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The contamination risks posed by laundered cleanroom apparel

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ABSTRACT

This paper details the findings of a study that raises concerns about the performance of reusable, laundered cleanroom apparel. The study found that the Bacterial Filtration Efficiency (BFE) of reusable garments degrades significantly after the garment has gone through wash and irradiation cycles. This poses a real yet invisible contamination risk to aseptic manufacturing environments.

The Contamination Risks Posed by Laundered Cleanroom Apparel

The drug development process is a costly enterprise. The average Research and Development investment for each new medicine is $1.2 billion, with more recent studies estimating the outlays to be even higher[1].

Another significant cost to pharmaceutical manufacturing is process contamination. Nothing is more serious than a contamination event in a cleanroom. Contamination can lead to expensive shutdowns and increased production expenditures as well as recalls and potentially loss of life. Just a single event can be catastrophic. On average, pharmaceutical manufacturers spend approximately $3.1 million a year to remediate contamination events and occurrences[2]. The charge for one alert, or interruption, can range from $1,000-$10,000 and the cost of a single action, or investigation, can be anywhere from $10,000 to $60,000.

Recalls from product damage and contaminated pharmaceuticals can cost companies millions. And they happen frequently – with more than 1,734 drug recalls reported by the U.S. Food and Drug Administration (FDA) between 2004 and 2011[3].

These incidents put human lives at risk. There were 91 reported FDA recalls between 2004 and 2011 that were designated Class 1[4], meaning they could potentially cause death. Bacterial contamination of pharmaceuticals can happen too and the consequences can be life threatening. A case in point: the deadly outbreak of fungal meningitis linked to tainted drugs from the New England Compounding Center (NECC), which led to 64 deaths and more than 700 illnesses.

Also damaging is the negative impact on reputation and consumer confidence from contamination episodes that result in illness, injury or fatalities.

On average, pharmaceutical manufacturers spend approximately **$3.1** million a year to remediate contamination events and occurrences[2].

This is one of the reasons why the 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. If these pharmaceutical products are contaminated with microorganisms, they 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. Therefore, 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. To protect the process, the cleanroom operator also needs to be "filtered" in a sense.

Wherever there are people, there is a risk of microbial contamination. The challenge in aseptic processing

People are the largest contributor to particle contamination in any cleanroom, accounting for **46%** of all particle contamination.

is always personnel[5]. People are the largest contributor to particle contamination in any cleanroom, accounting for 46 percent of all particle contamination. Humans shed and spread millions of particles throughout the day.

Body regenerative processes, such as skin flakes, oils, perspiration and hair all can contribute to cleanroom contamination. A human hair is about 75-100 microns in diameter. A particle 200 times smaller (0.5 micron) than a human hair can cause major disasters in a cleanroom. This risk can be mitigated by using sterile cleanroom apparel that protects the environment from viable particles such as bacteria and yeast, and non-viable particles such as hair, dead skin cells, and dandruff. For this reason, it's essential that cleanroom operators select apparel that provides the highest levels of contamination control.

Choosing the right type of apparel is paramount. ***But what if the garment itself poses a hazard to the cleanroom environment? Testing by Kimberly-Clark Professional found that the barrier on reusable protective garments declined after multiple washing, drying and sterilization cycles. This barrier decline poses a significant contamination risk for cleanrooms.***

Selecting Cleanroom Garments

There are no federal regulations for sterile cleanroom garments used in the pharmaceutical industry. However, guidance is available from The Institute of Environmental Sciences and Technology (IEST), which publishes a Recommended Practice (RP) IEST-RP-CC003.4, "Garment Considerations for Cleanrooms and Other Controlled Environments." IEST-RP-CC003.4 provides non-mandatory guidance for the selection, specification, maintenance, and testing of garments or apparel and accessories appropriate

People related contamination statistics

10,000
MICROORGANISMS
per square inch on hand surface

40,000
NUMBER OF SKIN CELLS
shed per minute

100,000
PARTICLES >0.3µm
generated by people when stationary

5 million
PARTICLES >0.3µm
generated by people when moving

for use in non-aseptic and aseptic environments. The RP is intended to assist the end user, system designer, supplier, and processor in defining required performance criteria, test methods, and procedures for gowning system use and maintenance, as well as in developing a quality control plan for the apparel and accessories that may be included in the system. The document also contains a section describing types of fabrics and relevant properties and methods of testing the materials used in cleanroom garments, as well as the design and construction of appropriate configurations and special features of such garments.

Garment Sterilization

Cleanroom garments in the U.S. may be sterilized via several methods, including gamma irradiation, e-beam sterilization and Ethylene Oxide (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-one-million probability of a garment being non-sterile. Once sterile, cleanroom suits must be treated in a way that maintains sterility throughout handling, transportation and storage.

Cleanroom garments fall into two main categories: single-use, disposable garments and reusable laundered garments.

Single-Use Garments

Single-use garments are made from two types of fabric: 1) flash-spun polyethylene fabric, which provides filtration efficiency for sub-micron sized particles and microorganisms and is suitable for light splash protection from non-hazardous liquids, and 2) spunbond meltblown spunbond (SMS) fabric, which has outer layers of spunbond polypropylene for strength and cloth-like comfort, and middle layers composed of a matrix of microfibers, which creates a strong barrier for particles and liquids.

100% of the worn sterile reusable garments tested showed a decline in BFE after washing.

Reusable Garments

Reusable cleanroom garments are typically made from woven polyester-blend fabrics, which may degrade after multiple laundering and sterilization cycles. ***Testing conducted by Kimberly-Clark Professional used garments that were randomly selected from pharmaceutical customers. The testing results showed a decline of more than 25 percent in Bacterial Filtration Efficiency (BFE) after an average of five washings. This presents a real yet invisible contamination risk to aseptic manufacturing environments[6].***

The testing also found:

- 100 percent of the worn sterile reusable garments tested showed a decline in BFE after washing.
- The filtration efficiency of the reusable garments was typically less than 70 percent.
- **Fabric degradation was visible at the sub-micron level – enough to allow bacteria to penetrate the material.**
- The product declined more rapidly than expected and that decline continued through multiple wash cycles.
- The total cost of ownership for reusable cleanroom apparel was much higher than projected.
- The average number of wash cycles was much lower than expected.

Results Confirmed by Additional Testing

Kimberly-Clark Professional conducted comparative testing of disposable and reusable cleanroom apparel. The testing method involved covering a container with a swatch of reusable garment material and another with a swatch from a Kimberly-Clark Professional disposable garment fabric[7]. The containers were then sprayed with an aerosolized form of Staphylococcus aureus bacteria. After 24 hours, the material was removed and the number of colony-forming units of bacteria were counted to measure the amount of bacteria that penetrated through to the test medium. The results?

- The disposable fabric maintained its 95 percent BFE.
- The reusable fabric had a 68 percent BFE.

What Does All of this Mean?

A 25 percent drop in BFE is comparable to 1 out of 4 workers not wearing sterile garments in a cleanroom. Keep in mind, too, that 5 million particles greater than .3 microns are generated just by walking.

Additional Concerns

The laundering process for reusable cleanroom garments involves multiple processing steps – such as sorting, multiple wash cycles, drying, cool-down and inspection – which all put the fabric under additional stress. This is repeated each time the gown is serviced. Therefore, the laundering process itself creates channels for bacteria to pass through.

Test data for the BFE of reusable garments is typically based on new garments, not on garments that have been washed and sterilized multiple times. The filtration efficiency and the lifespan of the gowns do not appear to be consistent with what is actually being observed in use.

Single-Use Garment Benefits

Disposable apparel offers a number of other advantages over reusable apparel, including:

- **Predictability** – these garments are washed once to guarantee optimal, predictable performance for each and every garment.
- **Data transparency** – Data on disposable garments is available for pre- and post-sterilization.
- **Ease of donning** – Unlike reusables, some disposable apparel is designed with innovative features that keep the garment from touching the floor during the donning process.
- **Comfort** – The Kimberly-Clark Professional SMS fabric is cool and breathable.
- **Easy recycling** – The Kimberly-Clark Professional RightCycle program enables cleanrooms to recycle single-use garments. RightCycle is the first large-scale recycling effort for nontraditional cleanroom waste. It mitigates waste and assures cleanrooms of a sustainable apparel solution. It makes it easy to recycle previously hard-to-recycle items, such as cleanroom apparel, gloves, hoods, boot covers and hairnets, and turns them into useful, eco-friendly products.
- **Consistent Performance** – Single-use apparel provides performance and consistency to ensure that the highest levels of sterility are being met.
- **Vacuum-sealed** – to ensure sterility.

CONCLUSION

To protect the purity of your scientific process, it's essential to use the most reliable protective apparel available. The risks of cleanroom contamination are simply too great. Gowning is designed to keep particles and microorganisms from reaching and contaminating the product being made. Not all garments perform equally when it comes to holding in particles. The test findings detailed here cast doubt on the efficacy and reliability of reusable protective apparel and its ability to meet cleanroom standards after laundering. All sterile reusable garments tested showed a decline in Bacterial Filtration Efficiency (BFE) after washing. By contrast, single-use disposable garments are washed once, guaranteeing optimal, predictable performance for each and every garment. When selecting apparel for an aseptic manufacturing environment, it's essential to choose the cleanroom garment that offers the highest level of BFE. Purchasers would be wise to consider these study results and choose sterile, disposable apparel for their facilities.

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2. 2012 Parenteral Drug Association (PDA) Environmental Monitoring survey
3. Archives of Internal Medicine study, June 2012
4. Archives of Internal Medicine study, June 2012
5. USP Guidances on Environmental Control including related USP, FDA, EMEA & PDA Activities, James Agalloco, Agalloco & Associates.
6. ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.
7. Kimtech Pure A5 fabric