microbioconsulting.com
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MicroBio™

MicroBio Consulting is a global scientific consulting company helping clients to be "Best in Class" and "First to Market". We bring you the expertise needed to get your project completed efficiently, in compliance, and supported throughout the entire life cycle.

Servicing the following industries:



- Medical Devices
- Testing Labs
- Pharmaceutical & Biologics
- Nanotechnology
- Lab Consumables
- Sterilizers & Sterilants
- Nucleic Acids & Proteins
- *In Vitro* Diagnostics
- Forensics
- Food & Bevarage
- Tattoo Inks
- Packaging
- Cannabis & Hemp



Leadership

Mollie Holter, ISO 13485 Certified Lead Auditor – Founder
MicroBio Consulting was founded in 2017 by Mollie Holter, who brings more than 25 years of experience in biotechnology and medical device development. From the lab bench to leading multidisciplinary teams of scientists and engineers, she has built a career translating strong technical expertise into practical regulatory and scientific solutions. Mollie helps companies navigate complex development challenges while ensuring product efficacy and patient safety.

The Team

MicroBio has a team of 20+ consultants who provide unique industry-specific expertise and experience. Our specialties include Microbiology, Sterilization, Cleaning, Disinfection, Reprocessing, Biocompatibility, Chemistry, Toxicology, and Quality Management Systems.

Project Examples

Gap Assessments ‖ Supplier/Internal Audits ‖ Sterilization Validations ‖ Microbiological Investigations ‖ Laboratory Design ‖ Toxicological Risk Assessments ‖ Biological Safety Evaluations ‖ CAPAs ‖ Regulatory Submissions/Responses ‖ Controlled Environments ‖ Cleaning/Disinfection ‖ Laboratory Testing Coordination ‖ Test Method Validation ‖ Project Management ‖ GLP Compliance

MEDICAL ALLEY ASSOCIATION

certified WBENC WOMEN'S BUSINESS ENTERPRISE

Are You Compliant with the Latest Standards?

Recent updates to key ISO standards and FDA regulations may require medical device manufacturers to reassess their biological evaluation, sterilization, and quality management processes.

Have you evaluated your compliance with:

ISO 10993-1:2025
Updates to biological evaluation planning and risk assessment may require revisions to your Biological Evaluation Plan (BEP), Biological Evaluation Report (BER), testing rationale, and supporting documentation.

ISO 10993-6:2026
Changes to implantation testing guidance may affect the design, execution, or interpretation of studies used to evaluate local tissue effects for implantable devices.

ISO 10993-7:2026
Revisions to ethylene oxide (EO) residual requirements and evaluation methods could impact residual testing strategies, acceptance criteria, and risk assessments for EO-sterilized devices.

ISO 11137-1:2025
Updates to radiation sterilization requirements may influence sterilization validation, dose substantiation, routine process controls, and documentation.

FDA Quality Management System Regulation (QMSR)
FDA's alignment with ISO 13485 introduces changes that may require updates to your quality management system, procedures, records, supplier controls, and internal audit practices.

How MicroBio Consulting Can Help

Our expert consultants perform comprehensive **Gap Assessments** to compare your current documentation, processes, and quality systems against the latest standards and regulatory expectations. We identify areas requiring attention, provide practical recommendations, and help you develop an efficient path toward compliance.

Reach out to MicroBio Consulting to schedule your gap assessment and stay ahead of compliance changes.

Call/Text: (763) 639-7111
Email: mollie.holter@microbioconsulting.com

Need Support with Internal or Supplier Audits?

Certified Lead Auditors on our team bring practical, hands-on experience, ensuring a smooth and efficient audit process.

Contact us today for a FREE intro call and quote!
763-639-7111