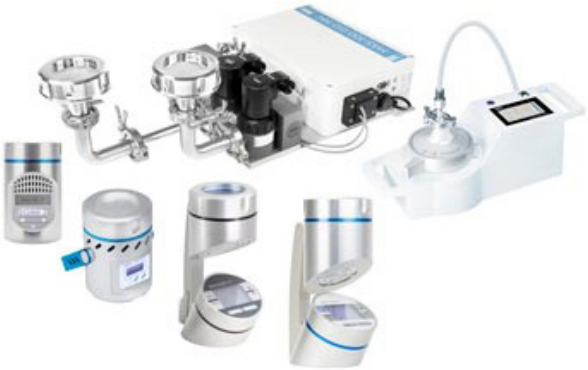
Millipore®
Preparation, Separation,
Filtration & Monitoring Products

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 very complex field. In our 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 for each of the different platform usage stages:



1. Evalution phase

2. Implementation phase

3. Routine use phase

1. During platform evaluation phase

Training

Understand good practices in environmental monitoring

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.

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

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

2. During platform implementation phase

STEP 1: Hardware, consumables, media and method validation

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.

Benefit from our validation expertise and best practices

We have experienced and trained field 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. They will perform the actual qualification activities using our Val@M™ Application. 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.

Products

Digital Validation Protocols

Our digital validation protocols are based on our internal product qualification test methods and are available for a fully digital execution workflow on our Val@M™ Application. These extensive protocols will enable the QC/QA lab to quickly initiate your Validation Master Plan. They follow international guidelines such as EP/USP and GMP. They must be completed by an on-site IQ & OQ execution service.

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 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)

Test Method suitability verification (microbiology validation procedures)

IQ/OQ Service at customer site

Support for the qualification of laboratory equipment:

- Execution of the test methods
- Calibration tools provided (flow meter, stopwatch, etc.)
- IQ & OQ protocols are completed in the Val@M™ Application, ready for QA approval
- Essential operator training
- Duration: 1 to 5 days depending on number of installations and consumables

Remote IQ & OQ Consulting Service

Support for the qualification of laboratory equipment provided via a video-conferencing system:

- Preparation call upfront to agree on topics and
- schedule of the consultancy
- Preliminary discussion about our Customer Validation
- Protocol: roles and responsibilities, list of tools, list of
- consumables needed, relevant tests
- Calls during and after the validation work to help with
- data formatting and protocol finalization
- Duration: minimum 1 day, customized depending on your needs

Essential PQ Consultancy Service at customer site

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

- Part 1: Functional test
  - Microbiological comparison of your air sampler versus a reference system, either yours or one provided by Merck: 48 samples in total taken over two sampling points
  - Data interpretation afterwards over the phone
- Part 2: Consultancy service for microbiology validation work
  - Presentation of the protocol's microbiological tests
  - On-site support for quick and efficient implementation of the PQ tests
  - Expendables calculation and scheduling
  - Training to perform the microbiological tests, if needed
  - Data interpretation on site and afterwards over the phone
- Duration: 1,5 days

SigmaAldrich.com/ValatM

SigmaAldrich.com/Microbio Services-Method-Validation

SigmaAldrich.com/Microbio-Services-Qualification

Step 3: Training Services

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

Benefits

Decades of expertise in air monitoring operations shared with your technicians

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.

Visit our on-line training platform:

LearnAtM.MerckGroup.com/global/learn

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Advanced Operator Training

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

- Presentation of the equipment, accessories, and consumables
- 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 equipment, 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: 0,5 day

3. During platform routine phase

Yearly preventative maintenance and service plans

Maintain your equipment compliance and optimal operation over time

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).

		Protection level		Risk level
Service	**Details**	**Total Service Plan[3]**	**Advanced Service Plan**	**Essential Service Plan**
System eligibility		**< 10 years**	**All ages**	**All ages**
Preventive maintenance (PM) visit	1 PM visit (labor and travel fees[1] or return shipment[2] included)	✓	✓	✓
Preventive maintenance (PM) service kit	System specific PM service kit	✗	✗	✗
Software & firmware updates	Last updates implementation	✓	✓	✓
Traceable and auditable documentation	PM performance service report	✓	✓	✓
Access to technical support	Remote support on system and software by phone and email	✓	✓	✓
Repair visits	Labor and travel fees or return shipment[2]	Unlimited	One per year	✗
Spare parts	Spare parts for repair	✓	✗	✗

[1] According to the region, travel fees might be quoted separately

[2] For workshop service plan only

[3] Not applicable to detection tower

Visit our dedicated webpage:
SigmaAdrich.com/Microbio-Services-MR

To place an order or receive technical assistance

Order/Customer Service: **SigmaAldrich.com/order**
Technical Service: **SigmaAldrich.com/techservice**

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