Elevate your expertise with biopharmaceutical courses.

MilliporeSigma

M Lab™ Collaboration Centers

Millipore®
Expert Pharm/BioPharm Products & CTDMO Services

SAFC®
Pharma & Biopharma Raw Material Solutions

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

The Power of Education

Are you harnessing the power of education to reduce risk and increase speed to market?

Enhance your skill set by taking practical, theoretical, and hands-on bioprocessing courses at our M Lab™ Collaboration Centers or invite our trainers to your site.

Our experts have trained more than 10,000 people and are real world scientists and engineers who work on applications daily, overcoming the same challenges that you face today.

For more information, please see our detailed program at **https://learnatm.emdgroup.com/global/learn** or contact us at ilearn@emdgroup.com.

Introduction

Why train with MilliporeSigma?

We deliver knowledge – it's our business. Whether in one of our state-of-the-art M Lab™ Collaboration Centers or at your facility, we support the continuous implementation of new technology and practices, as well as changes in regulatory guidelines.

Elevate your expertise with courses ranging from upstream and downstream processing to formulation and final fill.

Who should participate?

Whether you are an operator requiring a certified introduction to a technology or process, or you want to take your specialized skills to another level, you will find a course that is appropriate for you.

Whatever your experience, you will finish your course with new skills you can use now and in the future.

What are some key benefits of attending these courses?

- Minimized risk and reduced deviations in your processes
- Increased process efficiency
- Reduced downtime
- Improved troubleshooting ability
- Increased confidence at work
- Improved operator safety

carefully balance the theoretical and practical elements in our courses.

Our training courses offer participants a wide variety of hands-on options and workshop sessions in which theory is applied in practice, making it more tangible.

About our instructors

Our highly skilled and qualified instructors are experts in every sense, combining technical knowledge with field experience and teaching capabilities.

Our instructors do not spend all their time in the theoretical environment of the classroom; they are also working as scientists and engineers who deal with real applications on a daily basis, confronting the same problems as you.

Location

Training courses are either hosted on-site at our M Lab™ Collaboration Center or held at our partner sites. Some courses can also be held on your premises.*

Courses at the M Lab™ Collaboration Center provide:

- Easy access to state-of-the-art equipment
- Opportunities to share experiences with people from a variety of organizations
- Standard training equipment
- Undisturbed time for training away from workplace interruptions
- Opportunity to visit our manufacturing sites (where applicable)

On-site courses offer:

- Time and money savings on travel and accommodations
- Focus on the equipment and solutions to the real challenges you face in your own workplace
- An opportunity to discuss your specific challenges away from potential competitors

Virtual Reality (VR) training solution:

Our Virtual Reality training solution utilizes advanced VR headsets to immerse users in a highly realistic simulated environment. This allows your operators and engineers to train as frequently as necessary, without the need for any physical systems or consumables.

For more information, please refer to the dedicated section on Virtual Reality Training in this brochure.

*Course availability may depend on location.

Key Training Regulations

The U.S. Code of Federal Regulations 21 CFR Part 211.25a: "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs".

The EU Guide to Good Manufacturing Practice for Medicinal Products Part 1:

§ 2.10: "The manufacturer should provide training for all the personnel whose duties take them into production and storage areas or into control laboratories [...], and for other personnel whose activities could affect the quality of the product."

§ 2.11: "Besides the basic training on the theory and practice of the quality management system and Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programs should be available [...]. Training records should be kept."

M Lab™ Collaboration Centers

Every day pharmaceutical and biotech professionals face tough challenges. M Lab™ Collaboration Centers are your resource for designing smart solutions. Whether you're a just-launched biotech venture or an established drug developer, our global network of scientific experts, innovative technologies, and flexible non-GMP facilities is your invitation to explore novel modalities or test drive advanced techniques without disrupting your own operations. Strategically accessible around the globe and virtually via world-class remote access technologies, these vibrant collaboration centers are the key to helping you bring life-enhancing therapeutics to more patients, more efficiently, with more confidence.

Application expertise at your fingertips

M Lab™ Collaboration Centers global network is comprised of 300+ technical experts ranging from process development scientists to bioprocess engineers supporting a variety of modalities. The facilities and highly qualified experts are equipped to help you:

- Troubleshoot your process, identify efficiencies, and adopt innovative techniques.
- Collaborate with industry innovators to overcome barriers to single-use implementation, get guidance for process development, learn best practices for adopting biopharma 4.0 technologies, explore applications for novel modalities, and much more.
- Solve problems and save time annually, in process troubleshooting and deviation investigations.
- Encourage scientific leadership by producing peer-reviewed articles, technical presentations, and patent filings each year.

Explore our global network

The global network of interconnected M Lab™ Collaboration Centers are situated in the hubs of large biotech communities around the world and offer opportunities for collaboration, technical guidance and education to scientists and engineers during in-person or remote visits.

Our facilities include:

- A non-GMP lab setting where you can recreate your process, improve unit operations, and visualize possibilities for scaling up.
- Support in all areas of process development, optimization, scale up, and implementation.
- Access to pilot-scale labs, process development labs, and upstream labs. These allow you to recreate a manufacturing environment, operate equipment, evaluate processes, and receive training across the entire process train, from upstream to downstream and through final fill.
- The opportunity to experiment without disrupting your production line. You have the flexibility to run trials without the strict requirements of your own GMP facilities and SOPs.

Our M Lab™ Collaboration Centers are located all over the world to ensure close proximity to customers.


TABLE

Virtual Reality Courses

Empower your teams, anytime, anywhere.

Elevate your bioprocessing training journey with our innovative Virtual Reality trainings developed by our international engineers and scientists.

These trainings, part of our integrated services offering to support you along your process, offer remote sessions that equip your operators and engineers with essential skills in application, system use, and troubleshooting.

How does it work?

The Virtual Reality trainings use Virtual Reality headsets and immerse users in a highly realistic, simulated environment. Your operators and engineers can train as often as they need without any physical system or consumables.

Essential Program

Focuses on mastering system use, ensuring that your operators and engineers have the fundamental skills for operating our bioprocessing systems effectively.

Advanced Program

Provides in-depth training for self-troubleshooting, empowering your team to handle various system issues with confidence.

What are the benefits?

An interactive experience from the comfort of your office offers many benefits:

High cost efficiency

Our VR trainings do not require physical systems or consumables. Additionally, as they are performed remotely, there are no costs associated with travel and on-site training, further contributing to significant savings for organizations.

Training management optimization

Our VR training programs provide on- demand access, allowing for flexibility that accommodates both individual and organizational schedules, thereby enhancing operational efficiency.

Speed up time to proficiency

Through virtual practice and assessments, these sessions enable trainees to acquire skills more rapidly, ensuring that they can effectively operate our systems and contribute to the success of your projects in a shorter timeframe.

Discover which trainings are available in Virtual Reality format on each course description page.

Practical Information

Registration & price

You may register in one of three ways:

- Contact your account manager
- Send an email to ilearn@milliporesigma.com
- For open session: Register through our LMS platform, Learn@M, at learnatm.emdgroup.com/global/learn

Once we have received your request, we will send you a quote with additional information.

Your registration will be confirmed upon receipt of your Purchase Order. Prices are per person/course. 15% discount for early registration to open sessions (15 days prior to course date).

Accommodation and travel

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

We will be happy to provide you with a list of hotels close to your training venue.

Management through our platform Learn@M

- Individual account to follow training journey
- Access to training material for application trainings and product trainings when available
- Certificate of participation or achievement (applicable when a quiz or test is required to certify the training.)
- Access to a panel of free courses

What will you receive

(depending on the training)?

- Training material and presentation when available
- The latest regulatory guidelines
- A certificate of attendance or achievement
- Protocol and results of laboratory sessions

Hands-on session requirement

- Please refer to the number of attendees recommended to ensure a good experience with the equipment
- Please refer to the protective equipment needed

Catering

For training provided at our locations, refreshments including tea, coffee, and lunch are included.

Cancellation policy

Cancellation by attendee

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

Cancellation by us

- We reserve 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.
- We are not responsible for airfare penalties or other costs incurred due to cancellation.

Summary

Biopharmaceutical Courses

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Biopharmaceutical Courses

Application Trainings

List of available courses

Application trainings

Theses courses are available in different delivery formats. Find more information on the respective course description page.

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Normal Flow Filtration

Introduction to normal flow filtration principles and operation

Half-day course

Overview

During this half-day course, you will be introduced to the principles and steps of normal flow filtration (NFF) and its applications.

This training will also address the topic of integrity testing.

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

- Explain how normal flow filters are constructed and how they work
- Explain basic NFF concepts and terminology
- Explain how normal flow filters are integrity-tested, and use the troubleshooting tools

Who should attend?

This course is designed for staff from R&D, pilot and production departments who have little or no background in NFF.

Which of your challenges does this course address?

- Understanding normal flow principles and practices
- Translating NFF terminology and measurements
- Understanding normal flow processes such as clarification, prefiltration, viral filtration and final filtration
- Construction and operation of NFF modules

Ordering information

TRNFF01: Training in one of our M Lab® Collaboration Centers for 5-15 attendees

TRCSNFF01: Training at your site for 5-15 attendees

TRNFF01 and **TRTFF01** can be ordered together under category code **TRINTFILT**

TRCUSTOM: Customized training at one of our M Lab® Collaboration Centers or at your site

Course program

Duration: half-day

- Welcome and course introduction
- Basics of NFF in pharmaceutical & biopharmaceutical processes
- Purpose of filtration in pharm and biopharm processes
- NFF filter types, construction, and operation
- Bubble point, diffusion, integrity-testing principles and practices
- Basis of automatic integrity tests
- Assessment

Normal Flow Filtration

Introduction to normal flow filtration and sizing best practices

Two-day course

Overview

Using a combination of theory and hands-on instruction, you will learn how to select, screen, and optimize the filters to meet your process needs, and how to correctly scale normal flow filters using either constant flow or constant pressure.

What will you be able to do after

attending this course?

- Explain how normal flow filters (NFF) are constructed and how they work
- Explain NFF basics concepts along with retention and sizing terminology
- Understand how to appropriately size your filter and select the right configuration for your process
- Understand how to scale up a NFF step and factors to consider
- Understand the basics of troubleshooting

Who should attend?

The course is designed primarily for those who wish to increase their understanding of the sizing of NFF.

Ordering information

TRNFFSIZING: Training at one of our M Lab™ Collaboration Centers for 5-10 attendees

TRCSNFFSIZING: Training at your site for 5-10 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site

Course program

Day 1

- Welcome and course introduction
- Basics
- Pmax™ sizing approach
- Practical session: Pmax™ sizing
- Pmax™ workshop

Day 2

- Vmax™ sizing approach
- Practical session: Vmax™ sizing
- Vmax™ workshop
- Scale-up considerations
- Scale-up workshop
- Evaluation and conclusion

Normal Flow Filtration

Courses for automatic filter integrity testing

Overview

Using a combination of theory and hands-on instruction, you will learn the key procedures of filter integrity testing, how to read printouts from automatic filter-integrity testers, and troubleshoot filter-integrity test processes. This two-day course covers all current filter integrity tests, including bubble point, diffusive flow, and water-flow integrity testing that apply to all liquid and gas membrane filtration applications.

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

- Explain the basic science of manual and automated integrity testing
- Describe the principles of automatic integrity testers
- Setup, perform an integrity-test and interpret the data
- Understand and solve an invalid test
- Apply troubleshooting guidelines

Who should attend?

The course is designed for all people involved (operators, engineers and QA) in the integrity testing of sterilizing filters in the pharmaceutical and biopharmaceutical industry.

What will the hands-on session cover?

- Perform manual bubble-point and diffusive- flow testing
- Conduct testing and investigate the impact of artifact generation on automatic bubble-point and diffusive-flow measurements.
- Perform manual and automatic water-flow integrity testing

Which of your challenges does this course address?

- Understanding the filter-integrity test principles
- Signing an automatic filter-integrity test print-out without understanding the content
- Releasing or rejecting a sterile batch with a wrong filter-integrity test result
- Uncertainty on how to retest a filter
- Lost production time and deviations due to retesting filters

Ordering information

TRINTEST: Automatic Integrity testing, training at one of our M Lab™ Collaboration Centers for 5-15 attendees

TRCSINTEST: Automatic Integrity testing, training at your site for 5-15 attendees

TRAU0PCER: Automatic Integrity Testing Operator Certification, training at one of our M Lab™ Collaboration Centers for 5-10 attendees

TRCSAU0PCER: Automatic Integrity Testing Operator Certification, training at your site 5-10 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site

Normal Flow Filtration

Course Program: Automatic Filter Integrity Testing

Course Program: Automatic Filter Integrity Testing		
	Automatic integrity testing training	Automatic integrity testing operator certification training
	Course ID: TRINTEST	**Course ID: TRAU0PCER**
Course Properties		
Location	At your site or one of our M Lab™ Collaboration Centers	
Level	Intermediate	Advanced
Duration	1 day	2 days
Number of attendees	Minimum 5, maximum 20	Minimum 5, maximum 10
Training certificate	Certificate of attendance	Certificate of achievement
Hands-on session	✔ Up to 10 attendees per workstation Instructor led demonstration	✔✔✔ Up to 3 attendees per workstation independently
Course Agenda		
Introduction to sterilizing filtration	✔	✔
Bubble point and diffusion theory	✔	✔
Practical session: diffusion and bubble point	✔	✔✔✔
Automatic integrity testing method	✔	✔
Practical session: automatic integrity testing	✔	✔✔✔
Hydrophobic filter integrity test theory	✔	✔
Practical session: hydrophobic filter integrity testing	✔	✔
Certification test		✔
Establishing and troubleshooting filter integrity test processes	✔	✔

Normal Flow Filtration

Good design practices for sterile filtration

One-day course

Overview

This one-day course provides an in-depth knowledge of good design practices for sterile filtration processes. Based on fundamental design principles, it covers good engineering practices for sterile liquid and gas filtration.

Standard operating procedures (SOPs) and validation approaches are reviewed for fixed and autoclaved filtration equipment. Attention is given to current topics like pre-use post- sterilization integrity testing (PUPSIT), redundant filtration, single-use gamma-irradiated assemblies, and hybrid (i.e. a combination of stainless steel and disposable components) solutions for liquid transfer.

Who should attend?

The course is primarily designed for process design, process transfer, production management, manufacturing, technical support, and process validation personnel with a basic understanding of filtration practice.

Which of your challenges does this course address?

- Understanding in-place filter integrity testing
- Problems in sterilizing/autoclaving and integrity-testing filters
- Difficulties in qualifying SIP and autoclave cycles
- Poorly designed filtration systems
- Difficulties in sterilizing and testing vent filters in critical operations

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

- Explain how to design sterile filtration processes that include pre-use post sterilization as well as post-use filter-integrity testing procedures
- Correctly design new filtration systems
- Identify issues and optimize procedures in existing installations
- Write your own SOPs for inline sterilization and integrity testing of filters
- Perform validation of filter sterilization processes

Ordering information

TRSIPFLTR: Training at one of our M Lab™ Collaboration Centers 5-15 attendees

TRCSSIPFLTR: Training at your site for 5-15 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site

Course program

Day 1

- Welcome and course introduction
- Fundamentals of moist heat sterilization
- Designing a filtration system for steam sterilization
- Standard operating procedures – steam sterilization and integrity testing
- Filter autoclaving
- Validation of steam sterilization and autoclave cycles
- Conclusion

Normal Flow Filtration

Understanding regulation of sterile filtration applications

One-day course

Overview

The course provides an in-depth review of current global regulatory practice for filtration applications in aseptic processing. Detailed discussion of the qualification and validation of these applications will enable you to answer any questions which might arise during inspections or audits.

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

- Discuss the regulatory authorities current expectations for sterile filtration and specific validation of filtration applications
- Interpret guidance on filtration from the U.S. Food and Drug Administration (US FDA); European Medicines Agency (EMA); International Conference on Harmonization (ICH); World Health Organization (WHO); Parenteral Drug Association (PDA); and International Organization for Standardization (ISO)
- Describe filter validation studies such as microbial retention testing, extractable and leachable substance determination, compatibility studies, sterilization, formulation adsorption, and product-related filter-integrity testing
- Create your own validation master plan for filtration
- Explain filter validation studies to your regulatory inspector or internal auditor

Who should attend?

The course is primarily designed for quality assurance, quality control, and validation personnel with a basic understanding of filtration practice.

Participants should have a working knowledge of Good Manufacturing Practices (GMP), validation, qualification, and the relevant regulatory guidelines (e.g. Sterile Drug Products Produced by Aseptic Processing Current GMP, FDA Guidance for Industry, Sept. 2004 - Manufacture of Sterile Medicinal Products, EudraLex Volume 4, Annex 1, 2022.

Which of your challenges does this course address?

- Interpreting the current regulatory environment
- Understanding how to incorporate filter validation in a validation master plan
- Incomplete filter validation documentation
- Lack of expertise in preparing for regulatory inspections
- Problems understanding filter supplier's validation documentation

Ordering information

TRAPVALID: Training at one of our M Lab™ Collaboration Centers for 5-15 attendees

TRCSAPVALID: Training at your site for 5-15 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site

Course program

Day 1

- Welcome and course introduction
- Current regulatory requirements
- Sterilizing-grade filter - definition and manufacturing
- Validation master plan (VMP) for filtration applications
- Bacteria retention test
- Filtration line design for pre-use integrity test
- Extractables and leachables
- Filter steam sterilization validation
- Conclusion

Tangential Flow Filtration

Introduction to tangential flow filtration principles and operation

Half-day course

Overview

During this half-day course, you will be introduced to the principles and steps of tangential flow filtration (TFF) and its applications.

This training will also address the topic of integrity testing.

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

- Explain how tangential flow filters are constructed and how they work
- Explain basic TFF concepts and terminology
- Describe the different steps required in the operation of a TFF system: preparation, process, cleaning and storage, and explain why each is important
- Explain how tangential flow filters are integrity-tested

Who should attend?

This course is designed for staff from R&D, pilot and production departments who have little or no background in TFF.

Interactive workshop

The workshop will allow you to observe a basic TFF setting and the interactions between key operating parameters.

Which of your challenges does this course address?

- Understanding TFF principles, terminology, and measurements
- Understanding the TFF process, and troubleshooting when working on manual or automatic systems

Ordering information

TRTFF01: Training at one of our M Lab™ Collaboration Centers for 5-15 attendees

TRCSTFF01: Training at your site for 5-15 attendees

TRTFF01 and **TRNFF01** can be ordered together under category code **TRINTFILT**

TRCUSTOM: Customized TFF 01 training at one of our M Lab™ Collaboration Centers or at your site

Course program

Duration: 3 hours

- Welcome and course introduction
- Introduction and fundamental theory of TFF
- Membrane types and module design
- TFF process steps and operations
- System components and examples
- Applications of TFF in pharm and biopharm processes
- TFF integrity testing principle
- Assessment

Tangential Flow Filtration

Operator certification for tangential flow filtration module handling

Two-day course

Overview

Using a combination of theory and hands-on instruction, you will learn the key tangential flow filtration (TFF) procedures to increase process efficiency, quality, and consistency as well as to ensure reproducible TFF separation. This two-day course covers the central elements of TFF operation and maintenance including installation, sanitization, and integrity testing. Post-TFF procedures such as cleaning, cleaning assessments, and storage are also highlighted.

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

- Explain the steps required to maintain TFF modules using industry best practices
- Evaluate filter flushing effectiveness
- Conduct integrity testing to evaluate the integrity of the TFF system
- Take manual normalized water permeability (NWP) measurements to determine cleaning effectiveness
- Choose and implement a cleaning protocol based on the type of TFF membrane module and sample composition
- Identify TFF module replacement criteria
- Collect essential data and calculate important TFF module maintenance performance criteria
- Apply troubleshooting guidelines

What will the hands-on session cover?

- Perform manual and automatic integrity testing of TFF modules
- Perform standard cleaning procedures
- Measure normalized water permeability
- Troubleshoot using real case studies

Who should attend?

The course is designed primarily for operators and supervisors who are responsible for TFF processes in pharmaceutical and biopharmaceutical production operations.

Which of your challenges does this course address?

- Ensuring reproducible performance of TFF modules
- Avoiding yield losses and increasing production efficiency
- Maintaining module longevity
- Maintaining microbial control of modules during storage

Ordering information

TRTFF02: Training at one of our M Lab™ Collaboration Centers for 5-10 attendees

TRCSTFF02: Training at your site for 5-10 attendees

TRCUSTOM: Customized TFF 02 training at one of our M Lab™ Collaboration Centers or at your site

Course program

Day 1

- Introduction to TFF
- Basic TFF operation
- Practical session: installing and flushing modules
- Integrity testing TFF modules
- Cleaning TFF modules and practical applications
- Method to determine cleaning effectiveness
- Practical session: measuring integrity and NWP

Day 2

- Practical session: cleaning and NWP troubleshooting exercise
- Practical certification for integrity and NWP measurements
- Demonstration – automatic integrity test
- Integrity testing troubleshooting exercises
- Certification and conclusion

Tangential Flow Filtration

Process development, optimization and scale-up of tangential flow filtration applications

Two-day course

Overview

This two-day course examines the in-depth theory of tangential flow filtration (TFF) as well as the latest techniques to develop an efficient and effective TFF process. During a practical laboratory session, you will determine optimal operating conditions using a model feed stream in a laboratory system to perform flux excursion, concentration, and diafiltration steps.

Interactive case study

Participants will develop a concentration/diafiltration process focusing on aspects including:

- Membrane and module selection
- Operating parameter selection
- Data analysis
- Scale up principles

Who should attend?

This course is designed for R&D scientists and engineers who are responsible for developing and implementing production- scale TFF processes.

What are the prerequisites:

- Basic-TFF knowledge is mandatory.
- Participants must complete the assigned e- learning "Introduction to TFF principles and Operation" prior to the course or have equivalent experience.

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

- Identify and define TFF operating parameters
- Develop methodology for selection of critical TFF parameters
- Develop methodology for operation of TFF processes including concentration and diafiltration
- Operate a screening and optimization protocol
- Apply the scale-up methodology for TFF processes
- Address the challenge of high viscosity in TFF

Which of your challenges does this course address?

- Rapid development of a high performance TFF process
- Understanding process scale-up options
- Assurance of optimum TFF process parameters
- Process issues
- Meeting your product purity and quality targets

Ordering information

TRTFF03: Training at one of our M Lab™ Collaboration Centers for 5-10 attendees

TRCSTFF03: Training at your site for 5-10 attendees

TRCUSTOM: Customized TFF 03 training at one of our M Lab™ Collaboration Centers or at your site

Course program

Day 1

- Course introduction
- Selection of critical TFF parameters
- Operation of TFF processes: concentration
- Practical session: flux excursion
- Workshop: optimum TMP determination
- Practical session: product concentration
- Product concentration data analysis

Day 2

- Operation of TFF processes: diafiltration
- Data analysis: optimum DF point
- Establish scale-up methodology
- Practical session: diafiltration optimization
- Workshop: scale-up
- Course wrap up

Tangential Flow Filtration

Advanced topics in optimization, design, and operation of tangential flow filtration processes

One-day course

Overview

This two independent courses explores the implementation of specific tangential flow filtration processes (TFF) techniques and technologies.

These courses address high-level scientific concerns within TFF design and implementation, including single-pass TFF design and operation, and open ultrafiltration and microfiltration processes.

To fit with your training needs, these courses are modular and can be selected individually or in combination with each other.

Who should attend?

These courses are designed for technically capable engineers, scientists and managers within the biopharmaceutical industry who are responsible for designing, implementing and troubleshooting large-scale TFF systems for possible or current clinical manufacture.

What will the hands-on section cover?

- Implementation of single-pass TFF
- Optimizing TFF microfiltration and highly permeable ultrafiltration processes using permeate control

What will you be able to do after attending these courses?

Process development, optimization, and implementation, of single-pass TFF

- Explain single-pass TFF theory
- Understand the operation and optimization of a single-pass TFF process
- Understand the limitations, use, and implementations of SPTFF
- Understand the scaling principles of SPTFF

Process development, Optimization and implementation of open ultrafiltration, and microfiltration processes

- Explain the theory of permeate controlled TFF and how it differs from TMP controlled TFF
- Explain the challenges of TFF-MF and Open UF processes, and how to mitigate them
- Operate and optimize a TFF-MF or Open UF process in the laboratory and analyze the data

Which of your challenges does this course address?

- Awareness of new process demands on the TFF unit operation
- Fully understanding the theoretical and practical implications of advances in TFF
- Implementation and development of TFF techniques and processes

Ordering information

TRTFF04-SP: Process development, optimization, and implementation, of single-pass TFF, Training at one of our M Lab™ Collaboration Centers for 5-10 attendees

TRTFF04-UF: Process development, Optimization and implementation of open ultrafiltration, and microfiltration processes, Training at one of our M Lab™ Collaboration Centers for 5-10 attendees

TRCUSTOM: Customized TFF 04 training at one of our M Lab™ Collaboration Centers

Course program

Single-Pass TFF module

- Welcome and course introduction
- SPTFF principles
- Value and use
- Process development and implementation
- Case studies
- Practical sessions

Permeate controlled TFF module

- Welcome and course introduction
- TFF-MF and Open UF theory
- Operating parameter optimization
- Scale-up
- Practical session
- Assessment

Virus Safety

Virus filtration process development and validation: best practices

One-and-a-half-day course

Overview

Through a mix of theory, a hands-on part and an interactive case study, participants will learn the key best practices and methods for virus filter sizing, optimization, and validation preparation, enabling them to set up a cost-effective virus filtration process step.

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

- Develop a virus filtration process within a given process design space and regulatory framework
- Identify the key process parameters for optimum sizing and scale-up
- Explain and use the Vmax mathematical model
- Explain and mitigate virus validation artifacts

Who should attend?

The course is designed for process development engineers, QA, validation engineers, and technical support groups.

Participants should have a basic understanding of normal flow filtration and downstream processing.

What will the hands-on session cover?

Selection and sizing of virus filtration trains using a Vmax™ model

Which of your challenges does this course address?

- Interpretation of the current regulatory environment
- Selecting the filter right for your product and selection criteria
- Virus filter optimization to achieve best operational and economical performance
- Increasing production efficiency and robustness

Ordering information

TRVIRFILT: Training at one of our M Lab™ Collaboration Centers for 5-12 attendees TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site

Course program

Day 1

- Course introduction
- Basic virology
- Virus safety of biopharmaceuticals and regulatory
- Virus filtration best practice

Day 2

- Lab session: Vmax™ model
- Vmax™ Data understanding
- Vmax™ Data understanding/ troubleshooting
- Virus filter validation
- Points to consider for scale-up
- Quality by design
- Course wrap up

Single-Use Systems Care and Handling

Introduction to receipt, transportation, inspection, and use of single-use assemblies in manufacturing

One day course

Overview

Through a mix of theory and a hands-on part, participants will learn the key best practices and methods to use single-use assemblies with care for a successful manufacturing campaign.

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

- Understand the fundamental principles of safe single-use assembly handling from warehouse storage to the point of use
- Optimize the underlying SOPs for assembly handling and installation
- Successfully install and use single-use assemblies

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis with single-use assemblies or is involved in defining procedures by writing SOPs. This course is also interesting for warehouse staff involved with storage and unpackaging of single-use assemblies.

What are the pre-requisites?

New bag assemblies

What will the hands-on session cover?

Unpacking, inspection, and installation of a single-use bag assembly into a storage bin or mixer.

Which of your challenges does this course address?

- Minimize the risk of leaks through optimized single-use assembly handling procedures
- Identify and differentiate critical film markings from cosmetic film markings during visual inspection

Ordering information

ATRSUASSEMCS: 1 day training including hands-on, at your site for a minimum 5-10 attendees

ATRSUASSEMMLAB: 1 day training including hands-on at one of our M Lab™ Collaboration Centers for 5-10 attendees

ATRSUASSEMFLOC: 0.5-day theoretical training at one of our M Lab™ Collaboration Centers or at your site

Course program

One day – ATRSUASSEM CS or MLAB

- Assembly manufacturing and shipping
- Pre-use handling
- Bag opening
- Inspection recommendations
- Film background
- Categorizing film markings
- Handling guidance & recommendations
- Quality complaint best practices
- Lessons learned & questionsAssessment

Solid Formulation Box

Training concept of our Solid Formulation Boxes

Overview

The Formulation Box session is a unique virtual learning concept consisting of four main pillars:

- Formulation box
- Virtual event in a classroom
- Experimental time
- Individual consultancy meeting

Who should attend?

This course is designed for pharmaceutical industry scientists, lab technicians, engineers, and managers who are engaged in the development and process optimization of small molecule APIs and final solid dosage formulation science.

Available courses

GLBENG_PS_SFB_BAE02: Bioavailability Enhancement (BAE) online free training covers:

- How the Developability Classification System (DCS) emerged from the well-established Biopharmaceutics Classification System (BCS)
- How the DCS can be used for targeted formulation development of compounds with limited dissolution or solubility
- Give deeper insights into how functional excipients can support in solving bioavailability challenges through multiple case studies and video demonstrations

GLBENG_PS_SFB_COAT01: Tailor-made design of tablet coatings without titanium dioxide online free training covers:

- How to design tailor-made tablet coating formulations with rapid preparation time
- How particle-engineering supports an optimal performance of calcium carbonate in film coatings
- How high efficiency can be maintained in the spraying process
- Use of color measurements and screening methods for formulation development
- An update on regulatory trends for titanium dioxide in medicinal products in EU

GLBENG_PS_SFB_WG & DC: Wet Granulation & Direct Compression (WG & DC) online free training covers:

- How to reduce cost by using functional excipients for wet granulation and direct compression tableting processes
- Formulation development using a range of excipients visualized by video laboratory demonstration
- Best practices for API formulations presented through a series of case studies
- Trends in continuous manufacturing of solid dose formulation

Enrollment

The maximum number of registered companies is restricted to 15

Course program

2 to 2.5 hours

Plenary session:

In a virtual webinar & workshop session, you will learn how the received functional excipients will improve your formulation development.

About 6 Months

Training module I:

Experimental time: In your formulation laboratory you have the opportunity to implement the received excipients in your formulation

1 hour

Training module II:

Some weeks after having tried the excipients, we will invite you for a personal consultancy meeting with one of our solid formulation experts. This will be the time for you to share your formulation experience with our functional excipients.

Liquid Formulation Box

Training concept of our Liquid Formulation Boxes

Overview

The Formulation Box session is a unique virtual learning concept consisting of four main pillars:

- Formulation box
- Virtual event in a classroom
- Experimental time
- Individual consultancy meeting

Who should attend?

This course is designed for pharmaceutical industry scientists, lab technicians, engineers, and managers who are engaged in the development and process optimization of small molecule APIs and final solid dosage formulation science.

Available courses

GLBENG_PS_LFB_Sta & Aggre: Biomolecules Stabilization and Aggregation Prevention online free training covers:

- How to mitigate the strong constraints of biomolecule formulations categorized as **high risk applications**
- How to preserve and maintain biomolecules **stability and efficacy** along the downstream purification process
- How to balance **stability and viscosity** challenges of **highly concentrated antibody** solutions

Enrollment:

The maximum number of registered companies is restricted to 15

Course program

Category	Essential VR Program	Advanced VR Program
Plenary session:	**Training module I:**	**Training module II:**
In a virtual webinar & workshop session, you will learn how the received functional excipients will improve your formulation development.	Experimental time: In your formulation laboratory you have the opportunity to implement the received excipients in your formulation	Some weeks after having tried the excipients, we will invite you for a personal consultancy meeting with one of our solid formulation experts. This will be the time for you to share your formulation experience with our functional excipients.

Biopharmaceutical Courses

Product Trainings

List of available courses

Product trainings

Theses courses are available in different delivery formats. Find more information on the respective course description page.

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Chromatography Systems	
Quikscale® Chromatography Columns Packing	29
CoPrime® Biochromatography System with Common Control Platform® (CCP®) Software V6 - (Training: Operator - Basic – Intermediate – Advanced)	30-31
Mobius® Multi Column Capture System with Common Control Platform® (CCP®) Software V6 - Product Training Advanced	32
Mobius® Single-Use Chromatography System (all), with Common Control Platform® (CCP®) Software V6 - (Training: Operator - Basic – Intermediate – Advanced)	33-34
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Cogent® Lab Systems - Operator Training	35
Cogent® Process-Scale TFF System with Common Control Platform® (CCP®) Software V6 (Training: Operator - Basic – Intermediate – Advanced)	36-37
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ProCellis™ Raman Analyzer	
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Integrity Testing Systems

Integritest® 5 operator integrity testing systems

Half-day course

Overview

This training is recommended for all users of Integritest® 5 (IT5) equipment. The Integritest® 5 is an instrument which is dedicated to make the pre and post integrity verifications of your filters used during your process.

What will the hands-on session cover?

- Overview of Integritest® 5 instrument
- Installation and set-up of the system, tubing, and accessories
- Connection to the HIM
- Basic features of the software
- Receipts creation
- Operating the instrument
- Basic troubleshooting
- Service and maintenance
- Hands-on Session: Install equipment, perform filter test, review and sign test report

Ordering information

PTROPEIT5: Training at your site for a maximum of 4 attendees

Who should attend?

The course is primarily designed for operators and supervisors who are responsible for automatic integrity testing of sterilizing filters. We recommend at least: 2 Operators, 1 Manager and 1 Administrator (within the role in the IT5) to attend.

What are the pre-requisites?

- Only performed with MilliporeSigma filters included in an IT5 MilliporeSigma kit brought/shipped by the MilliporeSigma field service department
- Identify the test to be performed during the lab session: diffusion, or a bubble point or HydroCorr (only performed with water)
- Pressure needed 7.5 bar mini/8.2 bar Maxi
- WFI/purified water (5 to 7 ltr/mn)
- Meeting room and connection to a video projector

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

- Describe the principles of automatic integrity testers
- Setup an integrity-test system with your IT5
- Perform automatic integrity testing
- Interpret the outcome of the automatic report of the integrity tests
- Decide when a filter integrity test fails
- Apply basic troubleshooting guidelines
- Create a recipe/user and back-up of the system
- Follow the MilliporeSigma instructions to wet a filter

Course program

Duration: one-half-day (5 hours)

- Welcome & course introduction
- Presentation
- Overview of Integritest® 5 instrument
- Installation and setup
- Operating the instrument
- Troubleshooting
- Service and maintenance
- Quiz
- Lab Session
  - Install equipment and connect all interfaces
  - Prepare filter and review filter test information
  - Perform water diffusion, or a bubble point or HydroCorr™ test (only performed with water)
  - Review and sign test report

Related Trainings

Normal Flow Filtration Trainings:

- Introduction to automatic filter integrity testing
- Operator certification for automatic filter integrity testing training

Please refer to pages 14 & 15.

Chromatography Systems

QuikScale® Chromatography Columns packing training

Two-day course

Overview

Training is available for QuikScale® Chromatography Columns (all sizes) for operators.

Training is provided by a MSAT packing expert preferentially on customer's site or if required, in one of the our M Lab™ Collaboration Centers. This training includes a column handling, disassembling-reassembling part and the column packing part with the selected chromatography gel.

What will the hands-on session cover?

- Column description with focus on its specificities
- Functioning of the adjuster wedge-seal using compressed air or the delivered hand-pump
- Column packing and unpacking including tips & tricks
- Introduction to column maintenance

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

- Understand column functioning in detail
- Be able to safely disassemble and reassemble the column
- Pack the column with a high rate of success
- Efficiently unpack a column
- Clean and store the column properly
- Perform column maintenance

What are the pre-requisites?

- A column that ideally has been controlled by MilliporeSigma Field Service
- The chromatography gel to be packed
- A chromatography system with HETP measurement capability
- Hoses TC with adapted connectors for the set-up
- Packing buffer or solutions
- HETP/AS tracer solution either a 2% Acetone solution or 2M Sodium chloride
- A tool kit that includes the needed tool for column disassembling/reassembling detailed during the training preparation meeting

Who should attend?

The course is primarily designed for any function (operators and engineers) who will work in a regular basis with the equipment.

Which of your challenges does this course address?

- Emprove efficiency and reduce your workload
- Receive expert hands-on training to ensure optimal usage

Ordering information

TRCSQUIKSCL2: Quickscale® Chromatography Columns, Advanced training, column dis-re-assembling, packing with explanation, at your site for a maximum of 5 attendees

Course program

Day 1

- Welcome and course introduction
- Attendees' expectations monitoring
- Column description wedge seal functioning
- Column disassembling and reassembling
- Column preparation for packing
- Column packing

Day 2

- Column unpacking
- Column cleaning
- Column storage discussion
- Training wrap up

Chromatography Systems

CoPrime® Biochromatography System training

Overview

Our support services provide everything you need to operate your equipment confidently in a manual and/or automatic set-up.

These services can help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by experts who have unique internal knowledge of our equipment and years of experience.

What will the session cover?

- Theoretical session: overall design, P&ID, and components identification
- Hands-on session: practice on the system
- Question and answer session
- Assessment and correction
- Certificate of attendance

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work with the equipment on a regular basis

What are the pre-requisites?

- Functional system, IQOQ performed andpassed
- Access to water and pressurized air
- A usable/empty chromatography column
- Laptop with the CCP recipe editor software installed and operational

Which of your challenges does this courses address?

- Speed up systems integration and implementation
- Improve efficiency and reduce your workload
- Receive expert hands-on training to ensure optimal usage
- Offer optimal solutions for projects with high complexity and tight timelines

Ordering information

PTRCPBOP: CoPrime® Biochromatography System, Operator training, 0.5 day, at your site for a maximum of 5 attendees

PTRCPBCCP1: CoPrime® Biochromatography System with Common Control Platform® (CCP®) Software V6, Basic training, 1.5 days training, at your site for a maximum of 5 attendees

PTRCPBCCP2: CoPrime® Biochromatography System with Common Control Platform® (CCP®) Software V6, Intermediate training, 3 days training, at your site for a maximum of 5 attendees

PTRCPBCCP3: CoPrime® Biochromatography System with Common Control Platform® (CCP®) Software V6, Advanced training, 4.5 days training, at your site for a maximum of 5 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site (including remote capabilities)

Chromatography Systems

CoPrime® Biochromatography System training

Course Program: CoPrime® Biochromatography System with Common Control Platform® (CCP®) Software V6				
	Operator training	**Basic training***	**Intermediate training**	**Advanced training**
	Course ID: PTRCPBOP	**Course ID: PTRCPBCCP1**	**Course ID: PTRCPBCCP2**	**Course ID: PTRCPBCCP3**
Introduction to basics of chromatography		✔	✔	✔
Introduction and system overview	✔	✔	✔	✔
System installation			✔	✔
Human machine interface (HMI) overview	✔	✔	✔	✔
Manual control of the system			✔	✔
Recipe editor tool and batch reporting		✔	✔	✔
Process control			✔	✔
Troubleshooting			✔	✔
Programming basics		✔	✔	✔
Recipe writing session		✔	✔	✔
Water runs and recipe fine-tuning				✔
Assessment and correction		✔	✔	✔
Wrap up		✔	✔	✔
Recommended Audience	Operators and supervisors	Operators, supervisors and engineers	Operators, supervisors and engineers	Operators, supervisors and engineers

* For this training, participants should have already attended the operator training

Chromatography Systems

Mobius® Multi Column Capture System, product advanced training

Two-day course

Overview

Appropriate training for users is not only a GMP requirement, it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process.

Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money.

What will the session cover?

Our training services cover system use and programming with interactive hands-on sessions:

- Installing the Flexware® assemblies
- Interacting with the human machine interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Flexware® assemblies
- Access to water and pressurized air
- Ideally minimum one usable/empty Chromatography Column
- Laptop with the CCP recipe editor software installed and operational

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

Which of your challenges does this courses address?

- Speed up systems integration and implementation
- Improve efficiency and reduce your workload
- Receive expert hands-on training to ensure optimal usage
- Offer optimal solutions for projects with high complexity and tight timelines

Ordering information

PTRMCCCS3: Mobius® Multi Column Capture System with Common Control Platform® (CCP®) Software V6, Advanced Training, 2 days, at your site for a maximum of 5 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site (including remote capabilities)

Course program: Mobius® Multi Column Capture System

Day 1

- Welcome and course introduction
- Principle of Continuous Capture Chromatography refresher Working principles of MCC
- Hardware & Flexware® presentation (includes Flexware® installation)
- Software presentation
- Recipe and report editor presentation

Day 2

- System pre-use preparation
- Set, start and follow a continuous process
- Lab hands on water run
- MCC troubleshooting & what could go wrong
- Recipe writing for MCC, what is possible and what is not
- Wrap-up and Q&A

Chromatography Systems

Mobius® Single-Use Chromatography System training

Overview

Our support services provide everything you need to operate your equipment confidently in a manual and/or automatic set-up.

These services can help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by experts who have unique internal knowledge of our equipment and years of experience.

What will the session cover?

- Theoretical session: overall design, P&ID, and components identification
- Hands-on session: practice on the system
- Question and answer session
- Assessment and correction
- Certificate of attendance

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Flexware® assemblies
- Access to water and pressurized air
- Ideally a usable/empty chromatography column
- Laptop with the CCP recipe editor software installed and operational

Which of your challenges does this courses address?

- Speed up systems integration and implementation
- Improve efficiency and reduce your workload
- Receive expert hands-on training to ensure optimal usage
- Offer optimal solutions for projects with high complexity and tight timelines

Ordering information

OPTRMobChrom: Mobius® Single-Use Chromatography System, Operator Training, 1 day, at your site for a maximum of 5 attendees

PTRMobChromCCP1: Mobius® Single-Use Chromatography System, with Common Control Platform® (CCP®) Software V6, Basic Training, 1.5 days training, at your site for a maximum of 5 attendees

PTRMobChromCCP2: Mobius® Single-Use Chromatography System, with Common Control Platform® (CCP®) Software V6, Intermediate Training, 3 days training, at your site for a maximum of 5 attendees

PTRMobChromCCP3: Mobius® Single-Use Chromatography System, with Common Control Platform® (CCP®) Software V6, Advanced Training, 4.5 days training, at your site for a maximum of 5 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site (including remote capabilities)

Chromatography Systems

Mobius® Single-Use Chromatography System training

Course program: Mobius® Single-Use Chromatography System, with Common Control Platform® (CCP®) Software V6				
	Operator training	**Basic training***	**Intermediate training**	**Advanced training**
	Course ID: OPTRMobChrom	**Course ID: PTRMobChromCCP1**	**Course ID: PTRMobChromCCP2**	**Course ID: PTRMobChromCCP3**
Introduction to basics of chromatography		✔	✔	✔
Introduction and system overview	✔	✔	✔	✔
System installation			✔	✔
Human machine interface (HMI) overview	✔	✔	✔	✔
Manual control of the system			✔	✔
Recipe editor tool and batch reporting		✔	✔	✔
Process control			✔	✔
Troubleshooting			✔	✔
Programming basics		✔	✔	✔
Recipe writing session		✔	✔	✔
Water runs and recipe fine-tuning				✔
Assessment and correction		✔	✔	✔
Wrap up		✔	✔	✔
Recommended Audience	Operators and supervisors	Operators, supervisors and engineers	Operators, supervisors and engineers	Operators, supervisors and engineers

* For this training, participants should have already attended the operator training

Tangential Flow Filtration Systems

Cogent® Lab Systems - operator training

Half-day course

Overview

Training is available for operators of all sizes of Cogent® Lab systems. The training is provided by MSAT members on customer site or remotely, worldwide. This training aims to train operators in the installation and set-up of the system and in the use of the software.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system
- Knowledge in TFF
- Remote training: camera and Internet connection on the computer used as HMI is not mandatory but facilitates software training.

What will the course cover?

- Installation and set-up of the system, tubing, and accessories
- Connection to the HMI on computer
- Basic features of the software
- Controlling the system manually
- Receipts creation

Ordering information

OPTRCogentLab: Cogent® Lab Systems - Operator Training, 0.5 day training, at your site for a maximum of 4 attendees

Course program

Duration: 4 hours

- Welcome and course introduction
- Assembling the system
- Powering the system on and related golden rules
- Priming the pump and filling the system
- Instrument calibration
- Finding the PCV operating range
- Operations using manual mode
- Get started with recipes

Related Trainings

Tangential Flow Filtration Trainings:

- Introduction to Tangential Flow Filtration Principles and Operation
- Operator Certification for Tangential Flow Filtration Module Maintenance
- Process Development, Optimization and Scale-up of Tangential Flow Filtration Applications
- Advanced Topics in Optimization, Design and Operation of Tangential Flow Filtration Processes

Please refer to pages 18 to 21.

Tangential Flow Filtration Systems

Cogent® Process-Scale TFF System training

Overview

Our support services provide everything you need to operate your equipment confidently in a manual and/or automatic set-up.

Our appropriate training can help you save time, lower costs, and comply with regulations.

For users is not only GMP requirements, it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process.

Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- TFF cassettes holder
- Access to water and air pressurized
- Individual laptop with the offline CCP® recipe editor software installed and operational
- Meeting room for 6 people and connection to a video projector

What will the course cover?

- Interacting with the Human MachineInterface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

Ordering information

PTRCPSOP: Cogent® Process-Scale TFF System, Operator training offering during SAT & IQOQ session, 0.5-day training, at your site for a maximum of 5 attendees

PTRCPSCCP1: Cogent® Process-Scale TFF System, with Common Control Platform® (CCP®) Software V6, Basic training, 1.5 days training, at your site for a maximum of 5 attendees

PTRCPSCCP2: Cogent® Process-Scale TFF System, with Common Control Platform® (CCP®) Software V6, Intermediate training, 3 days training, at your site for a maximum of 5 attendees

PTRCPSCCP3: Cogent® Process-Scale TFF System, with Common Control Platform® (CCP®) Software V6, Advanced training, 4.5 days training, at your site for a maximum of 5 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site (including remote capabilities)

Tangential Flow Filtration Systems

Cogent® Process-Scale TFF System training

Course program: Cogent® Process-Scale TFF System, with Common Control Platform® (CCP®) Software V6				
	Operator training	**Basic training***	**Intermediate training**	**Advanced training**
	Course ID: PTRCPSOP	**Course ID: PTRCPSCCP1**	**Course ID: PTRCPSCCP2**	**Course ID: PTRCPSCCP3**
Introduction to basics of chromatography		✔	✔	✔
Introduction and system overview	✔	✔	✔	✔
System installation			✔	✔
Human machine interface (HMI) overview	✔	✔	✔	✔
Manual control of the system			✔	✔
Recipe editor tool and batch reporting		✔	✔	✔
Process control			✔	✔
Troubleshooting			✔	✔
Programming basics		✔	✔	✔
Recipe writing session		✔	✔	✔
Water runs and recipe fine-tuning				✔
Assessment and correction		✔	✔	✔
Wrap up		✔	✔	✔
Recommended Audience	Operators and supervisors	Operators, supervisors and engineers	Operators, supervisors and engineers	Operators, supervisors and engineers

* For this training, participants should have already attended the operator training

Tangential Flow Filtration Systems

Mobius® Single-Use TFF Systems training

Overview

Appropriate training for users is not only a GMP requirement, but it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process. Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water and air pressurized
- Individual laptop with the offline CCP® recipe editor software installed and operational
- Meeting room for 6 people and connection to a video projector
- Flexware® assemblies and TFF cassettes holder.

What will the course cover?

- Installing the Flexware® assemblies
- Interacting with the Human Machine Interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

Ordering information

OPTRMobTFF: Mobius® Single-Use TFF Systems, Operator training, 1 day training, at your site for a maximum of 5 attendees

PTRMobTFFCCP1: Mobius® Single-Use TFF Systems with Common Control Platform® (CCP®) Software V6, Basic training, 1.5 days training, at your site for a maximum of 5 attendees

PTRMobTFFCCP2: Mobius® Single-Use TFF Systems with Common Control Platform® (CCP®) Software V6, Intermediate training, 3 days training, at your site for a maximum of 5 attendees

PTRMobTFFCCP3: Mobius® Single-Use TFF Systems with Common Control Platform® (CCP®) Software V6, Advanced training, 4.5 days training, at your site for a maximum of 5 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers or at your site (including remote capabilities)

Tangential Flow Filtration Systems

Mobius® Single-Use TFF Systems training

Course program: Cogent® Process-Scale TFF System, with Common Control Platform® (CCP®) Software V6				
	Operator training	**Basic training***	**Intermediate training**	**Advanced training**
	Course ID: OPTRMobTFF	**Course ID: PTRMobTFFCCP1**	**Course ID: PTRMobTFFCCP2**	**Course ID: PTRMobTFFCCP3**
Introduction to basics of chromatography		✔	✔	✔
Introduction and system overview	✔	✔	✔	✔
System installation			✔	✔
Human machine interface (HMI) overview	✔	✔	✔	✔
Manual control of the system			✔	✔
Recipe editor tool and batch reporting		✔	✔	✔
Process control			✔	✔
Troubleshooting			✔	✔
Programming basics		✔	✔	✔
Recipe writing session		✔	✔	✔
Water runs and recipe fine-tuning				✔
Assessment and correction		✔	✔	✔
Wrap up		✔	✔	✔
Recommended Audience	Operators and supervisors	Operators, supervisors and engineers	Operators, supervisors and engineers	Operators, supervisors and engineers

* For this training, participants should have already attended the operator training

Tangential Flow Filtration Virtual Reality

Tangential Flow Filtration Virtual Reality for Mobius® TFF 80 System, Mobius® FlexReady Solution for TFF

Overview

The Virtual Reality training, part of our integrated services, immerses users in a highly realistic, simulated environment where operators and engineers can train as often as they need without any physical system or consumable.

Who should attend?

The course is dedicated to any function (from operators to engineers, and quality, and others) who need to understand how the different steps of the process are conducted on the equipment. However, it is primarily designed to train operators on the various manual actions they'll have to perform.

What are the pre-requisites?

- Individual virtual headset

What are the features?

- Product & operator training of the Mobius® FlexReady Solution with Smart Flexware® assemblies for TFF and the Mobius® TFF systems
- Virtual demonstration of key features of the product
- Most commonly faced error translated in troubleshooting case
- Tests & Attendance certificate provided
- On-Demand and collaborative platform, you can do trainings and re-fresh whenever you want

What will the course cover?

Our VR training offer includes system use and troubleshooting, enabling you to develop and maintain your skills, guaranteeing the success of your projects.

Ordering information

VRPTRMBSTFFESS: Mobius® TFF80 virtual reality training yearly subscription, essential program for TFF80 - system use

VRPTRMBSTFFADC: Mobius® TFF80 virtual reality training yearly subscription, advanced extension – additional to essential program for TFF80 - system self-troubleshooting

VRPTRTFF23SESS: Mobius® FlexReady® TF2S and TF3S virtual reality training yearly subscription, essential program for TF2S/3S - system use

VRPTRTFF23SADC: Mobius® FlexReady® TF2S and TF3S virtual reality training yearly subscription, advanced extension – additional to essential program for TF2S/3S - system self-troubleshooting

Course program

Category	Essential VR Program	Advanced VR Program
Subscription focus	Operator & Product	Operator, Product and Basic Troubleshooting
Live Q&A with MilliporeSigma expert		1 hour per month
Customer support	Included	Included
Troubleshooting		Included
Basic custom requests (integrate Video or PPT)	–	–
License type	Regional	Global
Subscription mode	Yearly	Yearly

Clarification Systems

Millistak+® Pod Holder product training

Half-day course

Overview

Designed for pharmaceutical and biotechnology manufacturing personnel who operate midstream processing equipment, our interactive course provides an overview of the Millistak+® Pod Holder as well as the entire Depth Filtration portfolio. To satisfy cGMP requirements, course graduates will receive a certificate upon completion.

With us as your guide, your operators and engineers will be better prepared to design a run an optimized clarification step.

Who should attend?

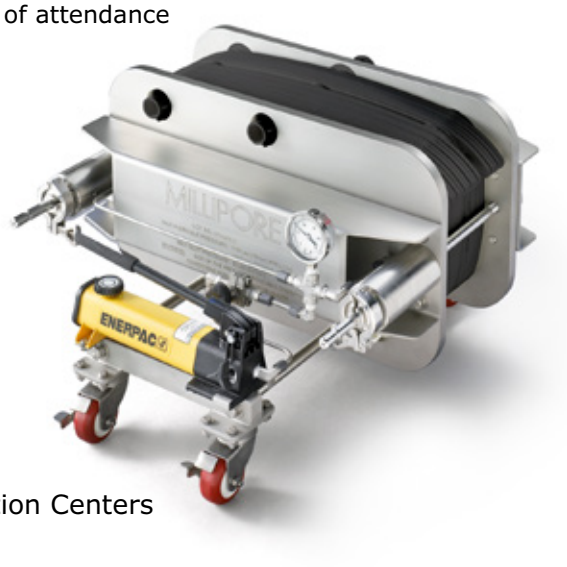
The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water, compressed air, and collection bins
- Tubings, devices, filters, and adaptors
- Meeting room for 6 people and connection to a video projector

What will the course cover?

- Theoretical session
- Hands-on session: practice on the system
- Question and answer session
- Certificate of attendance



Ordering information

PTRPODHLD: Millistak+® Pod Holder operation training, 0.5 day, at your site for a maximum of 4 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers

Course program

Duration: 0.5 day

- Depth filtration theory
- How to chose the right filtration train
- Hardware overview
- Manual operation of the assembled system – key parameters, step-by-step operation
- Safe disassembly

Clarification Systems

Mobius® FlexReady Solution for Large Scale Clarification training

One day course

Overview

Designed for pharmaceutical and biotechnology manufacturing personnel who operate midstream processing equipment, our interactive course provides an overview of the Mobius® FlexReady Solution for Large Scale Clarification, installation of Flexware® assemblies and software during theoretical and hands-on sessions. To satisfy cGMP requirements, course graduates will receive a certificate upon completion.

With us as your guide, your operators will be better prepared to operate and manage your Mobius® FlexReady Solution for Large Scale Clarification with greater confidence.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water
- Flexware® assemblies, depth filters, and adaptors
- Meeting room for 6 people and connection to a video projector

What will the course cover?

- Theoretical session
- Hands-on session: practice on the system
- Question and answer session
- Certificate of attendance

Ordering information

PTRFRSTCF: Mobius® FlexReady Solution for Large Scale Clarification training, 1 day, at your site for a maximum of 4 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers

Course program

Duration: 0.5 day

- Depth filtration theory
- How to chose the right filtration train
- Hardware overview
- System assembly and software review
- Operation of the assembled system – key parameters, step-by-step operation
- Safe disassembly

Virus Filtration Systems

Mobius® FlexReady Solution for Large Scale Virus Filtration training

One day course

Overview

Designed for pharmaceutical and biotechnology manufacturing personnel who operate downstream processing equipment, our interactive course provides an overview of the Mobius® FlexReady Solution for Large Scale Virus Filtration, installation of Flexware® assemblies during theoretical and hands-on sessions. To satisfy GMP requirements, course graduates will receive a certificate upon completion.

With us as your guide, your operators will be better prepared to operate and manage your Mobius® FlexReady Solution for Large Scale Virus Filtration with greater confidence.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water
- Flexware® assemblies
- Filters and adaptors
- Meeting room for 6 people and connection to a video projector

What will the course cover?

- Theoretical session
- Hands-on session: practice on the system
- Question and answer session
- Certificate of attendance

Ordering information

PTRFRSTVF: Mobius® FlexReady Solution for Large Scale Virus Filtration training, 1 day, at your site for a maximum of 4 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers

Course program

Duration: 1 day

- Virus filtration theory
- Presentation of the Viresolve® Pro solution
- Best practices for operation
- System assembly and installation
- Software overview
- System water runs
- Safe disassembly

Virus Filtration Systems

Viresolve® Pro/Pro+ Magnus Holder training

Half-day course

Overview

Through a mix of theory and hands-on training, with tips and tricks included and troubleshooting guides targeted towards manufacturing, participants will learn the key best practices and methods for installing, prepping and running an optimized virus filtration step.

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

- Successfully install and run a large scale Viresolve® Pro/Pro+ Magnus Holder installation
- Identify the key process parameters to use when designing your process guides and recipes.
- Perform quick and efficient RCA if any manufacturing problems should arise

Who should attend?

The course is designed for process engineers, operators, and technical support groups.

Participants should have a basic understanding of normal flow filtration and downstream processing.

What are the pre-requisites?

- Functional filter devices
- Two power outlets
- Access to water and pressurized air
- Flexware assemblies/tubings
- Meeting room and connection to a video projector

What will the course cover?

Viresolve® Pro/Pro+ Magnus Holder installation and disassembly, preparation and water runs to simulate a process run. Prefiltration included.

Which of your challenges does this courses address?

- Understanding the mechanisms at play in virus filtration
- Selecting the right process parameters to focus on
- Design the most optimized processing recipe
- How to address the most common failure modes

Ordering information

PTRVIRHLD: Viresolve® Pro/Pro+ Magnus holder operation training, 0.5 day, at your site for a maximum of 4 attendees

TRCUSTOM: Customized training at one of our M Lab™ Collaboration Centers

Course program

Duration: 4 hours

- Course introduction
- Basic virus safety regulations
- Viresolve® Pro mechanics
- Operating the Viresolve® Pro device at large scale

Single-Use Connectors

Lynx® S2S Connector product training

Half-day course

Overview

Designed for pharmaceutical and biotechnology manufacturing personnel who need to perform safe sterile connections with high sterility assurance.

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

- Make a proper connection with Lynx® S2S devices and improve process sterility assurance level (SAL)
- Demonstrate the quality, the robustness, the safety and the easy-of-use properties of Lynx® S2S to your colleagues
- Unify SOPs for Lynx® S2S Connector handling across all departments

Who should attend?

The course is designed for operators that need to perform safe sterile connections using the Lynx® S2S sterile connector. This training is also useful for personnel involved in the creation of the associated SOPs.

What are the pre-requisites?

The Lynx® S2S Connector is not provided and should be ordered separately if needed.

What will the hands-on session cover?

Each participant performs three sterile connections under the guidance and with quality feedback from the trainer.

What will the course cover?

- Providing an in-depth understanding of the Lynx® S2S Connector functionality, properties and watch-outs
- Focus on correct Lynx® S2S Connector actuation through the hands-on
- Good assembly design and handling practices

Which of your challenges does this courses address?

- Ensure safe and reproducible sterile connections
- Improve process safety in critical applications

Ordering information

PTRLNXS2S: Lynx® S2S product training, 0.5 day training course on customer site for maximum of 12 attendees

PTRVLNXS2S: Lynx® S2S product training video

Course program

Duration: 4 hours

- Welcome and course introduction
- Lynx® S2S: description of functionality, properties, and watch-outs
- Lynx® S2S handling instructions
- Good assembly design and handling practices
- Hands-on session

MAST® Autosampling Solution

MAST® Autosampling Solution training

Two-day course

Overview

To facilitate seamless integration of the MAST® Autosampling Solution into your process, we offer comprehensive training delivered by our team of global experts that help you save time, lower costs, and comply with relevant regulations.

Our training ensures users have the expertise to properly implement the MAST® Autosampling Solution as part of their process.

Who should attend?

The course is designed for any function (operators, engineers, MSAT, QC & QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water and pressurized air

What will the session cover?

- An overview of the components and functions of the MAST® Autosampling Solution
- Safety information and recommendations
- Utilization of the software interface to perform tasks such as data acquisition, management, and exportation, troubleshooting, integration to analytical instruments (bioanalyzers, HPLC, cell counters)

Which of your challenges does this courses address?

- Speed up systems integration and implementation
- Improve efficiency and reduce your workload
- Receive expert hands-on training to ensure optimal usage
- Offer optimal solutions for projects with high complexity and tight timelines
- Experience automation in sampling requirements and criticalities

Ordering information

PTRMASTCS: MAST® Autosampling Solution intermediate training, 2 days, at your site for a maximum of 10 attendees

Course program

Day 1

- Introduction of autosampling
- MAST® components and capabilitites
- MAST® configuration overview
- MAST® source applications
- MAST® destination applications
- MAST® layout guideline

Day 2

- MAST® software introduction
- MAST® communication capabilities (OPC-UA)
- Troubleshooting
- Hands-On practical session in Lab
- Q&A/Quiz

Mobius® Bioreactor Systems

Mobius® Bioreactor Systems training

One day course

Overview

Designed for biopharmaceutical and biotechnology manufacturing personnel who operate upstream processing equipment, our interactive course provides an overview of the Mobius® Bioreactors, installation of Flexware® assemblies and CCP® software during theoretical and hands-on sessions. To satisfy GMP requirements, course graduates will receive a certificate upon completion.

With us as your guide, your operators will be better prepared to operate and manage your Mobius® Bioreactors with greater confidence.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water and pressurized air
- Flexware® assemblies
- Individual laptop with the offline CCP® recipe editor
- Meeting room for 6 people and connection to a video projector

What will the course cover?

- Theoretical session
- Hands-on session: practice on the system
- Question and answer session
- Assessment and correction
- Certificate of attendance

Ordering information

OPTRBioreact: Mobius® Bioreactor operator training, 1 day, at your site for a maximum of 4 attendees

PTRBioreact-adv: Mobius® Bioreactor advanced training, 1 day, at your site for a maximum of 6 attendees

Course program

Duration: 1 day, operator training

- Overall design, P&ID, identification of all the components of the hardware and flexware
- Understanding of the top-level features of the HMI
- Installation of the Flexware® assembly
- Manual operation of the bioreactor (probe calibration, control loops settings and other components)
- Assessment (optional)

Duration: 1 day, advanced training

- Software overview
- Trends creation
- Report creation
- Recipe writing
- Troubleshooting
- Assessment (optional)

Mobius® Mixing Systems

Mobius® MIX System product operation training

One day course

Overview

Appropriate training for users is not only a GMP requirement, it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process. Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money.

Who should attend?

The course is designed for any function (operators, engineers, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed
- Access to water and pressurized air
- Flexware® assemblies
- Meeting room and connection to a video projector

What will the course cover?

- Installing the Flexware® assemblies
- Interacting with the Human Machine Interface
- Using the Bio4C® ACE software
- Manual and automatic system operation
- Troubleshooting issues
- Managing your own recipes
- Process recommendations

Ordering information

PTRMIXSYS: Mobius® Mixing System operator training, 1 day, at one of our M Lab™ Collaboration Centers (including remote capabilities) for a maximum of 4 attendees

Course program

Duration: 1 day

- Welcome and course introduction
- Introduction and system overview
- System installation
- Human machine interface (HMI) overview

ProCellics™ Raman Analyzer with Bio4C® PAT Raman Software

ProCellics™ Raman Analyzer training

Two-day course

Overview

To ensure smooth and efficient implementation of ProCellics™ Raman analyzer with Bio4C® PAT Raman software, we offer comprehensive training to help you save time, lower costs, and comply with regulations.

Our trainings are delivered by our global experts who have extensive experience with this technology.

What will the session cover?

- An overview of the components and functions of the ProCellics™Raman analyzer with Bio4C® PAT Raman software
- Safety information and recommendations
- Utilization of the software interface to perform tasks such as data acquisition, management, and exportation.

Who should attend?

The course is designed for any function (operators, engineers, PDS, MSAT, and QA) who will work in a regular basis on the equipment.

What are the pre-requisites?

- Functional system, IQOQ performed and passed

Which of your challenges does this courses address?

- Speed up systems integration and implementation
- Improve efficiency and reduce your workload
- Receive expert hands-on training to ensure optimal usage
- Offer optimal solutions for projects with high complexity and tight timelines

Ordering information

PTRCPCLIL: ProCellics™ Raman Analyzer with Bio4C® PAT Raman software training, 2 days, at your site for a maximum of 10 attendees

Course program

Day 1

- Introduction of Raman in bioprocess
- ProCellics™ platform introduction
- Hardware overview
- Software overview

Day 2

- Application Bioprocess
- Monitoring overview demonstration
- Model building overview demonstration
- Hands-on practical session: how to build a Raman model
- Q&A/quiz

Training & Education

Training & Education, part of a comprehensive support services offering

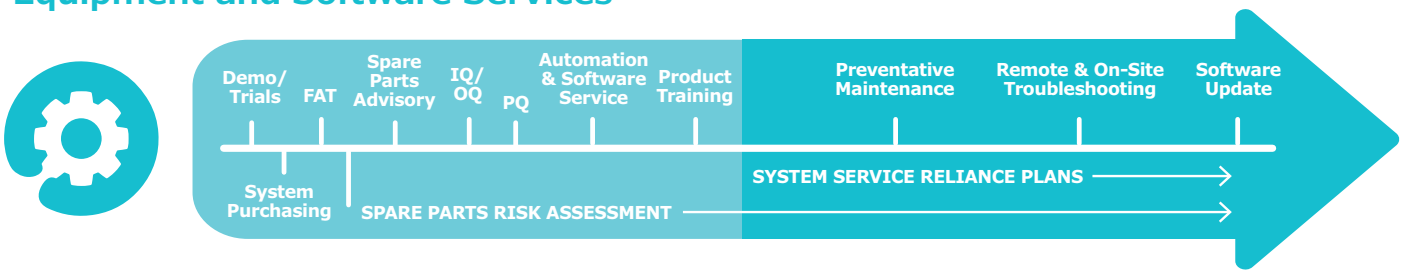
We aim to support all your processes and applications. Our expertise in technical and regulatory matters ensures robust and reliable aid. We assist you at every stage of drug development and manufacturing, aligned with risk management approaches in current regulatory guidance.

Our digital platforms and international team of engineers and scientists are at your disposal. We help you overcome challenges in process development and manufacturing, allowing you to meet your process objectives.

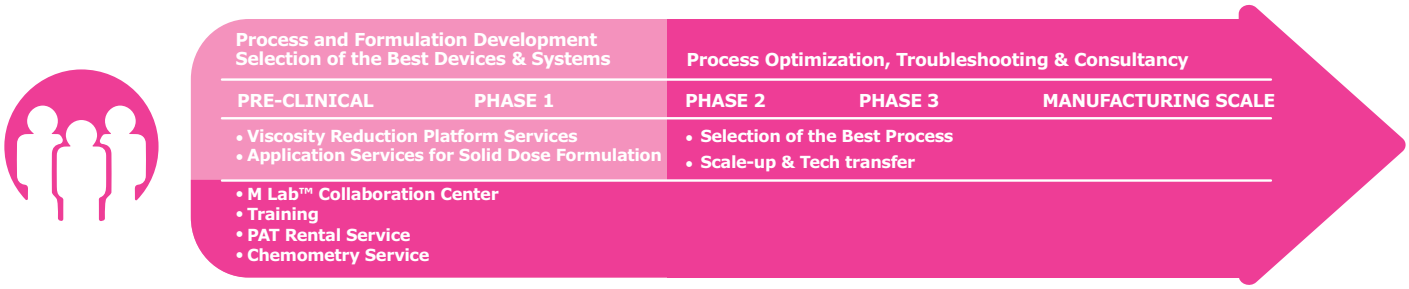
We offer a comprehensive suite of services. These services are designed to help you either implement established proven technologies, approved by regulatory agencies, or adapt to the latest Pharma and Biopharma technologies and processes. We ensure you're always ahead, helping you stay at the forefront of your field.

How we can help you: Our offerings include equipment and software services, process development support, along with quality and regulatory support.

Equipment and Software Services



Process Support



Quality & Regulatory Support

Learn more about our services

- System Service Reliance Plans
- M Lab™ Collaboration Center Training Viscosity Reduction Platform
- Emprove® Program Validation Services Quality and Regulatory Management

For additional information
please visit SigmaAldrich.com

To learn more about us and the M Lab™ Collaboration Centers,
visit **www.sigmaaldrich.com/mlab**

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