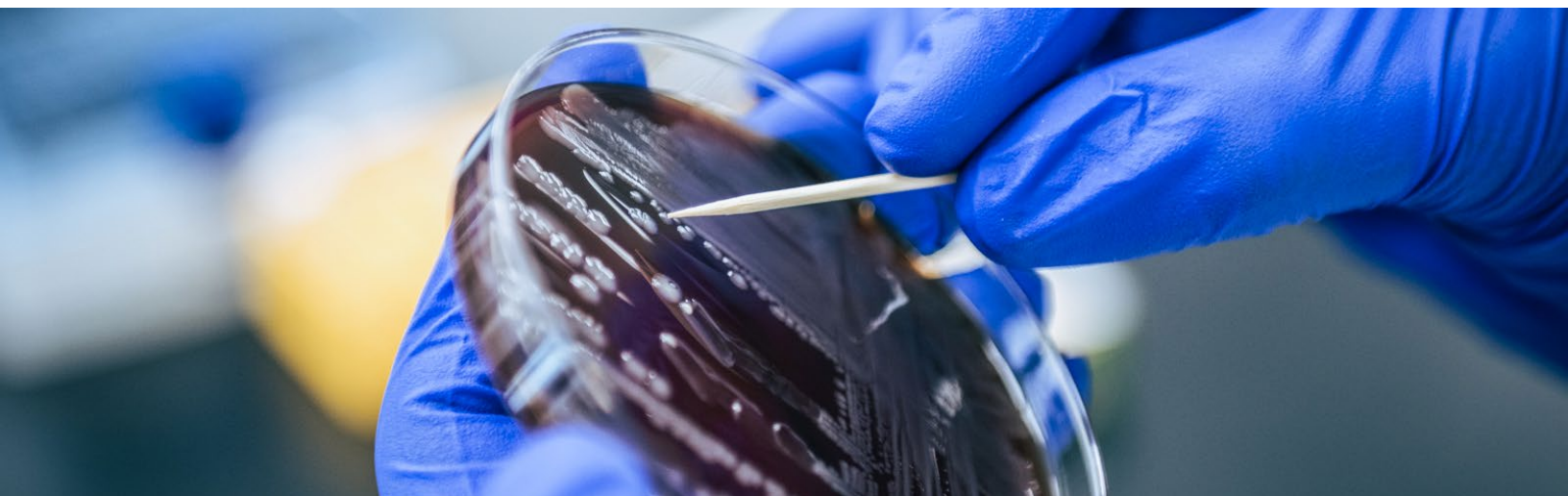




OVERCOME MICROBIOLOGICAL TESTING CHALLENGES AND ENSURE REGULATORY COMPLIANCE

Microbial contamination risks, environmental monitoring, and demanding regulatory requirements can disrupt even the most well-designed pharmaceutical and healthcare environments. When patient safety is non-negotiable and production continuity depends on maintaining controlled environments, you need a scientific partner who transforms compliance burdens into manageable processes. Element's experts work alongside your team, delivering reliable microbiology and environmental monitoring services that ensure regulatory compliance while flexibly scaling with your operational needs. Partner with our Acton team to focus on your innovative therapies while we provide the specialized testing that helps identify risks, protect your controlled environments, and maintain manufacturing continuity.

STREAMLINE ENVIRONMENTAL MONITORING AND ELIMINATE QUALITY RISKS

PARTNER WITH ELEMENT ACTON TO:

- Identify and mitigate microbial contamination risks that threaten product safety and manufacturing continuity
- Meet rigorous environmental monitoring requirements with comprehensive protocols
- Maintain consistent environmental control with reliable, compliant testing
- Address regulatory expectations with precise, well-documented testing services

GMP-COMPLIANT, ISO 17025 ACCREDITED TESTING THROUGHOUT YOUR PRODUCTION LIFECYCLE

Safeguard your manufacturing environments and processes with specialized microbiological testing designed to identify risks before they compromise product quality. Our expert laboratory services help you maintain control over critical environmental factors from facility validation through ongoing production:

- Environmental Monitoring (EM)
- Microbiology Testing
- Disinfectant Efficacy Studies
- Cleanroom Validation and Certification



FACILITY QUALIFICATION

- Establish environmental baseline testing, pre-cleaning and post-cleaning
- EMPQ
- Certify ISO classification

PROCESS VALIDATION

- Build submission-ready safety documentation
- Document aseptic processing conditions
- Meet stringent regulatory timelines

ROUTINE MONITORING

- Ensure consistent environmental quality
- Perform testing to support ongoing maintenance



COMPREHENSIVE ENVIRONMENTAL AND MICROBIOLOGICAL SOLUTIONS

Our Acton laboratory is FDA-registered and inspected, ISO 17025 accredited, and DEA licensed, providing specialized testing services:

ENVIRONMENTAL MONITORING (EM)

- **Complete EM Services** - EMPQ to routine monitoring
- **Water System Sampling and Analysis** - Critical utility qualification
- **Gowning Qualifications** - Personnel, media fill, and product fill qualification
- **Viable Surface, Air, and Non-viable Particle Testing** - Comprehensive cleanroom monitoring
- **Compressed Gas Sampling and Testing** - Specialized utility qualification
- **Media Incubation** - Support for in-house monitoring programs

CLEANROOM CERTIFICATION AND VALIDATION

- USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments
- USP <797> Pharmaceutical Compounding – Sterile Preparations
- ISO 14644-1 Classification of Air Cleanliness Certifications
- Cleanroom Certification, EMPQ

MICROBIOLOGY

- USP <85> Endotoxin – Gel-Clot, Turbidimetric/Chromogenic Techniques
- USP <51> AET
- USP <112> Water Activity
- USP <800> Hazardous Drugs - Handling Healthcare Settings
- USP <71> Sterility
- USP <61> Bacterial Enumeration
- USP <55> Biological Indicators
- ANSI/AAMI/ISO 11137 Sterility Tests
- Water Bioburden
- USP <62> Specified Organisms
- USP <1231> Water activity determination for nonsterile pharmaceutical products
- Microbial ID by MALDI-TOF
- USP <62> Specified Organisms (*Burkholderia cepacia* complex)

DISINFECTANT EFFICACY (DE) STUDIES

- Typical Challenge Organisms Including:
 - BACTERIA: *S. aureus*, *S. enterica*, *P. aeruginosa*, *E. coli*, *B. subtilis*, other in-house isolates
 - FUNGI: *A. brasiliensis*, *C. albicans*, client specific in-house isolates
- Disinfectant Studies Using Bacteria and Fungi Challenge Organisms
- Custom Studies
- USP <1072> Disinfectant Challenge Testing

READY TO ENSURE MICROBIOLOGICAL CONTROL AND REGULATORY COMPLIANCE?

Discover how Element Acton's comprehensive environmental monitoring and microbiology expertise can help ensure the safety and quality of your controlled environments. Our experienced scientists are ready to discuss your specific contamination control and testing requirements.

Click or scan the QR code to learn more.

