2024 Western Europe BioMonitoring

Pharma Schools Program

The Life Science business of Merck operates as MilliporeSigma in the U.S. and Canada.

Millipore®

Preparation, Separation, Filtration & Monitoring Products

Index

The benefit of our trainings: **Customers recognize our added value**

On average the courses and trainers have been rated close to excellence by the attendees with more than 90% of the total score.

"It goes into great depth in methods and equipment relevant to my job."

"Very clear and concise, very good tutor who made it easy to understand for people who are not familiar with the test."

"Very helpful and the tutor always took the time to listen."

BioMonitoring Pharma Training and Consulting Program

Being always **up to date** on the best testing procedures and regulatory requirements is fundamental to be able to implement good practices in your laboratory and your cleanrooms environment.

We are aware of this need and decided to expand our existing offer by providing you with additional training opportunities.

In this brochure you will find a list of trainings provided by our experts on Sterility Testing, Bioburden Testing, and Environmental Monitoring. These trainings can be held at our location or at customer site.

An opportunity to learn about cutting edge testing systems and devices and best working operations as well as to network with other users in your field of interest!

BioMonitoring Training Center

Steritest® School

Understanding good practices in sterility testing

Full-day course

According to the United States Pharmacopeia (USP)'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."

The pharmaceutical inspection authority, PIC/S, recommends that "sterility testing should only be performed by personnel who have been trained, qualified and certified to perform the various tasks and procedures related to sterility testing." In addition, PIC/S states that, "personnel should undergo periodic recertification."

Overview

This course provides an in-depth review of the regulatory requirements of sterility testing, its validation and practical implementation. The course is based on the most recent editions of international pharmacopoeias and provides information about the harmonization and differences between the United States Pharmacopeia (USP) and the European Pharmacopoeia (EP).

As an essential part of the course, you will participate in an interactive workshop on how to perform a sterility test. Participants' case studies will also be discussed. Our experienced instructors also provide valuable suggestions for regulatory compliance.

Interactive workshop

The interactive workshop is a core part of the course, aiding the understanding of the lecture contents with practical applications. All critical handling steps in the sterility testing procedure and its consequences for test results are discussed and solutions are explained and demonstrated.

The interactive workshop covers:

- Use of Steritest® hardware
- Use of Steritest® units
- Demonstration of general and specific sterility testing applications
- Answers to specific user-related questions

What will you be able to do after attending this course?

- Understand the current requirements of pharmacopoeias and be familiar with good sterility testing procedures from method development/ validation to routine test result interpretation
- Take preventive actions to avoid false positive or false negative test results
- Develop and optimize sterility testing procedures
- Understand and identify root causes for common handling issues

What will you receive?

- A full set of course notes
- A certificate of attendance

Duration: One day minimum. Can be on a centralized location or at customer site.

What challenges do these courses address?

- Handling issues
- False positive test results
- Validating products with inhibitory activities – false negative test results
- Optimizing sterility testing procedures

Who should attend?

- These courses are dedicated to users of the Steritest® system only and they are designed for Quality Control, Quality Assurance or Regulatory Affairs personnel who have responsibility for the performance of the sterility test

Steritest® School Program

- Introduction
- Theoretical aspects of sterility testing including:
  - Regulations
  - Environmental considerations
  - Pharmacopoeia methods
  - Steritest® system overview
  - Sample considerations
  - Method development
  - Validation
  - Interpretation of results
- Visit to the BioMonitoring Center of Excellence (if the course is held at the Merck facility in Molsheim, France)
- Training on
  - Correct usage of: Steritest® pump
    Steritest® filtration units
    Steritest® media and fluids
  - How to select the best Steritest® device
  - Quality assurance and manufacturing and accessories
  - Steritest® NEO
- Steritest® Symbio pumps and accessories
- Interactive workshop, including:
  - Performing a sterility test
  - Demonstration of general and specific applications
- Answers to specific user-related questions
- Conclusion

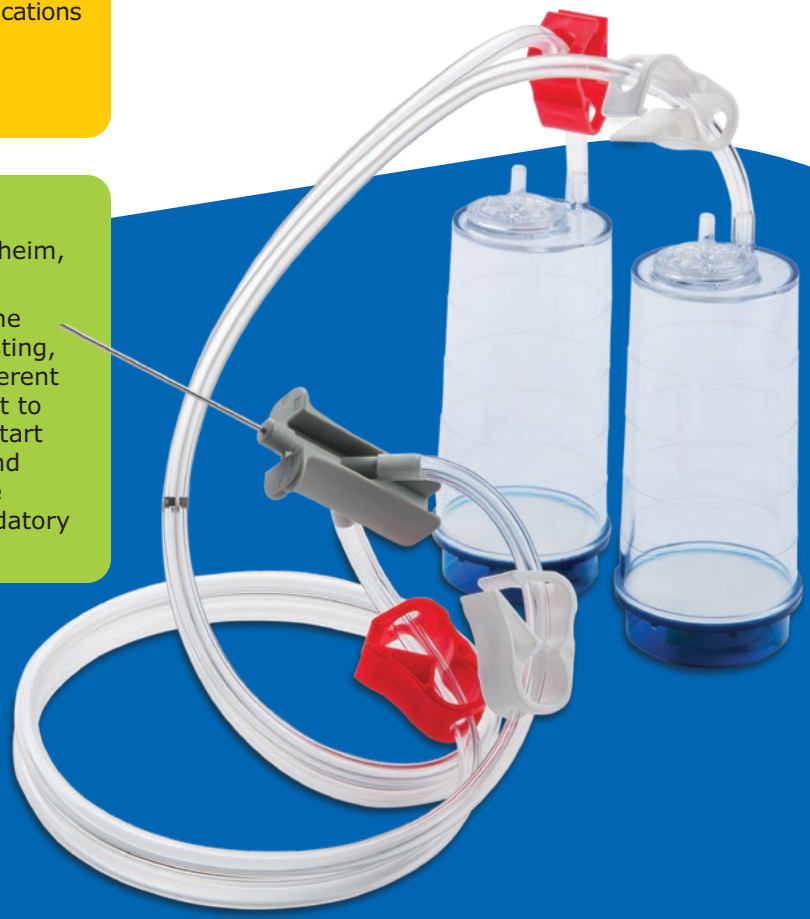
Steritest® School Advanced Practice

Training module (optional): Available in Molsheim, France only.

During this hands-on session you will have the opportunity to gain experience in sterility testing, practicing with the Steritest® pumps and different units. Please ask in advance in case you want to try a specific unit. This training module will start right after the end of the Steritest® school and last 2 and half hours. Note that to attend the Advanced Practice Training module it is mandatory to participate in the entire Steritest® School.

"Being a sterility testing analyst I wasn't sure what I would get from this course but I found it very interesting and came away with many things, tips, and a clear understanding of why we perform every action."

"Learnt a lot from the presentation about the theory and was very impressed."



BioMonitoring Training Center

Steritest® Advanced Operator Training

Half day/Full day (depending on the number of attendees)

PIC/S 2007. Supervisors should ensure that all personnel are monitored and follow Standard Operating Procedures (SOPs).

Personnel should undergo periodic recertification.

Personnel training should be documented, and records maintained.

Overview

With this course you will have the opportunity to gain experience in sterility testing, practicing with the Steritest® pump, media and filtration units. Please ask in advance in case you want to try a specific unit. The training will cover an introduction to the theoretical aspects before moving to a deep practical session and final examination.

Theoretical presentation of the Steritest® portfolio:

- Overview of the Steritest® portfolio
- Overview of the sterility testing procedure
- Regulation overview: pharmacopoeia chapter(s) about sterility testing

On-site training of operators:

- Assembling the pump, usage: theory and practice using a standardized unit and procedure, cleaning, troubleshooting and common mistakes. Each action is first demonstrated by the trainer, then rehearsed by the trainees.
- Question session: collection / answering of the questions from the audience regarding the use of the equipment or the way(s) to perform sterility testing.
- Final examination and grading: attendees answer a series of questions and must reach a minimum score to pass the exam

Benefits of attending this course

- You will get confident with performing a sterility test using Steritest® Symbio, media and filtration units
- You will get tips and tricks to avoid common handling issues
- You will learn how to analyze and interpret test results

Enrollment to the course is limited

Due to the interactive nature of these courses, enrollment is limited. We recommend early booking to ensure a place.

Price

Please contact our local representative for a quote.

Course ordering information

Course	Cat. No.
Steritest® School at Merck or a central location	**TSSEMIN01**
Steritest® Advanced Practice at Merck	**TSSEMIN02**
Steritest® School at customer site	**TSSEMIN11**
Steritest® Advanced Operator Training at customer site	**TSTRAIN12**

BioMonitoring Training Center

Milliflex® School

Understanding good practices in microbial enumeration by membrane filtration

Full-day course

"Each person engaged in all phases of pharmaceutical manufacture should have the education, training, and experience to do his or her job.

Training curricula should be established for each laboratory staff member specific for his or her job function. They should not independently conduct a microbial test until they are qualified to run the test. Training records should be current, documenting the microbiologist's training in the proper revision to the particular SOP." USP

What challenges do these courses address?

- Handling issues
- False positive results
- Basic troubleshooting
- Optimizing bioburden testing by filtration

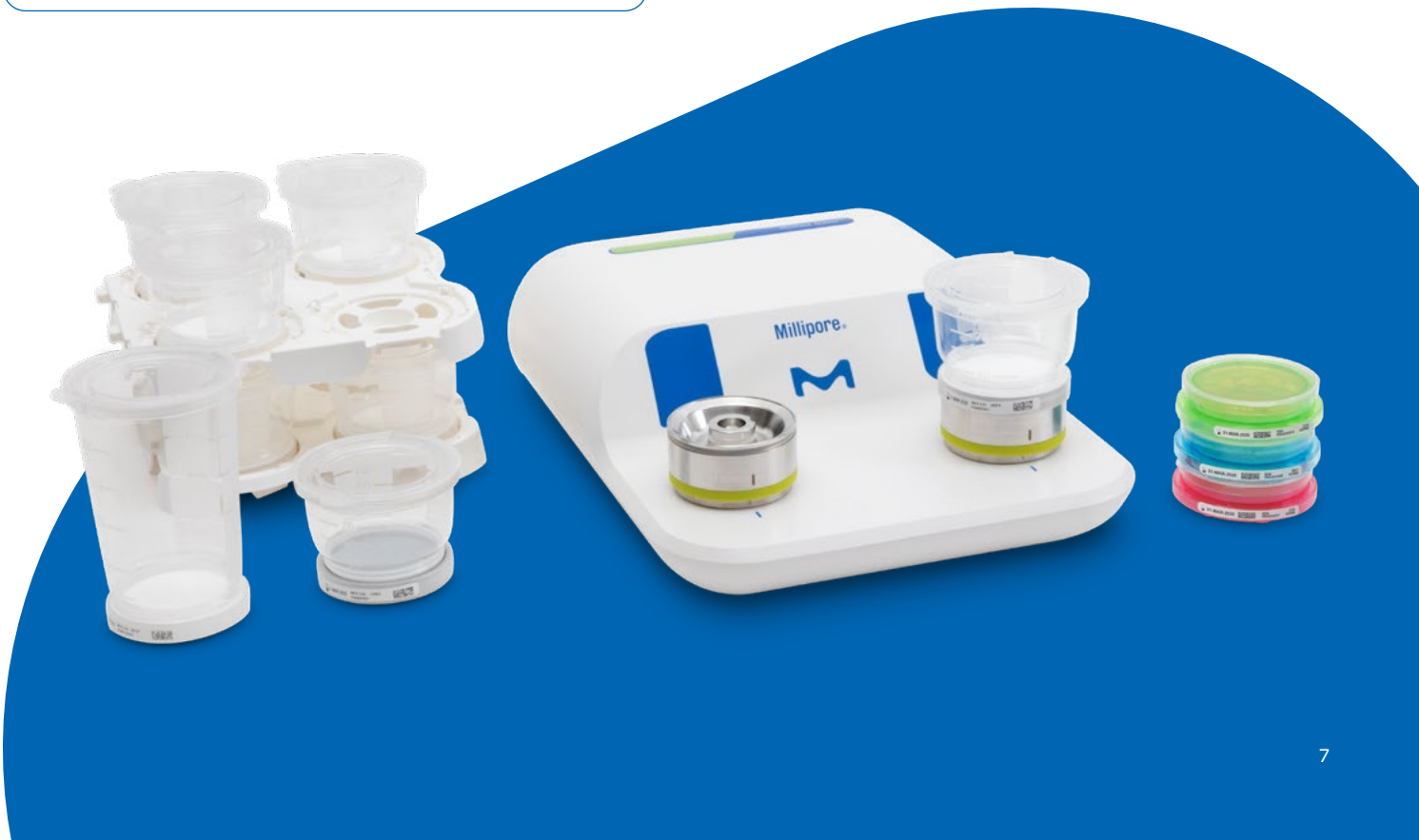
Who should attend?

- These courses are dedicated to users of the Milliflex® system only
- They are designed for Quality Control analysts, and Quality Assurance personnel who have responsibility for the performance of the bioburden test

Overview

The course is based on the most recent editions of the international guidelines with specific focus on United State Pharmacopeia (USP) and European Pharmacopeia (EP).

It provides an in-depth review of technical and regulatory information on bioburden testing of raw materials, water for pharmaceutical use, in process and final products. In addition it offers valuable information on new rapid methods.



Milliflex® School Program

- Introduction
- Theoretical aspects of Bioburden Testing:
  - Regulations related to 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 & Millilfex® Rapid systems
- Interactive Workshop :
  - Review of all Milliflex® components (funnels, agar, hardware) and how to make the best choice for your biorburden testing
  - Demo of Milliflex® system and review of the best practices for routine use and daily cleaning and maintenance of the system
  - Optional: Demo of Milliflex® Quantum system

Milliflex® School Advanced Practice

Training module (optional): Available in Molsheim, France only.

During this hands-on session you will have the opportunity to gain experience in bioburden testing, practicing with the Milliflex® pumps and devices. This training module will start right after the end of the Milliflex® school and last 2 and half hours. Note that to attend the Advanced Practice Training module it is mandatory to participate in the entire Milliflex® School.

Interactive workshop

The workshop covers:

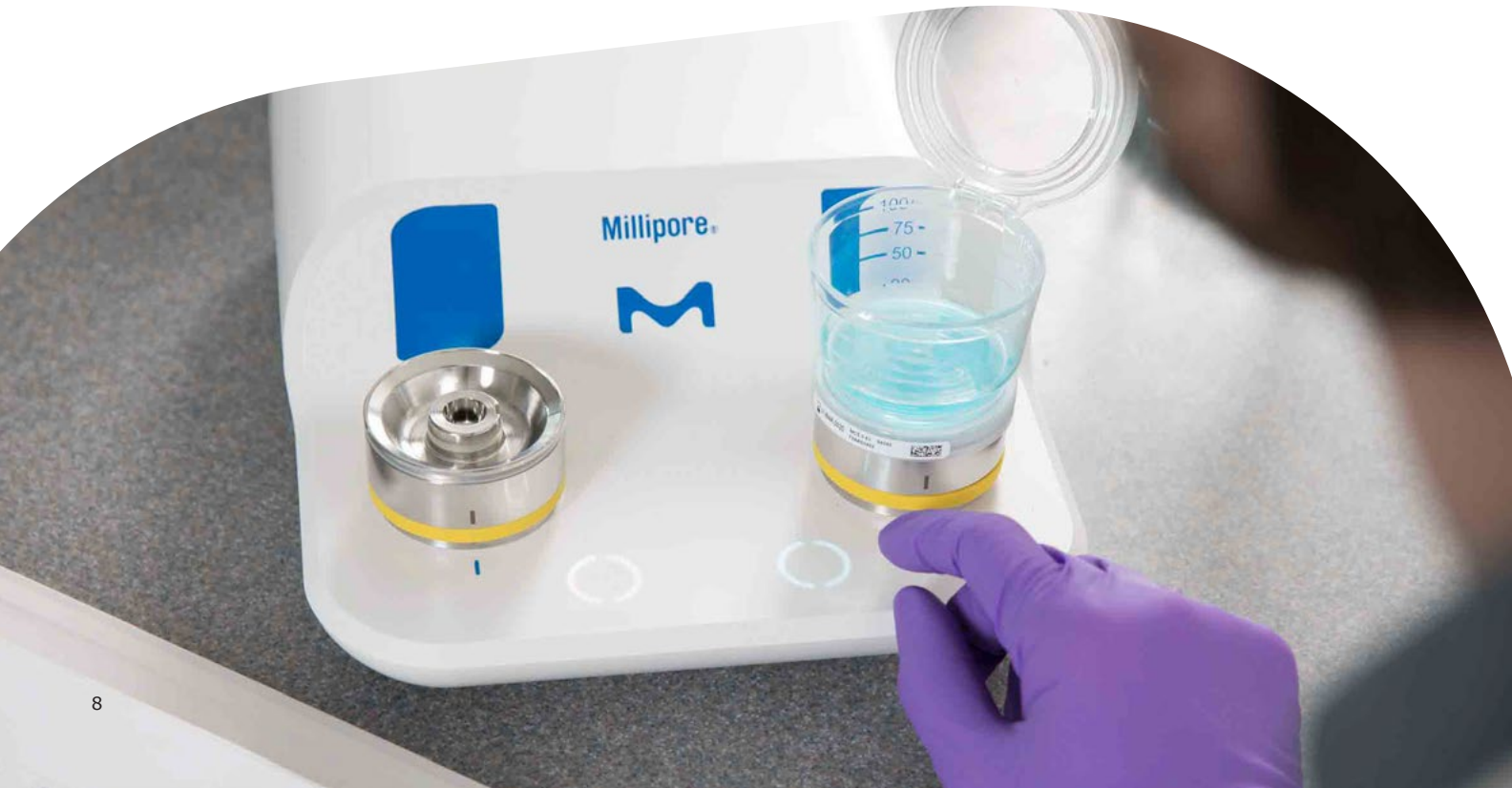
- Use of the Milliflex Oasis® range of products, including the Milliflex Oasis® Pump, Milliflex Oasis® Funnels, Milliflex Oasis® prefilled Agar Cassettes
- Demonstration of best practices for use and maintenance of the Milliflex® System
- Optional: Demonstration of the Milliflex® Quantum Rapid Detection System
- Answers to specific user-related questions

Benefits of attending this course

- You will understand the current requirements from pharmacopoeias and other international guidelines and be familiar with the good bioburden testing procedure by membrane filtration from method development/validation to routine test result interpretation
- You will learn how to take preventive actions to avoid false positive or false negative test results
- You will understand and identify root causes for common handling issues
- You will find out about novel rapid alternative methods that can optimize your workflow

What will you receive?

- A full set of course notes
- A certificate of attendance



BioMonitoring Training Center

Milliflex® Advanced Operator Training

Half day/Full day (depending on the number of attendees)

Benefits of attending this course

- You will learn basics about the filtration method applied to bioburden
- You will understand how the system works and learn about all the components (instrument and consumables)
- You will learn the best practices on how to perform a bioburden test using Milliflex® Plus or Milliflex Oasis® pump
- You will get tips and tricks to avoid common handling issues and basic troubleshooting

Comments from attendees

"Great tutor!"

"Very good tutor, very knowledgeable and very good at explaining course content."

"Great course, learnt a lot, thank you."

Overview

With this course you will have the opportunity to gain experience in bioburden testing, practicing with the Milliflex® or Milliflex Oasis® platforms including filtration pump, media and filtration units. The training will cover an introduction to the theoretical aspects before moving to a deep practical session and final examination.

Theoretical presentation of the Milliflex® portfolio

- Overview of the Milliflex® portfolio
- Overview of the bioburden testing procedure
- Regulation overview: pharmacopoeia chapter(s) about bioburden testing

On-site training of operators

- Installing and using the pump, cleaning, troubleshooting and common mistakes. Each action is first demonstrated by the trainer, then rehearsed by the trainees
- Question session: collection / answering to the questions from the audience regarding the use of the equipment or the way to perform a bioburden test
- Final examination and grading: attendees answer a series of questions and must reach a minimum score to pass the exam.

Enrollment to the course is limited

Due to the interactive nature of this course, enrollment is limited. We recommend early booking to ensure a place.

Price

Please contact your local Merck representative for a quote.

Course ordering information

Course	Cat. No.
Milliflex® School at Merck or central location	**BSSEMIN01**
Milliflex® Advanced Practice	**BSSEMIN02**
Milliflex® School at customer site	**BSSEMIN11**
Milliflex® Advanced Operator Training at customer site	**BSTRAIN12**

BioMonitoring Training Center

Environmental Monitoring School

Full-day course

In the pharmaceutical industry (especially in aseptic or parenteral production) Environmental Monitoring (EM) plays an important role to ensure the 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. It is a crucial element of the Contamination Control Strategy described in the part 9 of the European Union (EU) Good Manufacturing Practice (GMP) Annex 1, along the process. In the worst case such 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.

The EM School will help you and your company to release safer products with the highest quality.

Interactive workshop on:

- Microbial air sampling practices
- General microbial sampling practices including culture media selection, quality aspects
- Setting up your EM program, sharing a case study

Understanding good practices in Environmental Monitoring

Overview

This course provides an in-depth review of the regulatory requirements of environmental monitoring of cleanrooms, its validation and practical implementation. The course is based on the most recent editions of GMP and USP guidelines and provides information about cleanroom biocontamination control and monitoring according to the ISO and EN standards.

You will participate in an interactive workshop including a case study on how to implement an environmental monitoring sampling plan.

The course provides an in-depth review of technical and regulatory information on monitoring the air, surface and personnel in cleanrooms, isolators and RABS used in the pharmaceutical industry.

Interactive workshop

The interactive workshop helps to understand the lecture content with practical applications. Most critical handling steps in the microbial monitoring procedure and its consequences for test results are discussed. Sampling methods are explained and demonstrated.

The interactive workshop covers:

- 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 sampling plan in a cleanroom (air, surface and personnel microbial monitoring)
- Answers to specific user-related questions

What will you be able to do after attending this course?

- You will understand the current requirements from GMP and other international guidelines and be familiar with the good environmental monitoring procedures using microbial samplers and culture media from method development/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

What will you receive?

- A full set of course notes
- A certificate of attendance

What challenges do these courses address?

- Secure program implementation (microbial monitoring)
- Sampling method: best practices
- Optimizing EM procedures
- Compliance to the most relevant guidelines and significant increase of regulatory requirements in progress
- Latest trends assessment in order to minimize both false negative and cross contamination

Who should attend?

The course is dedicated to users of MAS or RCS families samplers and/or Merck ICR (Isolators Cleanrooms) culture media for Environmental Monitoring.

It is designed for operators, supervisors and managers of the environmental monitoring department, QC laboratories involved in environmental sampling and/or test readings and it is also of interest for personnel from QA, regulatory affairs, production and validation departments. Personnel responsible for the performance of the environmental microbial monitoring.

Environmental Monitoring School Program

- Introduction
- Theoretical aspects of environmental monitoring including:
  - Regulations
  - Basics on microbial environmental air monitoring of cleanrooms and isolators
  - Microbial monitoring of surface, personnel
  - Knowledge on culture media for environmental monitoring
  - Basics about data analysis and interpretations
- Interactive workshop, including:
  - Microbial air sampling practices
  - Environmental culture media selection, quality aspects and handling
- Case study on: “Setting up your EM sampling plan“
  - Practicing on how to build the microbial sampling plan
  - When and where to take the sample
  - Outcome

Environmental Monitoring School Advanced Practice

Training module (optional): Available in Molsheim, France only.

During this hands-on session you will have the opportunity to gain experience in environmental monitoring practicing different samplers and devices. Please ask in advance in case you want to try a specific unit. This training module will start right after the end of the Environmental Monitoring school and last 2 and half hours. Note that to attend the Advanced Practice Training module it is mandatory to participate in the entire Environmental Monitoring School.

BioMonitoring Training Center

Air Sampler Advanced Operator Training

Half day/Full day (depending on the number of attendees)

Cleanroms Biocontaminations Standards and Pharmaceuticals GMP:

Personnel shall be competent and have the necessary education, experience, skills and training to ensure performance of their assigned functions.

Overview

With this course you will have the opportunity to gain experience in Environmental Monitoring of Cleanrooms and Isolators with Merck air samplers (hand helded or in-line systems, Compressed Gaz sampler), sampling Data Management software and culture media. The training will cover introduction to the theoretical aspects before moving to a deep practical session and final examination. The air sampler model must be selected upfront.

Theoretical presentation of the MAS-100 NT® and MAS -100 ISO ® portfolios:

- Overview of our air sampling portfolio
- Overview of the air sampling procedure
- Regulation overview: GMP and other standard about environmental monitoring, qualification of critical equipment, training and maintenance (life-cycle management)

On-site training of operators:

- Handling with the air sampler, usage (theory and practice using the customer's facilities), cleaning, troubleshooting and common mistakes. Each action is first demonstrated by the trainer, then rehearsed by the trainees
- Question session: collection / answering of the questions from the audience regarding the use of the equipment or the way(s) to perform air monitoring
- Final examination and grading: attendees answer a series of questions and must reach a minimum score to pass the exam

Benefits of attending this course

- You will get confident with performing an air sampling test using our MAS air sampling instruments
- You will get tips and tricks to avoid common handling issues
- You will learn how to analyze and interpret test results

Enrollment to the course is limited

Due to the interactive nature of this course, enrollment is limited. We recommend early booking to ensure a place.

Price

Please contact your local representative for a quote.

Course ordering information

Course	Cat. No.
Environmental Monitoring School at Merck or central location	**EMSEMIN01**
Air sampler Advanced Practice at Merck	**EMSEMIN02**
Environmental Monitoring School at customer site	**EMSEMIN11**
Air sampler Advanced Operator Training at customer site	**ASTRAIN12**

Practical information

Location

Training courses can be held at Merck offices, in hotel meeting rooms or at your site depending on the training course chosen. The Advanced Operator Training will be held exclusively at customer site.

Catering

For schools held at Merck sites refreshments, including tea, coffee and lunch (and dinner for some courses) are included.

Accommodation and travel

Accommodation and travel costs are not included in the course prices.

Cancellation policy

Cancellation by attendee

- You are liable to pay 100% of the fees in case of cancellation 2 weeks or less from the course start date
- You are liable to pay 50% of the fees in case of cancellation 3 to 4 weeks from the course start date
- There are no cancellation fees to pay in case of cancellation more than 4 weeks before the course start date
- As an alternative to a cancellation, you can name a replacement to attend in your place

Cancellation by Merck

- Merck serves the right to modify course location, material or instructors, or to restrict course registration
- It may be necessary for reasons beyond our control to cancel a course. We will automatically register you for the following session of this course or the fee will be refunded if no session is available
- Merck is not responsible for airfare penalties or other costs incurred due to cancellation

Scan the QR codes to get more information about our related portfolio

Bioburden Testing

Sterility Testing

Viable Air Monitoring

Millipore®

Preparation, Separation,
Filtration & Monitoring Products

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

MerckMillipore.com

Image: This material image was produced before the Covid19 crisis started. We take our responsibility seriously and fully comply with all protection rules.

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