



Personal Protective Equipment

## Why Choosing the Right Cleanroom Apparel Matters

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In sterile pharmaceutical manufacturing, maintaining cleanroom standards is not just about compliance—it's essential for ensuring product integrity, protecting human health, and preventing costly contamination issues. Operators, the biggest source of contamination, require the right apparel to mitigate risks, making cleanroom apparel one of the most important investments in these critical environments.

### The Role of Apparel in Contamination Control

Controlling contamination in cleanrooms is crucial, especially in **Grade A and B zones**, where sterility is paramount. The wrong apparel can result in particulates or microbial contaminants entering sensitive production environments, leading to severe consequences. Every piece of apparel, from hoods to shoe covers, acts as a barrier, ensuring contaminants from operators don't compromise the manufacturing process.

Regulatory Guidelines such as **EU GMP Annex 1** emphasize the need for sterile, single-use garments in high-risk areas. Failure to adhere to these regulations can result in penalties, plant shutdowns, and product recalls. Single-use apparel is often recommended for high-risk environments because it minimizes the risk of cross-contamination between uses.

### The Risks of Reusable vs. Single-use Apparel

Choosing between **Single-use** and **reusable** apparel involves weighing the risks of contamination, cost, and environmental impact.

- **Single-use Apparel:** Sterile, single-use garments, like **Ansell's BioClean-D™ Sterile Coveralls**, provide superior protection in critical environments by eliminating the risk of contamination that can occur during laundering or sterilization processes. These garments are ideal for **Grade A and B zones**, where maintaining absolute sterility is essential. Disposables reduce contamination risks because they are discarded after each use, eliminating concerns about fabric degradation after repeated washes.

- **Reusable Apparel:** While reusable garments may offer cost benefits in certain scenarios, they come with increased contamination risks. Improper sterilization or laundering can reintroduce contaminants into the cleanroom environment. Moreover, the **repeated sterilization process** can degrade the integrity of reusable garments, compromising their ability to protect both the product and the worker.

To learn more about the benefits of single-use cleanroom coveralls and proper aseptic donning techniques, [\*read more here\*](#).

## Product Integrity: Why Apparel Matters

The risks of improper apparel choices extend beyond contamination—they can also compromise **product integrity**. One of the most alarming examples of this was the 2012 fungal meningitis outbreak in the USA, caused by improper gowning and sterilization practices. This incident led to 60 deaths and over 750 infections, illustrating the dire consequences of inadequate protective apparel.<sup>1</sup>

Choosing sterile, properly fitted, and non-linting apparel is essential to maintaining the integrity of pharmaceutical products. Sterile environments require head-to-toe protection, including **sterile gloves, goggles, and coveralls**, to ensure that operators do not introduce contaminants into the production area.

## Protecting Human Health: The Right Apparel for Worker Safety

While protecting products is crucial, ensuring the safety of the personnel is equally important. In cleanroom environments, workers are exposed to hazardous chemicals and particulates, making **personal protective equipment (PPE)** a necessity.

**Ergonomics and Comfort:** One often overlooked aspect is the comfort of the apparel. Poorly fitting or uncomfortable PPE can lead to improper donning or adjustments during critical operations, increasing contamination risks. To address this, Ansell offers products designed with ergonomics in mind, such as the **Ergoform gloves**, which reduce hand fatigue while maintaining high dexterity, allowing workers to perform tasks with ease.

To learn more about why finding the right fit for workers is so important in cleanroom environments, [\*read more here\*](#).

## Choosing the Right Apparel: Best Practices

Selecting the correct cleanroom apparel is critical for protecting product integrity, preventing contamination, and ensuring operator safety. To make the right choices, there are several key factors to consider:

1. **Evaluate Your Environment** Understand the contamination risks in your cleanroom, taking into account the classification level (A, B, C, D). The more sensitive the environment, the stricter the apparel requirements.
2. **Regulatory Compliance** Always ensure that the apparel meets industry standards such as **EU GMP Annex 1**. Apparel should be designed for sterile environments and follow regulations related to barrier protection, sterility, and particle control.

3. **Material Selection** Choose materials that provide effective particulate and microbial barrier protection. Disposable options, such as those made from **non-linting fabrics**, are ideal for minimizing contamination risks in critical areas.
4. **Fit, Comfort, and Ergonomics** Apparel must not only protect but also fit well and be comfortable for workers to wear for extended periods. Poor fit can lead to incorrect usage and contamination risks. Opt for ergonomic designs that allow freedom of movement without compromising protection.
5. **Sterilization Compatibility** Apparel should be compatible with the sterilization methods used in your cleanroom, whether gamma, ethylene oxide, or another method. For instance, **Ansell's BioClean-D™ Sterile Coveralls** are pre-sterilized and packaged for immediate use in Grade A and B environments.
6. **Productivity** Choose apparel that allows workers to perform tasks efficiently without frequent adjustments or discomfort. Disposable solutions often improve productivity by eliminating the need for laundering or repeated sterilization.
7. **Durability, Reusability, and Resource Consumption** Assess the balance between cost and safety. While reusable garments may seem cost-effective, the additional risks of contamination during laundering and increased resource consumption make **single-use sterile apparel** a better choice for critical zones.
8. **Supplier Certification** Ensure that the apparel supplier has the necessary certifications and can provide **validated sterile products** that comply with international standards.
9. **Training and Education** Provide your staff with comprehensive training on proper donning, doffing, and handling techniques to maintain the sterility of the apparel and minimize contamination risks.
10. **Regular Evaluation** Periodically review your cleanroom practices, including apparel effectiveness, to ensure continued compliance and protection. As regulations evolve, regular assessments help to keep your cleanroom processes up to date.

*Previously Featured on Ansell's blog.*