

Millipore
SIGMA



At YOUR SERVICE

Microbiology Services

The life science business of
Merck KGaA, Darmstadt,
Germany 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

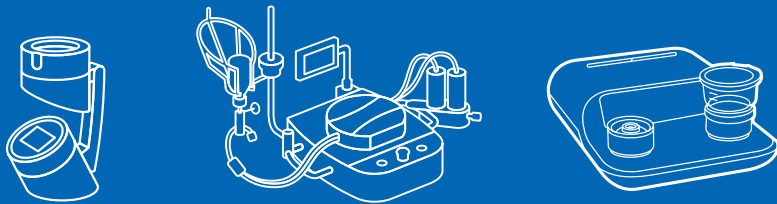
- **FDA Compliance Program Guidance Manual Drug Manufacturing Inspections Pilot Program**
"A firm in a state of control produces finished drug products for which there is an adequate level of assurance of quality, strength, identity and purity".
- **EU GMP vol. 4, 3.41**
"Measuring, weighing, recording 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."

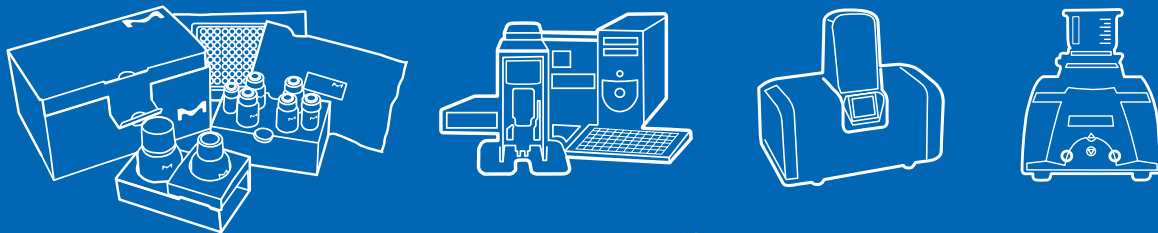


Pharmaceutical Microbiological Safety

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.



We can support you during the **entire** microbiology method lifecycle.



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.

What we provide:

- Customer Validation Protocol
 - Ready and easy-to-use GMP compliant
- IQ/OQ
 - Carried out on site
- Operator Training
 - Certify your lab staff
- Maintenance and Service Plans
 - Ensure system reliability and increase lifetime
- Best Training
 - Ensure correct interpretation of results





Bioburden Testing and Sterility Testing

Steritest™ system

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

Improve efficiency and reduce the workload for your lab team



[EMDMillipore.com/
sterility-testing](https://www.emdmillipore.com/sterility-testing)

Milliflex Oasis® filtration system

The 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 fulfil the necessary regulatory requirements.

Optimize or simplify your method for an easy validation and cost effective testing

What we provide:

- Method Development & Consultancy
 - Optimize your testing method
- Customer Validation Protocol
 - Ready and easy-to-use GMP compliant
- IQ/OQ
 - Carried out on site
- PQ Consultancy and Execution
 - Reduce your lab team workload
- Operator Training
 - Certify your lab staff
- Maintenance and Service Plans
 - Ensure system reliability and increase lifetime
- Best Training
 - Ensure correct interpretation of results

Rapid Methods

What we provide:

- Feasibility Study
 - Check the suitability for your application
- Method Development & Consultancy
 - Customized SOPs
 - Method optimization
 - Testing method development
- In-House and On-Site Evaluations
 - Try the system under actual conditions of use
- Customer Validation Protocol
 - Ready and easy-to-use GMP compliant
- IQ/OQ
 - Carried out on site
- PQ Consultancy and Execution Services
 - Reduce your lab team workload
- Operator Training
 - Certify your lab staff
- Maintenance and Service Plans
 - Ensure system reliability and increase lifetime
- Best Training
 - Ensure correct interpretation of results

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.

[We can help you implement a routine rapid testing method](#)

Milliflex® Rapid system

The Milliflex® Rapid System is an automated 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 sterility test results than traditional detection methods.

[We can help you implement a routine rapid testing method](#)





[EMDMillipore.com/
pyromat](https://www.emdmillipore.com/pyromat)

PyroMAT™ pyrogen detection kit

Pyrogen contaminations in pharmaceutical products, biotherapeutics, cosmetics and medical devices can induce a life threatening fever, and therefore testing is mandatory for manufacturers. We offer a robust *in vitro* pyrogen test in accordance with the European Pharmacopoeia regulations.

We can help you make the shift to *in vitro* methods

What we provide:

- Pyrogen Testing School
 - Understand regulations and ensure optimal usage of the kit
- Feasibility Study
 - Check the suitability for your application
- Method Development & Consultancy
 - Customized SOPs
- Product Specific Validation Consultancy and Service
 - Speed up the implementation of your new method
- Software Data Analysis for PSV
 - Ensure proper data interpretation for validation
- Advanced Operator Training
 - Certify your lab staff
- Software Data Analysis Service
 - Reduce the workload for your team



Millipore®

Preparation, Separation,
Filtration & Monitoring Products

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

EMDMillipore.com

To place an order or receive technical assistance

In the U.S. and Canada, call toll-free
1-800-645-5476

For other countries across Europe and the
world, please visit: [EMDMillipore.com/offices](https://www.emdmillipore.com/offices)

For Technical Service, please visit:
[EMDMillipore.com/techservice](https://www.emdmillipore.com/techservice)

[EMDMillipore.com/biomonitoring](https://www.emdmillipore.com/biomonitoring)

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

© 2019 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved. MilliporeSigma, the vibrant M, Millipore, Steritest, Milliflex, Milliflex Oasis, PyroMAT are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. MAS-100 NT is a registered trademark of MBV AG. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.

MS_BR1419EN Ver. 2 2018-15168 07/2019