Fast Trak™

Training and education

cytiva

Contents

Gain specialist knowledge in bioprocessing

With our Fast Trak education, you can access application training in specialized bioprocessing techniques. The courses provide a tangible learning experience for process development and manufacturing scientists, relevant to everyday work. We offer these courses in a variety of formats to meet your unique learning needs, including hands-on lab experience, instructor-led training (both in-person and virtual), self-paced eLearnings, and custom trainings. Courses can be delivered at our global Fast Trak training centers or at your premises (terms and conditions apply).

Comprehensive training for your specific needs

The Fast Trak courses cover various topics from upstream to downstream. These include cell culture, bioreactor scale-up, column packing, basic chromatography, as well as optimization and scale-up for both pilot and manufacturing scales. Courses can be led in various languages including English, German, Mandarin, Japanese, or other as applicable by location.

Learn best practices in enabling technologies

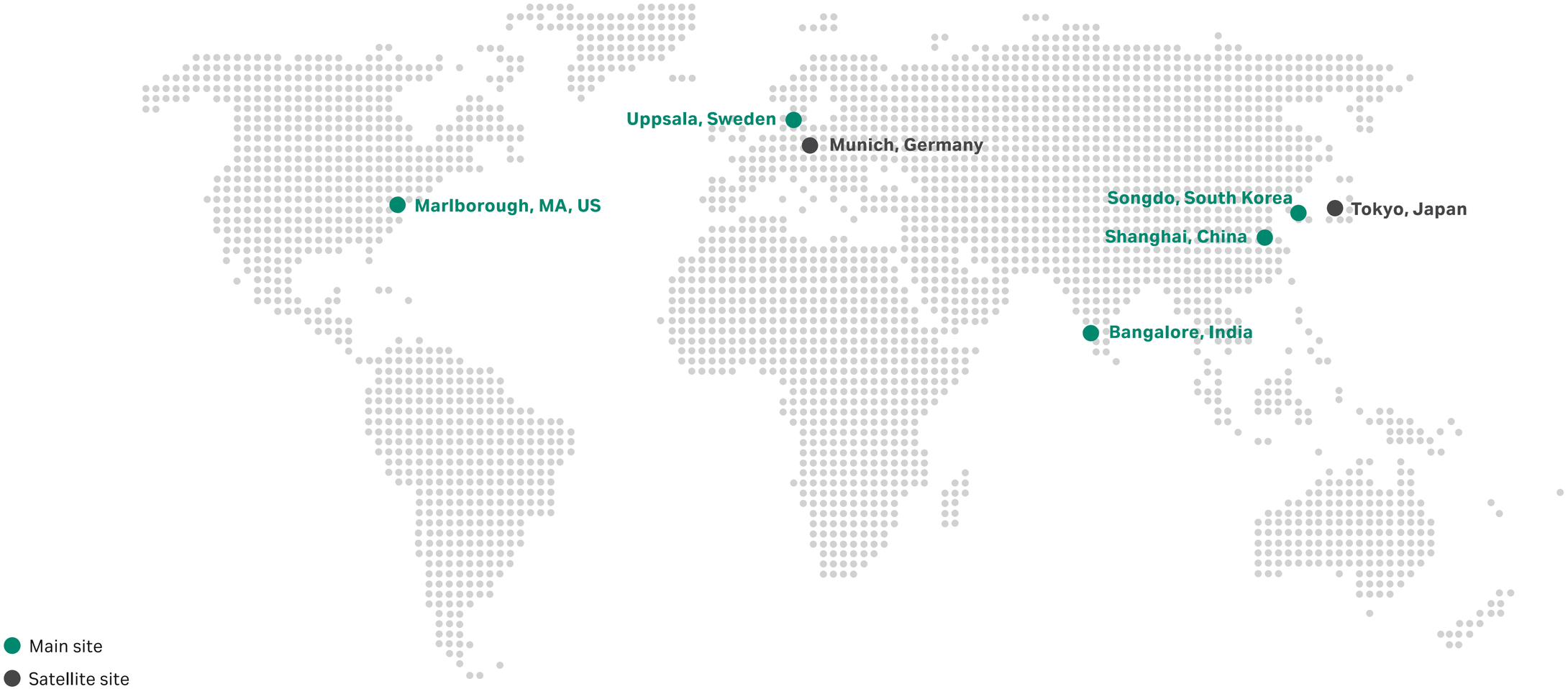
Key aspects of traditional and single-use bioprocessing are covered in our courses. To ensure you learn key considerations for scale-up and manufacturing, we incorporate many opportunities for hands-on learning to complement our instruction on the theoretical concepts.

Expert instructors with insights in today's biomanufacturing challenges

Our regional instructors are passionate about training. They draw on their experiences gained in the biomanufacturing and pharmaceutical industries. The Fast Trak courses allow you to access their deep product knowledge and understanding of the application of those products to your process. By sharing our experts' insights we can empower you to solve your bioprocess challenges.

Global training and education centers

Fast Trak courses are offered around the world, in-person and online, for convenient access to global knowledge. Our training centers include teaching labs furnished with the latest equipment. The Fast Trak regional centers are located in the US, Sweden, South Korea, India, and China. Satellite centers are found in Germany and Japan. While each contributes its own area of expertise, they also serve as a common training and education center for local operations.



01
Upstream processing

Advanced bioreactor cultivation technology (CELL1)

Duration: 3.5 days

Course description

This course covers bioreactor cultivation and upstream process development strategy using single-use equipment. You will learn how to optimize processes and monitor critical parameters for scale-up.

We also discuss validation and process design considerations for good manufacturing practice (GMP).

Practical sessions include bioreactor inoculation and evaluation of cell culture performance using analytical techniques. You will develop a medium and feed strategy based on cell metabolism and scale it up using key engineering principles.

- In-depth training on cell culture technology
- Optimization and development of medium and feed strategy
- Process development and evaluation, scale-up, and bioengineering in an animal cell culture

Who should attend?

This training course will be useful for R&D (research and development) scientists, process engineers, and manufacturing technicians. A basic understanding of cell culture and corresponding techniques is required for this course.

After the course, you will:

- Have a detailed theoretical background about process control strategies in bioreactors and culture scale-up
- Be trained in controlling and evaluating fed-batch cultures
- Understand perfusion culture
- Know how to perform basic characterization of a bioreactor and interpret the results
- Have an overview of strategies used for process optimization

Topics covered

- From cell culture to bioreactor
- Determine mixing time and k_La
- Aseptic fluid transfer
- Process control in bioreactors
- Inoculate fed-batch culture
- Development of cell culture media
- Cell metabolism
- Inoculate a micro-carrier culture
- Process evaluation
- Calculate cell specific nutrient consumption and design a feed concentrate
- Process optimization
- Culture scale-up
- Validation of cell culture-based processes
- Cell separation
- Analysis of product concentration
- Harvest culture

Advanced bioreactor cultivation technology pilot scale (CELL2)

Duration: 3.5 days

Course description

This course covers bioreactor cultivation and upstream process development strategy using single-use equipment at pilot scale (up to 200 L scale). You will learn how to optimize processes and monitor critical parameters for scale-up. It will help you learn how to establish a pilot production process for your preclinical sample production including validation and process design considerations for good manufacturing practice (GMP).

Practical sessions include bioreactor inoculation and evaluation of cell culture performance using analytical techniques. You will develop a medium and feed strategy based on cell metabolism and scale it up using key engineering principles.

- In-depth training on cell culture technology
- Optimization and development of medium and feed strategy for up to 200 L scale
- Process development and evaluation, scale-up, and bioengineering in an animal cell culture

Who should attend?

This training course will be useful for R&D scientists, process engineers, and manufacturing technicians. A basic understanding of cell culture and corresponding techniques is required for this course.

After the course, you will:

- Have a detailed theoretical background about process control strategies in bioreactors and culture scale-up
- Be trained in controlling and evaluating fed-batch cultures
- Know how to perform basic characterization of a bioreactor and interpret the results
- Have an overview of strategies used for process optimization
- Know how to establish a pilot scale production process

Topics covered

- From cell culture to bioreactor
- Determine mixing time and k_La
- Aseptic fluid transfer
- Process control in bioreactors
- Inoculate fed-batch culture
- Perfusion culture
- Development of cell culture media
- Cell metabolism
- Micro-carrier culture
- Process evaluation
- Calculate cell specific nutrient consumption and design a feed concentrate
- Process optimization
- Culture scale-up
- Validation of cell culture based processes
- Cell separation
- Analysis of product concentration
- Harvest culture

Perfusion cultivation technology (CELL3)

Duration: 3.5 days

Course description

This course focuses on perfusion cultivation and process development strategy using single-use equipment. You will learn how to set-up and optimize perfusion processes. Practical sessions include media preparation, line assembly, bioreactor inoculation and evaluation of cell culture performance using analytical techniques. You will develop a perfusion strategy based on cell growth and nutrient consumption.

- Equipment and line setting for aseptic fluid transfer
- In-depth training on perfusion cell culture technology
- Process development and evaluation

Who should attend?

This training course will be useful for R&D (research and development) scientists, process engineers, and manufacturing technicians who are interested in perfusion culture. A basic understanding of perfusion process and corresponding techniques is required for this course.

After the course, you will be able to:

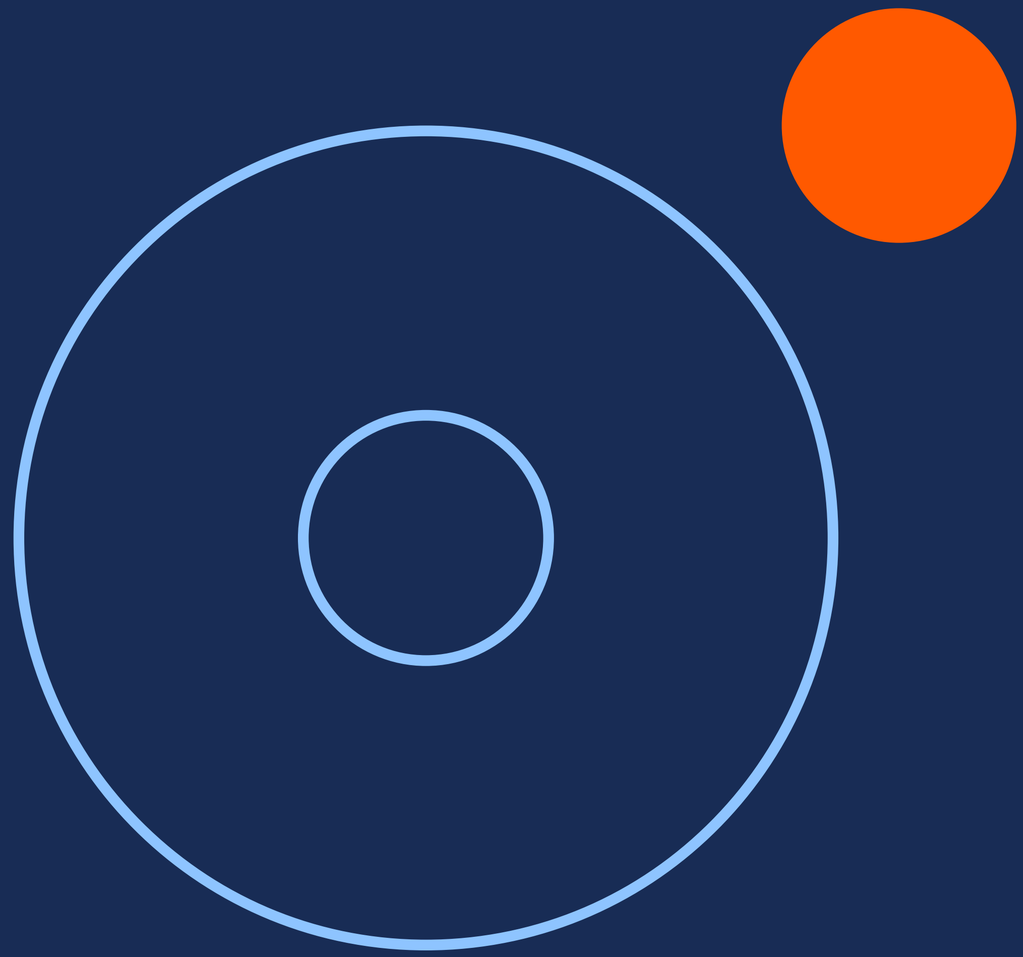
- Have a detailed theoretical background about perfusion process control strategies in bioreactors and scale-up
- Be trained in controlling and evaluating the perfusion culture
- Know how to perform the perfusion culture from material preparation to bioreactor operation
- Have an insight into interpretation of the results and troubleshooting

Topics covered

- Media preparation
- Hollow fiber preparation
- Line preparation
- Aseptic fluid transfer
- Process control in bioreactors
- Development of cell culture media for perfusion culture
- Cell metabolism
- Process evaluation
- Calculate cell specific nutrient consumption and design a perfusion rate scheme
- Process optimization
- Culture scale up
- Validation of cell culture based processes
- Analysis of Product concentration

02

Downstream processing



Introduction to downstream techniques and bioprocessing (DEV1)

Duration: 3 days

Course description

Learn downstream processing techniques suitable for large-scale protein purification and considerations for process development. The course provides understanding of the techniques and parameters governing separation.

You will operate lab-scale ÄKTA avant systems using a variety of chromatography resins to separate and purify a sample of protein.

- Basics in industrial processing and chromatographic techniques suitable for large-scale purification
- Different chromatographic techniques
- Purification strategies and optimization
- Process hygiene and column packing
- Hands-on demonstration of different separation techniques using a sample of purified protein mixture

Who should attend?

- Scientists new to industrial chromatography
- R&D scientists and process engineers interested in reviewing the basics of protein purification

After the course, you will be able to:

- Apply effective chromatographic techniques in your downstream purification process
- Screen and optimize bioprocesses in your process development work
- Understand the issues associated with optimizing chromatographic unit operations in biopharmaceutical production processes

Topics covered

- Purification techniques and strategies
- Size exclusion chromatography (gel filtration)
- Ion exchange chromatography
- Hydrophobic interaction and reversed phase chromatography
- Affinity chromatography
- Column packing and testing
- Optimization
- Scale-up and fine tuning
- Process hygiene
- Regulatory requirements

Advanced downstream bioprocess development (DEV2)

Duration: 5 days

Course description

This hands-on course covers advanced downstream processing design, optimization, and troubleshooting of chromatographic processes. The training is geared towards strategic thinking.

The focus is on design and optimization of critical operating parameters involved in developing a scalable, economic, and robust chromatographic process. Related topics covered include process hygiene, column maintenance routines, and scale-up issues.

You will develop a three-step chromatographic process. You will also optimize the process for purity, recovery, and productivity suitable for manufacturing scale.

- How strategic thinking, optimal choice, and development of chromatographic techniques secure a highly productive and economical process
- Key issues in process development
- Practicals: design and development of a scalable process for purification of a model target protein, enhanced green fluorescent protein (EGFP) from cell homogenate of *E.coli*

Who should attend?

- R&D scientists and process development engineers with basic knowledge of chromatography principles and UNICORN software.
- Scientists and engineers interested in deepening their knowledge about design, optimization, and troubleshooting of chromatographic processes

After the course, you will be able to:

- Identify critical issues in designing a scalable chromatographic process
- Evaluate chromatographic resins and combinations of techniques suitable for industrial purification and scale-up
- Understand optimization strategies for maximizing process performance

Topics covered

- Adsorption chromatography
- Design issues in downstream processing
- Method optimization
- Resin cleaning
- Scale-up with calculations
- Development of a scalable three-step purification process:
  - Optimization of selectivity/binding, elution, capture, intermediate, and polishing steps
  - Optimization of load/dynamic breakthrough capacity
  - Scale-up and verification
  - Different elution strategies
  - Resin screening

Bioprocess scale-up and technology transfer (DEV4)

Duration: 3 days

Course description

Understand advanced late stage process development, scale-up, and transfer. This course will cover process design and optimization for production. It will provide an introduction to validation and column packing. The importance of safety and economic issues related to automation will also be discussed.

You will optimize conditions in a two-step process and work on maintaining separation performance at increasing scales. Group exercises and discussions will focus on "real-life" scale-up issues, complementing the hands-on work.

- Focus on smooth scale-up, well-prepared technical transfer, and the use of chromatography as a manufacturing tool
- Process design, optimization, management, and economy
- Practicals: separation of yeast glucoamylase isozymes at lab-, pilot-, and manufacturing-scale via desalting and ion exchange chromatography

Who should attend?

- R&D scientists or engineers who need to learn more about scale-up, scale-down, and operation of chromatographic methods in a production environment
- Scientists at either end of the transfer process, from lab to production and QA/QC, who need to understand the pitfalls and critical issues

After the course, you will be able to:

- Understand the theory and practice of scaling up chromatographic processes
- Identify critical issues that impact final production performance and economics of bioprocessing
- Suggest improvements for increased productivity, efficiency, effectiveness, and economy

Topics covered

- Process design and optimization
- Scale-up and technical transfer of chromatography and filtration
- Process management, economy, and hygiene
- Qualification
- Validation
- Optimization of chromatography experiments
- Lab- and pilot-scale verification runs
- Final-scale runs
- Scale-up case study exercise

Introduction to design of experiments (DOE1)

Duration: 3 days

Course description

This course gives an introduction to design of experiments (DoE) principles and the statistical terms associated with them. We will also discuss different DoE designs and the process of evaluating results.

Hands-on exercises will provide experience in evaluating various pregenerated DoE data files. You will also set up and run your own DoE experiment on an ÄKTA avant™ or ÄKTA pure™ system, assess potential responses, and evaluate the results.

- Overview of DoE in process development and its application using ÄKTA avant or ÄKTA pure system
- Understand the concept of DoE, how it relates to quality by design (QbD) and how it plays an important role in establishing a process design space
- Discover how to choose a suitable experimental design according to different applications and scenarios
- Learn how to evaluate data from DoE investigations and how DoE results can be employed to define design and operating spaces
- Gain systems and application knowledge related to DoE

Who should attend?

- R&D scientists

After the course, you will be able to:

- Run and design various DoE experiments
- Assess potential response and evaluate DoE data files

Topics covered

- QbD: overview and relevance of DoE
- DoE theory: key concepts, various experimental designs and their properties, evaluation of results from DoE investigations
- Introduction to UNICORN control software

Downstream bioprocessing of monoclonal antibodies (MAB1)

Duration: 4 days

Course description

Get an introduction to the opportunities and challenges involved in the production of monoclonal antibodies (mAbs). You will learn general purification strategies focusing on platform processes using affinity chromatography for capture. We will also discuss polishing steps, including multimodal techniques for key contaminant removal.

In the practical session, you will define operating conditions for a human mAb process optimized for yield, productivity, and process economy. Biosimilars, analytical techniques, and manufacturing-scale considerations for purification of mAbs will also be discussed.

- Downstream processing of mAbs using chromatography
- Discussion of generic purification processes for mAb purification
- Strategies for optimization of the individual chromatography steps
- Introduction to common analytical techniques used for mAb characterization
- Discussion of manufacturing-scale considerations related to the purification of mAbs

Who should attend?

- Scientists and engineers looking for an introduction to process development methods for mAb purification intended for biopharmaceutical applications

After the course, you will be able to:

- Define a platform process for mAb purification suitable to the process objectives
- Develop optimization methods and understand regulatory concerns unique to mAb manufacturing processes
- Understand different purification techniques based on source material

Topics covered

- Introduction to mAb purification
- Sequencing of chromatography steps
- Optimization of capture step
- Purification strategies
- Affinity chromatography in mAb purification
- Ligand leakage from affinity chromatography resins
- Optimization of polishing steps
- Ion exchange chromatography in mAb purification
- Hydrophobic interaction chromatography in mAb purification
- Process hygiene and regulatory issues

Introduction to high-throughput process development (HTPD1)

Duration: 3 days

Course description

This course, with practical exercises, focuses on process development and process optimization of chromatographic purification steps using HTPD. It shows how PreDictor™ 96-well filter plates and PreDictor RoboColumn™, pre-filled with chromatography media (resins) are used both in manual and automated mode to define optimal process conditions. In the laboratory exercises, the use of PreDictor plates for uptake and elution studies is practiced. Furthermore, the automated use of PreDictor RoboColumn units will be discussed. Application examples for the use of HTPD PreDictor plates are presented including practical hints and tips.

Who should attend?

The course is aimed at R&D scientists, development scientists and process engineers who have a working knowledge of chromatographic techniques but would like to benefit from a deeper insight into the use of HTPD.

After the course, you will be able to understand:

- How to plan, design and conduct high throughput process development experiments
- Comprehend key factors to be taken into consideration when executing HTPD applications
- Process applications with case studies

Topics covered

- Basics of high-throughput process development
- Assist software and data evaluation
- Process development workflows
- Binding and elution studies
- Batch uptake and adsorption isotherms
- Application examples

03
Techniques

Large-scale column packing (COL1)

Duration: 3 days

Course description

This hands-on course focuses on optimizing large-scale column packing and handling methods as well as testing and maintenance of chromatography resins in large-scale columns. We will address factors influencing separation performance and the relationship to reproducibility, stability, and economy in an industrial manufacturing setting.

You will pack and test large-scale columns, with different design features and dimensions, using several types of chromatography resins.

- Hands-on practice for preparing and maintaining large-scale chromatography columns
- Column packing — lectures and exercises
- Column testing and troubleshooting
- Detailed column packing procedures as part of course material
- Column qualification and resin lifetime

Who should attend?

- Production personnel responsible for column packing or column performance issues
- Process development scientists, engineers, and operators working with chromatographic columns at pilot- and production-scale (BPG, Chromaflow™ columns, and AxiChrom™ columns).
- System engineers interested in the design and handling aspects of column-based production operations

After the course, you will be able to:

- Understand the critical issues in large-scale column packing based on your own practical experience
- Pack and test large-scale columns more reliably and efficiently
- Identify and troubleshoot operational problems common to column chromatography

Topics covered

- Column packing requirements and techniques
- Column/resin considerations
- Column evaluation and qualification
- Column and resin cleaning, sanitization, and maintenance
- Troubleshooting

Small-scale column packing (COL2)

Duration: 3 days

Course description

This hands-on course focuses on optimizing small-scale (up to 50 mm diameter) column packing and handling methods, as well as testing and maintenance of chromatography resins. We will address factors influencing separation performance and the relationship to reproducibility and stability.

You will pack and test small-scale columns, with different design features and dimensions, using several types of chromatography resins.

- Hands-on practice for preparing and maintaining lab-scale chromatography columns (HiScale™, Tricorn™ and XK)
- Column packing — lectures and exercises
- Column testing and troubleshooting
- Column qualification and resin lifetime

Who should attend?

- Laboratory technicians and scientists responsible for column packing or column performance issues
- Process development scientists, engineers, and operators working with chromatographic columns at lab scale
- System engineers interested in the design and handling aspects of column-based production operations

After the course, you will be able to:

- Understand the critical issues in lab-scale column packing based on your own practical experience
- Pack and test lab-scale columns more rapidly and efficiently
- Identify major issues, troubleshoot current concerns and avoid problems in the future

Topics covered

- Protein purification strategies
- Column packing requirements and techniques
- Column/resin considerations
- Column evaluation
- Column and resin cleaning, sanitization, and maintenance
- Troubleshooting

Advanced cell therapy (CELLT2)

Duration: 3 days

Course description

This course provides both classroom and laboratory instruction within cell therapy processes and cell manufacturing under good manufacturing practice (GMP) procedures. Divided into upstream, cell expansion, and downstream applications, practical laboratory sessions will provide beginning-to-end technical knowledge and training on industry standard equipment and reagents. Guidance to standard operating procedure (SOP) development will also be discussed. Templates for SOPs are provided upon request.

Who should attend?

This training course will be useful for research and development scientists, process engineers, and manufacturing technicians. A basic understanding of cell culture and corresponding techniques is required for this course.

Some instances of the CELLT2 course are presented in collaboration with the National Institute for Bioprocessing Research and Training (NIBRT), a global center of excellence for training and research in bioprocessing. NIBRT is located in a world-class facility in Dublin, Ireland.

After the course, you will be able to:

- Apply detailed theoretical cell therapy process knowledge to upstream, cell expansion, and downstream applications
- Identify bottlenecks and troubleshoot your specific processes
- Perform industry-standard techniques related to cell therapy manufacturing, with an emphasis on T-cell processes
- Implement strategies used for process optimization and evaluation

Topics covered

- Overview of cell therapy workflows and cell types
- Tube welding and aseptic fluid transfer
- Cell counting
- Isolation technologies
- Transduction and vectors
- Activation process and technologies
- Cell culture media development and design
- Cell expansion and perfusion applications
- Harvesting platforms
- Final formulation and cryopreservation
- Scale-up and scale-out
- SOP development
- Process evaluation and optimization
- Documentation, automation, and digitalization

04

UNICORN system control

Advanced UNICORN system control for chromatography systems (UNI1)

Duration: 3 days

Course description

Learn both basic and more advanced UNICORN programming. The basic overview covers aspects like user and system set-up, manual control, performing runs, editing method, creating methods using block programming as well as use of air sensors and alarms or warnings. The overview is followed by more advanced programming instruction, such as conditional programming, watch commands, and start protocols.

Advanced evaluation procedures, importing/exporting data, comparing results and developing reports are also covered. Optimization of system variables, networking and validation issues will be discussed.

- Advanced hands-on use of UNICORN software for system control, programming, administration, and data management
- Advanced method programming
- User and system administration
- Method writing and verification runs

Who should attend?

- Process operators and supervisors, researchers, engineers, QA/QC personnel, and project managers who need a better understanding of system control
- Scientists, engineers, operators, system owners, and administrators responsible for ensuring the performance of UNICORN-based systems, and those who support hands-on users of the UNICORN software in manufacturing environments

After the course, you will be able to:

- Use UNICORN software to help achieve optimal performance from your system
- Document and report results in accordance with regulatory requirements
- Understand system settings and network options

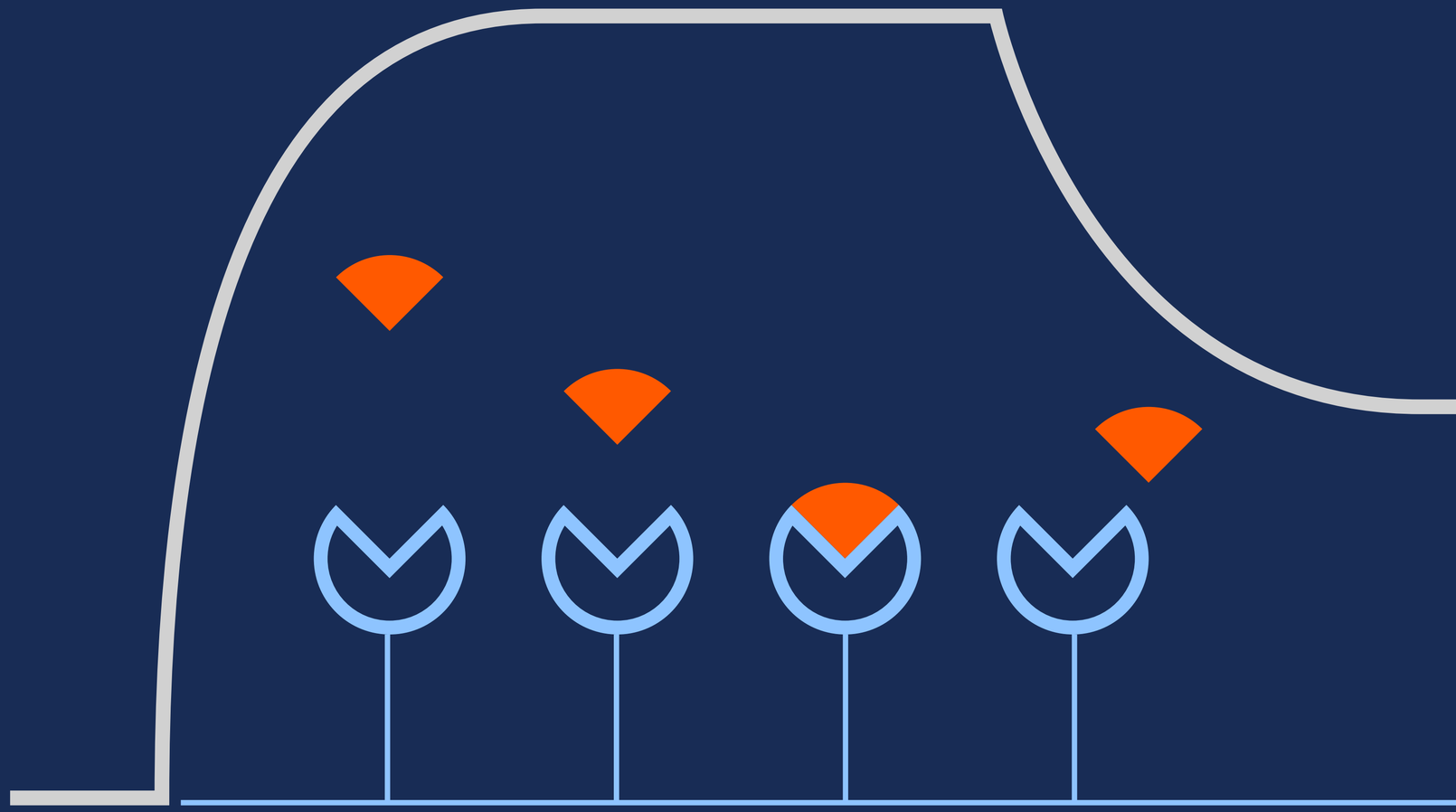
Topics covered

- Introduction to UNICORN software
- Method programming
- Method queues
- Column handling
- Conditional control (watch commands)
- System control
- Administration
- Evaluation module
- Networking, floating licenses

Virtual class available

UNI1 is also available in a live online format. You'll interact directly with our instructors from the comfort of your computer.

05
Biacore training



Introduction to Biacore system and assay development

Offered only in India
Duration: 1 day

Course description

This basic 1-day course is aimed at beginner analysts and academic students new to handling of a Biacore system. The course covers basic introduction to surface plasmon resonance (SPR) technology and Biacore system and combines theory (lectures) and hands-on exercises. You will gain insight into the fundamental steps in setting up a Biacore assay, evaluation of data and maintenance of the system. During the hands-on exercise you will setup a method for capture of beta-2 microglobulin (b2M) on protein A and evaluate the data obtained.

At the end of the course, you will gain confidence in working with the system and software independently. The course is available for the Biacore T200, 1 Series, and 8 Series systems either at customer site or at a Fast Trak facility.

Who should attend?

- R&D and process development scientists
- Analytical scientists
- Academic students

After the course, you will be able to understand:

- Function and application of a Biacore system
- Different types of data generated by a Biacore system
- Key steps in developing a Biacore assay
- Data evaluation and analysis for a capture assay

Topics covered

- Setup assay using wizard or predefined method
- Affinity and kinetic analysis
- Evaluation of data
- Hands-on maintenance
- Do's and don'ts of experiments

Biacore assay development and data evaluation

Offered only in India
Duration: 2 days

Course description

In this 2-days course you will learn advanced Biacore assay development and optimization using Biacore T200, 1 Series, and 8 Series systems. You will learn the key steps in an assay development, understand the different coupling chemistries, optimize regeneration conditions, and evaluate the data. The course also covers fundamentals of single-cycle, multi-cycle and parallel kinetics, and determination of the right kinetic approach for an assay. Gain confidence to work with your own samples and molecules with this course that combines theory and hands-on exercises.

During the hands-on exercises you will setup a multi-cycle kinetic assay, perform regeneration scouting and analyze the data using Biacore evaluation software. This course is designed for those with prior experience of handling Biacore systems. If you do not have this experience yet, we recommend attending our Biacore basics course as a prerequisite. The course curriculum is aimed more at analytical development scientist, senior scientists and academics with more complex setups.

Who should attend?

- R&D and process development scientists
- Analytical scientists
- Quality control analysts

After the course, you will be able to:

- Understand diverse immobilization strategies, binding models, and assay parameters
- Properly set up kinetic, steady-state affinity, and thermodynamic assays
- Conduct data visualization and analysis using evaluation software
- Understand tips and tricks for better data quality

Topics covered

- Surface preparation, sample injection, regeneration and evaluation
- Setup multi-cycle kinetics assay
- Parameter optimization
- Biacore hardware
- Control software to run and program assays
- Sanitization commands and system maintenance
- Do’s and don’ts of experiments

Advanced kinetics and affinity data evaluation

Offered only in India
Duration: 2 days

Course description

This 2-days course covers principles of binding kinetics and affinity, experimental design considerations for kinetic and affinity analysis and evaluation of data. You will learn in detail the fundamentals of kinetic measurements using Biacore, steps in setting up an assay, different assay formats (multicycle versus single cycle), selecting the binding model and troubleshooting. The software exercises in this course will guide you on using predefined evaluation methods in Biacore Insight Evaluation Software and includes software exercises for real-time data analysis.

This course is designed for those with prior experience of handling Biacore systems. If you do not have this experience yet, we recommend attending our Biacore basics course as a prerequisite. The course curriculum is aimed more at analytical development scientist, senior scientists and academics with more complex setups.

Who should attend?

- R&D and process development scientists
- Analytical scientists
- Quality control analysts

After the course, you will be able to understand:

- Theory behind kinetics and affinity and the importance of binding kinetics
- Considerations for experimental setup and assay formats
- Workflow for kinetic and affinity data evaluation in Biacore Insight Evaluation software
- Choice of data and model selection

Topics covered

- Kinetics in Biacore systems
- Mass transport in Biacore systems
- Assay setup
- Sample preparation
- Surface preparation
- Interaction mechanisms
- Choosing a binding model
- Evaluating and assessing results

06

Quality assurance

Validation workshop (VWS1)

Offered only in Japan
Duration: 1 day

Workshop description

Gain knowledge in current approaches to process validation. The course includes using QbD and process analytical technologies (PAT). It also covers the validation of processes based on disposables. This workshop is a direct response to positive customer feedback from earlier validation workshops.

Our regulatory experts will present and discuss current aspects of validation and related issues. The understanding of downstream process validation will be enhanced by group exercises.

Who should attend?

- Process development scientists, process engineers, QA/QC personnel, validation specialists, and management personnel working in the downstream bioprocessing area

After the course, you will be able to:

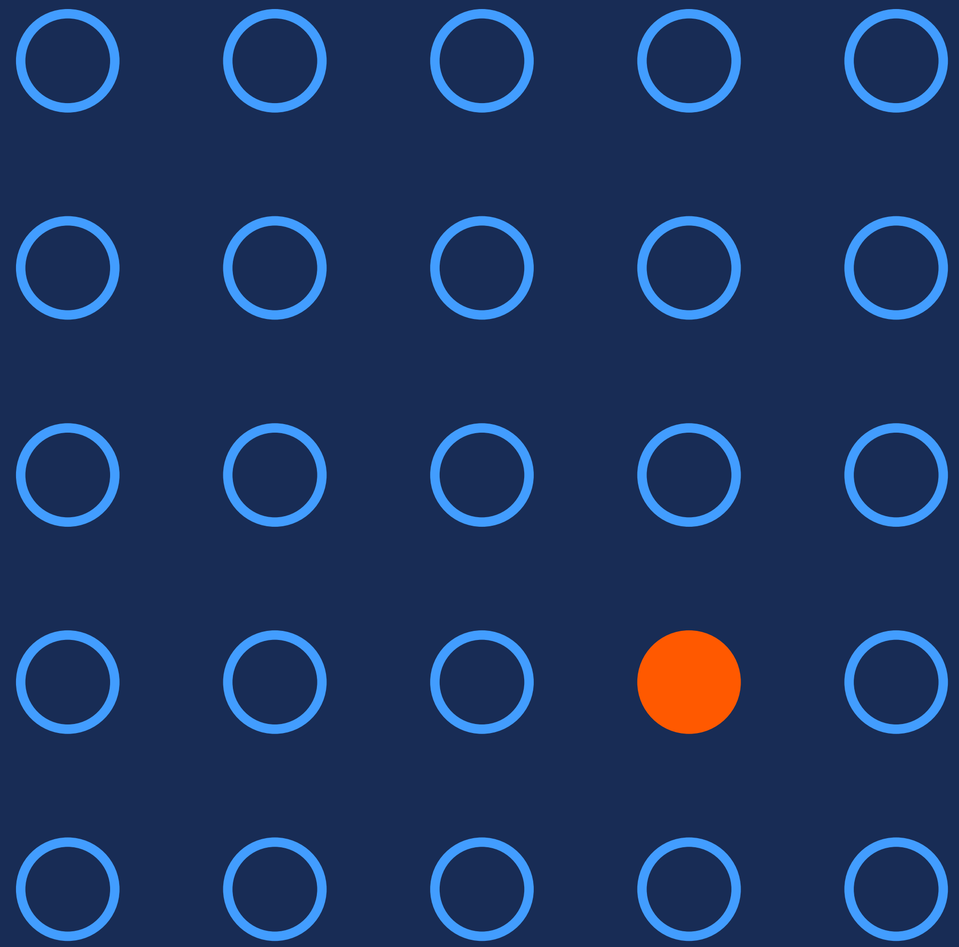
- Design a validatable downstream process
- Implement cost-effective strategies for downstream process validation
- Understand specific issues for validation of mAb and vaccine manufacturing processes
- Design resin lifespan studies
- Implement the latest practices in downstream cleaning validation

Topics covered

- Qualification vs validation, equipment qualification, software validation, and GAMP® principles
- Cost effective process validation
- Raw materials, leakage, performance, and storage
- Validation at small- and manufacturing-scales
- Cleaning validation
- Sanitization
- Validation of disposables
- Resin lifespan
- Special validation issues for mAb and vaccine, examples for clinical phase 1
- Rapid development with regulatory compliance

07

Fast Trak eLearnings



Learn at your own pace with Fast Trak eLearnings

Access to specialized talent is one of the biggest opportunities for your organization to grow and develop industry leaders. By combining innovative new approaches for talent sourcing with blended digital learning, you can keep pace with changes and fill skills gaps.

Fast Trak courses cover a range of advanced topics in bioprocessing. Interactive, up-to-date content makes learning easy and effective. When you pass the assessment at the end of the course, you'll receive a certificate for your records.

Complete Fast Trak eLearnings at your own pace and gain skills across different subject-matter areas. Keep track of your learning journey with a record of the courses you're enrolled in, your current progress in each one, and certificates of completion.

Start learning today

Overview of the biopharma industry and products
Biomanufacturing process capability requirements
Overview of host cells for bioprocessing
Understanding upstream bioprocessing
Get confident: TFF process development
Get confident: DFF process development
Introduction to preparative protein chromatography
Advanced IEX chromatography for bioprocessing
Advanced MM chromatography for bioprocessing
Advanced UNICORN method editing for cell therapy (UNI2)
Introduction to cell therapy (eCELLT1)

Viral vector production for gene therapy

Viral vectors are fundamental to gene therapy and gene-modified cell therapies which are the frontier of modern medicine. Sign up for these eLearnings:

- Viral vector production for gene therapy: introduction
- Viral vector production for gene therapy: upstream
- Viral vector production for gene therapy: downstream
- Viral vector production for gene therapy: quality control
- Viral vector production for gene therapy: full learning plan

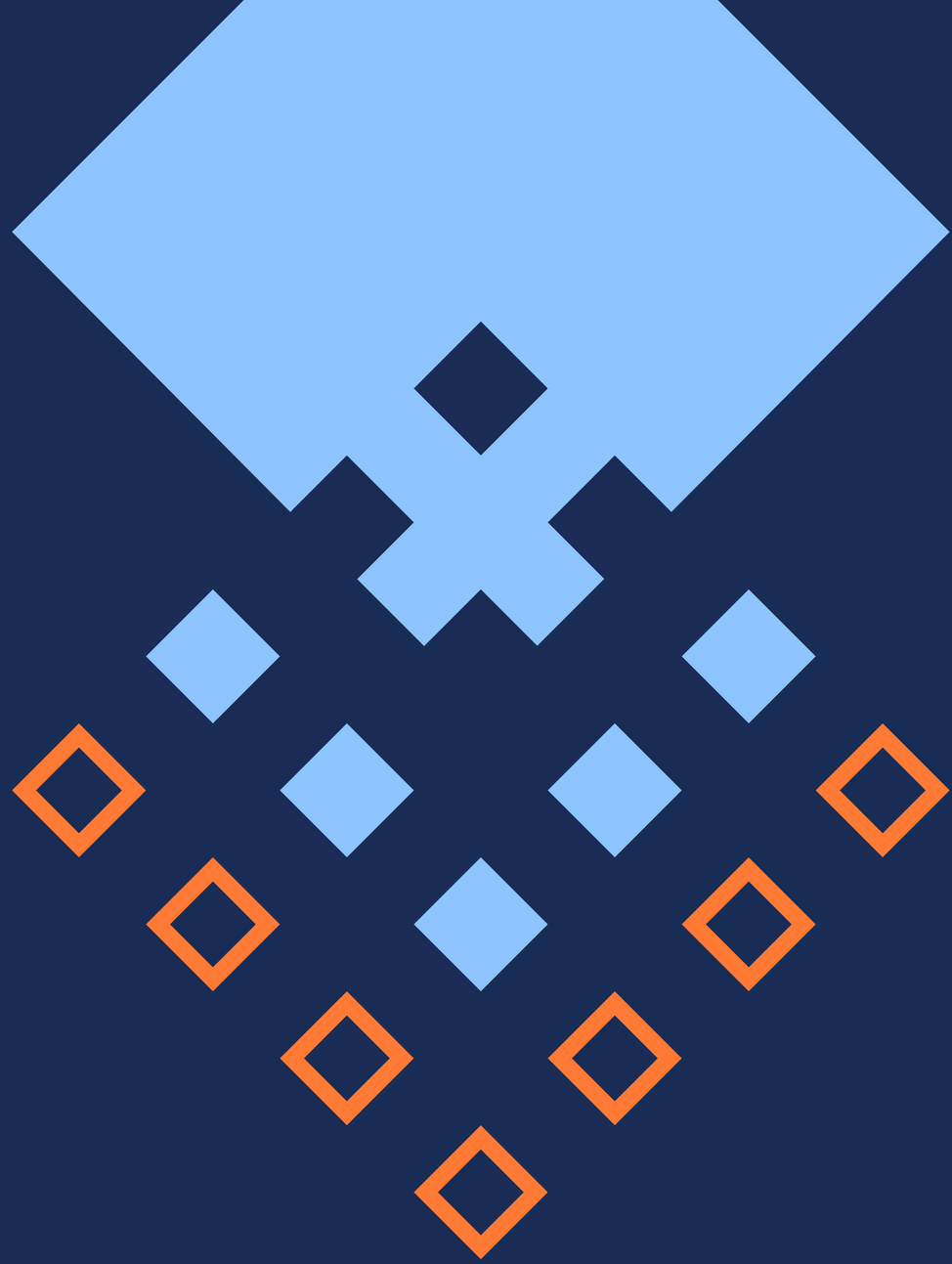
Find in-person and online training courses

What's new?

Get to know: filtration for plasmid DNA
Get to know: upstream plasmid DNA processing
Get to know: mRNA IVT reaction
Get to know: mRNA workflow

08

Custom, on-demand courses



Custom training and process consultancy

Our global team of bioprocessing experts can provide guidance for existing unit operations as well as support in designing new processes that meet current regulatory demands and reduce time-to-market by:

- Reviewing and assessing existing processes to help define critical parameters
- Offering technical guidance and oversight for developing scalable upstream and downstream processes
- Recommending ways to increase process efficiencies
- Troubleshooting different unit operations
- Training operators at your site

FlexFactory operator training

Duration: 5 to 10 days, depending on the number and scale of equipment

Course description

This course provides training on FlexFactory equipment, consumables, and automation at your qualified FlexFactory site. Training will be focused on day-to-day operation of the various components of the FlexFactory configurable manufacturing train. This includes set-up and installation of consumables, connection and transfer between unit operations, start-up and running in automated mode, as well as troubleshooting. The course is developed for operators and those involved in daily operation of a FlexFactory configurable manufacturing train.

Who should attend?

Operators/technicians, manufacturing personnel, and scientists involved in operation of the FlexFactory configurable manufacturing train.

Topics covered:

- Single use consumables and technologies for upstream and downstream
- Hardware operations and setup include: Xcellerex™ XDR, WAVE™ bioreactor, Xcellerex XDUO Mixer, ÄKTAprocess™ system, AxiChrom chromatography columns, ÄKTA readyflux™ system, ÄKTA readyflux XL system, filtration (harvest/depth filtration and TFF)
- Installations of bags, probes, filters, etc.
- Making sterile connections
- UNICORN control software, Figurate™ automation for DeltaV™ DCS, and Figurate automation powered by PlantPAx® DCS
- Column packing (using a Cytiva column with the resin you provide)
- Troubleshooting, alarms, strategy tips and maintenance at operator level

Bioprocessing using membrane separations (MEM1)

Duration: 3 days

Course description

Learn about membrane separation techniques used in bioprocessing with emphasis on tangential flow filtration (TFF) techniques using open and/or screen channel devices. The course provides a general understanding of optimization, cleaning, validation, and scale-up.

In the practical sessions, you will learn basic methods including membrane preparation, air diffusion, and integrity testing. You will also conduct experiments on optimizing clarification and concentration/diafiltration steps.

- Membrane separation techniques for the purification of biomolecules
- Comparison of alternative filtration techniques
- Presentation and discussion of tangential flow techniques
- Focus on process optimization, cleaning validation, and scale-up of membrane separation procedures
- Hands-on work with filtration system testing and maintenance exercises

Who should attend?

- R&D, process development and manufacturing personnel designing, executing, or advising on membrane unit operations in the biopharmaceutical industry
- Scientists and engineers working in primary recovery and clarification stages through to final purification steps
- Anyone interested in primary clarification of mammalian, bacterial, yeast, or baculovirus/insect cells

After the course, you will be able to:

- Choose the optimum membrane format or technique based on target molecule and process objective
- Define process conditions critical to the success of membrane applications
- Evaluate experimental results for optimization and scale-up calculations

Topics covered

- TFF theory and practice for upstream and downstream processing
- Hollow fiber and cassette materials and configuration
- Process design strategies: process development, optimization, and scale-up
- System design: hardware configuration and automation
- Current topics in validation
- Hands-on training with manual and automated systems for both hollow fiber and cassettes

Virtual class available

MEM1 is also available in a live online format. You'll interact directly with our instructors from the comfort of your computer.

General course information

Fast Trak Education is one means by which Cytiva provides application training in the various aspects of bioprocessing. The courses are designed to provide a learning experience for process development and manufacturing staff.

Fast Trak offers training courses on column packing, basic chromatography, optimization and scale-up for both pilot and production scales. We also offer courses on validation issues and chromatography theory.

The courses are offered in a variety of formats to meet your unique learning needs, including hands-on lab-based courses, live virtual classes, self-paced e-learning courses, and custom courses. To view our Fast Trak course schedule, please visit **cytiva.com/fasttraktraining**.

Cancellation policy

In case you need to cancel your registration, the following charges will apply:

- 30 to 21 days prior to course: 50% of course fee
- 20 to 8 days prior to course: 80% of course fee
- 7 days or less prior to course: 100% of course fee

If you are unable to attend after registration, you may send a colleague in your place or attend another course.

Cytiva reserves the right to modify course location, course material, substitute speakers, or to cancel the course. If the course is cancelled, registrants will be notified as soon as possible and will receive a full refund of paid fees. Cytiva will not be responsible for airfare penalties or other costs incurred due to a course cancellation.

Course certificate

Upon completion of the course, each participant receives a course certificate in which course name and course date is stated.

Course evaluation

At the end of each course, you will be asked to fill in a course evaluation form. We value your opinion of the course, the speakers, the material, and presentations and use this feedback to continuously improve the courses and their contents.

Travel and hotel costs

Travel and hotel costs are not included in the course price.

Language

Standard courses are held in English at Fast Trak Centers in the US, Sweden, India, Singapore, and South Korea, unless otherwise specified. In China, most courses are in Mandarin with occasional courses in English. The courses in Germany are held in German and English, and courses in Japan are held in Japanese. Customized courses can be presented in other languages. Please contact your local Fast Trak center for more information.

Lunches

All lunches during course days are included in the course prices.

Material in binders

Each course participant will receive the lectures and other relevant material in a binder.

Requirements for biosafety level 1 (BSL-1) laboratories

Every course participant who enters our laboratories for the practical sessions must comply with certain safety requirements. Please notice that open-toe shoes are not allowed in the lab. Obligatory protective clothing and safety devices will be provided.

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For local office contact information, visit cytiva.com/contact

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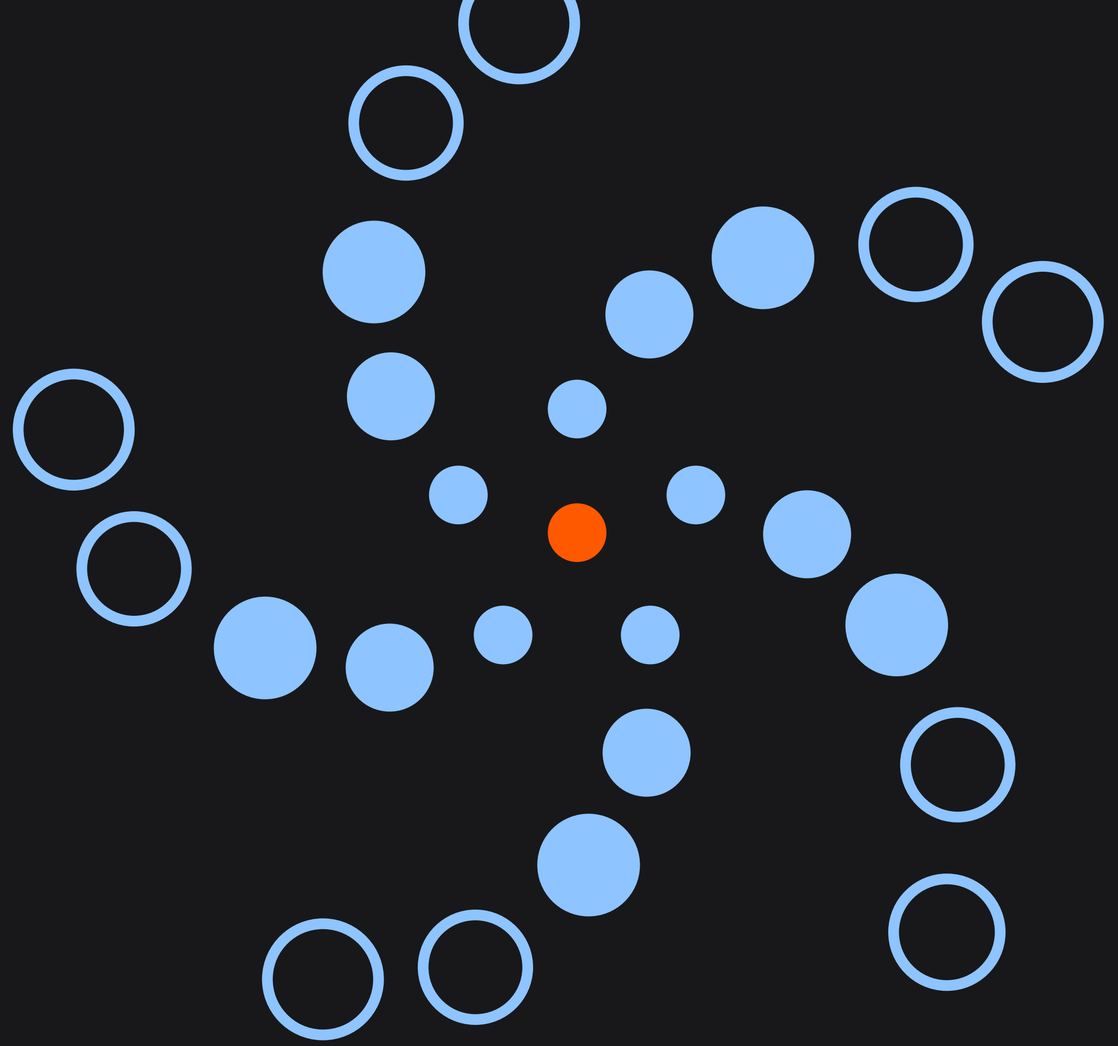

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