charles river

Customized Solutions for Your Cleanroom Facility

As a manufacturer, ask yourself:

Are the products we're producing *really* safe?

How "clean" is my cleanroom?

Is it in compliance with GMP regulations?

Regulators require manufacturers to maintain GMP compliance when producing products in a cleanroom facility. Partnering with Microbial Solutions gives you the confidence and ability to ensure your cleanroom is compliant and free of contamination, enabling you to manufacture safe and effective products.

Through Every Step of Validation

Design Qualification
Prove that the design is fit for its intended use.

Installation Qualification
Confirm through verification that installed equipment fulfills user and design requirements.

Operational Qualification
Demonstrate the cleanroom operates in line with design requirements and user-defined requirements while consistently operating within a defined range of conditions.

Performance Qualification
Show that the cleanroom consistently operates within defined parameters to produce the defined, desired environmental outcome.

Monitor & Control
Implement an Environmental Monitoring program to maintain a state-of-control, reduce risks, and ensure products are free of contamination.

Revalidation
Every 6-12 months, depending on Cleanroom Grade.

Microbial Solutions

	Design Qualification	Installation Qualification	Operational Qualification	Performance Qualification	Monitor & Control
Environmental	Identify microflora present in your facility through surface/air sample testing and identify recovered organisms using Accugenix® microbial identification (ID) services.			Ensure cleaning agents and processes can remove identified organisms.	Trend current recoveries and track microbial IDs utilizing Accugenix® Tracking & Trending (T&T) feature.
Water System	Determine endotoxin and bioburden levels of incoming water using Endosafe® Endotoxin Testing and Celsis® Rapid Microbial Methods (RMMs).	Install filtration and distillation systems that can remove incoming bioburden and endotoxin loads.	Verify water generated has endotoxin and bioburden at or below desired levels.	Challenge the system with multiple tests to ensure performance.	Routinely monitor for changes to baseline endotoxin levels. Use Accugenix® T&T tool to determine source and root cause of microbial contamination.
Product Contact Equipment	Ensure proper installation with quick bioburden results using Celsis® RMMs.			Complete system qualification with expedited incubation times.	Identify and respond to contamination events in a third of the time as with traditional testing by utilizing Celsis® RMMs and ensure accurate IDs of any positives with Accugenix® microbial ID services.

Accugenix® Microbial Identification

- Environmental monitoring support
- Accurate identifications utilizing DNA sequencing and MALDI-TOF technologies
- Validated, industry-relevant libraries with 12,000+ species
- Tracking and trending data management tools

Celsis® Rapid Microbial Detection

- Automated, instrument-based analysis
- Objective results
- Sterility results in six days
- Bioburden in 24 hours

Endosafe® Endotoxin Testing

- Simplified, 15-minute quantitative LAL testing
- Software powered by GMP and data integrity compliance standards
- Investigation and human error reduction through lab automation