize Contamination Risk

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Abstract:
This paper addresses the importance of process protection in cleanrooms via the appropriate cleanroom suit. It provides an overview of the sterile cleanroom apparel category and defines key areas for improvement. It introduces a new concept for sterile cleanroom gowning to help minimize the problems associated with current technologies.

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In the pharmaceutical industry, the investments needed to bring a product to market are staggering. In fact, it is widely reported that the fully capitalized cost to develop a new drug can range from $800 million to nearly $900 million.

The steep price of product rejects and recalls makes it crucial to ensure high product yields by maintaining strict cleanroom cleanliness and sterility. That is one of the reasons that the U.S. Federal Drug Administration (FDA) mandates that any product that is injected, or used in the eyes or on open wounds must be sterile, i.e., free from viable microorganisms. That is because, if contaminated with microorganisms, these pharmaceutical products can adversely harm patients.

Microorganisms introduced into a cleanroom environment need only three things to grow: moisture, food and temperature – all of which exist in a cleanroom. Consequently, all incoming air, water, chemicals, and materials must be filtered or sterilized to meet high standards of purity and microbiological control, so as not to contaminate processes or products in production. Also to be "filtered," in a sense, is the cleanroom operator, who, most will agree, is the dirtiest thing to enter a cleanroom.

Consider the following:

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

Keeping the operator's dirt and germs out of the sterile cleanroom environment and away from sensitive products and processes is the main objective of the sterile cleanroom suit. The suit needs to protect the environment from viable particles such as bacteria and yeasts, and non-viable particles such as hair, dead skin cells, and dandruff. To that end, it is critical for cleanroom operators to select cleanroom suits that provide not only the highest levels of inherent sterility, but also the greatest chances of maintaining that sterility through the gowning process.

Sterile Cleanroom Suits: An Overview

Although there are no federal regulations for sterile cleanroom garments used in the pharmaceutical industry, guidance for the industry is available from The Institute of Environmental Sciences and Technology (IEST), which publishes a recommended practice IEST-RP-CC003.3, "Garment Considerations for Cleanrooms and Other Controlled Environments." The recommended practice provides guidance for the selection of fabric, garment construction, cleaning and maintenance of cleanroom garments, and testing of cleanroom apparel for use in aseptic and non-aseptic cleanrooms.

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While cleanroom garments can either be disposable or reusable, according to industry analysts, most sterile facilities will opt for disposable garments due to contamination concerns relating to reusable garments returned from laundering facilities. In some companies, disposables may be used at some locations and reusables at others. This can depend on the classes of the various cleanrooms at different locations.

Disposable garments may be easier to manage from a cost standpoint as well, since the price for reusable garments often carry "hidden" charges such as delivery and pick-up fees (and related energy surcharges), lost/unused garment charges, laundering and sterilization charges, and more.

For the past 40+ years, disposable cleanroom suits have been made from flash-spun polyethylene fabric. According to industry analysts, flash-spun polyethylene provides filtration efficiency for sub-micron sized particles and microorganisms and is suitable for light splash protection from non-hazardous liquids.

Disposable suits also can be made from spunbond-meltblown-spunbond (SMS) fabric, which has outer layers of spunbond polypropylene for strength and cloth-like comfort, with middle layers composed of a matrix of microfibers, which creates a torturous path for fine particles and liquids.

Reusable cleanroom suits are typically made from woven polyester-blend fabrics, which may degrade after multiple laundering and sterilization cycles.

Most operators in a sterile cleanroom environment in the pharmaceutical industry will wear three to four disposable suits in a day, each suit being worn for two to three hours at a time. Often, cleanroom protocol dictates that garment changes must be made each time the cleanroom is re-entered. Once discarded, these suits can be incinerated, or they can be re-purposed through a garment recovery service that will take the used garments and sell them back into non-sterile applications.

Cleanroom garments in the U.S. may be sterilized via several methods, including gamma irradiation, e-beam sterilization and ETO sterilization. Gamma sterilization is widely considered to be the most cost-effective method. The desired Sterility Assurance Level (SAL) for garments to be used in sterile pharmaceutical manufacturing is 10-6, which translates into a one-in-a-million probability of a garment being non-sterile. Once sterile, cleanroom suits must be packaged in a way that this sterility is maintained throughout handling, transportation and storage.

Sterile Gowning: Room for Improvement

Ask any cleanroom operator and chances are he or she will find something about sterile gowns that could be improved. In fact, Kimberly-Clark Professional did just that, spending the better part of two years interviewing cleanroom operators, visiting them in their workplaces and evaluating the features and functions of traditional sterile cleanroom gowns to identify areas in which there was potential room for improvement.

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Key findings of that research:

- The sterile cleanroom gowning process takes between 5 and 10 minutes for the vast majority of cleanroom operators.
- Almost one-third of cleanroom operators indicate that cleanroom coveralls are the most difficult part of the six-step gowning process, and that donning coveralls takes an average of 30 percent of the entire gowning process time.
- Cleanroom operators are disposing of an average of 10 percent of their sterile cleanroom garments every week due to exterior contamination during the gowning process.
- Most new cleanroom operators need 30 hours of initial training on cGMP donning procedures before they are allowed in the cleanroom itself, and an average of 6 hours of ongoing training each week.
- More than 50 percent of cleanroom operators reported garments ripping out or billowing due to poor fit.
- One-third of cleanroom operators report being unsure of their garment's sterility due to the appearance of its packaging.
- Approximately 87 percent of cleanroom operators would consider switching to a new garment if it was more comfortable and offered less risk of contamination.

The issue of garment comfort was also addressed. Scientific research in the workplace has revealed that a moderate variation in body temperature can greatly reduce concentration and increase risk-inducing behavior. Workers unable to maintain a thermo-neutral zone, or comfort zone, have a higher tendency to become injured and need time off from work, thus reducing productivity. In fact, more than 40 percent of cleanroom operators polled during Kimberly-Clark's research report employees need to exit the cleanroom due to overheating on a regular basis.

Inside R&D: Designing a New Gowning Approach

A multi-functional product development team at Kimberly-Clark Professional set out to design a new approach to sterile gowning that would eliminate the problems identified during the company's research. The resulting Clean-Don Technology provides the following features:

- A patent-pending snap technology that features built-in snaps which gather up legs and arms to lower the risk of the garment touching the floor, then automatically release as the garment is put on. This eliminates problems associated with traditional cleanroom garments, in which the garments' arms and legs typically dangle freely as the operator dons the garment, thus increasing the chance that those dangling arms and legs may touch the floor, thus contaminating the garment. This problem with traditional garments is particularly acute with individuals who are on the shorter, yet portlier side, meaning they often have to go up one garment size and therefore would have an even more difficult time keeping the longer dangling arms and legs of the garment from touching the floor.
- An innovative inside-out fold pattern that presents the inside of the garment as the package is opened, reducing the risk of touching and contaminating the outside of the apparel.
- A highly visible blue line along the inside of the garment that signals the proper place to grasp while gowning, helping workers avoid touching the exterior of the garment.

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- Thumb loops that help keep the garment from riding up the arm and help to maintain the glove/garment interface.
- A unique process to package the new garments for sterility assurance. The technology uses a vacuum seal process to allow the breathable SMS fabric to be sterilized with Gamma irradiation. The unique look and irradiation indicators on each package help to confirm irradiation and sterility.
- A roomy design that is less likely to rip out than ANSI minimums since it provides 12 percent more chest room and six percent longer body length. At the same time, the garments' elastic waist and back reduce loose-fitting material that could contact work surfaces or billow out, forcing air to exit the garment at its extremities.
- An SMS (Spunbond Meltblown Spunbond) material that provides a cloth-like feel and is 25 times more breathable than TYVEK.

Sharing and evaluating the new garment and donning concepts with cleanroom operators were crucial to ensuring the new approach was successful. Testing of the Clean Don Technology with cleanroom operators found the following:

- 93 percent of operators preferred the heavy vacuum-sealed package for providing greater sterility assurance. Operators also said they would have no problems stacking the heavily vacuumed packages.
- 86 percent of the operators prefer the coverall's thumb loops to hold the sleeves in place.
- 86 percent of operators felt the blue stripe would lower the risk of contamination that would result from touching the outside of the garment or contacting a non-sterile surface, and would help facilitate aseptic gowning. Operators estimated that the disposal of coveralls contaminated during the donning process would be reduced by 52 percent with the new garment and donning concept.
- A full 100 percent of operators agreed that the arm and leg snaps would help prevent contamination during the gowning process and that the overall approach would provide better compliance in maintaining sterility.
- A full 100 percent of operators thought the material felt more like cloth than the leading competitive sterile cleanroom coverall, which was largely described as "hot, sweaty and plastic-feeling."
- 93 percent of operators felt the new coverall design would provide greater ease of training. The average estimated time saved in the donning process among all operators studied was approximately one minute.

Validation & Training: Inculcating the New Approach

One of the necessary steps when validating a new sterile cleanroom gown is to carefully review the garment's certification. Be sure to ask the garment supplier for the following:

- Certificates of Conformance – these verify that a specific product lot conforms to all specifications before the lot is released. Physical characteristics should be tested in accordance with relevant ASTM standards. Particles should be tested in accordance with relevant IEST standards.

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- Certificates of Irradiation – these document the minimum and maximum dosage of irradiation that a product received. Look for sterilization validation documentation that confirms that the doses have been verified, the loading patterns were sufficient, and that the process is audited on a regular basis.

A variety of functions will need to be involved in the approval process for a new cleanroom gown. First, safety must approve the use of a new product. Each local safety officer must ensure that the product will not violate any EPA or OSHA regulations or permits. Any changes to processes are also concerns for regulatory personnel, as they may impact the company's FDA license. After acceptance by safety and regulatory, Quality must be included and will play a key role in testing and accepting the new product or process. Quality Assurance personnel are involved in reviewing all of the procedures and process records, testing the product to ensure its sterility, and approving the final selection based on the data. The Quality Control organization will inspect all incoming sterile products, policing the environment and reporting the result. The purchasing department is the final step in the process and often provides rubber-stamp approval for ordering the products already accepted by the other players.

Most pharmaceutical companies will conduct a new garment validation process for three to nine months, during which time the new garments would be worn in a controlled area, though not necessarily in the actual cleanroom in which the garment is designed to be worn.

In many pharmaceutical companies, a new sterile gown also will need to undergo testing on three lots before validating and approving it. In some cases, a change to the standards of practice for that environment will also be required.

Many users will assess a garment's sterility on-site by using contact plates or swabs containing a nutrient media. To formally validate gamma- or e-beam-irradiated garments for sterility assurance levels, use ANSI/AAMI/ISO 1137-1994 "Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization" and ANSI/AAMI/ISO 11737-1-1995 "Sterilization of Medical Devices – Microbiological Methods – Part 1: Estimation of Population of Microorganisms on Products."

Conclusion

Validating a new sterile cleanroom garment is not a task to be undertaken lightly. However, when a new approach to sterile gowning can help improve the gowning process, reduce opportunities for operator error, and minimize the risk of contamination, it provides a strong incentive for pharmaceutical companies to consider switching.