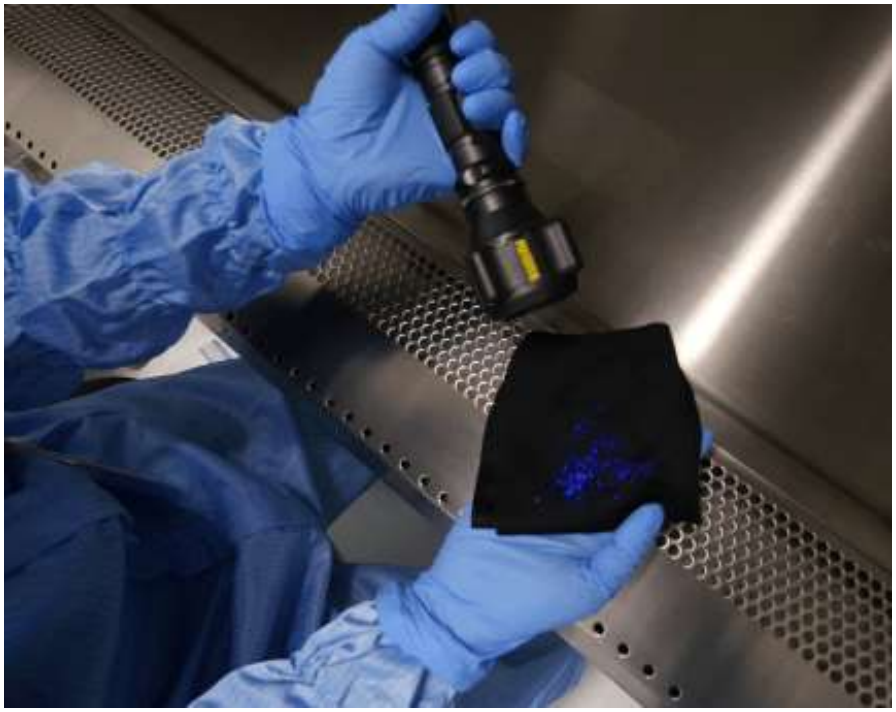
PDA Midwest Chapter

Microbial Contamination and Control Conference

May 7th & 8th

Transforming Particle Contamination Identification in Aseptic Facilities

Advanced, In-Process Solutions Beyond Traditional SEM Stubs



Foamtec International
Wilshire Contamination Control Division

Presentation by
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Introduction

Persistent Challenge of Particle Contamination in Aseptic Environments

- Particle contamination is a major cause of batch rejection, product recall, and regulatory CAPAs.
- Rapid and accurate root cause identification is essential for compliance and patient safety.
- Traditional tools like SEM stubs provide detailed data but have practical limitations.

Limitations of Traditional SEM Stub Sampling

1. Requires production interruption and cleanroom access.
2. Limited sample size and poor representation of overall environment.
3. Delays between sampling and analysis extend the investigation timeline.
4. Difficult to associate particles with specific sources or process steps.

Annex 1 and FDA Expectations

- Annex 1 (2022) emphasizes a contamination control strategy (CCS) that includes proactive risk identification.
- Facilities must demonstrate trend analysis, traceability, and rapid identification of contamination events.
- Investigations must support a quality risk management (QRM) approach.

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Advancing Identification with In-Process Sampling

Non-Disruptive Surface Sampling Paired with SEM/EDX and FTIR

- Utilizes high-efficiency wipes for broader and more representative sampling.
- Sampling is performed without interrupting aseptic operations.
- Can target critical surfaces and hard-to-access areas such as filling lines, isolators, and carts.
- Enables timely and compliant investigations aligned with Annex 1's CCS requirements.

Comparative Analysis

Traditional SEM Stub vs. In-Process Surface Sampling

Criteria	SEM Stub	In-Process Sampling
Sample Coverage	Localized (~1" stub)	Broad (entire surface area)
Production Interruption	Required	Not Required
Recovery Rate	Variable	High
Speed to Analysis	Delayed	Accelerated
Traceability to Source	Limited	Enhanced
Annex 1 Alignment	Indirect	Directly supports CCS & QRM

Major Differences

Many forensic/analytical companies offer SEM/EDX & FTIR services. These are the major differences that Foamtec has learned can be highly beneficial to identifying foreign particles in aseptic manufacturing sites.

Employing a high static attraction, black inspection wipe to sample surfaces, allowing for entire work surfaces to be sampled greatly increases sample size compared to a single SEM Stub.

We do not only collect contamination/foreign particles, we also collect cleanroom wipes, swabs, packaging, garments, tools and any other factors that may play in contaminating the cleanroom.

We compare the size of fiber contamination with potential sources of contamination.

We help identify and link the particle contamination with the source of contamination

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Case Study

Reducing Visible Particle Rejection in Aseptic Pharmaceutical Manufacturing

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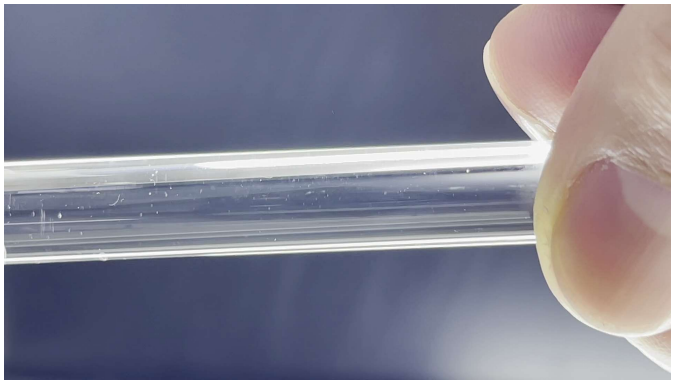

Problem Statement

An aseptic manufacturing site producing parenteral drug products experienced repeated issues with visible particles found on syringe plungers and vial stoppers. Investigations traced the source to fiber-like particles, likely introduced during routine cleanroom cleaning procedures or gowning activities.

Objectives

1. Reduce the rate of product rejection due to visible particle contamination
2. Identify and mitigate particle sources linked to routine cleaning practices
3. Maintain compliance with cGMP and Annex 1 contamination control requirements

Methods

1. **Baseline Monitoring**: Historical batch rejection data were reviewed, and high-risk particle-generating operations were identified.

2. **Contamination Source Assessment**: A structured evaluation was conducted on cleanroom-compatible materials used during daily operations, including wipes, mops, and operator garments.

3. **Controlled Intervention**: Cleaning materials were substituted with alternatives that had lower documented fiber release and improved electrostatic dissipation characteristics.

4. **Performance Tracking**: Visual inspection reject rates were monitored for three months before and three months after implementation.

Employing Scanning Electron Microscopy with Energy Dispersive X-ray Spectroscopy (SEM/EDX)

1. Provides high-resolution imaging of particles at micron and submicron scale
2. Determines elemental composition (e.g., carbon, silicon, titanium, etc.)
3. Useful for identifying inorganic particles like metals, glass, and oxides
4. Correlates morphology and chemistry to probable sources (e.g., stainless steel wear, packaging, or filtration media)

Employing Fourier Transform Infrared Spectroscopy (FTIR)

1. Identifies organic materials through molecular fingerprinting
2. Matches particle spectra to known materials in a reference library
3. Useful for identifying polymers, oils, adhesives, and fibers
4. Enables correlation to cleaning materials, gloves, or gowning items

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PolyCHECK®
Wipes or Swabs

Small
Resealable Bag

DI
Water

MiraWIPE®
Microfiber Wipes

UV
Inspection Light

Baseline Inspection

Foamtec employed the use of the following tools to create a baseline assessment:

1. PolyCHECK – Black Inspection Wipe to collect foreign particle contamination
2. Resealable Bag
3. MiraWIPE – Cleanroom Microfiber Wipe
4. DI Water
5. UV Light

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Method of Sample Collection

Step 1 – Identify area on the tool to conduct sampling.

Step 2 – Quarter fold the PolyCHECK® wipe.

Step 3 - Wipe the sampling area with your thumb slightly raised and edge of your palm on the surface. This will ensure the majority of contamination is gathered together at the center of the wipe.

Step 4 – Inspect the PolyCHECK® Wipe for the collected contamination

Step 5 – Fold the PolyCHECK® wipe over to cover the collected contamination.

Step 6 - Put the PolyCHECK® wipe into a resealable bag. Seal and label the resealable bag.

Step 7 - Wipe the sampling area over with MiraWIPE® + DI water.

Step 8 – Collect potential sources of contamination such as garments, mops, wipes, etc…

Step 9 - Ship all collected samples to Foamtec Thailand CRM lab for analysis or pass to customer if they want to analyze the sample themselves.

Important Note: The PolyCHECK® needs to be used dry when collecting defect sample. This is because Foamtec utilizes it electrostatic property to attract and capture loose fiber.

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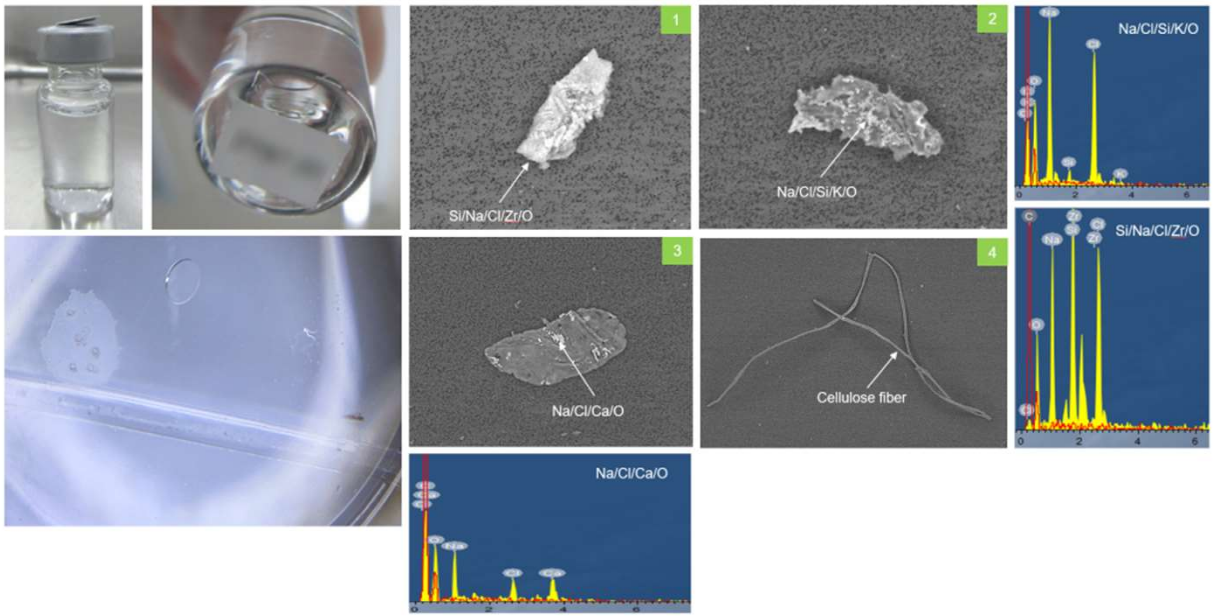
SEM/EDX & FTIR Findings

Sample: Vial Rejected for FM



SEM/EDX identified that a vial was contaminated with:

1. Si/Na/Cl/Zr/O
2. Na/Cl/Si/K/O
3. Na/Cl/Ca/O
4. Cellulose fibers.

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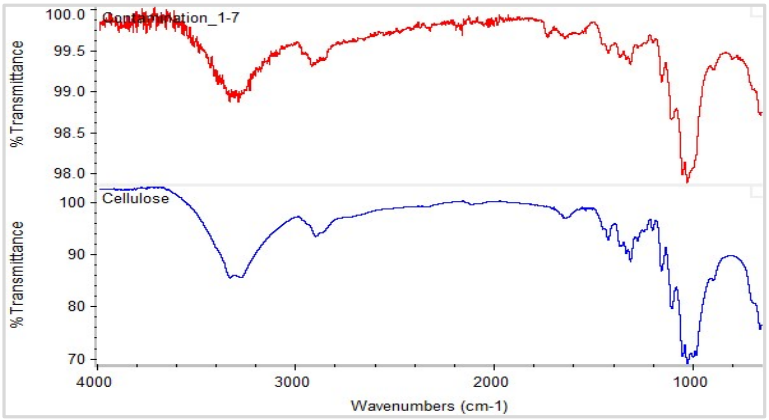
SEM/EDX & FTIR Findings



Foamtec was able to match the contamination found on the vial with the facility's cleanroom polycellulose wipes by comparing the FTIR readings and the size of the fibers using SEM/EDX.

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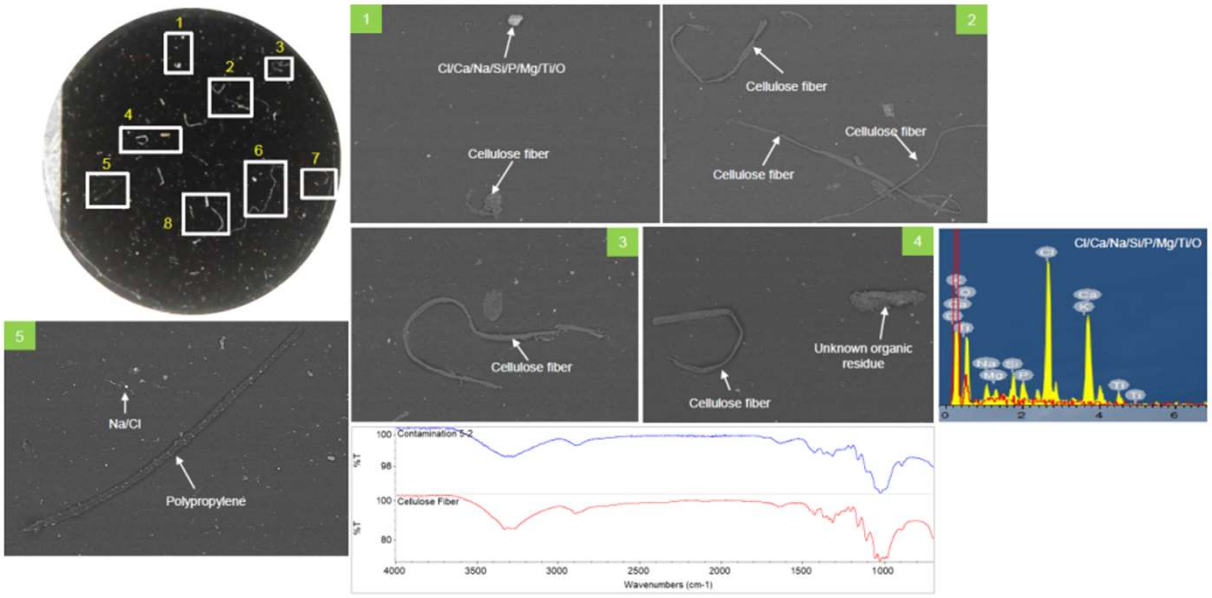
SEM/EDX & FTIR Findings

Sample 2: Laminar Flow Hood



SEM/EDX identified that the Laminar Flow Hood was contaminated with:

1. Cl/Ca/Na/Si/P/Mg/Ti/O
2. Cellulose Fibers
3. Na/Cl
4. Polypropylene
5. Unknown Organic Residue

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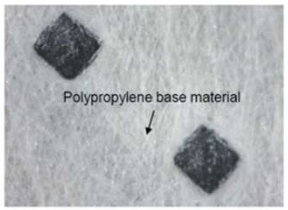
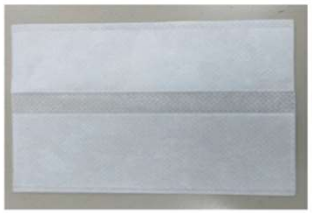
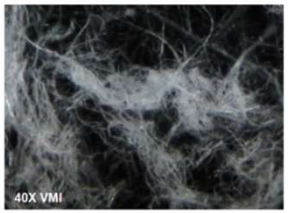
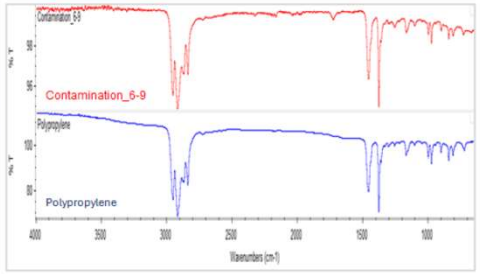
SEM/EDX & FTIR Findings

Sample 25 : TX8723 PolySat









Foamtec was able to match the contamination found in the laminar flow hood with the facility's cleanroom presaturated wipes by comparing the FTIR readings and the size of the fibers using SEM/EDX.

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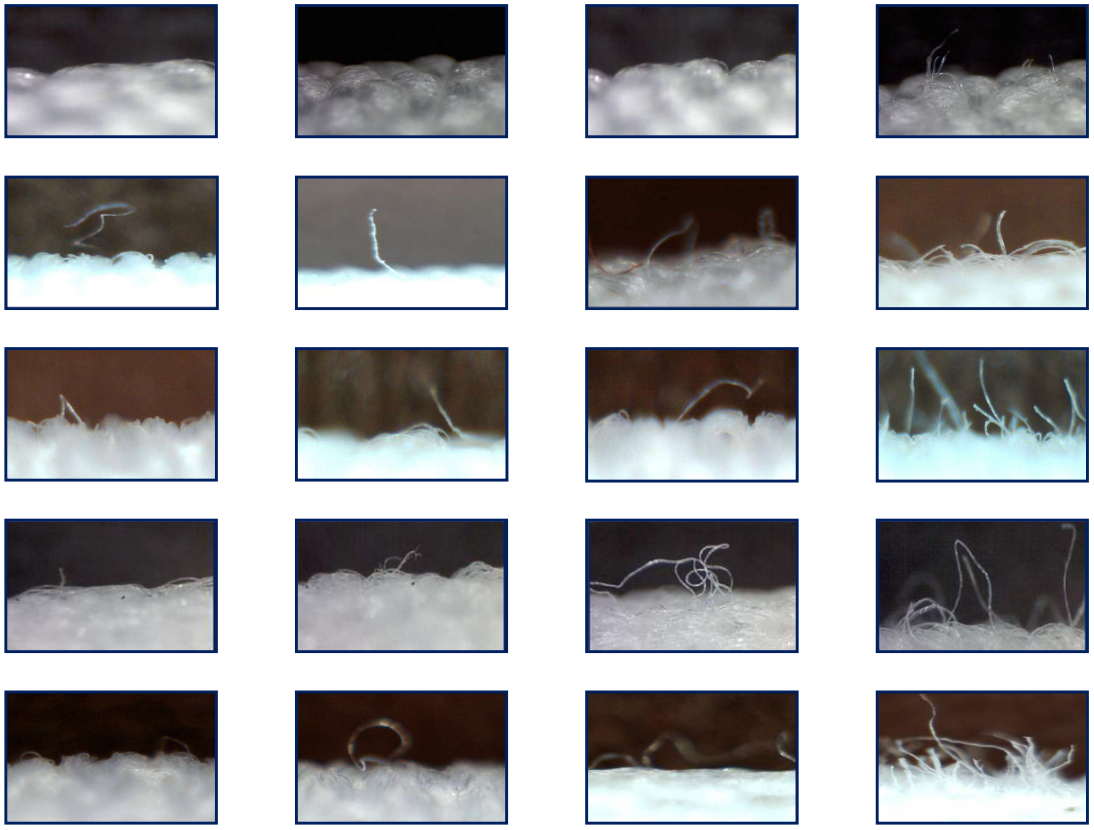
Inspected Each Wipe After Wiping Different Surfaces



Results

We worked closely together with pharmaceutical manufacture partnered with the distributor to understand the different materials that were qualified, validated, and approved.

Goal: find a cleanroom wiper that performed the best in cleaning critical surfaces, based off the surface contamination acceptable and reduce the contamination making its way to the final product.

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Discussion

This case highlights the critical role of particle control in sterile production. While cleaning tools are often considered cleanroom compatible, not all are optimized for fiber shedding or surface attraction properties. By taking a risk-based approach to evaluating cleaning supplies and implementing materials that minimize fiber release and maximize surface pickup, facilities can significantly reduce visible particle contamination risk.

Conclusion

Proactive evaluation and optimization of cleaning materials can yield measurable improvements in product quality and compliance. This case demonstrates that contamination control enhancements, even at the material level, can have significant operational impact—especially in facilities focused on injectable or ophthalmic drug products where visual clarity is paramount.

Validation and Implementation Considerations

- Evaluate wipe material compatibility and validation for particle recovery efficiency.
- Establish standard operating procedures (SOPs) for aseptic technique and traceability.
- Integrate with existing deviation and environmental monitoring programs.
- Confirm analytical accuracy through method validation per QRM principles.

Final Conclusion

Supporting Faster, More Accurate Contamination Investigations

- In-process methods enhance contamination visibility and reduce investigative lag.
- Align with Annex 1 by supporting proactive, risk-based contamination control.
- Contribute to robust CCS frameworks and faster CAPA closure.

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How can I help?

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