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Optimizing contamination control

By minimizing the risks posed by contaminants, pharma manufacturers can prevent costly delays, product recalls and potential harm to patients

Drugmakers face stringent regulations to ensure that products remain free from contaminants that could compromise safety and efficacy.

Effective contamination control requires meticulous monitoring of environmental conditions, rigorous testing of products, and implementation of robust cleaning and sterilization procedures.

To better understand these challenges, Pharma Manufacturing spoke with Emily Alkandry, analytical services and quality control manager and Gabrielle Wilson, sterility assurance program manager at Saint-Gobain Life Sciences about the importance of comprehensive contamination control strategies for ensuring product quality and regulatory compliance.

What types of contamination can be present in a pharma manufacturing facility, and what risks does this pose?

Emily Alkandry: Contamination in a pharma manufacturing process using single-use technology falls into three categories: particulate, microbiological and chemical contamination. The risk level is tied to contamination characterization and detection ability. Inability to prevent and detect contamination early can jeopardize product quality, patient safety and regulatory compliance.

Particulate contamination is defined as any unintentionally present loose or embedded matter on a single-use component or assembly that may end up in the process fluid. Loose extrinsic particulate poses the highest risk and is the most difficult to characterize, while intrinsic particulate is comparatively lower risk.

Microbiological contamination includes bioburden and endotoxin contamination. High or uncontrolled bioburden levels can threaten the ability to sterilize single-use samples under appropriate conditions, and endotoxin contamination can lead to discarded products.

Chemical contamination requires consideration of material construction and its contribution to the extractables profile of the single-use system. Material selection is crucial, as trace amounts of extracted compounds can alter a drug's efficacy or be unsuitable for the application.

What is a contamination control strategy and why has it become increasingly important in pharma manufacturing environments?

Gabrielle Wilson: A contamination control strategy (CCS) is a collection of procedures, measures and risk assessments designed to identify, control, monitor and minimize the risk of contamination at a pharma manufacturing site. This includes microbial contamination, endotoxins and particulates.

A CCS calls out critical points in the manufacturing process and details what measures are in place to mitigate contamination risks. It is usually developed by a cross-functional team with detailed technical and process knowledge and is continuously reviewed and updated.

The importance of CCS has risen due to new guidelines in Annex 1 of the EU GMP guideline, which emphasizes a holistic, risk-based approach to contamination control and requires a CCS at each pharma manufacturing facility. Even small levels of contamination can pose significant risks to patients, making a robust CCS essential for patient health and treatment efficacy. Noncompliance can lead to costly delays, product recalls and damage to a company's reputation.

What are some of the key elements to be considered within a CCS?

GW: At Saint-Gobain Life Sciences, we recognize the criticality of a strong CCS. Our expertise extends beyond providing high-quality, low-contamination materials and assemblies. We collaborate with our partners to develop tailored strategies for their specific products and processes.

Key elements of a CCS include:

- Facility design: How the facility, equipment, processes and utilities are designed with contamination in mind, supported by validation documentation
- Raw materials handling: How the site handles raw materials and the approval process for key components and single-use system suppliers
- Personnel training: Training and qualification of personnel in gowning, aseptic techniques and cleanroom best behaviors
- Monitoring systems: Environmental monitoring, product testing and all the different monitoring systems at the site
- Risk management: Risk management processes, quality system elements like Corrective and Preventive Actions (CAPAs), trend analysis and investigations

> **Even small levels of contamination can pose significant risks to patients, making a robust contamination control strategy essential for patient health and treatment efficacy.**
>
> — **Gabrielle Wilson**

How is Saint-Gobain Life Sciences supporting their pharma partners in compliance with the new Annex 1 guidelines?

EA: Saint-Gobain Life Sciences is committed to helping our pharma partners navigate these new requirements through several initiatives:

Product design and facilities: Our facilities are designed with Annex 1 in mind. We offer single-use components and assemblies made from materials with low-risk extractables profiles, minimizing contamination risks. Our material science knowledge and chemical compatibility guidance help customers make informed decisions about material selection.

Pre-sterilized assemblies: We offer pre-sterilized assemblies to reduce the need for in-house sterilization, a critical control point for microbial contamination.

Custom solutions: We work closely with customers to design and manufacture custom single-use solutions that meet their specific process needs and risk profiles. Customers can leverage our product knowledge and risk assessments for assemblies with representative product sub-visible particulate or bacterial endotoxin claims or use our ISO 17025 accredited test laboratory for lot release testing.

Quality control: Our manufacturing processes adhere to strict quality control standards, including robust cleaning and sterilization procedures, advanced barrier packaging for stability during storage and transportation, and rigorous quality checks at every stage.

GW: We don't just react to industry changes; we anticipate them. We're constantly evaluating and improving our product materials, designs, manufacturing processes and services to align with the most stringent standards, including the updated Annex 1 guidelines.

Saint-Gobain manufactures several materials designed to minimize contamination. For example:

- C-Flex tubing: Engineered for low particulate shedding, maintaining cleanliness in the pharma manufacturing environment
- Sani-Tech platinum-cured silicone tubing: Minimizes the risk of extractables, protecting the fluid inside
- PureFlo filtration products: Incorporate membranes that are absolute rated for efficient reduction of bioburden and particulates; These high-throughput filters maximize process efficiency and mitigate contamination risk from underperforming filters
- Sterilizing grade filters: Rated for bacterial retention, these filters remove contaminants from both liquids and gases in the single-use process.

Our pre-sterilized single-use custom assemblies use secure leak-free connections, such as our patented overmolding technology or BarbLock technology for a 360° compression fit.

Our deep understanding of contamination risks and regulatory requirements allows us to guide customers in custom single-use design, selecting appropriate materials and technology for their applications.

What approach has Saint-Gobain Life Sciences developed for cleanroom environmental control?

EA: Saint-Gobain Life Sciences has developed a comprehensive approach to cleanroom environmental control based on controlling individual influential systems to microbial endotoxin and particulate levels. Procedures are in place globally and harmonized at each manufacturing location to reduce and control contamination.

Our contamination control strategy focuses on having all contamination controls, validation and monitoring documented in one governance document. This program explains how all individual elements work together to form a holistic contamination control paproach.

Having a documented contamination control strategy allows us to share something tangible with our pharma customers as part of their vendor approval process requirements as laid out in Annex 1.