



## **Biomufacturing Facility Adopts New Approach to Sterile Cleanroom Gowning**

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New Garment Design & Donning Procedures  
Help Minimize Contamination Risks

The Waisman Clinical BioManufacturing Facility (WCBF) at the University of Wisconsin-Madison is a state-of-the-art cleanroom facility that conducts GMP manufacturing of cell therapeutics, gene therapy vectors, and biologics for phase I/II human clinical trials.

The WCBF serves researchers as they enter early development of novel biological therapies and catalyzes the advancement of therapies into human clinical trials. With broad and comprehensive capabilities, the WCBF specializes in assisting researchers and companies with the entire process of developing a manufacturing process and producing and testing materials for human clinical trials.

The WCBF knows how important it is to maintain strict cleanroom cleanliness and sterility in their Class 7 and 8 cleanrooms. That is because, if contaminated with microorganisms, the products the WCBF manufactures can adversely harm patients. In addition, the steep price of product rejects and recalls makes it crucial to ensure high product yields.

“We are committed to ensuring that our operations are performed to the highest quality principles, in compliance with the FDA and other regulatory requirements,” says Chuck Valliere, Quality Control Specialist (Gowning Training), WCBF, noting that a failed batch of cell-based products can cost upwards of \$100,000.

The bane of cleanroom operators like the WCBF is microorganisms. 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.

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.

The ability to maintain sterility through the gowning process is one reason the WCBF turned to a new approach to sterile gowning with CLEAN-DON® technology from KIMBERLY-CLARK PROFESSIONAL®.

#### **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 opera-

tors, 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.

*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.

Cleanroom workers at the WCBF echoed Kimberly-Clark's research findings.

"We've always used disposable cleanroom gowns because reusable gowns have a high initial investment," says Bill Kreamer, manufacturing and maintenance specialist, WCBF. "But even our traditional disposable cleanroom gowns had problems and were not as convenient as we would have liked."

Kreamer notes that, not only were their old disposable cleanroom gowns costly and their packaging bulk made them difficult to store, they also required a tremendous amount of "precise handling," such as rolling up the arms and legs to keep them off the floor during gowning.

### **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.
- 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.

Kreamer, who is responsible for testing new personal protective equipment for use in the WCBF cleanrooms, notes that the new gowning approach is more convenient for their employees and has a better cost-in-use.

“The novel packaging has a number of benefits for us,” he explains. “First of all, the vacuum packaging makes the garments more compact and easier to store. As you open the package, the garment stays in a compact shape, preventing it from unfolding and touching the floor, which would be unacceptable in our sterile environment. It is also packaged inside-out, with a stripe to indicate which side is which. This helps prevent our cleanroom employees from contaminating the sterile outside of the garment during the gowning process and saves steps and valuable time during the gowning process.”

The WCBF estimates that the new gowning approach allows employees to gown up in about three-quarters of the time they used to spend on the gowning process with their previous disposable gowns.

“Our employees like the convenience of having the gowns already prepared for entry,” Valliere adds. “They also like the fit over our previous gowns, as well as the integral thumb loop. The durability of the material also makes the gowns more resistant to tearing than our previous cleanroom garments.”

#### **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.
- 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.

In most pharmaceutical companies, 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.

At the WCBF, cleanroom workers received training in the new gowning procedures as part of their annual aseptic gowning qualification. In order to pass, employees need to demonstrate three consecutive acceptable gownings. Personnel environmental monitoring was also conducted.

### **Conclusion**

Validating a new sterile cleanroom garment is not a task to be undertaken lightly. However, the WCBF found that this new approach to sterile gowning can help improve the gowning process, reduce opportunities for operator error, and minimize the risk of contamination -- providing a strong incentive for switching.