



## OUR EXPERTS AT YOUR SERVICE

Discover our Milliflex Oasis® services portfolio for bioburden testing

Microbiological monitoring and testing in the pharmaceutical industry is highly regulated and thus a 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 you a comprehensive range of professional, best-in-class services.



### Method Development Services

Optimize or simplify your method for 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 an experienced scientific team 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 is 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 pumps.

### 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.

## Products

### Method Development

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

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

### Validation Protocols and On-Site Validation Services

Get ready to start any PQ work within 1 to 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 method 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

We have experienced and trained validation engineers who are skilled to assist in Validation Protocol implementation within the QC microbiology laboratory, so your QC/QA departments do not have to allocate resources. Technical training on your installed equipment is also provided during the validation engineer's visit. In order to maintain regulatory compliance over time we recommend performing a periodic requalification of your pump.

## Method Development Consultancy

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

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

## 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.

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

#### 1. Validation Master Plan

Define structure, responsibilities for qualification

#### 2. Installation Qualification (IQ)

- Verification and identification of with your Milliflex Oasis® 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
- IQ/OQ Section of the final report is completed, ready for QA approval
- Operator training
- Duration: 1.5 day depending on number of installations

## Essential PQ Consultancy Service

Support for the implementation of microbiological tests (PQ) of the Validation Protocol:

- Detailed and complete presentations of microbiological test up to date with regulations
- On-site support for implementation of tests
- Tips and tricks to optimize time and quantity of consumables for the PQ
- On-site data analysis support and report generation
- Continued support over phone and email
- Duration: 0,5 day

## Advanced PQ Consultancy Service:

Close coaching all along the PQ of the consumable and test method:

- Presentation of the equipment, accessories and consumable
- Regulation overview
- Hands-on training
- Setting up the lab, equipment, consumable
- Test campaign – Supervision of the microbiological tests (several days):
  1. The validation engineer demonstrates the test with the first microorganism
  2. The technician(s) repeats what has been demonstrated on the further replicates and microorganisms
  3. Result read-out and interpretation
- Duration: customized depending on customer needs

## Service plans at repair center or at customer site

Rely on your Milliflex Oasis® pump and minimize the breakdown risk

## Benefits

### Ensure Optimum Performance

Preventive maintenance and pump verification ensure efficient operation of critical testing equipment. Every pump 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 pumps on an annual basis guaranteeing that your pump 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.”*

## Essential Requalification Service

Requalification work performed on laboratory equipment after the yearly preventive maintenance:

- Requalification protocol to be ordered separately
- IQ and OQ test procedures (physical tests) + data formatting and report finalization
- Furniture of calibrated tools (flow meter, stopwatch, etc.)
- Duration: 0,5 day, recommended frequency: every year

## Advanced Requalification Service:

Requalification work and consulting service for laboratory equipment:

- Requalification protocol to be ordered separately
- SOP review
- Maintenance review
- IQ and OQ test procedures (physical tests) + data formatting and report finalization
- Provision of calibrated tools (flow meter, stopwatch, etc.)
- Operator training review
- OOS results review
- Duration: 1 day, recommended frequency: every 3 to 5 years

*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 Preventive Maintenance

Annual preventive maintenance will reduce the risk of breakdown by ensuring the pump works within the system specifications. As part of the yearly preventive 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 pump as well as our recommendations. This performance report also guarantees that the pump 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™
Preventive Maintenance	Yes	Yes	Yes
Maintenance kit (quoted separately)	Yes	Yes	Yes
Number of repairs included	0	1	As required
Spare Parts	Excluded	Excluded	All inclusive
Shipment/Travel Zone 1	Yes	Yes	Yes
Options	To be ordered separately!		
Second Preventive Maintenance	Yes	Yes	Yes

\*Where available

## Training Services

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

### Benefits

#### Benefit from Decades of Expertise

According to the United States Pharmacopeia 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

### Milliflex® School

#### Theoretical aspects of Bioburden Testing

- Regulatory aspect of bioburden testing (raw material, in process, final product release, water testing)
- Critical needs for filtration method
- How to ensure reliable results (avoid false positive and negative results)
- Introduction to rapid technologies & Milliflex® Quantum System

Learn more at [SigmaAldrich.com/Product-Services](https://SigmaAldrich.com/Product-Services)

## To place an order or receive technical assistance

Order/Customer Service: [SigmaAldrich.com/order](https://SigmaAldrich.com/order)  
Technical Service: [SigmaAldrich.com/techservice](https://SigmaAldrich.com/techservice)

### Interactive Workshop

- Review of all Milliflex® features (funnels, agar, hardware) and how to make the best choice for your bioburden testings
- Demo of Milliflex Oasis® system and review of the best practices for routine use and daily maintenance of the system
- Demo of Milliflex® Quantum System
- Duration: 1 day

### Milliflex® Advanced Operator Training

- This course will cover the same theoretical aspects and interactive workshop than the Milliflex® School and in addition a hands-on session on the best practices of use of the Milliflex Oasis® system.
- A training certificate is delivered to each participant after evaluation.
- Duration: to be defined based on the number of participants

### 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

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