



BIOSCENSION

Laboratory Services

YOUR BIOSCIENCE PARTNER

Bioscension Laboratory Services is a state-of-the-art bioscience lab, focused on supporting advanced, emerging medical device companies with high-quality testing, monitoring, and consulting services.



Testing



Monitoring



Consulting



Demand for lab services is growing rapidly, due to demographics, heightened regulatory requirements, and increasing R&D spend and innovation. One of the consequences has been pent up demand, increasing prices, and long wait times.

Our specialized bioscience offering is designed to help you quickly get the results you need to support your core business processes.

Testing

Bioscension offers all the testing services needed for an FDA 510(k) clearance.

Bioburden:

- Bioburden testing (Enumeration/estimation)
- Sterility testing (Absence/presence)
- Microbiological monitoring activities (surface, equipment or environment testing)
- Fourier Transform Infrared Spectroscopy (FTIR)
- Gas Chromatography/Mass Spectrometry (GC/MS) testing
- Gram/spore staining

Cleaning Validation:

- Protein
- Hemoglobin
- Total Organic Carbon



Monitoring

Bioscension offers testing and monitoring services to ensure your facility meets important quality control standards.

- Water monitoring (LAL testing)
- Environmental monitoring (cleanroom setup)

Consulting

Bioscension staff can support your FDA – 510(k) – clearance process.

- Data analysis
- FDA/responses/interaction
- Test development
- 510(k) process
- Methods to extract bioburden



Quality

Bioscension Laboratory Services' advanced quality control system assures you of test accuracy and high-quality results. Bioscension has state of the art certifications including ISO 17025 and ISO 11737.

Bioscension Laboratory Services has a highly advanced quality system and has developed extensive material analysis and sample handling procedures.