The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.
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.
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

**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

EMDMillipore.com/sterility-testing
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
**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

EMDMillipore.com/pyromat