



**Medical Device and Pharmaceutical  
Contract Testing Laboratory**



# Medical Device Testing

## Medical Device Testing

### Testing Services

- ANSI/AAMI/ISO 11737 Bioburden Evaluation
- USP <61>/<62>, Microbial Limits Testing
- USP <71> and AAMI Sterility Testing
- Biological Indicator Sterility Testing
- USP <85>/<161>, Bacterial Endotoxin
- USP <51> Antimicrobial Effectiveness
- EP Antimicrobial Effectiveness
- Ethylene Oxide Residual Measurements
- Cytotoxicity
- Biological Indicator Population Verification and D-value Determinations
- Microbial Identifications
- Container Closure Integrity Testing
- Package Integrity Testing (Dye Penetration, Aerosol Studies)
- Burst and Seal Peel Testing
- USP<788>/<789> Particulate Analysis

## Reusable Medical Device Testing

- End of Life Conditioning
- Cleaning Validations (Automated and Manual)
- Disinfectant Validations (High Level, Intermediate, and Low Level)
- Sterilization Validations (Steam and Ethylene Oxide)

**FOR MORE INFO.**

**CALL: 888-232-5227**  **705 Front St. Toledo, OH 43605**  **[sales@lexamed.com](mailto:sales@lexamed.com)**



# Pharmaceutical Testing



## Pharmaceutical Services

### Testing Services

- USP <61>/<62>, Microbial Limits Testing
- USP <71>, Sterility Testing
- USP <85>, Bacterial Endotoxin
- Stability Testing
- Potency Testing
- USP <791>, pH Measurements
- Total Organic Carbon
- Microbial Identifications
- Container Closure Integrity Testing
- USP <788>/<789>, Particulate Analysis
- USP <51>, Antimicrobial Effectiveness
- Disinfectant Efficacy



## Environmental Monitoring USP <797>

LexaMed is an industry leader in designing, validating and monitoring your controlled environment. We are your cleanroom partner from start to finish. We can help you fulfill International Organization for Standardization (ISO), European Union (EU), and U.S. Food and Drug Administration (FDA) regimens. LexaMed provides a full range of best-in-class Environmental Monitoring Services which includes experienced consultants to help with development of an environmental monitoring master plan for your facility based on guidance provided in USP Chapter <797>

**FOR MORE INFO.**

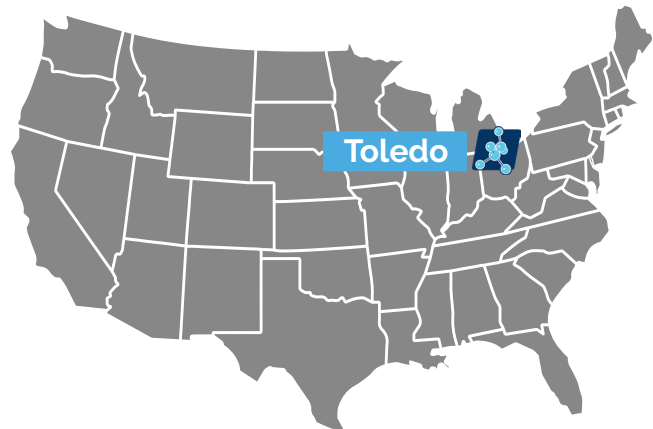
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# Who We Are

LexaMed is a leading provider of laboratory and consulting services for the medical device and pharmaceutical industries. LexaMed offers a wide range of microbiology and analytical assays. We have a highly trained staff of experienced scientists who are recognized as leaders in the industry.

We partner with our clients to guide them through the regulatory pathways to mitigate risk, decrease time to market, and help keep them in regulatory compliance. At LexaMed, we are fully committed to exceeding our clients' expectations and to our uncompromising commitment to quality.

**We are here to help you succeed!**



## Mission Statement

LexaMed's mission is to offer Quality, Compliant Value-Added services and products to our clients in a courteous and expeditious manner at a fair price.

## LexaMed's Compliance

By working with LexaMed, you can be assured that you are working with a fully registered partner that is committed to quality, rapid turnaround time, regulatory compliance and our clients' satisfaction.

- **US FDA Medical Device Establishment**  
Registration #1525897
- **US FDA Drug**  
Registration #787817696
- **US DEA**  
Registration #RL0367753
- **State of Ohio DEA**  
Registration -#LR.021706000
- **ISO 13485**  
CERT-0042714 (SAI GLOBAL)
- **ISO 17025 Accreditation**  
CERT - AT-2689 (ANAB)
- **Certified Women's Business Enterprise**  
**National Council (WBENC)**

## Contact LexaMed Today

705 Front Street  
Toledo, OH 43605

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For more information on LexaMed's services, visit us on the web at [www.lexamed.com](http://www.lexamed.com)