SIMCO ION™
An ITW Company

CASE STUDY

Eliminating Particle Contamination Using Ionization

A Success Story from a Pharmaceutical and Chemical Bag Manufacturer

Summary

A leading manufacturer specializing in medium to large-sized bags for pharmaceutical and chemical applications faced significant particle contamination challenges caused by electrostatic attraction (ESA) in its cleanroom manufacturing process. These specialized bags often include plastic fittings molded externally, which sometimes arrive already contaminated, compounding existing cleanliness challenges. Recognizing the critical importance of maintaining strict cleanliness and precision standards in the highly sensitive life sciences industry, the company's senior management initiated a Quality Improvement Project (QIP) at one facility, intending to expand successful strategies organization-wide. Adopting advanced ionization solutions effectively addressed these contamination issues, significantly improving product quality, reducing defects, and enhancing overall operational efficiency—achievements essential for complying with rigorous industry and customer specifications.

Problem

The primary challenge faced by the manufacturer was severe particle contamination driven by electrostatic attraction (ESA), which resulted in:

- Higher rejection rates for manufactured bags
- Increased production costs from reworking or discarding contaminated materials
- Reliability concerns of single-use assembly products containing bags, tubing, connectors, disposable mixers, and filters
- Risks of non-compliance with industry standards and internal customer requirements

Solution

To tackle these challenges, the company implemented a comprehensive ionization strategy, consisting of:

- **Room Ionization Grid**: This grid is installed throughout gowning areas, transfer rooms, and the main cleanroom area, significantly reducing airborne particles and cross-contamination.
- **Ionizing Air Guns**: Used for precise, targeted elimination of static charges.
- **Continuous Monitoring and Maintenance**: Regular particle count testing alongside routine cleaning and adjustments to the ionization equipment.

Key Results

1. **Comprehensive Control**: The integrated ionization system spanning the entire cleanroom process—from gowning and kitting to assembly and packaging—dramatically reduced contamination, virtually eliminating product rejections and the need for rework.
2. **Rapid ROI**: Despite upfront investment costs, the reduction in defects and enhanced production efficiency quickly led to substantial financial savings.

Conclusion

The manufacturer successfully tackled its contamination challenges by adopting a holistic ionization approach. This case study emphasizes the importance of proactive, comprehensive cleanroom management strategies in high-precision industries. The impressive improvements in quality and efficiency serve as a compelling example for other companies facing similar particle contamination issues, demonstrating how targeted technology and thoughtful process improvements can deliver exceptional results.