ARE REUSABLE LAUNDERED GARMENTS PUTTING YOUR CLEANROOM AT RISK?
CHAPTER 1:
Cleanroom Contamination: What are the biggest threats?

CHAPTER 2:
Understanding the Differences Between Risk-Mitigation Controls: Bacterial Filtration Efficiency

CHAPTER 3:
The Laundering Process

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The Single-Use Solution
CLEANROOM CONTAMINATION

What are the biggest threats?
Watch Out for

DIRTY LAUNDRY

There’s no doubt about it. Contamination is bad for business. It can lead to shutdowns, recalls and loss of life. And it puts manufacturers in a negative spotlight.

To avoid contamination you have to understand its source: People.

People are the #1 cause of contamination in the cleanroom

Cleanroom garments are the #1 cause for alerts & actions

What stands between you and the risk of contamination? The personal barriers you choose to protect your process as well as your employees. When contamination occurs, the assumption is that the cleanroom operator didn’t follow the right procedures when gowning. But it’s not always the operator. Many times, the problem is with the gown itself.
People-Related Contamination Statistics

1 in 3 PEOPLE agree that donning coveralls is the most difficult part of the gowning process.

1 in 3 CLEANROOM OPERATORS report being unsure of garment sterility because of packaging.

50% of cleanroom operators reported poor fit of coveralls.

87% of operators would change to PPE that is more comfortable or helps to reduce contamination risk.

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.

Understanding the Source
50% of contamination Alerts and Actions in the PDA study were people related.

Spent per year on sterile PPE for a site with 100 entries per day.

more than $250,000

18 Average number of annual contamination action events per company, related to personnel gowning.

Average cost of dealing with contamination action events at a site, in the course of a year.

more than $3.1 million
UNDERSTANDING THE DIFFERENCES BETWEEN RISK-MITIGATION CONTROLS

Chapter 2

Bacterial Filtration Efficiency
Laundered reusable garments typically contain a single layer of woven polyester-blend fabric, which, coupled with the weave, may allow particles to pass through. The fabric also may degrade after multiple laundering and sterilization cycles – compromising the barrier built into the garment material.

Kimberly-Clark Professional* conducted testing on laundered reusable garments and found that the Bacterial Filtration Efficiency (BFE) declines more than 25% after an average of five washings. That’s like 1 out of 4 workers not wearing sterile garments at all.

This presents a real, yet invisible, contamination risk to cleanroom environments.

All cleanroom garments are not created equal!

Cleanroom garments fall into two main categories:

1. **Single-Use Disposable Garments**
   - Single-use disposable garments are made from two types of fabric:
     1) Flash-spun polyethylene fabric, which provides filtration efficiency for submicron sized particles and microorganisms, is suitable for light splash protection from non-hazardous liquids.
     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 fine particles and liquids. The three SMS layers have a maze-like quality that traps particles, while maximizing airflow to keep the operator cool and comfortable.

2. **Laundered Reusable Garments**
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Chapter 3

THE LAUNDERING PROCESS
The Laundering Process

1. Inspection
2. Sort
3. Repair
4. Wash/Dry
5. Package
6. Transport
7. Sterilize
8. Transport
9. Inventory
10. Stock
11. Wear
12. Laundry Bin

The steps in red pose the greatest contamination risk.
The life of a laundered garment is filled with repetition.

The steps in red pose the greatest contamination risk.

So, it’s no wonder that the material barrier of the garments can break down.

What is the useful life of these garments and when should they be retired? The answers vary – from 100 times, according to the material manufacturer, to 19, according to one pharmaceutical company.

What’s the right answer? Our recommendation – and our testing – found that the Bacterial Filtration Efficiency (BFE) of a garment should determine its retirement date. Here is what our testing revealed:

- 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%.
- Fabric degradation was visible at the submicron level – enough to allow bacteria to penetrate the material.
- As the number of washes went up, the BFE went down.
- The average number of wash cycles was lower than expected.
- The total cost of ownership for reusable cleanroom apparel was much higher than projected.
If you're using laundered garments, can you afford the risk when so much is at stake?

Filtration efficiency declined quickly after the first few initial washes.

Compromised Barrier Integrity
Chapter 4

THE SINGLE-USE SOLUTION
Sterile single-use garments offer a number of advantages over laundered reusable apparel, including:

<table>
<thead>
<tr>
<th>Consistent Performance</th>
<th>Kimberly-Clark Professional* Kimtech Pure* A5 Sterile Cleanroom Apparel offers a 95% BFE rating, vs. 68% for laundered apparel.</th>
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<tbody>
<tr>
<td>Predictability</td>
<td>The garments are washed once to guarantee optimal, predictable performance.</td>
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<td>Ease of donning</td>
<td>Unlike reusable garments, single-use apparel from Kimberly-Clark Professional* features advanced Clean-Don* Technology to facilitate aseptic donning and lower contamination risk.</td>
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<tr>
<td>Comfort</td>
<td>The Kimberly-Clark Professional* SMS fabric is cool and breathable.</td>
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<tr>
<td>Recyclable</td>
<td>The RightCycle* by Kimberly-Clark Professional* program enables cleanrooms to recycle single-use garments and accessories. It turns previously hard-to-recycle items into useful, eco-friendly products.</td>
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<tr>
<td>APEX</td>
<td>A unique employee engagement program designed to enhance protection, performance and acceptance.</td>
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Don’t let your choice of apparel endanger your scientific process. To ensure its purity, select the most reliable protective apparel available. The risks of cleanroom contamination are simply too great.

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