

### TOXIKON AT A GLANCE

#### Services

DEVICES



BIOTECH



PHARMA



CUSTOM



#### Capabilities

- Bioburden
- Endotoxin
- Sterility
- Package integrity
- Shelf life / Life cycle
- Microbial identification
- Compendia testing
- Antimicrobial challenge
- Cleaning validation
- Customized microbial assessments

#### Locations:

##### Corporate Headquarters

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Toxikon's Microbiology Department effectively collaborates with clients to develop customized study protocols that meet your specific requirements. Our staff of experienced microbiologists apply their technical expertise when conducting each study to generate timely, quality data to fit your program's requirements.

Our services include, but are not limited to routine lot release programs, bioburden determination, endotoxin evaluation, and sterility testing. Additionally, we provide non-routine studies, including reusable device processing (cleaning, disinfection, and sterilization), validations, microbial or viral ingress assessments, antimicrobial efficacy, as well as packaging, product shelf life and life cycle validations.

The diverse scientific capabilities within the department are leveraged appropriately to address each unique product requirement. With the emergence of complex devices, such as combination products, our team has become recognized by the industry as a valuable resource in developing early stage screening studies to final product verification and validation studies. Our experience and direct interaction with regulatory agencies have provided Toxikon a unique understanding of product development and regulatory needs. With our vast knowledge of ASTM, AAMI, FDA, ICH, ISO, JP, and USP, we work with you to navigate the regulatory landscape to achieve your development goals.



# Microbiology Overview

## Services at a Glance

Toxikon is an ISO/IEC 17025-accredited Contract Research Organization (CRO) registered with the FDA for drug, biologic, and medical device testing. With approximately 200 employees, Toxikon is committed to staying at the forefront of life science product development. Toxikon's safety services include toxicology (acute, subchronic, and chronic toxicity, reproductive toxicity, genetic toxicology, carcinogenicity), pharmacokinetics, toxicokinetics, bioavailability, ADME, chemical characterization, impurities analysis and synthesis, bioanalysis, and microbiology. Additionally, full IND/NDA enabling studies are performed with a multidisciplinary approach to program management. Toxikon's extensive certifications and licenses allow it to meet international regulatory requirements for data acceptability and harmonization.

To meet all applicable international GxP requirements, Toxikon's facilities are fully registered with FDA and USDA, and accredited with the Association for the Assessment and Accreditation of Laboratory and Animal Care International (AAALAC), and the International Organization for Standardization (ISO). Toxikon also has assurance with the National Institutes of Health so federally funded work can be performed at our facilities in compliance with NIH's Public Health Service Policy on Human Care and Use of Laboratory Animals (PHS Policy).

### Bioburden and Validations

- » Aerobic
- » Anaerobic
- » Yeast and Molds
- » Gram Staining and Identification
- » Package Integrity

### Endotoxin Detection

- » LAL-gel clot
- » Chromagenic Assays
- » Inhibition and Enhancement (Validation)

### Sterilization

- » Bacteriostasis/Fungistasis
- » Membrane Filtration Sterility
- » Direct Transfer Sterility
- » Bi Strip Population Verification

### Reusable Device Studies

- » Cleaning, Disinfection, and Sterilization Validation
- » Life-Cycle Validation

### Other Services

- » Mycoplasma Detection
- » Residual DNA and Contaminant Analysis
- » Preservative Effectiveness Assays
- » Microbial Limits Assay
- » Minimum Inhibitory Concentration
- » Zone of Inhibition Assays
- » Microbial Ingress Studies
- » Antimicrobial Efficacy

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To learn more about Toxikon and our microbiology services, please visit us at [www.toxikon.com](http://www.toxikon.com)