Fast Trak
Training & Education

Our expertise, your advantage
Contents

General course information 3
Introduction to Chromatographic Techniques and Bioprocessing (DEV1) 4
Downstream Bioprocess Development (DEV2) 6
Bioprocess Scale-up and Technology Transfer (DEV4) 8
Introduction to High-Throughput Process Development (HTPD1) - Workshop 10
Theory, Setup and Operation of Single-use WAVE Bioreactor (WAV1) 12
Large-scale Column Packing (COL1) 14
Downstream Bioprocessing of Monoclonal Antibodies (MAB1) 16
Bioprocessing using Membrane Separations (MEM1) 18
Introduction to UNICORN System Control for Chromatography Systems (SYS1) 20
Advanced UNICORN System Control for Chromatography Systems (SYS2) 22
UNICORN System Control for Automated Filtration Systems (SYS3) 24
Online Basic Training Course for UNICORN (eSYS1) 26
UNICORN 6 eCourse (eSYS6) 27
Column Validation – Advanced Workshop (VWS1) 28
Custom Fast Trak Training and Education Courses 30
Now in its third decade, Fast Trak Training & Education continues to provide a unique learning experience for process development and manufacturing scientists, engineers, plant operators, and support staff. Fast Trak delivers hands-on training courses in:

**Upstream processing**
- Cell culture
- Disposable technologies

**Downstream processing**
- Column packing
- Basic chromatography
- Membrane filtration
- Optimization and scale-up to pilot and production scales

For our customers using UNICORN™ system control, we offer several courses for new users as well as more advanced programmers.

The 2 to 5 day standard courses are run at our regional Fast Trak Centers in Piscataway (New Jersey, USA), Munich (Germany), Bangalore (India), and Shanghai (China). The eCourses are taken at your convenience from your computer, and are available to you for the duration of one year.

Custom courses and strategic training programs to suit your organization’s specific needs can be given at your facility or at a Fast Trak Center.

**The presentations and hands-on exercises allow participants to:**
- Integrate theory and practice with a high ratio of instructors and instruments to trainees
- Understand the purification issues using automated systems for both chromatography and filtration
- Gain an awareness of the regulatory aspects in today’s biotechnology processes
- Fully utilize the tools and principles of effective biomanufacturing
Introduction to Chromatographic Techniques and Bioprocessing (DEV1)
Course description
This three-day hands-on course covers chromatographic techniques suitable for production-scale protein purification. You will learn about techniques, screening and optimization strategies, scale-up issues, column maintenance and process hygiene, regulatory requirements, and column packing.

During practical sessions, you will apply these concepts to understand how to screen and optimize the purification of a target protein from a crude feedstream.

Who should attend?
• Scientists new to industrial chromatography
• R&D scientists and process engineers — to review the basics of protein purification

After the course, you will be able to:
• Screen and optimize bioprocesses in your process development work
• Apply effective chromatographic techniques in your downstream purification process
• Understand the issues associated with optimizing chromatographic unit operations in biopharmaceutical production processes

Topics covered
• Introduction to the course
• Purification techniques and strategies
• Gel filtration
• Ion exchange chromatography
• Hydrophobic interaction (HIC) and reversed phase (RPC) chromatography
• Affinity chromatography
• Column packing and testing
• Optimization
• Scale-up and fine tuning
• Process hygiene
• Regulatory requirements
Downstream Bioprocess Development (DEV2)
Course description
This five-day hands-on course is geared towards strategic thinking. Lectures and practical work focus 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.

In the comprehensive practical sessions, you will develop a three-step chromatographic process and optimize for purity, recovery, and productivity suitable for manufacturing scale.

Course requirements
A basic knowledge of chromatographic principles used in protein purification is assumed.

Who should attend?
• R&D scientists and process development engineers with a basic knowledge of chromatographic techniques used in biopharmaceutical processes
• 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 media and combinations of techniques suitable for industrial purification and scale-up
• Understand optimization strategies for maximizing process performance

Topics covered
• Introduction to practical work
• Adsorption chromatography
• Design issues in downstream processing
• Method optimization
• Media cleaning
• Scale-up with calculations
• Development of a scalable three-step process for purification of an example protein, alpha-glucosidase:
  - Optimization of selectivity/binding, elution, capture, intermediate, and polishing steps
  - Optimization of load/dynamic breakthrough capacity
  - Scale-up and verification
  - Different elution strategies
  - Media screening
Bioprocess Scale-up and Technology Transfer (DEV4)
Course description
This three-day practical course focuses on the relevant issues involved in late stage process development. The course will cover process design and optimization for production. It will provide you with an introduction to validation and column packing. We will also discuss safety and economic issues related to automation.

In the practical sessions, you will work on optimizing a two-step process and maintaining separation performance at increasing scales. Group exercises and discussions will focus on “real life” scale-up issues, which will complement the hands-on work.

Course requirements
A solid knowledge of chromatographic principles used in protein purification is assumed.

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 High-Throughput Process Development (HTPD1) – Workshop
Workshop description
This two and a half day workshop focuses on the methodology of high-throughput process development (HTPD). It shows how PreDictor™ 96-well filter plates, prefilled with chromatography media (resins), can be used both in manual and automated mode (using a robotic system) for initial screening of chromatographic conditions. The workshop covers how data from plates are transferred to column chromatography. Practical exercises include uptake and elution studies. Application examples for the use of HTPD PreDictor plates are presented (e.g., Cleaning-in-Place study) including practical tips and hints discussed with internal and external experts.

Workshop requirements
A solid knowledge of chromatographic principles used in protein purification is assumed.

Who should attend?
• Process development scientists and development engineers who need an introduction to the use of HTPD for the design, development, optimization, and troubleshooting of chromatography processes.

After the workshop, you will be able to:
• Plan, design, and conduct HTPD experiments
• Comprehend key factors that should be taken into consideration when executing HTPD applications

Topics covered
• Introduction to high-throughput process development
• HTPD with PreDictor plates
• Assist software
• Uptake studies
• Elution studies
• Automation utilizing a robotic system
• Column verification
• Wash and flow through studies
• Cleaning-in-place studies
• Monoclonal antibody process development and optimization
Theory, Setup and Operation of Single-use WAVE Bioreactor (WAV1)
Course description
This practical two-day training course provides hands-on experience and theoretical background information for operation and optimum performance of the WAVE Bioreactor™ system. Training focuses on the system and experimental setup, probe calibration, sterile sampling, culture seeding, cell culture optimization, and scale-up using practical laboratory exercises and theoretical training.

You will practice standard techniques used in single-use environments such as sterile tube sealing and welding. Various applications of WAVE Bioreactor and associated devices for cell culture, perfusion, cell therapy, and use of microcarriers are presented and discussed during the lecture sessions.

Who should attend?
• R&D and process development scientists, process engineers, technical support, as well as QA/QC and management personnel working with upstream bioprocessing applications interested in single-use technologies.

After the course, you will be able to:
• Develop cell culture applications based on a thorough understanding of WAVE products and technologies
• Set up and operate a WAVE Bioreactor and ancillary equipment
• Perform the probe calibration, sterile sampling, sealing, welding, and seeding procedures

Topics covered
• Introduction to the WAVE Bioreactor concept
• Angle and rocking experiment
• Sterile sealing and welding
• Optimization of culture conditions
• Calibration of probes and handling of WAVE controllers
• Seeding the Cellbag™ bioreactor
• Sampling and controlling the culture
• Perfusion culture
• Microcarriers
• Regulatory requirements
• Troubleshooting WAVE Bioreactor
Large-scale Column Packing (COL1)
Course description
This three-day hands-on course focuses on optimizing large-scale column packing and handling methods, as well as testing and maintenance of chromatographic media in production-scale columns. The training addresses factors influencing separation performance and their relationship to reproducibility, stability, and economy in an industrial production setting.

During practical sessions, you will pack and test large-scale columns with different design features and dimensions using several types of chromatographic media.

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

Topics covered
• Protein purification strategies
• Column packing requirements and techniques
• Column/media considerations
• Column evaluation
• Column and media cleaning and maintenance
• Troubleshooting
• Sanitization of chromatography media and equipment
Downstream Bioprocessing of Monoclonal Antibodies (MAB1)
Course description
This three and a half day practical course begins with an introduction to monoclonal antibodies, antibody fragments, and current challenges involved in biopharmaceutical production. You will be presented with general purification strategies focusing strongly on platform processes using affinity chromatography for capture. This will be followed by discussions on polishing steps, including multimodal techniques for key contaminant and bioburden removal. In the practical session, you will define operating conditions for a human monoclonal antibody process optimized for yield, productivity, and process economy. Validation and regulatory concerns related to the purification process will also be discussed.

Course requirements
A basic understanding of chromatographic techniques is recommended, but not a prerequisite

Who should attend?
• Scientists and engineers looking for an introduction to process development methods for monoclonal antibody purification intended for biopharmaceutical applications.

After the course you will be able to:
• Communicate the usefulness of different techniques dependent on source material
• Define a platform process for antibody purification suitable to the process objectives
• Develop optimization methods and understand regulatory concerns unique to antibody manufacturing processes

Topics covered
• Introduction to antibody purification
• Sequencing of chromatography steps
• Optimization of capture step
• Purification strategies
• Affinity chromatography in antibody purification
• Optimization of polishing steps
• Ion exchange chromatography in antibody purification
• Hydrophobic interaction chromatography in antibody purification
• Ligand leakage from affinity chromatography media
• Process hygiene and regulatory issues
Bioprocessing using Membrane Separations (MEM1)
Course description
This three-day course offers an introduction to membrane separation techniques used in bioprocessing. The emphasis is on cross flow filtration (CFF) techniques using open and/or screen channel devices providing a general understanding of optimization, cleaning, validation, and scale-up.

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

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
• Cross flow filtration 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
Introduction to UNICORN System Control for Chromatography Systems (SYS1)
Course description
This two-day basic course on UNICORN 3, 4, and 5 will teach you how to control the ÄKTA™ chromatography system manually, perform runs, create methods using block programming, edit methods, use start protocols, calibrate the pH monitor, and use air sensors, alarms, and warnings.

You will practice creating and printing reports, backing up files, and learn about aspects to consider when using UNICORN versions 3, 4, and 5 controlled systems in a cGMP/GLP environment.

Course requirements
Some basic experience with UNICORN is recommended.

Who should attend?
• Process operators, process supervisors, lab assistants, QA/QC personnel, and project managers who need a basic understanding of system control using UNICORN

After the course, you will be able to:
• Control your system and document results based on practical experience and theoretical knowledge about the use of UNICORN 3, 4, and 5 software

Topics covered
• Introduction, structure, and concepts
• File handling
• System control
• Basic method programming using Method Wizard
• Introduction in method programming using Text Instructions
• Scouting and buffer preparation
• Handling and maintenance of the ÄKTA system
• Evaluation module
• Regulatory issues
Advanced UNICORN System Control for Chromatography Systems (SYS2)
Course description
A three-day advanced course on UNICORN 3, 4, and 5, covering the use of conditional control programming, using analogue and digital signals for ‘watch’ commands, creating start protocols, systems and user administration, and documentation. Theoretical lectures on how to optimize run variables and how to define system settings are part of the course. Evaluation procedures, including integration, manipulations, importing and exporting data, comparing results and creating reports will also be covered in demonstrations and exercises. Network considerations and validation issues related to UNICORN 3, 4, and 5 will be covered during the lecture sessions.

System features of BioProcess™ and ÄKTA systems will be addressed when needed for method writing and transfer of methods for scale-up. Exercises using a PC, and BioProcess and ÄKTA systems constitutes the main part of the course.

Course requirements
A good understanding of UNICORN software is required; a level equivalent to that described in SYS1 is necessary. SYS2 is recommended only after having gained some practical experience.

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 UNICORN in manufacturing environments

After the course, you will be able to:
- Use UNICORN to achieve optimal performance from your system
- Document and report results in accordance with regulatory requirements
- Understand system settings and network options

Topics covered
- Structure and concepts
- File handling
- Method programming using Text Instructions
- System and user administration
- Method queues
- Conditional control (watch commands)
- Programming conditional control for desalting and ion exchange experiments
- System control
- Experiments and verification runs
- Optimization of programming and verification runs
- Evaluation module
- Networking
- Regulatory issues
UNICORN System Control for Automated Filtration Systems (SYS3)
Course description
This two and a half day course is designed to teach you how to control your ÄKTAcrossflow™ system manually and in automated mode. You will perform micro- and ultrafiltration experiments using the method wizard and learn to edit methods using start protocols and watch commands. You will also learn how to utilize the evaluation module, create customized reports, and operate UNICORN systems in a GLP/cGMP environment.

Who should attend?
• Process operators, process development scientists, and project managers working with cross flow filtration for the downstream processing of biopharmaceuticals
• Owners of ÄKTAcrossflow systems and anyone wishing to learn more about automated systems for cross flow filtration. Some basic experience with UNICORN system control and cross flow filtration is recommended, but not a prerequisite

After the course, you will be able to:
• Use UNICORN software to control your ÄKTAcrossflow system and to evaluate/document results
• Create and modify template methods
• Design automated cross flow filtration experiments

Topics covered
• Cross flow filtration basics with automation
• Introduction, structure, and concepts of UNICORN
• System setup
• File handling and administration
• System control
• System flow path and manual control
• Programming with the method wizard
• Modifying methods created with the wizard
• Advanced wizard training
• Cell clarification
• Concentration and diafiltration
• TMP/flux scouting
• Evaluation of results
Online Basic Training Course for UNICORN (eSYS1)

Course description
This basic eCourse is accessed via a Web site, the Fast Trak Education Gateway, where you can complete the training at your own pace (purchase of an eCourse gives access for one year). The course covers UNICORN versions 3, 4, and 5. It is structured into logical modules, includes interactive tutorials, and provides an overview for beginners. The examples in the course are taken from ÄKTApurifier™ and ÄKTAexplorer™. The course is however also relevant for ÄKTApilot™, ÄKTAfplc™, and ÄKTAmicro™ users.

Who should attend?
• Process operators, process supervisors, laboratory scientists, QA/QC personnel, and project managers who need a basic understanding of system control using UNICORN

After this course, you will be able to:
• Use UNICORN to exploit the capabilities of your system
• Document and report in accordance with regulatory requirements
• Comply with your internal training objectives

www.gelifesciences.com/pr-eSYS1

Topics covered
• Controlling the sample path and gaining a deeper understanding of the flow scheme
• Mastering the method wizard to create a customized program
• Building a new program from scratch using milliliters, column volumes, or time
• Use of some advanced functions including air sensors, alarms, or warnings
• Adjusting the chromatogram layout and generating customized reports
• Performing system and user administration
UNICORN 6 eCourse (eSYS6)

Course description
This eCourse is accessed via a Web site, the Fast Trak Education Gateway, where you can complete the training at your own pace (purchase of an eCourse gives access for one year). The course includes interactive step-by-step tutorials on how to perform different tasks and provides an excellent overview for beginners, as well as for users of earlier versions of UNICORN that need to become acquainted with the new features of UNICORN 6.

Who should attend?
• Researchers: learn how UNICORN 6 can simplify your protein purification
• Process developers: learn how UNICORN 6 can help you understand, optimize, characterize, and document your purification process
• People working in a UNICORN controlled manufacturing environment: scientists, engineers, operators, system owners, and administrators responsible for ensuring the performance of UNICORN-based systems and those who support hands-on users of UNICORN in production

After this course, you will be able to:
• Use UNICORN to achieve optimal performance from your system
• Document and report in accordance with regulatory requirements
• Comply with your internal training objectives

www.gelifesciences.com/eSYS6

Topics covered
• The Crash Course section gives you a quick overview and introduces some advanced features
• UNICORN installation and administration functions
• Method creation including keeping track of columns
• The system control module interface, manual and method runs, and calibration of instrument components
• Result evaluation including calculation of the amount and concentration of a protein in fractions
• Different concepts for performing multiple runs
• Evaluation of results from multiple runs including statistical evaluation of runs based on Design of Experiments
• Editing and customizing methods with text editing
Column Validation – Advanced Workshop (VWS1)
Workshop description
This two-day workshop presents current approaches to process validation including Quality by Design (QbD), Process Analytical Technologies (PAT), and the validation of processes based on disposables. This workshop is a direct response to the positive feedback we have received from customers attending our earlier workshop.

Our regulatory experts will present and discuss the latest aspects in column validation and related issues. Group work enhances participants understanding of downstream process validation.

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 monoclonal antibody 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
• Cost effective process validation
• Raw materials, leakage, performance, and storage
• Validation at small- and manufacturing-scales
• Cleaning validation
• Sanitization
• Validation of disposables
• Chromatography media lifespan
• Special validation issues for MAb and vaccine, examples for clinical Phase 1
• Rapid development with regulatory compliance
Custom training and education courses

Based on existing course material, custom courses and training programs can be designed to meet your company’s specific training needs and held either at the Fast Trak Training Centers in Munich, Piscataway, Shanghai, or Bangalore, or on-site at your facility.

**Custom training courses provide solutions for:**
- Standardizing training for large groups and teams within the same organization
- Encouraging open dialogue among company scientists in an educational setting
- Engagement in creating training programs and agendas to meet specific company needs and timelines
- Tailored training specifications to meet equipment and process demands
- Maintaining training compliance schedules and receiving formal GE Healthcare training certification
- Significant cost reduction due to reduced travel/accommodation and out-of-office