Fast Trak Training & Education

Our expertise, your advantage
General course information

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.

Hands-on training courses in all aspects of bioprocessing, from cell culture and downstream process development to scale-up and manufacturing allow participants to:

- Integrate theory and practice with a high ratio of instructors and instruments to trainees
- Fully utilize the tools and principles of effective biomanufacturing

www.gelifesciences.com/fasttrak
Advanced Bioreactor Cultivation Technology (CELL1)

Course description
This three and a half day course will provide you with in-depth training on cell culture technology with a strong practical component, combining scientific background and hands-on experimentation for animal cell cultivation. In particular the feasibility of running a complete bioprocess with single-use equipment will be demonstrated by growing cultures in disposable bioreactors.

Key topics are process development and evaluation, scale up and bioengineering in animal cell culture applications.

Course requirements
A basic understanding of cell culture and corresponding techniques is required for this course.

Who should attend?
Research and development scientists, process engineers and manufacturing technicians.

After the course you will be able to:
• Control and evaluate fed-batch and perfusion cultures
• Perform basic characterization of a bioreactor and interpret the results
• Understand and deploy strategies used for process optimization

Topics covered
• Aseptic fluid transfer
• Process control in bioreactors
• Inoculate fed-batch, perfusion and microcarrier cultures
• Development of cell culture media
• Cell metabolism
• Process evaluation and optimization
• Culture scale up
• Cell separation
• Product concentration
• Scale up of primary recovery process
• Validation of upstream bioprocess
• Label free interaction alysis of IgG in cell culture supernatant
Introduction to Downstream 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, 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 demonstrated and discussed. Application examples for the use of HTPD PreDictor plates are presented including practical hints & tips.

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

Who should attend?
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 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 and PreDictor RoboColumn
- 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
Introduction to Design of Experiments (DOE1)

Course description
This three day training course aims to give an overview of DoE in process development and its application using the ÄKTA™ avant system. First, participants will be introduced to DoE and the statistical terms associated with it, followed by a discussion on different DoE designs and the process of evaluating results. The course also includes hands-on exercises evaluating various pre-generated DoE data files. In the wet lab, the attendees will set up and run their own DoE experiments on an ÄKTA avant, assess potential responses and evaluate their results. The conjunction of wet lab experiment and evaluation exercises will provide participants beneficial hands-on experience with DoE.

Course requirements
A basic understanding of chromatography techniques and UNICORN™ 6 is required for the course.

The participants will upon registration be given free access to eSYS6, the online Fast Trak training course on UNICORN 6. It is highly recommended for the participants to take the course prior to attending DOE1.

Who should attend?
Research and development scientists.

After the course you will be able to:
• Understand the concept of DoE, its relationship to QbD and its role in the establishment of a process Design Space
• Choose a suitable experimental design according to different applications and scenarios
• Evaluate data from DoE investigations and how DoE results can be employed to define Design and Operating Spaces
• Apply systems and application knowledge related to DoE

Topics covered
• Quality by Design: Overview and relevance of DoE
• Introduction to statistics
• Key concepts, various experimental designs and their properties
• Hands-on exercises
  - Resin screening and optimization
• Result evaluation
• DoE and QbD case studies

Downstream processing

Downstream processing
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
Single-Use Manufacturing Technologies (SUM1)

**Course description**
This three day training course focuses on the practical aspects of single-use technology in process development and biomanufacturing.

The training starts with an overview of the various features of the current technology, complemented by discussions and exercises on the deployment in a regulated environment. In addition, hands-on exercises guide the participant in the application of single-use tools in both upstream and downstream process development. Implementation of single-use bioreactors, crossflow and normal flow filtration devices, and chromatography configurations in the lab illustrate the flexibility and diversity of the systems.

Industry best practices and case studies will illustrate the main learning points of the course.

**Course requirements**
A basic understanding of cell culture, crossflow, and normal flow filtration, and chromatography techniques is required for this course.

**Who should attend?**
Research and development scientists, process engineers and manufacturing operators/technicians.

**After the course you will be able to:**
- Setup and implement single-use and hybrid solutions for cell culture, filtration, and chromatography
- Understand process economy and operational excellence principles
- Recognize the validation challenges and approaches for single-use concepts

**Topics covered**
- Up- and downstream process development in a single-use processing environment: Theory and practice
- Scale up and tech transfer
- Data acquisition and automation
- Validation in single-use applications
- Process economy and risk management
- Operational excellence and environmental impact
- Conversion from stainless steel to single-use configurations
- Equipment manufacturing tour (only in Westboro)
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
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
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, as well as 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
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™, AKTAfplc™, 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

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

www.gelifesciences.com/pr-eSYS1
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
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, Bangalore, Singapore, 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