

## Cleanroom capabilities and expertise

Cambrex is **the** small molecule company that provides drug substance, drug product and analytical services across the entire drug lifecycle. Enjoy working with our experts to accelerate your small molecule therapeutics into the market.

With over 35 years' experience and a growing team of over 2,000 experts servicing our global clients from our sites in North America and Europe, we are tried and trusted in branded and generic markets for API and dosage form development and manufacturing.

### Cleanroom services Quality assured

Cambrex is the industry leader to test, validate and monitor your controlled environment.

#### All-inclusive support includes:

- Risk assessments, site specific and routine environmental monitoring programs
- Provide trained staff to supplement your existing environmental monitoring program during start-ups or qualification activities
- Plate analysis-only program delivers quality control-tested media for your use, which can be returned for incubation and analysis

**Marisel Dimov**  
Analytical Chemist II



### ISO 14644-2:2015 risk assessment

Cambrex experts will work with your team in a systematic manner to identify hazards and evaluate the risks associated with maintaining the microbial state of control within your facility.

Current regulations require a risk-based EM plan for:

- Faster response to adverse conditions and events
- Ability to develop more impactful data trends
- Data integration from multiple sources
- Enhanced knowledge of system processes
- Improved control of operational costs and product losses

Our risk assessments offer a roadmap to compliance:

- On-site cross-functional facility evaluation
- Gemba
- Cause and effect analysis
- Process flow analysis and generation of sampling plans
- FMEA based risk assessment tool

## Cleanroom qualification support

Cambrex's cGMP-trained analysts provide full technical oversight for cleanroom qualification and certification – from start to finish – including:

- ISO 14644-1 cleanroom certification by particle concentration
- Laminar flow hood certification to manufacturer specification and certified to ISO 5 per request
- Biological safety cabinet certification to manufacturer and/or NSF specifications
- Isolator/glovebox certification
- Chemical fume hood performance verification

Industry standard cleanroom qualification services to include:

- HEPA filter integrity testing
- Room pressurization measurements
- Airflow volume/velocity profiling
- Calculated room air exchange rates
- Airflow visualization studies
- Airflow pattern studies (smoke study)
- Room recovery studies
- Temperature and humidity monitoring
- Maximum occupancy studies
- Other cleanroom tests as per IEST, NEBB, or ISO

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## Routine environmental monitoring

We offer full support for your routine environmental monitoring needs. Our experts will work with you to define your program from frequency and duration of testing to specific methods and sampling plans.

- Active viable air monitoring
- Passive air monitoring
- Viable surface monitoring
- Anaerobic monitoring
- Absence of specified microorganisms
- Total air particulate monitoring
- Specific incubation conditions
- Gloved finger-tip analysis
- Personnel monitoring & support
- In-process monitoring
- Temperature and humidity monitoring
- Pressure differential monitoring
- Water sample collection for laboratory analysis
- Data analysis and trending services
- Incubation, analysis and reporting
- Isolate characterization and identification
- USP <797> specific incubation conditions
- USP <797> gloved finger-tip analysis

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## Compressed gas monitoring

Cambrex's range of compressed gas monitoring can support your organization's compliance with GMP regulations on cleanroom qualification. Our experienced cleanroom certification service experts can assist with establishing the correct testing program and parameters based on your needs.

Testing capabilities include:

- Viable air monitoring (aerobic and anaerobic)
- Particulate monitoring
- Dräger analysis for moisture, hydrocarbons, carbon monoxide (other indicators may be available upon request)
- Dew point analysis
- USP nitrogen identity testing (flame and odor test)
- USP nitrogen content (GC analysis)
- USP oxygen content (GC analysis)

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## Microbial identification

Cambrex provides expert, compliant microbial testing and identification of bacteria, fungi and yeasts. With decades of experience, our state-of-the-art micro ID lab contains:

- Two 16 capillary Microseq™ genetic analyzers
- Vitek® MS (matrix assisted laser desorption ionization time-of-flight mass spectrometer):
  - Allows for robust microbial ID analyses and increased throughput