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An ITW Company

Life Sciences Market
CASE STUDY

Improved Manufacturing through Contamination Control

Catheter Manufacturer

A catheter manufacturer specializing in minimally invasive medical devices for vascular and urological applications faced significant challenges due to static-induced particle contamination during manufacturing processes. Addressing these issues was essential to maintain product integrity, operational efficiency, and regulatory compliance.

Problem

Static buildup during catheter extrusion and assembly resulted in particle adhesion, compromising product quality. Elevated contamination levels posed risks of non-compliance with strict FDA, EU MDR, ISO 13485, and ISO 14644 standards, leading to high rejection rates, increased material waste, frequent cleaning cycles, operational delays, and escalating production costs. The root causes included friction-induced static charges, inadequate cleanroom airflow and filtration design, and insufficient operator training on contamination control protocols.

Solution

The company implemented a comprehensive strategy addressing static control, cleanroom optimization, operator training, and advanced cleaning techniques to effectively mitigate contamination:

- Installed comprehensive ionization systems and replaced standard tools with ESD-safe materials to control static charges.
- Redesigned cleanroom layouts and upgraded filtration to HEPA/ULPA (99.999% efficiency) for optimized airflow and cleanliness.
- Conducted extensive contamination prevention training and implemented real-time particle monitoring systems.
- Integrated advanced plasma and ultrasonic cleaning for catheter surfaces and pre-assembly components.

Results

- Achieved a 40% reduction in contamination-related defects within the first year.
- Increased production yield by 25% by significantly reducing rejections and rework.
- Successfully passed FDA and ISO 14644 audits with zero critical findings.
- Enhanced company reputation as a trusted supplier of high-quality medical devices.
- Improved operational efficiency by reducing downtime associated with cleaning and rework.

Key Takeaways

This case study highlights critical success factors, potential improvements, and broader applications to consider for enhancing contamination control and manufacturing excellence:

- Implemented advanced ionization, cleaning technologies, and proactive real-time monitoring.
- Comprehensive approach covering equipment, cleanroom environment, and enhanced operator training.
- Expanded preventive maintenance, including regular calibration of ionization equipment.
- Applicable methodologies for other precision medical devices (e.g., guidewires, implantable components).

By strategically addressing static and particle contamination with advanced technology, improved cleanroom practices, and enhanced operator protocols, [Catheter Manufacturer] successfully elevated product quality, operational efficiency, and regulatory compliance. This case study underscores the critical role of continuous improvement and integrated contamination control measures in achieving excellence in medical device manufacturing.