SARTORIUS

Listicle

Keywords:
Microbiology, Biopharamaceuticals, Bioprocess, Microsart® @filter, Microsart® @media, qPCR, ATMP, Quality Control Release Testing

Master the Five Strategies of Microbial Safety to Safeguard Your Biopharma Pipeline

Introduction

Ensuring patient safety begins in the early stages of therapeutic drug development and extends through the production of clinical-grade materials. Cell-based bioprocesses are particularly vulnerable to contamination, making stringent microbial control critical for success from research and development through clinical phases.

During this transition, it is crucial to employ well-characterized, qualified test methods, validated from clinical phase 3, to ensure that cell cultures, product intermediates, raw materials, and reagents are contamination-free. Maintaining sterility is vital for human clinical trials, supporting patient safety, regulatory compliance, and ethical responsibility.

An effective contamination control strategy starts with identifying potential sources, such as materials and supplements used in media preparation, environmental factors like cleanroom air, and lab tools and equipment involved in the cell culture process. Implementing reliable and well-validated test methods is essential to verify that cell cultures, intermediates, raw materials, and reagents remain free from contamination.

Establishing strong microbial control practices early on is key! Here are five essential strategies to protect your biopharma pipeline against microbial threats.

1. Monitor Your Cell Culture with Rapid Testing for Microbial Contamination

Undetected microbial contamination poses a significant challenge in cell cultures, leading to inconsistent results and wasted resources. Mycoplasma, for example, can inhibit protein biosynthesis, cell growth, and alter RNA and DNA synthesis, affecting data reproducibility.

Regular testing for microbial contamination is a critical part of Good Cell and Tissue Culture Practice. In clinical settings, streamlined testing workflows are vital to reduce costs and speed up time to results.

The Microsart® ATMP Sterile Release Kit and Microsart® Mycoplasma qPCR Kits address these needs with a rapid, real-time PCR-based test method that produces results in just 3 hours, compared to traditional methods that can take 14 to 28 days. These kits comply with standards for advanced therapy medicinal products (ATMPs).

Download Flyer: Mycoplasma Assays for PCR

Download Flyer: Microsart® ATMP Sterile Release

Learn More: Microsart® Mycoplasma qPCR Kits

2. Prevent Mycoplasma Contamination with Sterile Filtration Consumables

Mycoplasma contamination is a persistent issue in cell culture due to the tiny size of these microorganisms, which can slip through standard filters. While autoclaving is effective, it's not suitable for certain media and reagents as the heat can degrade essential nutrients and growth factors.

Using a 0.1 µm pore size filter, instead of the standard 0.22 µm, is the best way to prevent contamination, particularly for media prepared from powder. However, this process can be slow and inefficient, especially when filtering multiple samples at once. Researchers often face delays due to slow flow rates and protein loss from suboptimal membrane properties.

Sartolab® RF Vacuum Filtration Units with a 0.1-µm PES membrane solve these challenges with a large filtration area for higher flow rates, saving time. The low-protein affinity membrane and support minimize sample loss, and the Sartolab® Multistation allows parallel filtration of up to six samples for more throughput. Importantly, use pipettes that are easy to clean and fitted with the right sterile filter tips.

Explore More: Tacta® Mechanical Pipettes

Application Note: How to Avoid Contamination in Pipetting

Explore More: Vaccum Filtration Units

Application Note: Mycoplasma Retention with Sartolab® RF Vacuum Filtration Units in Pipetting

3. Ensure Cell Culture Media and Product Candidates are Contamination-Free

Microbial enumeration testing is vital to maintain the safety and quality of cell culture media used in biopharmaceutical research and development. This testing quantifies viable microorganisms to confirm that the media is free from harmful levels of contamination. However, traditional transfer methods can introduce secondary contamination when the membrane filter encounters non-sterile surfaces or is mishandled, leading to false positives.

Microsart® @filter and Microsart® @media tackle contamination risks with touch-free membrane transfer, eliminating the need for forceps. These ready-to-use, sterile filtration units and pre-filled media feature a patented design for precise filter placement onto agar plates, preventing contamination and false positives.

Datasheet: Microsart® @Filters: Sterile Single-Use Filtration Units Featuring a Click-Fit Closure

Datasheet: Microsart® @media Advanced System for Touch-free Membrane Transfer

Learn More: Microsart® Mycoplasma qPCR kits

4. Test the Air of Cleanrooms and Controlled (c)GMP Environments

Airborne contaminants are a common source of contamination in cell-based bioprocesses. As products transition from research discovery to clinical phases 2-3, full (c)GMP compliance is mandated, including environmental monitoring of cleanrooms and controlled areas.

Air monitoring is performed through a combination of active and passive sampling techniques. Air is filtered/sampled through a membrane that captures microorganisms for culturing and enumeration of colony-forming units (CFUs) per unit of air. For accurate measurement, it is crucial that the membrane inside the device does not dry out to preserve the microbes.

The MD8 Airscan® addresses this challenge with unique agar-free gelatin membrane filters that do not dry out during long-term active sampling of up to 8 hours. The proprietary, USP-approved filter retains even the smallest airborne microorganisms and viruses and monitors viability at the most accurate level.

Explore More: Air Monitoring

Webinar: Annex I Impacts on Microbial Air Monitoring

5. Perform Sterility Testing to Safeguard Quality and Patient Safety

Sterility is crucial for clinical trial products to ensure participant safety and valid results. Technologies designed for barrier environments like cleanrooms and isolators need enhanced integration for improved user experience and accurate data documentation.

The Sterisart® Universal | Gen 4 pump and consumables minimize risks during batch release testing by ensuring precise, contamination-free transfer of samples and reagents into Sterisart® canisters for sterility testing. The pump is compatible with most sterility testing canisters and features advanced electronic reporting software compliant with 21 CFR Part 11.

Explore More: Sterility Testing

Webinar: Solutions for Sterile Sample Extraction & Rapid Release Sterility Testing Video

Summary

During the early stages of drug development, microbial safety testing focuses on screening raw materials, cell cultures, and initial formulations for contamination. As the product advances, testing of clinical supply materials becomes crucial, involving regular sampling and testing at various stages to detect and control contamination early, ensuring patient safety and enhancing the overall drug development process. Sartorius supports microbial safety at all stages of biopharma product development with reliable, reproducible, and accurate testing methods.

Discover More

References

1. Pamies, D. (2022) "Guidance document on Good Cell and Tissue Culture Practice 2.0 (GCCP 2.0)", A*LTEX - Alternatives to animal experimentation,* 39(1), pp. 30–70. doi: 10.14573/altex.2111011.
2. Roche KL, Levy RV. *Methods used to validate microporous membranes for the removal of Mycoplasma*. Biopharm 1992:22-33.

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Straße 20
37079 Göttingen
Phone +49 551 308 0

USA
Sartorius Corporation
3874 Research Park Drive
Ann Arbor, MI 48108
Phone +1 734 769 1600

Find Out More: www.sartorius.com

CLD-Biologics-Mibi-Contamination-Listicle-en-Sartorius
Status: 03 | 2026