



## **Implementing Disposable Cleanroom Apparel into the Manufacturing Process**

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Minimizing contamination risks in sterile gowning

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The pharmaceutical development process is long, complex and costly. Contamination levels must be closely monitored and controlled in aseptic cleanroom environments to prevent events detrimental to product yield. The “Golden Rule” of sterile manufacturing is to always be on the lookout for potential contamination and ways to prevent it. Also, drugs with hazardous components require heightened vigilance to prevent cross contamination. Global standards for cleanrooms are evolving and organizations are looking to improve the quality of their manufacturing facilities, procedures and practices.

Disposable technologies are playing an increasingly important role in the pharmaceutical manufacturing business. Disposables are proving to provide increased control or elimination of variables that impact contamination control. In addition, they can offer significant cost savings as these technologies become more widely accepted. In the case of disposable cleanroom apparel the benefits can include an easier gowning process, elimination of variability in filtration performance that can result from reusing apparel, less waste and improved levels of contamination control. However, because product designs and procedures can influence cleanroom compliance, pharmaceutical manufacturers need to consider the most effective ways to integrate disposable cleanroom apparel into the manufacturing process.

#### **Easier Gowning and Reduced Variability**

It is critical for cleanroom operators to select cleanroom apparel that provides not only the highest levels of inherent sterility and cleanliness, but also the greatest chances of maintaining that sterility and cleanliness through the gowning process. According to industry analysts, most sterile facilities will opt for disposable garments due to potential contamination concerns related to reusable garments returned from laundering facilities. Disposables eliminate the need for repeat washing, packing and sterilization, all of which are variables that can impact contamination control. There are additional concerns surrounding the risk of traditional cleanroom apparel touching the floor during gowning. Selecting apparel that is designed to prevent contamination during the gowning process will drive compliance, save time and cut down on employee frustration and waste.

#### **Less Waste**

Sustainable practices and products are quickly becoming a responsible priority and cost-effective differentiator for pharmaceutical manufacturing facilities. Disposable cleanroom apparel can actually play a role in helping pharmaceutical manufacturers reduce their waste stream while reducing the risk of contamination in a number of ways. As mentioned above, some disposable cleanroom apparel leads to less waste associated with contamination as a result of garments touching the floor i.e. which reduces the number of coveralls that need to be thrown away because they were contaminated during donning. Well-designed, disposable coveralls feature internal snaps that hold up the arms and legs of the garment to prevent them from touching the floor during aseptic donning. In addition, special packaging features such as an airtight vacuum seal reduce the waste associated with improper handling or contamination in transport to cleanroom environments.

At KIMBERLY-CLARK PROFESSIONAL®, we recently formed a partnership with TerraCycle™, an “upcycling” company, to help pharmaceutical manufacturing facilities recycle cleanroom garments, including coveralls, hoods, boot covers, hair nets and masks. This is the one of the first large scale recycling programs for non-traditional cleanroom waste streams. Pharmaceutical manufacturers can sign up for the recycling program at the time of purchase and will receive a recycling bundle with all of the materials needed to implement the program in their facility. TerraCycle™ will collect, convert and resell all waste materials as either bulk plastics or eco-friendly consumer products, and the company’s bar code system will allow KIMBERLY-CLARK PROFESSIONAL® to track waste reduction and report that information back to each facility.

### **Getting Started**

In most pharmaceutical companies, a variety of functions will need to be involved in the transition to disposable cleanroom apparel. It is important to create an implementation plan that establishes who will be involved and assigns specific responsibilities. First, the safety team 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 will play a key role in testing and qualifying the new product for possible use in their process. Quality Assurance personnel must be 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, policy the environment and report the result.

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 will also need to undergo testing on three lots before it is validated and approved. In some cases, a change to the standards of practice for that environment will also be required.

The purchasing department is the final step in the process and facilitates the coordination and delivery of the product. Once the decision has been made to implement disposable cleanroom apparel, operators must be trained to don the new apparel. Instructors should provide an introduction to the apparel, conduct a donning exercise and answer questions. Successful education includes follow up training as needed as well as periodic check-ins on user acceptance.

In some companies, cleanroom workers receive training in the new donning procedures as part of their annual aseptic donning qualification. In order to pass, employees need to demonstrate the donning technique at least three times in a consecutive acceptable manner. As with all new processes, practice makes perfect.

### **Conclusion**

There are many new and diverse disposable technologies available to pharmaceutical manufacturers. The process of implementing them can become complex and overwhelming, particularly in terms of certification. However, in the case of disposable cleanroom apparel, the benefits are proving to far outweigh the complexities. In many of the facilities that have introduced disposable cleanroom apparel, cleanroom technicians are reporting improved productivity and compliance as well as 100% employee acceptance.