MERCK

EXPLORE LEARN COLLABORATE

Elevate your expertise with biopharmaceutical and pharmaceutical courses.

M Lab™
Collaboration
Centers

The life science business of Merck 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.merckmillipore.com/training** or contact us at ilearn@merckgroup.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 Molsheim, France or 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)

Whereas onsite courses offer:

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

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:

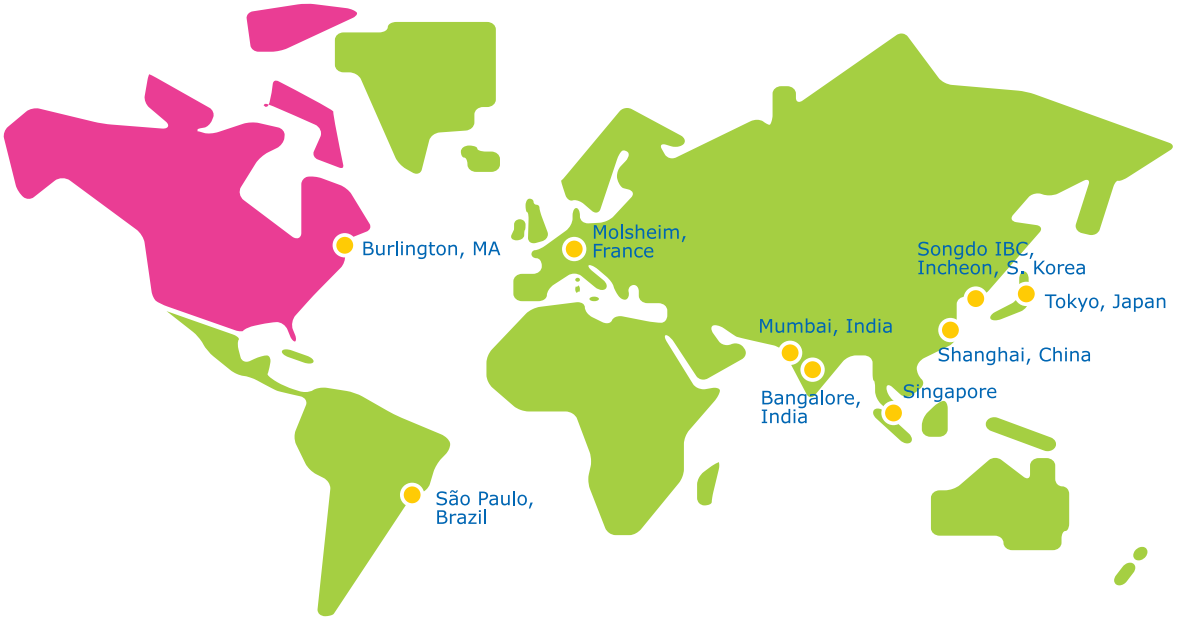
- Product and technology demonstrations, evaluations and training at every scale
- Development, optimization, scale-up and implementation of complex applications in a range of processes
- Analytical and modelling support using analytical equipment, custom test equipment and analysis software
- Custom 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.


E TABLE

Practical information

Registration

You may register in one of two ways:

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

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

Mannheim University of Applied Sciences courses:

Steinbeis Transfer Centre courses at Mannheim University of Applied Sciences courses:

To register, please email:

Andrea Bentz – Transfer Center
Mannheim University of Applied Sciences

Paul-Wittsack-Str. 10
68163 Mannheim, Germany
Tel. +49 (0) 621 2 92 63 16
Fax +49 (0) 621 2 92 64 52
Email stz-tb@hs-mannheim.de

Venue

Training courses can be held at our offices or manufacturing facilities. Please visit www.merckmillipore.com/training for the most up-to-date information on our course locations.

Most courses can also be held at your location (for more information, please see the location information at the end of each course description on www.merckmillipore.com/training).

Mannheim University of Applied Sciences courses are held at:

Steinbeis Transfer Center
Mannheim University of Applied Sciences
Paul-Wittsack-Str. 10
68163 Mannheim, Germany

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@merckgroup.com for a quotation.

Description	Days	Reference
Upstream		
Continuous and Intensified Processing in Upstream Cell Culture	3	TRUPSTREAM
Downstream		
Normal Flow Filtration		
Introduction to Filtration Principles and Operation (TRNFF01 + TRTFF01)	1	TRINTFILT
Introduction to Normal Flow Filtration Principles and Operation	0.5	TRNFF01
Virus Filtration Process Development and Validation: Best Practices	1.5	TRVIRFILT
Operator Certification for Automatic Filter Integrity Testing	2	TRAU0PCER
Good Design Practices for Filter Sterilization	1	TRSIPFLTR
Understanding Regulation of Aseptic Processing and Filtration Applications	1	TRAPVALID
Tangential Flow Filtration		
Introduction to Tangential Flow Filtration Principles and Operation	0.5	TRTFF01
Operator Certification for Tangential Flow Filtration Module Maintenance	2	TRTFF02
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
Chromatography		
Operator Certification for Pilot and Process Chromatography Column Packing	2	TRCHROPCER
Method Development and Scale up of Ion Exchange Chromatography	3	MANNHEIM01
Chromatographic Methods, Strategies and Optimization	3	MANNHEIM02

*Products trainings are also available. Please contact ilearn@merckgroup.com for more information

Summary

Biopharmaceutical Courses

Biopharmaceutical Courses

Upstream Cell Culture

Normal Flow Filtration

Tangential Flow Filtration

Chromatography

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 of 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

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 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@merckgroup.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.merckmillipore.com/training for the dates and locations available for this course.

This training is delivered only at our third party sites. Please contact your local representative or email ilearn@merckgroup.com to discuss the options.

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

What will you receive?

- A copy of the course materials
- A certificate of attendance

Who should attend?

This course is designed for new 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

Enrollment limited to 15 participants

We recommend early booking to ensure a place.

Price

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

Ordering information

Course ID: TRNFF01

Introduction to filtration principles and operation = TRNFF01 + TRTFF01 (Course ID: TRINTFILT)

Course Program

Duration: 3 hours

- Welcome and course introduction
- 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

Dates and Locations

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

This training can be delivered on your site or at our Molsheim site at a convenient time. Please contact your local representative or email ilearn@merckgroup.com to discuss the options.

Normal Flow Filtration

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.

What will you receive?

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

Who should attend?

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

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

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

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@merckgroup.com for a quote.

Ordering information

Course ID: TRVIRFILT

Hands-on practical section

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

Course Program

Day 1
8:30 – 17:00

- Course introduction and welcome
- Basic virology
- Virus safety of biopharmaceuticals, and regulatory
- Break
- Virus filtration introduction and sizing: best practices
- Lunch
- Practical session – Vmax™ filter sizing model: understanding the data, examples, troubleshooting

Day 2
8:30 – 12:00

- Virus filtration validation: best practices
- Break
- Points to consider for scale-up and QbD

Dates and Locations

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

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

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@merckgroup.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.merckmillipore.com/training for the dates and locations available for this course.

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

Normal Flow Filtration

Good design practices for filter sterilization

One-day course

Overview

This one-day course provides an in-depth knowledge of good design practices for aseptic and sterilizing 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.

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

- Explain how to design aseptic filtration processes that include post-sterilization and pre-use as well as post-use filter-integrity testing procedures during production
- 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

Which of your challenges does this course address?

- Understanding inline 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 receive?

- A copy of the course materials
- A certificate of attendance

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.

Enrollment limited to 15 participants

We recommend early booking to ensure a place.

Price

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

Ordering information

Course ID: TRSIPFLTR

Course Program

9:00 – 16:30

- 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

Dates and Locations

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

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

Normal Flow Filtration

Understanding regulation of aseptic processing and 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 authority's current expectations for aseptic filtration and specific validation of filtration applications
- Interpret guidance on filtration and aseptic processing 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

What will you receive?

- A copy of the course materials
- The latest regulatory guidelines
- A certificate of attendance

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 cGMP, validation, qualification and the relevant regulatory guidelines (e.g. Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice, FDA Guidance for Industry, Sept. 2004 - Manufacture of Sterile Medicinal Products, EU Guidelines to Good Manufacturing Practice, Volume 4, Annex 1, Nov. 2008).

Enrollment limited to 15 participants

We recommend early booking to ensure a place.

Price

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

Ordering information

Course ID: TRAPVALID

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

Course Program

9:00 – 17:00

- 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

Dates and Locations

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

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

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.

Interactive workshop

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

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

What will you receive?

- A copy of the course materials
- A certificate of attendance

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

Who should attend?

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

Enrollment limited to 15 participants

We recommend early booking to ensure a place.

Price

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

Ordering information

Course ID: TRTFF01

Introduction to filtration principles and operation = TRNFF01 + TRTFF01 (Course ID: TRINTFILT)

Course Program

Duration: 4 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 principles
- Assessment

Dates and Locations

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

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

Tangential Flow Filtration

Operator certification for tangential flow filtration module maintenance

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 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

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

What will you receive?

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

Who should attend?

The course is designed primarily for production quality or validation personnel who are responsible for TFF processes in pharmaceutical and biopharmaceutical production operations.

Enrollment limited to 8 participants

Due to the hands-on nature of this course, enrollment is limited to 8. We recommend early booking to ensure a place.

Price

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

Ordering information

Course ID: TRTFF02

Hands-on practical section

The practical element of this course covers how to:

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

Course Program

Day 1
8:30 – 17:30

- Welcome and course introduction
- 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
8:30 – 15:45

- 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

Dates and Locations

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

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

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 (pg. 24-25) 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@merckgroup.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.merckmillipore.com/training for the dates and locations available for this course.

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

Tangential Flow Filtration

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

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@merckgroup.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.merckmillipore.com/training for the dates and locations available for this course.

For logistical reasons, this training can only be held at our training facility in Molsheim, France. Please contact your local representative or email ilearn@merckgroup.com to discuss the options.

Chromatography

Operator certification for pilot and process chromatography column packing

Two-day course

Overview

Using a combination of theory, workshops and hands-on practical sessions, this course provides a review of key chromatography process steps and focuses on the methodology to successfully combine equipment with chromatographic media to give reproducible column and separation performance.

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

- Explain the fundamentals of chromatography required to properly pack chromatography columns and assess their performance.
- Identify the components required in well-designed chromatography columns and their influence on column performance.
- Pack and unpack different-sized columns under GMP-compliant conditions.
- Employ several methods for manual and automatic column packing.
- Use advanced troubleshooting techniques to review column and media performance.
- Identify the causes of poor or irreproducible column performance.
- Apply suggested preventive actions when there are column performance issues.

Which of your challenges does this course address?

- Understanding chromatography column components and their correct operation and maintenance
- Insufficient product purity and low process yield due to incorrect column packing
- Lost time due to diagnosing and repacking poorly performing columns

What will you receive?

- A copy of the course materials.
- A certificate of successful completion. The assessment comes from the results of the workshop and a practical quiz.

Who should attend?

The course is designed primarily for operators and engineers responsible for chromatographic column operation in the production of a reliable and reproducible product.

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@merckgroup.com for a quote.

Ordering information

Course ID: TRCHROPCER

Hands-on practical section

The practical sessions use a range of chromatography columns and media commonly found in today's biopharmaceutical processes and cover how to:

- Manually pack and unpack lab and pilot-scale columns
- Automatically pack and unpack an industrial column
- Measure and check column efficiency

Course Program

Day 1
8:30 – 18:30

- Welcome and course introduction
- Review of chromatography fundamentals
- Demonstration - components, column packing and disassembly
- Column packing
- Chromatography systems and columns
- Practical session

Day 2
8:30 – 17:30

- Column troubleshooting
- Practical sessions
- Certification test
- Conclusion

Dates and Location

Please visit www.merckmillipore.com/training for the dates available for this course.

For logistical reasons, this training can only be held at our training facility in Molsheim, France.

Purification Strategy for Biomolecules
in partnership with Steinbeis Transfer Center at Mannheim University of Applied Sciences

Putting theory into practice

In today's evolving workplace, it is vital to understand why and how a technology works. In our Mannheim University of Applied Sciences "Experience purification strategy" courses, you will learn information that can be applied immediately to daily job requirements. We carefully balance the theoretical and practical elements of our courses, providing learning that's critical to success.

Due to the increasing use of recombinant proteins and other biomolecules (such as mAbs) in pharmaceuticals, the development of efficient purification processes for these substances is of major importance. Only safe and efficient production steps guarantee the manufacturing of new drugs. Commonly, the scale-up of a purification process is crucial to the success of a project – after all, only a robust process can be transferred directly to the final production scale without compromising timelines.

Our training program focuses on protein chromatography, optimization and scale-up of chromatographic steps, column packing and testing, and troubleshooting. Additionally, these training courses offer participants a wide variety of hands-on options where theory is applied in practice, making it more tangible.

Who should participate?

Our courses are designed for process development scientists, chemical and biochemical engineers, R&D scientists, downstream process managers, and people interested in gaining a deeper understanding of chromatographic purification processes.

Venue

Steinbeis Transfer Center
Mannheim University of Applied Sciences

Paul-Wittsack-Str. 10
68163 Mannheim, Germany.

Course language

The training will be held in English.
The course manual is also in English.

Course instructors

About our instructors

Our highly skilled and qualified instructors are experts in chromatography from the industry, and combine technical knowledge with field experience and teaching capabilities bringing a balance between theory and real life industry experience.

Purification of Biomolecules Method development and scale-up of ion exchange chromatography

Instructors: Prof. Dr. Christian Frech and Dr. Lothar Jacob.

Purification of mAbs and related proteins Chromatographic methods, strategies and optimization

Instructors: Prof. Dr. Christian Frech and Dr. Lothar Jacob.

Prof. Dr. Christian Frech

Steinbeis Transfer Centre at the University of Applied Sciences, Mannheim

- 2004-present: Director of Steinbeis Transfer Center
- Since 2004: Head of the Institute for Biochemistry at Mannheim University of Applied Sciences
- March 2002: Appointment as Professor for Bioanalytics at Mannheim University of Applied Sciences
- 1996–2002: Head of Pilot Plant Protein Purification, Process Development department at Chiron Behring, Marburg, Germany (now GSK Vaccines GmbH)
- Post-doc at Boehringer Mannheim, Penzberg, Germany (now Roche Diagnostics)

Dr. Lothar Jacob

Consultant, Darmstadt, Germany

- 2015-present: Consultant, Downstream Processing
- 1992-2015: various Marketing roles within the Life Science Business of Merck KGaA, Darmstadt, Germany, focusing on Chromatography media development
- 1987-1992: Laboratory Head Protein Purification, Max-Planck Research for Structural Molecular Biology at DESY, Hamburg, Germany

Method Development and Scale-up of Ion Exchange Chromatography

Course description

This hands-on course introduces tools for the development and scale up of protein separations, focusing on ion exchange chromatography.

The combination of theoretical lectures, industrial case studies and experiments in the lab enables participants to understand and use systematic models and methodologies to develop ion exchange unit operations and transfer these processes from lab to pilot plant or production scale.

Course content

- Basic principles of protein purification and column chromatography
- Theory and Application of the linear gradient elution (LGE) model for optimization and scale-up of ion exchange chromatography
- Case studies presented by experts from industry
- Aspects of resin selection, column packing and large-scale manufacturing

Learning goals

- Understanding of process parameters critical to ion exchange chromatography at small and large scale
- Understanding of principles of gradient elution processes and the LGE model
- Practical optimization and scale up of ion exchange separations using the LGE model

Who should attend?

- Process development scientists
- R&D scientists and technicians
- Process engineers involved in scale up and manufacturing of ion exchange chromatography unit operations

What will you receive?

- Comprehensive course documentation
- Summary of experimental results
- Certificate of participation

Enrollment limited to 8 participants

Due to the hands-on nature of this course, enrollment is limited to 8. We recommend early booking to ensure a place.

Ordering information

Course ID: MANNHEIM01

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

Course fee

€1050

Venue

Steinbeis Transfer Center
Mannheim University of Applied Sciences

Paul-Wittsack-Str. 10
68163 Mannheim, Germany

Course schedule and program:

Day 1:
Start 12:00

- Registration and Welcome
- Basic principles of production chromatography
  - Non-linear vs. linear chromatography
  - Adsorption isotherms and distribution coefficients
  - Screening and selection criteria for resins
  - Important factors in ion exchange chromatography
- Manufacturing of biologics
  - Examples of mAb, recombinant protein and virus processes
  - Chromatographic resins for cGMP production
- Practical, part I
  - Static and Dynamic IgG binding capacity in ion exchange chromatography Column performance testing (plate number, HETP, asymmetry)
- Analysis and discussion of results
- Dinner

Day 2
8:30 – 17:30

- Introduction to linear gradient separation experiments (LGE)
- Practical, part II
  - Design of gradient separations
  - Influence of different parameters on the gradient separation of proteins
- Lunch
- Case study “Optimization and scale up of ion exchange separations”
- Practical, part III
  - Optimization and scale-up of LGE
  - Prediction of step elution
  - Isoresolution curves
- Analysis and discussion of results

Day 3
9:00 – 16:00

- Large-scale protein chromatography
- Column-packing demo and column performance testing
- Packing procedures, column design and troubleshooting
- Lunch
- Summary of course results and final discussion

Purification of mAbs and related proteins: Chromatographic methods, strategies and optimization

Course description

This hands-on course provides a fundamental understanding of chromatographic methods and strategies to purify monoclonal antibodies and related molecules.

The combination of theoretical lectures, industrial case studies and experiments in the lab enables participants to gain a profound knowledge of biochromatography processes.

Course content

- Theory and application of Protein A, ion exchange and mixed-mode chromatography
- Purification strategies for antibodies and related molecules
- Case studies presented by experts from industry
- Quality and safety aspects

Learning goals

- Designing robust chromatographic unit operations
- Defining and optimizing suitable purification strategies
- Evaluating the pros and cons of different techniques
- Selecting analytical tools for process development
- Understand and use all the tools needed to remove process impurities and contaminants

Who should attend?

- Process development scientists
- Chemical and biochemical engineers
- R&D scientists and technicians
- Professionals in areas related to antibody processing

What will you receive?

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

Enrollment limited to 8 participants

Due to the hands-on nature of this course, enrollment is limited to 8. We recommend early booking to ensure a place.

Ordering information

Course ID: MANNHEIM02

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

Course fee

€1050

Venue

Steinbeis Transfer Center
Mannheim University of Applied Sciences
Paul-Wittsack-Str. 10
68163 Mannheim, Germany

Course schedule and program:

Day 1:
Start 12:00

- Registration and Welcome
- Basic principles of antibody purification
  - Antibody structure
  - Protein A affinity chromatography
  - Antibody purification by ion exchange chromatography
  - Static and dynamic binding capacities
- Practical part I
  - Capture of antibodies by Protein A affinity chromatography
  - Ion exchange chromatography for antibody purification
  - Determination of dynamic IgG binding capacities
  - Analysis and discussion of results
- Dinner

Day 2
8:30 – 17:30

- Different chromatographic techniques for the purification of antibodies:
  - Hydrophobic interaction chromatography, hydroxyapatite & mixed mode chromatography, size exclusion chromatography
- Case studies:
  - Regulatory aspects in protein purification and impurities testing
- Practical part II
- Design of an antibody purification process
  - Purification strategies and sequencing of purification steps
  - Post-Protein-A – steps in antibody purification
  - Optimization of intermediate purification steps
  - Optimization of polishing steps

Day 3
9:00 – 16:00

- Case studies:
  - Production of monoclonal antibodies (Xavier Le Saoût)
- Scale up in chromatography
- Presentation and discussion of results
- Course summary and final discussion

Contact us for more information

For more information, please visit our website at www.merckmillipore.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@merckgroup.com, or contact your local representative via one of the following numbers.

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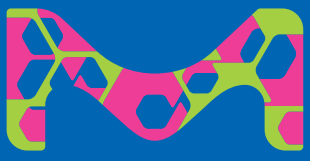

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