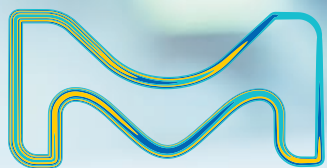




MERCK



At YOUR SERVICE

with a complete portfolio of services supporting your Pharma QC micro laboratory

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Millipore®

Preparation, Separation, Filtration & Monitoring Products

Microbiology services

Optimize your QC lab workflow and ensure regulatory compliance

Microbiological monitoring and testing in the pharmaceutical industry is a highly regulated and extremely complex field. With our long history of serving the pharmaceutical industry, we have pioneered and refined ground-breaking solutions, demonstrating the regulatory and technological expertise to share this know-how with our customers to make compliance as simple as possible and help save your valuable resources.

Our services ensure compliance with numerous regulations

- **FDA's Compliance Program Guidance Manual Drug Manufacturing Inspections Pilot Program**

"A firm in a state of control produces finished drug products for which there is an adequate level of assurance of quality, strength, identity and purity."

- **EU GMP vol. 4, 3.41**

"Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests should be maintained."

- **21 CFR 58.63 (GLP)**

"Equipment shall be adequately inspected, cleaned, and maintained."

- **FDA Guide to inspections of microbiological pharmaceutical quality control laboratories**

"Verify that the laboratory has the equipment necessary to perform the tests and that the equipment was available and in good operating condition on the dates of critical testing."

- **USP, 1058**

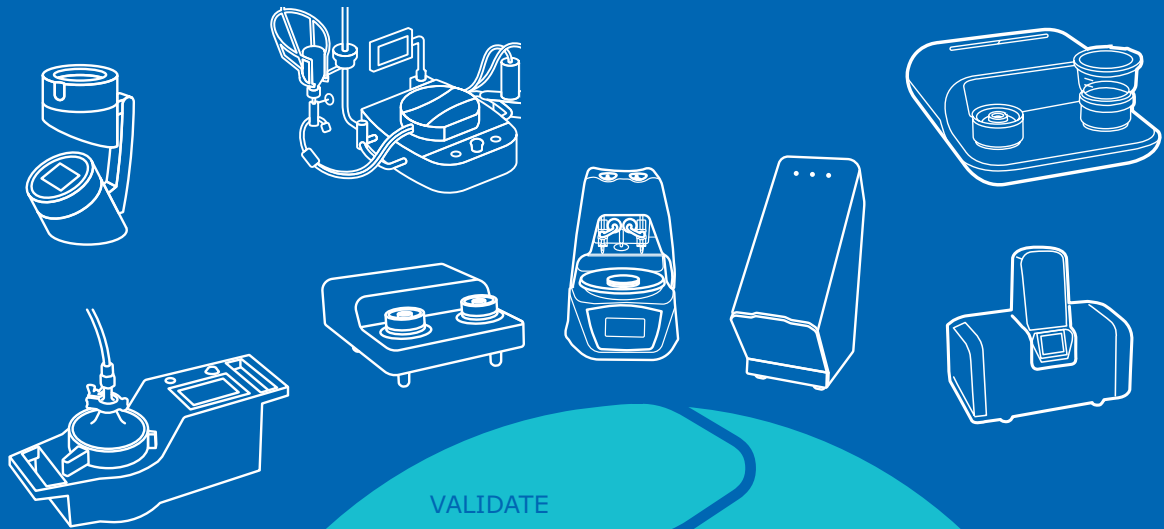
"This chapter provides a scientific approach to AIQ and considers AIQ as one of the major components required for generating reliable and consistent data."

"Use of a validated procedure with qualified analytical instruments provides confidence that the procedure will generate test data of acceptable quality."



Pharmaceutical Microbiological Safety

From sampling to final release, our complete solutions for environmental monitoring, traditional & rapid microbial detection and sterility assurance help you meet the highest quality standards and regulatory demands.



Traditional Methods

Active Air Monitoring

MAS solution family

Our MAS-100® series is the most complete and accurate system for reliable and easy monitoring of ambient air. To help maintain compliance while enhancing lab productivity and reducing down-time, we offer a full range of services.



[SigmaAldrich.com/
portable-air-samplers](https://SigmaAldrich.com/portable-air-samplers)

Benefit from our support during the entire microbiology method lifecycle:

Validation protocols & services

- Experience a fully digital validation workflow on our Val@M™ Application
- Get faster to routine use
- Ensure regulatory compliance and audit-ability

Training services

- Implement optimal testing procedures
- Learn best practices in managing your routine testing
- Ensure correct test result interpretation

Maintenance & service plans

- Ensure the reliability of your air sampler
- Reduce its downtime
- Increase its lifetime



Sterility Testing and Bioburden Testing

Steritest® system

We are a renowned expert in sterility testing: reducing the risk of false positive and false negative results, increasing reliability and improving workflow for lab technicians around the world. We provide an extensive portfolio of quality control products, and services.



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Milliflex Oasis® filtration system

Milliflex Oasis® filtration system is an integrated solution for bioburden testing giving reliable and accurate results in high throughput production environments. Allow us to help you to streamline your microbial contamination testing workflow and fulfill the necessary regulatory requirements.



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Take advantage of our complete range of services:

Method development services

- Optimize your current test method
- Outsource the development of test methods for your new products
- Learn how to develop optimized test methods on your own

Validation protocols & services

- Experience a fully digital validation workflow on our Val@M™ Application
- Get faster to routine use
- Ensure regulatory compliance and audit-ability

Maintenance & service plans

- Ensure the reliability of your air pump
- Reduce its downtime
- Increase its lifetime

Training services

- Implement optimal testing procedures
- Learn best practices in managing your routine testing
- Ensure correct test result interpretation

Rapid Methods

Rapid microbiological detection solutions for bioburden testing and sterility testing effectively address the diverse contamination issues which face the pharmaceutical and cosmetics industries every day. Innovative rapid technologies provide earlier results, increased assay sensitivity, ease-of-use, excellent accuracy and reliability.



Milliflex® Quantum microbial detection system

The Milliflex® Quantum system is designed for fast, fluorescence-based quantitative detection of microorganisms in the course of bioburden testing in pharmaceutical and cosmetics manufacturing facilities.



SigmaAldrich.com/quantum

Milliflex® Rapid System 2.0

The Milliflex® Rapid System 2.0 is a solution for rapid and accurate detection of microbial contamination in all filterable samples. Based on the detection of adenosine triphosphate with a bioluminescence reaction, this system delivers faster and bioburden sterility test results than traditional detection methods.



SigmaAldrich.com/milliflex-rapid

Rely on our expertise to provide you with best-in-class services:

Method development services

- Verify the suitability of the platform for your products
- Outsource the development of test methods or a fast implementation and validation
- Learn how to develop optimized test methods on your own

Validation protocols & services

- Experience a fully digital validation workflow on our Val@M™ Application
- Get faster to routine use
- Ensure regulatory compliance and audit-ability

Training services

- Implement optimal testing procedures
- Learn best practices in managing your routine testing
- Ensure correct test result interpretation

Maintenance & service plans

- Ensure the reliability of your system
- Reduce its downtime
- Increase its lifetime

Explore our services offering

Want to get the most from your microbiology testing equipment from the people who designed and built it?

Want to own your future and learn new skills relevant to your daily activities?

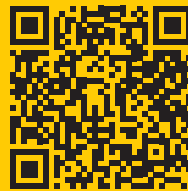
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Training services



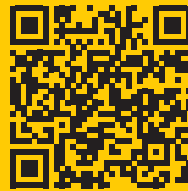
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Validation protocols & services

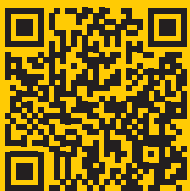


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Maintenance & repair services plans



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