



# OVERCOME COMPLEX ANALYTICAL CHALLENGES AND ENHANCE PRODUCT QUALITY

Regulatory complexities, microbial contamination risks, and quality control challenges can compromise even the most promising pharmaceutical programs. When product safety is critical and undetected contaminants threaten manufacturing continuity, you need a scientific partner who transforms these risks into manageable processes. Element's experts work alongside your team, delivering reliable microbiological and analytical testing that ensures regulatory compliance while flexibly scaling with your pharmaceutical program requirements. Partner with our Concord team to focus on your innovative therapies while we provide the specialized testing that helps identify risks, protect your products, and accelerate patient access.

## COMPREHENSIVE TESTING TO PROTECT PRODUCT INTEGRITY

Partner with Element Concord to:

- Identify and address microbiological contamination risks that threaten product safety and manufacturing continuity
- Comply with environmental monitoring requirements through individualized protocols
- Product safety with reliable USP-compliant testing
- Save valuable time with our local sample pick-up service

## ISO 17025 ACCREDITED AND GMP-COMPLIANT TESTING ACROSS YOUR PRODUCT LIFECYCLE

Safeguard your manufacturing processes and finished products with specialized microbiological and analytical testing designed to identify risks before they become problems. Our expert testing services help you maintain control over critical quality factors from raw materials through final product release:

- Microbiology Testing
- Environmental Monitoring
- Virology & Molecular Services



### EARLY DEVELOPMENT

- Accelerate research with robust microbiological screening
- Make data-driven contamination prevention decisions
- Establish environmental monitoring baselines

### CLINICAL & REGULATORY

- Build submission-ready safety documentation
- Navigate complex USP/EP regulatory requirements
- Meet strict regulatory timelines

### COMMERCIAL

- Ensure consistent product safety and quality
- Support continuous process improvements
- Maintain ongoing compliance

## COMPREHENSIVE MICROBIOLOGICAL AND ANALYTICAL SOLUTIONS

Our Concord laboratory is US FDA registered and inspected, ISO 17025, DEA licensed, providing specialized testing services:

### MICROBIOLOGY

- **Microbiology Testing to Compendial Methods** - Ensuring product safety with validated analyses
- **Bioburden & Endotoxin Detection** - Comprehensive contamination screening
- **Sterility Testing** - Verification of aseptic processes
- **Rapid Sterility Testing (BacT/ALERT®)** - Accelerated results for time-sensitive applications
- **Water Bioburden Analysis** - Critical utility testing for manufacturing
- **Bacteria/Mold Identification** - Species-level characterization of contaminants
- **Custom Studies** - Tailored protocols for unique challenges
- **Disinfectant Efficacy Studies** - Demonstrate effective microbial (bacteria, fungi, and virus) control for compliant cleanroom use

### ENVIRONMENTAL MONITORING (EM)

- **Complete EM Services** - Routine and performance qualification (PQ)
- **Viable Surface, Air, and Non-viable Particle Testing** - Comprehensive cleanroom monitoring
- **Water Sampling and Analysis** - Critical utility verification
- **Compressed Gas Sampling and Testing** - Specialized utility qualification
- **Media / Fill Product Support** - Personnel, media fill, and product fill verification
- **Media Incubation** - Support for in-house monitoring programs

### VIROLOGY AND MOLECULAR SERVICES

- **Virology Assays** - Customized virology assays
- **Biological Reactivity USP <87>** - Safety assessment
- **Cytotoxicity Assays** - Cell-based safety testing
- **Residual Host Cell Protein & DNA Detection** - Critical impurity analysis
- **Residual RNase, DNase, Protease Activity** - Process impurity verification
- **Bulk Harvest Lot Release Testing** - Batch verification
- **Mycoplasma Testing for Cell Culture Products** - Contamination screening
  - Rapid PCR - MycoSEQ
  - USP <63>/EP 2.6.7 compendial culture methods

### ANALYTICAL CHEMISTRY

- **USP Monograph Testing** - Comprehensive analysis of compressed gases and raw materials
- **Chemical Water Testing** - Utility verification
- **USP <643>, <645>, <1231>, EP Nitrates, Water Coliform Studies**
- **Particulate Matter Testing (USP <787>, <788>, <789>)** -
- **USP <921>, <785>, <733>, <731>, <841>** - Compendial method compliance



## HOW CAN ADVANCED MICROBIOLOGY AND ANALYTICAL TESTING PROTECT YOUR PRODUCTS?

Discover how Element Concord's specialized microbiology, virology, and analytical chemistry expertise can help ensure the safety and quality of your pharmaceutical products. Our experienced scientists are ready to discuss your specific testing needs.

Click or scan the QR code to learn more.

