Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Our Experts at Your Service

Discover our services portfolio supporting the MAS-100® family for active air monitoring

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 you a comprehensive range of professional, best-in-class services.

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.

Rely on our comprehensive and ready-to-use validation protocols consisting of the following sections:

1. Validation Master Plan

Defined structure, responsibilities for qualification

2. Installation Qualification (IQ)

- Verification and identification of the our 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)

Verification of test method suitability (microbiology validation procedures)

5. Final Report

Summarizes all testing performed for final approval of validation

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.

- New lab equipment
- Testing new or reformulated products
- Compliance with updated regulations: EP, USP, JP, etc.

IQ/OQ Service:

Support for the qualification of laboratory equipment:

- Execution of the test methods
- Supply of tools (anemometer, stopwatch, etc.)
- IQ/OQ section of the final report is completed, ready for QA approval
- Essential operator training
- Duration: 1 to 5 days depending on number of installations and consumables

Service Plans at Repair Center or at Customer Site

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

Benefits

Ensure Optimum Performance

Preventive maintenance and equipment verification ensure efficient operation of critical testing equipment. Each piece of 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 air sampler on an annual basis to guarantee 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 Preventive Maintenance

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

- Visual and functional checks
- Checking and calibration of the air flow rate including new certificate of calibration
- Performance tests as found and as left

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 (where available).

	Service Essential™	Service Advanced™	Service Total™
Preventive 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 Preventive Maintenance	Yes	Yes	Yes
Second Calibration	Yes	Yes	Yes

Training Services

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

Benefits

Benefit from Decades of Expertise

In the pharmaceutical industry (significantly in aseptic or parenteral production), Environmental Monitoring (EM) plays an important role to ensure safety during the manufacturing of health care products. The implementation of a detailed and reliable EM program will reduce the number of corrective actions and related investigation and report time. In the worst case, an EM contamination could lead to the loss of an entire production batch.

Only personnel who have been trained, qualified and certified on the different aspects of EM (guidelines for monitoring air, surface and personnel) are able to minimize the risks and to maintain the required production quality in isolators, RABS (Restrictive Access Barrier Systems) and cleanrooms.

Our training packages will help you and your company to release safer products with the highest quality.

Products

Environmental Monitoring School

Theoretical aspects of Environmental Monitoring:

- Regulatory aspect of EM (air monitoring, surface and personnel monitoring)
- Critical handling steps
- How to ensure reliable results

Interactive Workshop:

- Demonstration of best procedures for using microbial air samplers and agar plates media for surface, personnel and passive air sampling
- A case study for implementing an environmental monitoring program in a cleanroom (air, surface and personnel microbial monitoring)
- Answers to specific user-related questions
- Certificate of attendance
- Duration: 1 day minimum

Environmental Monitoring Advanced Operator Training

- This course will cover the same theoretical aspects and interactive workshop as the EM School and, in addition, a hands-on session on the best practices of use of the MAS and/or RCS® air sampling systems will be covered.
- A training certificate is delivered to each participant after evaluation.
- **Duration:** to be defined based on the number of participants

Which of your challenges do these courses address?

- You will understand the current requirements from GMP and other international guidelines, and be familiar with the good environmental monitoring procedures using our microbial samplers and/or our culture media from method development and validation to routine test result interpretation.
- Take preventive actions to avoid false positive or false negative test results
- Develop and optimize environmental monitoring procedures
- Understand and identify root causes for common handling issues

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