

Your trusted CRO partner for drug development expertise

Microbiologics has been creating confidence in science for more than 50 years. Our team has a proven record of success in navigating the drug development process from discovery and development through clinical research and FDA review. We offer a wide range of standard and custom antimicrobial assays, advanced microbial identification, extraction and preservation, as well as strategic consulting services.

Our experienced team will collaborate with you each step of the way and manage the project from start to finish. We have deep expertise in designing and executing testing programs that lay the groundwork for seamless FDA submission. Our partners also gain access to our extensive repository comprising more than 12,000 clinically important microbial isolates to test compounds against.



Our Services Include:

Screening / Susceptibility Testing

- Repository of 12,000+ Clinical Isolates (aerobes, anaerobes, fungi)
- High-Throughput Screening
- Primary Profiling (screening, spectrum of activity) and Secondary Profiling (MIC₅₀/MIC₉₀)
- Susceptibility Testing Methodology (CLSI M2, M7, M100)
- Susceptibility Testing of *Mycobacterium tuberculosis* (BSL-3) and nontuberculous mycobacteria (NTM)

Lead Characterization Studies

- Mechanism of Action Studies (whole-cell, cell-free)
- *In Vitro* Pharmacodynamic Studies (extracellular time-kill, intracellular time-kill, PAE/SME/PA-SME)
- Development of Resistance Studies (mutation frequency, serial passage)
- Biofilm Studies

Test Method Development

- Tier 1 Quality Control and Parameter Studies per CLSI M23
- Tier 2 Broth/Agar MIC and Disk Quality Control Studies per CLSI M23
- Disk Diffusion/Alternate Test Methods Development and/or Evaluation
- Method Correlation Studies

Microbiome Studies

- LBP and probiotic enumeration, characterization and ID
- Antibigrams
- Microflora isolation
- Evaluation of impact of prebiotics on organisms in co-culture

Characterization / Preservation / Extraction

- Microbial Propagation
- Biobanking and Cryopreservation
- Molecular ID and Characterization (MALDI, PFGE, PCR, sequencing)
- Nucleic Acid Extraction (gDNA, High-Throughput)
- Isolation of Target Organisms from Mixed Samples (consortia, environmental, or clinical)

Consulting

- *In vitro* and *in vivo* potency of antimicrobial agents
- Due diligence activities
- Determining the right indication for potential new products
- Planning a strategy to generate the data required for FDA submissions
- Planning and/or writing the microbiology section of INDs or NDAs

Tissue Culture-based Assays

- Intracellular Killing Assays against NTM and GC
- Chlamydia Susceptibility Testing
- MTT Toxicity Assay

Ask us about our *M. tuberculosis* susceptibility testing capabilities including MDR and pre-XDR strains!



Microbiologics is compliant to GLP Regulation 21 CFR 58.