

Millipore
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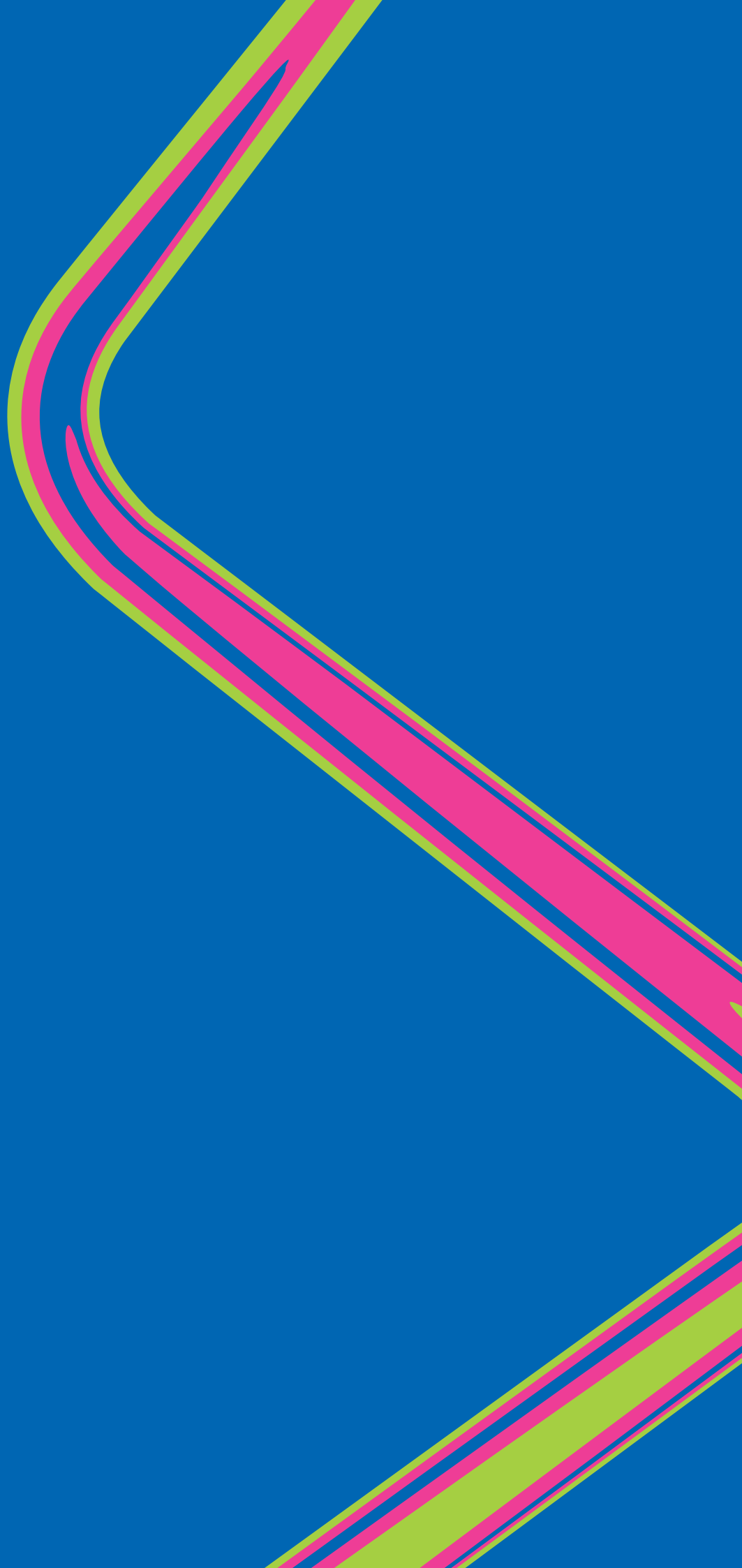
EXPLORE LEARN COLLABORATE

Elevate your expertise with
biopharmaceutical courses.

M Lab™
Collaboration
Centers



The life science business of Merck KGaA,
Darmstadt, Germany operates as
MilliporeSigma in the U.S. and Canada.



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, hands-on bioprocessing and formulation 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 www.emdmillipore.com/training or contact us at ilearn@emdmillipore.com.

Introduction

Why train with M Lab™ Collaboration Centers?

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 our course with 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

Putting theory into practice

It is vital to understand why a technology works as well as how it works. We 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 scientists and engineers who deal with real applications on a daily basis, confronting the same problems as you.

Tailored to your specific requirements

Most of our courses and training materials are modular, enabling our instructors to offer a customized service. They can recommend which modules should be emphasized within the balance of a course. Training can also be adapted to reflect your existing skills and language requirements.

Process technology training is divided into different levels so that you can take the course most appropriate for your required skill level.

Please contact us to discuss your specific training requirements.



Location

Training courses are held at our M Lab™ Collaboration Center in Burlington, MA, USA.

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)

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:

§ 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 programmes should be available [...]. Training records should be kept.”

M Lab™ Collaboration Centers

In today's biopharmaceutical industry, speed is key. Manufacturers are facing growing demand to get to market faster – and with that comes the need for consistent and predictable processes that minimize risk while delivering higher product quality and yield.

We understand the hurdles you can face to meet these requirements. Through good science, services and innovation, we are committed to solving your development and processing challenges. The 200+ scientists and engineers supporting the M Lab™ Collaboration Centers deliver hands-on trainings and technical expertise through all stages of biopharmaceutical and pharmaceutical development and manufacturing.

Global application expertise at your fingertips

M Lab™ Collaboration Centers provide a global network of vibrant collaboration spaces for industry professionals to explore ideas, learn innovative techniques and work side by side with experts to solve critical process development challenges. These non-GMP labs offer customers the flexibility to troubleshoot and test without impacting their production line. Staffed by a network of technical experts, these labs are resource centers for:

- Product and technology demonstrations, evaluations and training at every scale
- Development, optimization, scale-up and implementation of complex applications in a range of processes
- Analytical and modelling support using analytical equipment, custom test equipment and analysis software
- Custom sizing, simulation tools and methodologies
- Access to our scientific and engineering network, R&D personnel, support staff, analytical and development laboratories

State-of-the-art facilities

The M Lab™ Collaboration Centers enable customers to test, assess, and simulate products and technologies to optimize their process, while providing the appropriate training courses.

Our facilities include:

- A pilot phase zone, where processes can be simulated in practice-oriented ways
- A process development and application testing zone, where various experimental procedures can be carried out on a small scale
- A seminar and training zone with state-of-the-art equipment to offer certification courses and seminars



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



Practical information

Registration

You may register in one of two ways:

- Complete the online registration form at www.emdmillipore.com/training
- Send an email to ilearn@emdmillipore.com

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

Venue

Training courses are held at our M Lab™ Collaboration Center in Burlington, MA, USA. Please visit www.emdmillipore.com/training for the most up-to-date information on our course locations.

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, together with travel information.

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.

Course reference table

Please contact your local representative or email ilearn@emdmillipore.com for a quotation.

Description	Days	Reference
Upstream		
Continuous and Intensified Processing in Upstream Cell Culture	3	TRUPSTREAM
Downstream		
Normal Flow Filtration		
Operator Certification for Automatic Filter Integrity Testing	2	TRAUOPCER
Tangential Flow Filtration		
Optimization and Scale Up of Tangential Flow Filtration Applications	2	TRTFF03
Optimization, Implementation, and Scale Up of High Concentration TFF	1	TRTFF04 - HC
Optimization, Implementation, and Scale Up of Single Pass TFF	1	TRTFF04 - SP
Optimization and Implementation of Open Ultrafiltration and Microfiltration Processes	1	TRTFF04 - UF

Summary

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Biopharmaceutical courses

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Upstream Cell Culture

Continuous and Intensified Processing in Upstream Cell Culture

Three-day course

Overview

This course combines lectures, hands on laboratory practices and simulation exercises covering the most critical concepts in upstream animal cell culture technology, specifically focusing on continuous and intensified processes.

Topics include cell line engineering and development, animal cell culture media and its optimization, and understanding critical bioreactor parameters and scalability.

Learning Goals:

- Perfusion systems and their potential applications, as well as general knowledge on available cell retention devices
- Overview of the process and techniques used in the development of recombinant cell lines, including troubleshooting and Go/No-Go decisions throughout
- Critical steps utilized during a transfection process and recognition of technical challenges and potential solutions
- Principles of methods and criteria used for screening and for selection of recombinant cell lines
- Cell culture media forms, properties, and components, including their characterization
- Differences between fed batch and perfusion small scale models and media optimization methods and selection criteria
- Hydration methods with different types of media and feeds
- Assessment techniques for filter sizing and selection for different formulations and scales
- Understanding of bioreactor components and controls
- Basic operation of a perfusion system using a filtration base cell retention device
- Principles of bioreactor scalability
- Tests to assess learning objectives and presenting results

Who should attend?

- Bioprocessing professionals transitioning from fed-batch processes to next generation intensified processes such as perfusion or intensified fed-batch
- Individuals with experience in upstream animal cell culture but are looking to deepen or review their knowledge
- Anyone interested in extending their knowledge outside their focus of expertise in the area of upstream cell line, cell culture media and process development
- Anyone interested in enhancing their knowledge in the upstream area, from business development partners to upstream development teams

What will you receive?

- A comprehensive course documentation file
- Summary of experimental results
- Certificate of participation

Enrollment limited to 9 participants

Due to the hands-on nature of this course, enrollment is limited to 9. We recommend early booking to ensure a place.

Price

Please contact your local representative or email ilearn@emdmillipore.com for a quote.

Ordering information

Course ID: TRUPSTREAM



Course Program

Day 1 8:00 – 18:00

- Registration and Welcome
- Cell line lecture
- Cell transfection and medium hydration lab
- Lunch
- Bioreactor preparation lab
- Cell freeze/thaw and media filtering lab
- Dinner

Day 2 8:00 – 18:00

- Cell media lecture
- Cell transfection and small scale perfusion lab
- Lunch
- Bioreactor inoculation lab
- Cell media optimization lecture
- Dinner

Day 3 8:00 – 18:00

- Bioreactor lecture
- Bioreactor sampling lab
- Lunch
- Bioreactor lecture continued
- Summary of course results and final discussion

Dates and Locations

Please visit www.emdmillipore.com/training for the dates and locations available for this course.

This course can only be offered at our M Lab™ Collaboration Center in Burlington, MA, USA. Please visit www.emdmillipore.com/training or email ilearn@emdmillipore.com for more information.

Normal Flow Filtration

Operator certification for automatic filter integrity testing

Two-day course

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 a manual integrity-test system and an automatic integrity tester
- Perform manual and automatic integrity testing
- Interpret the outcome of manual and automatic integrity tests
- Decide when a filter integrity test fails
- Apply troubleshooting guidelines

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

What will you receive?

- A copy of the course materials
- A certificate of successful completion

Who should attend?

The course is primarily designed for operators and engineers who are responsible for automatic integrity testing of sterilizing filters in the pharmaceutical and biopharmaceutical industry.

Enrollment limited to 10 participants

Due to the hands-on nature of this course, enrollment is limited to 10. We recommend early booking to ensure a place.

Price

Please contact your local representative or email ilearn@emdmillipore.com for a quote.

Ordering information

Course ID: TRAU0PCER

Hands-on practical section

The practical element of this course covers how to:

- Perform manual and automatic bubble-point testing
- Perform manual and automatic diffusive-flow testing
- Perform manual and automatic water-flow integrity testing
- Troubleshoot integrity-testing procedures



Course Program

Day 1 8:30 – 16:30

- Welcome and course introduction
- Introduction to sterilizing filtration
- Bubble point and diffusion theory and manual test methods
- Practical session - diffusion and bubble point
- Automatic integrity testing method
- Practical session - automatic integrity testing

Day 2 8:30 – 15:00

- Hydrophobic filter integrity testing method
- Practical session - hydrophobic filter integrity testing
- Certification test
- Establishing and troubleshooting filter integrity testing processes
- Conclusion

Dates and Locations

Please visit www.emdmillipore.com/training for the dates and locations available for this course.

Tangential Flow Filtration

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 concentration and cleaning steps. Then, through a real-life case study, you will scale-up and size a TFF process with specific product purity objectives.

Interactive case study

Using data from a real-life case study, participants will develop a concentration/diafiltration process focussing on aspects including:

- Membrane and module selection
- Operating parameter selection
- Data analysis
- System scaling
- Mass balance and yield assessments

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

What will you receive?

- A copy of the course materials
- Protocol and results of laboratory sessions
- The solution from the workshop, showing the design of a production-scale TFF process
- A certificate of attendance

Who should attend?

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

NB: Participants should have a basic understanding of tangential flow filtration, ideally by having completed our "Introduction to tangential flow filtration principles and operation" course or by having equivalent experience.

Enrollment limited to 10 participants

Due to the hands-on nature of this course, enrollment is limited to 10. We recommend early booking to ensure a place.

Price

Please contact your local representative or email ilearn@emdmillipore.com for a quote.

Ordering information

Course ID: TRTFF03

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



Course Program

Day 1 8:30 – 18:15

- Welcome and course introduction
- Tangential flow filtration refresher
- Selection of critical TFF parameters
- Practical session – flux excursion
- Workshop – optimum TMP determination
- Operation of TFF processes - concentration
- Practical session - product concentration

Day 2 8:30 – 17:00

- Operation of TFF processes - diafiltration
 - Workshop - product concentration data analysis
 - Practical session - diafiltration optimization
 - Workshop – optimum diafiltration determination
 - Establish scale-up methodology for TFF processes
 - Workshop – scale-up case study
 - Final assessment
 - Course wrap-up
-

Dates and Locations

Please visit www.emdmillipore.com/training for the dates and locations available for this course.

This training can be delivered on your site or at our Burlington and third party sites at a convenient time. Please contact your local representative or email ilearn@emdmillipore.com to discuss the options.

Tangential Flow Filtration

Advanced Tangential Flow Filtration Courses

Overview

This tangential flow filtration (TFF) techniques course explores the implementation of cutting-edge TFF techniques and technologies.

These courses address high-level scientific concerns within TFF design and implementation, including high-viscosity TFF, 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.

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

Optimization, implementation, and scale up of high-concentration TFF

- Explain the hydrodynamics and rheology which influences pressure drops in TFF processes
- Explain the challenges and strategies employed to successfully process high-viscosity products using TFF
- Describe phenomena which can occur at high concentrations, such as the Donnan effect

Operate and optimize processes with highly concentrated material in the laboratory

Which of your challenges do these courses 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

Optimization, implementation, and scale up of single-pass TFF

- Explain the theory of SPTFF and how it differs from conventional TFF processes
- Explain the applications of SPTFF and where it is appropriate to place in a process
- Explain the optimization of SPTFF and how it differs from conventional TFF optimization
- Carry out SPTFF in the laboratory and analyze the data

Optimization and implementation of open ultrafiltration and microfiltration processes

- Explain the theory of TFF-MF and how it differs from TFF-UF processes
- Explain the challenges in optimizing TFF-MF processes and how to mitigate them
- Operate and optimize a TFF-MF process in the laboratory and analyze the data

What will you receive?

- A copy of the course materials
- Protocol and results of laboratory sessions
- A certificate of attendance

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.

Enrollment limited to 6 participants

Due to the hands-on nature of this course, enrollment is limited to 6. We recommend early booking to ensure a place.

Price

Please contact your local representative or email ilearn@emdmillipore.com for a quote.

Ordering information

Course ID: TRTFF04-HC
TRTFF04-SP
TRTFF04-UF



Hands-on practical section

The laboratory exercise takes place using a realistic feed stream and typical process conditions. Depending on the modules chosen, the laboratory sessions may include:

- Successfully operating very high-concentration TFF processes
- Implementation of single-pass TFF
- Optimizing TFF microfiltration and highly permeable ultrafiltration processes using permeate control

Course Program

High-Concentration TFF module 9:00 – 17:30

- Welcome and course introduction
- HVTFF theory
- Processing challenges
- Practical operative recommendations
- High protein concentration phenomena (Donnan effect)
- Practical session
- Assessment

Single-Pass TFF module 9:00 – 17:30

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

Open UF and MF module 9:00 – 17:30

- Welcome and course introduction
- MFTFF theory
- Operating parameter optimization
- Scale-up
- Practical session
- Assessment

Dates and Locations

Please visit www.emdmillipore.com/training for the dates and locations available for this course.

Contact us for more information

For more information, please visit our website at www.emdmillipore.com/training. Here you will find up-to-date information about course schedules, descriptions, registration, location and contact information.

You can also email our training group at ilearn@emdmillipore.com, or email your local representative at PSClientCare@emdmillipore.com.

To learn more about the us and the M Lab™ Collaboration Centers, visit www.emdmillipore.com/mlabs

