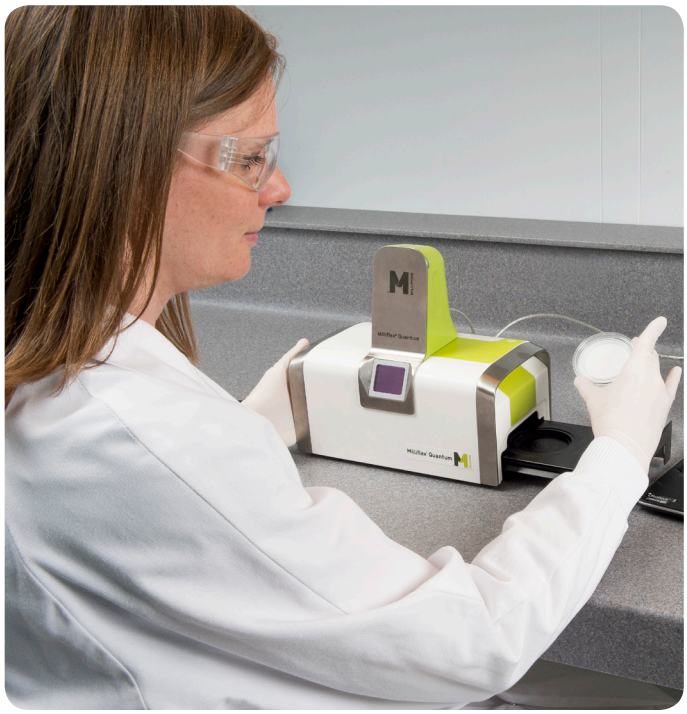
Millipore®
Filtration, Separation
& Preparation

Data Sheet

Our Experts at your Service

Discover our services portfolio supporting the Milliflex® Quantum system for bioburden testing

Microbiological monitoring and testing in the pharmaceutical industry is a highly regulated and thus very complex field. In its long history of serving the pharmaceutical industry by pioneering and refining groundbreaking solutions, we have gained the regulatory and technological expertise to offer its customers a comprehensive range of profession al, best-in-class services.



Method Development Services

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

Benefits

A name you know

We are known for the quality of our products. We apply these same high standards to our method development assignments and keep the same strict attention to regulatory compliance.

People you can trust

Depending on the scope of your project, we can assemble a team of our experienced scientists with expertise in membrane filtration, molecular biology, biochemistry, microbiology, pharmacology or regulatory affairs.

Methods you can validate

Whatever the assignment is, we know that the ultimate goal is validation. This why we provide detailed, ready-to-validate methods (Standard Operating Procedure). Furthermore, to provide you with a complete solution, we offer detailed validation protocols (IQ/OQ) for our systems.

Ready when you need us

It can take weeks or even months to develop a new test method in-house, especially in today's busy QC or QA laboratories where time and technicians are often in short supply. Our team of experts is available around the globe to help you develop the methods you need, when you need them.

MERCK

Products

Feasibility Study

Experimental study done in our application laboratory using customer samples and microbial strain(s):

- Assessment of the compatibility of customer sample with the Milliflex® Quantum system and of time to result
- Service includes 1 product matrix & 1 strain
- Additional strains can be quoted as an option
- Duration: 2 to 3 weeks
- Deliverable: study report

On-Site Evaluation

Evaluation of the Milliflex® Quantum system at customer site using real samples:

- Installation of a demo system on-site and extensive 2 to 3 day-training by our Application Scientist
- Customized test plan, real tests initiated on-site, then weekly follow-up calls to support customer
- Consumables charged based on consumption
- Duration: 2-3 months
- Deliverables: customized protocol, results sheet, final report

Method Development

Experimental study done in our application laboratory using customer samples and microbial strain(s):

- In case of compatibility issue with standard protocol or of new product to be tested
- Development of an appropriate method to overcome the interferences or improve filterability
- Service includes 1 product matrix & 5-6 strains
- Additional strains can be quoted as an option
- Duration: 4 weeks to 3 months
- Deliverables: study protocol, study report

Method Development Consultancy

Consultancy service by our application scientist to support customer's method development:

- In case of compatibility issue with standard protocol or of new product to be tested
- 1-day training at customer site covering equipment use and how to develop an appropriate method
- Customized test plan, real tests initiated on-site, then weekly follow-up calls to support customer
- Consumables charged based on consumption
- Duration: 3 months from the initial testing
- Deliverables: customized protocol, result sheets, final report

Validation Protocols and On-Site Validation Services

Get ready to start any PQ work in less than 5 days!

Benefits

Proven protocols and expertise to qualify our products for use in your testing processes

cGMPs/cGLPs require equipment and test methods to be validated before routine use. This can be time consuming and delay the start of critical QC procedures. Receive prepared protocols and have your new QC systems validated quickly and efficiently by our experts and save time with this process.

Reduce the Development Time & Cost of the Validation

Your protocol preparation may require around 4 weeks of development (research on applicable regulations, acceptance criteria definition, test methods writing, formatting, etc).

Estimated IQ/OQ completion time:

- Without pre-written protocol: 6 to 7 weeks.
- With our pre-written protocol: 2 to 3 weeks.
- With on-site validation service: less than a week.
- Quickly integrate equipment into your process pipeline with confidence using product specific test methods.

Products

Validation Protocols

Our validation protocols are based on our internal product qualification test methods. These extensive protocols will enable the QC/QA Lab to quickly initiate your Validation Master Plan and perform IQ, OQ and PQ (suitability of the test methodology) with ease. They follow international guidelines such as EP/USP and GMP.

On-site Validation Services

We have experienced and trained validation engineers who are skilled to assist in Validation Protocol implementation within the QC Microbiology laboratory, so the QC/QA Departments do not have to allocate resources. Technical training on your installed equipment is also provided during the validation engineer's visit. Rely on our expertise in various situations such as:

- New lab equipment
- New product or reformulated product to be tested
- Compliance with updated regulations: EP, USP, JP, etc.

Rely on our comprehensive and ready-to-use Validation Protocols consisting of the following sections:

1. Validation Master Plan

Define structure, responsibilites for qualification

2. Installation Qualification (IQ)

- Verification and identification of the Merck product
- Verification of product's utilities and operating environment requirements
- Equipment and personnel preparation

3. Operational Qualification (OQ)

Verification of product's functionality (hardware, software, devices)

4. Performance Qualification (PQ)

Test Method suitability verification (microbiology validation procedures)

5. Final Report

Summarizes all testing performed for final approval of validation

IQ/OQ Service:

Support for the qualification of laboratory equipment:

- Execution of the test methods
- Furniture of calibrated tools (flow meter, stopwatch, etc.)
- IQ/OQ Section of the Final Report is completed, ready for QA approval
- Essential operator training
- Duration: 2 days (Milliflex® Quantum system only)

Essential PQ Consultancy Service:

Consulting service for microbiological validation in order to plan and start the PQ:

- On-site support for implementation of the PQ tests
- Consumables and media calculation
- Training on recovery test techniques
- Data formatting and report finalization
- Scheduling of the tests
- Data interpretation, comments and conclusion
- Duration: 1,5 day

Service plans at repair center or at customer site

Rely on your equipment and minimize the breakdown risk

Benefits

Ensure Optimum Performance

Preventive maintenance and equipment verification ensure efficient operation of critical testing equipment. Every equipment should be serviced regularly to ensure its performance remains compliant with the specifications, as per GLP 21 CFR 58.63 (FDA) and EU GMP vol.4, 3.41. We recommend checking and adjusting the equipment on an annual basis guaranteeing that your equipment meets manufactured specifications and GMP/GLP requirements after every preventive maintenance and service.

cGMP require ALL equipment to be properly maintained. 21 CFR §211.67 Equipment cleaning and maintenance "(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product."

EU GMP Vol.4, 3.41: Measuring, weighing, recording and control equipment should be calibrated and checked at define intervals by appropriate methods. Adequate records of such tests should be maintained.

Annual Preventative Maintenance

Annual preventative maintenance will reduce the risk of breakdown by ensuring the equipment works within the system specifications. As part of the yearly preventative maintenance program the service engineer performs:

- Visual and functional checks
- Performance tests as found and as left
- Replacement of critical wear parts

Comprehensive Documentation

Upon completion of the service, we will provide you with a report defining the service performed on your equipment as well as our recommendations. This performance report also guarantees that the equipment meets system specifications. This document ensures compliance with regulations.

Products

Service Plans

We offer a variety of service plans that can be executed either in our local repair center or at customer site*.

	Service Essential™	Service Advanced™	Service Total™
Preventative Maintenance	Yes	Yes	Yes
Maintenance kit (quoted separately)	Yes	Yes	Yes
Number floating repair	0	1	N/A
All repairs	No	No	Yes as needed
Spare Parts	Excluded	Excluded	All inclusive
Shipment/Travel Zone 1	Yes	Yes	Yes
Options	**To be ordered separately!**		
Second Preventative Maintenance	Yes	Yes	Yes

Training Services

Ensure your lab team can make the best out of your equipment

Benefits

Benefit from Decades of Expertise

According to the United States Pharmacopeia's guidelines, "training curricula should be established for each laboratory staff member… They should not independently conduct a microbial test until they are qualified to run the test."

Our training packages include an in-depth review of regulatory requirements, their validation and practical implementation. The courses are based on the most recent editions of international pharmacopeias and international guidelines.

Products

Advanced Operator Training

In-depth training on bioburden testing for up to 5 participants. Each participant receives a customized handout:

- Presentation of the equipment, accessories and consumable
- Regulation overview: pharmacopoeia chapter(s) about the application, qualification of critical equipment, method validation, training and maintenance (life-cycle management)
- Hands-on training: assembling the system, usage (with customer's products in their final containers), cleaning, troubleshooting and common mistakes
- Question session
- Final examination and grading of the attendees with certificate of training
- Duration: 1 day

Milliflex® School

Which of your challenges does this course address?

- Regulatory background
- Handling issues
- False positive test results
- Validating products with inhibitory activities – false negative test results
- Optimizing bioburden testing by filtration

Course Program

8:30 - 17:30

Introduction

Definitions

- Regulations
- Interpretation of results
- Validation and maintenance
- Introduction to rapid detection
- Bioburden tests in the pharmaceutical industry
  - Microbial examination of non sterile product
  - Water testing
- Milliflex® range of products
  - Milliflex® Filtration System
  - MilliSnap® System
  - Milliflex® Quantum System
- Interactive session on the Milliflex® System

*Includes coffee break and lunch

merckmillipore.com/biomonitoring

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To place an order or receive technical assistance:

Find contact information for your country at:
merckmillipore.com/offices

For Technical Service, please visit:
merckmillipore.com/techservice

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