



Fast Trak

Services from *molecule* to *market*

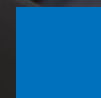
Fast Trak

Accelerating molecules
to market

Process
development



Bridge
manufacturing



Training &
education



Fast Trak global reach

With GE's worldwide footprint, our expert teams offer training in local languages



Vaccine manufacturing



Major challenges

- | | | | | | |
|---|--|---|---|---|--|
| <ul style="list-style-type: none">• Product titer• Regulatory• Old substrates | <ul style="list-style-type: none">• Yield• Scale-up• Consistency• Open handling | <ul style="list-style-type: none">• Yield• Aggregation | <ul style="list-style-type: none">• Yield• Aggregation• DNA and HCP reduction | <ul style="list-style-type: none">• Potency• Stability | <ul style="list-style-type: none">• Analytical precision• Number of methods |
|---|--|---|---|---|--|

Potential solutions

- | | | | | |
|--|---|---|--|--|
| <ul style="list-style-type: none">• Vaccine technologies• Cell lines• Expression systems | <ul style="list-style-type: none">• Disposable bioreactors• Cell culture media• Microcarriers vs suspension | <ul style="list-style-type: none">• Filters• Novel capture formats | <ul style="list-style-type: none">• Chromatography resins• Novel purification formats | <ul style="list-style-type: none">• Analytical methods• Bioassays |
|--|---|---|--|--|

Single-use technologies, FlexFactory™ platform and facility solutions



The history of polio vaccines and GE

1955

Inactivated polio vaccine (IPV) launched (Salk Type)

1960

Attenuated polio vaccine launched (Sabin type)

1960s

Collaboration between Prof. Van Wezel (RIVM/NVI Netherlands) and GE (former Pharmacia) around microcarrier cultures of primary monkey cells

1970s

New IPV purification method using GE's chromatography resins

1980s

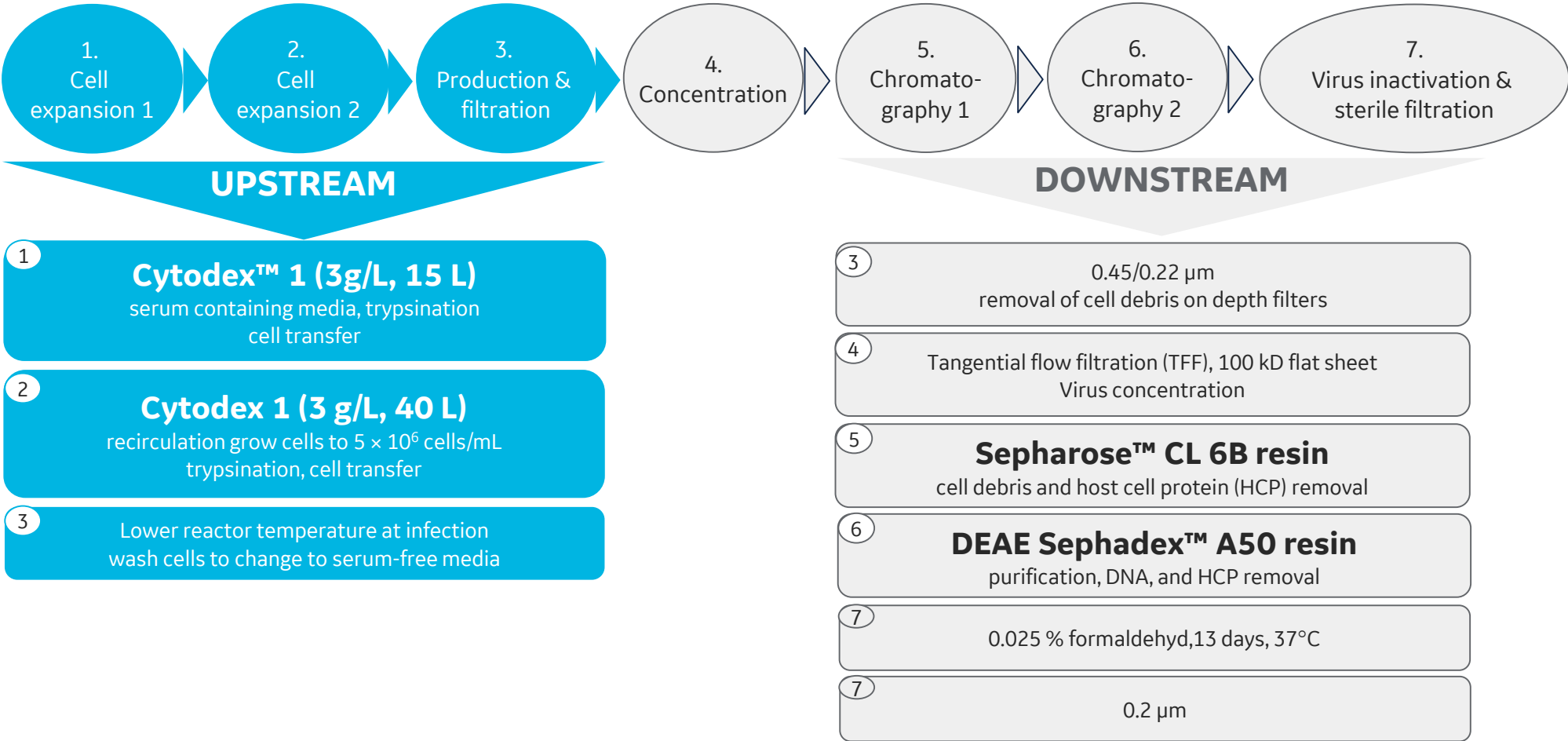
Switch to Vero cell production using Cytodex™ 1 microcarriers

2010s

Updating the IPV processes using modern technology from GE



Polio vaccine process

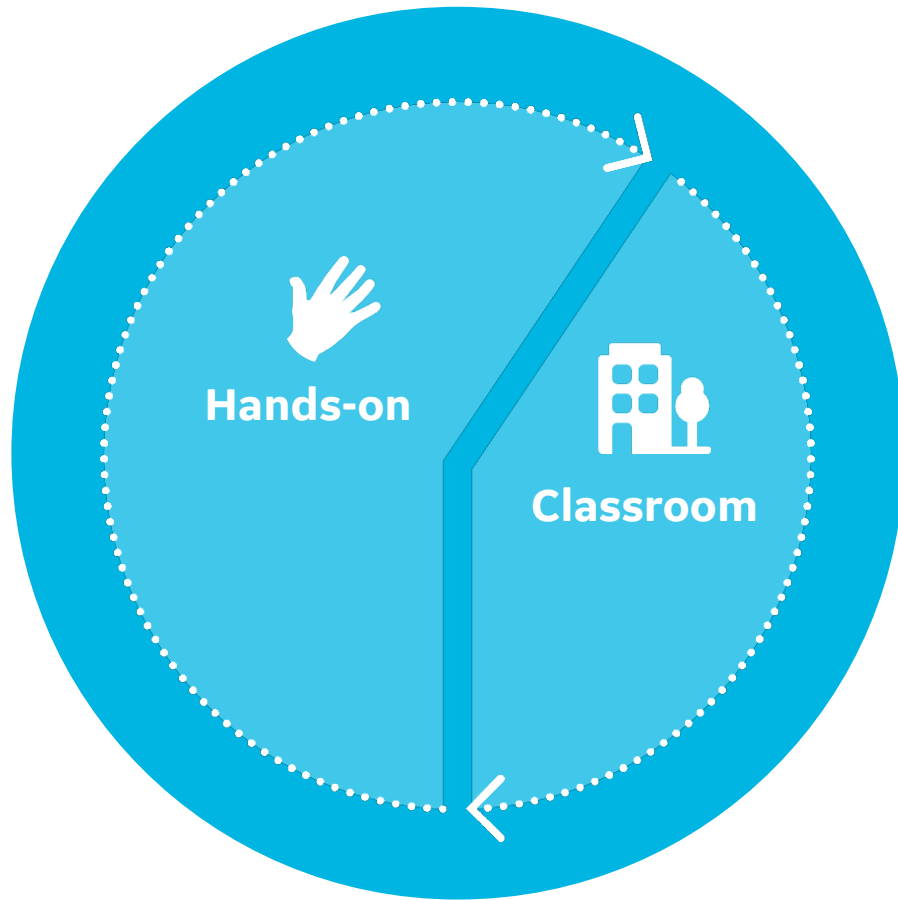


Production system	Vaccine type	Reference
Vero cell line	Polio vaccine (IPV). Naked virus (~ 30 nm). Type 1, 2, and 3 subtypes in the vaccine. (Sabine –OPV, Sabine-IPV, Salk-IPV)	Netherlands Vaccine Institute (NVI) - Vaccine 29, p.7188– 7196, 2011 - www.plosone.org, 1 December 2013, Vol. 8, Issue 12



Fast Trak Services Training & Education Courses

Training and education

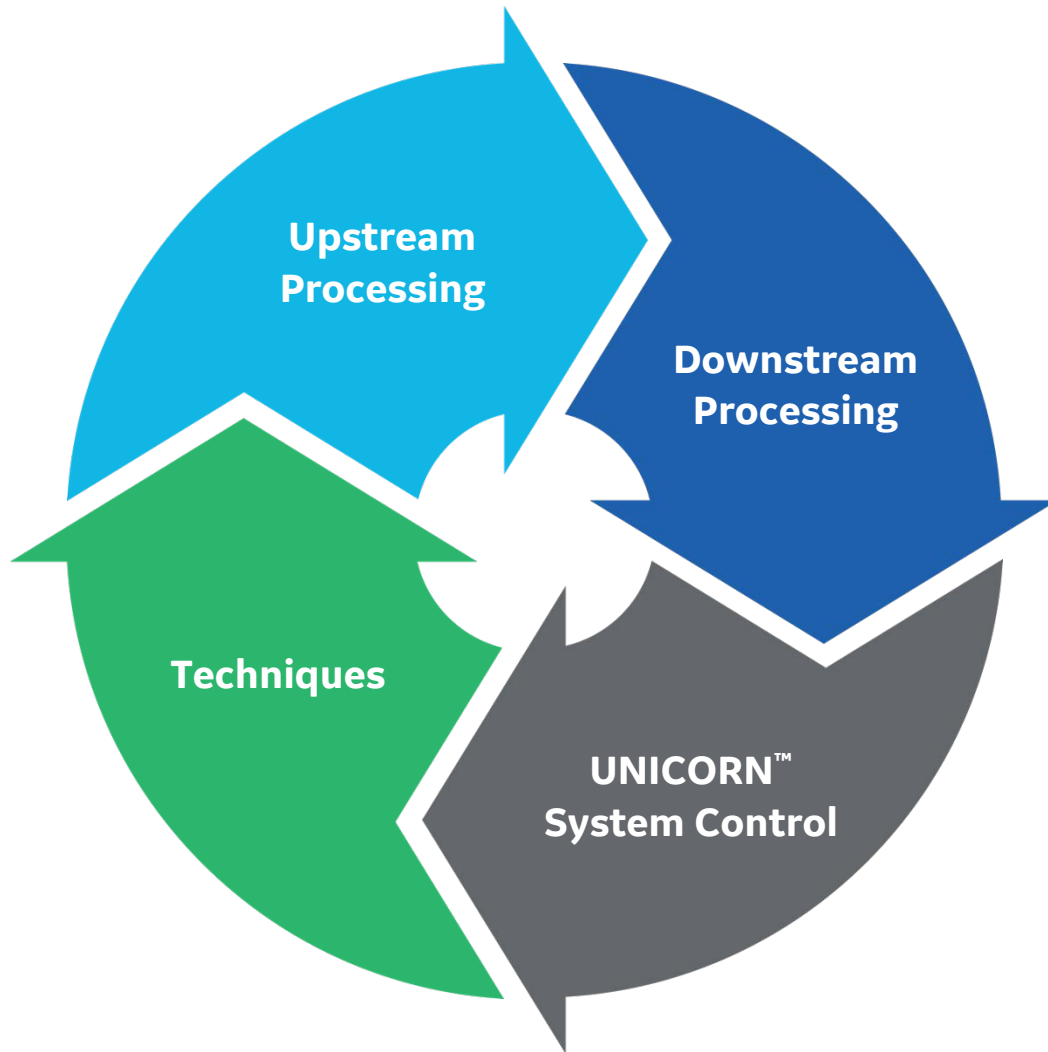


Our training courses in specialist manufacturing techniques are held at our global training centers

- Classroom, on-site, and online education
- Courses held at regional centers around the globe
- Access to the latest bioprocessing equipment and techniques
- Trained by expert scientists from the biopharma industry
- Global curricula in local languages



Standard Training Courses



- Advanced bioreactor cultivation technology (CELL1)
- Advanced bioreactor cultivation technology pilot scale (CELL2)
- Introduction to downstream techniques and bioprocessing (DEV1)
- Downstream bioprocess development (DEV2)
- Bioprocess scale-up and technology transfer (DEV4)
- Introduction to design of experiments (DOE1)
- Downstream bioprocessing of monoclonal antibodies (MAB1)
- Advanced UNICORN system control for chromatography systems (UNI1)
- Large-scale column packing (COL1)
- Small-scale column packing (COL2)
- Advanced cell therapy technology (CELLT1)

Also available: Japan: Validation – workshop (VWS1)



Upstream processing

Advanced bioreactor cultivation technology (CELL1)

Duration: 3.5 days

Training & education

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
- Process development and evaluation, scale-up, and bioengineering in an animal cell culture



Topics covered

- From cell culture to bioreactor
- Determine mixing time and kLa
- Aseptic fluid transfer
- Process control in bioreactors
- Inoculate fed-batch and perfusion cultures
- 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
- Scale up of filtration-based methods
- Harvest culture



Upstream processing

China: Advanced bioreactor cultivation technology pilot scale (CELL2)

Duration: 3.5 days

Training & education

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 establish a pilot production process for your preclinical sample production. 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
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Topics covered

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Downstream processing

Introduction to downstream techniques and bioprocessing (DEV1)

Duration: 3 days

Training & education

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 crude feed.

- Basics in industrial processing and chromatographic techniques suitable for large-scale purification
- Different chromatographic techniques
- Purification strategies and optimization
- Process hygiene and column packing
- Laboratory practicals: purification of protein from clarified *E. coli* lysate or milk whey



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



Downstream processing

Downstream bioprocess development (DEV2)

Duration: 5 days

Training & education

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: development of a scalable process for purification of α -glucosidase from cell homogenate of *S. cerevisiae*

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
 - Harvest culture



Downstream processing

Bioprocess scale-up and technology transfer (DEV4)

Duration: 3 days

Training & education

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



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



Downstream processing

Introduction to design of experiments (DOE1)

Duration: 3 days

Training & education

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 pre-generated DoE data files. You will also set up and run your own DoE experiment on an ÄKTA avant system, assess potential responses, and evaluate the results.

- Overview of DoE in process development and its application using ÄKTA avant systems
- 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

Topics covered

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



Downstream processing

Downstream bioprocessing of monoclonal antibodies (MAB1)

Duration: 4 days

Training & education

Get an introduction to mAbs and current challenges involved in biopharmaceutical production. 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



Topics covered

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



Techniques

Large-scale column packing (COL1)

Duration: 3 days

Training & education

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
- Guidelines for writing standard operating procedures (SOPs)
- Column qualification and resin lifetime



Topics covered

- Protein purification strategies
- Column packing requirements and techniques
- Column/resin considerations
- Column evaluation
- Column and resin cleaning and maintenance
- Troubleshooting
- Sanitization of resin and equipment



Techniques

Small-scale column packing (COL2)

Duration: 3 days

Training & education

This hands-on course focuses on optimizing small-scale column packing, 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 lab or pilot scale columns, with different design features and dimensions, using several types of chromatography resins.

- Hands-on practice for preparing and maintaining small-scale chromatography columns
- Column packing-lectures and exercises
- Column testing and troubleshooting
- Guidelines for writing standard operating procedures (SOPs)
- Column qualification and resin lifetime



Topics covered

- Protein purification strategies
- Column packing requirements and techniques
- Column/resin considerations
- Column evaluation
- Column and resin cleaning and maintenance
- Troubleshooting
- Sanitization of resin and equipment



Techniques

Advanced cell therapy technology (CELLT1)

Duration: 4 days

Training & education

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.

In practical sessions, you will learn 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



UNICORN™ system control

Advanced UNICORN system control for chromatography systems (UNI1)

Duration: 3 days

Training & education

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



Topics covered

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



Quality assurance

Japan: Validation – workshop (VWS1)

Duration: 1 day

Training & education

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.



Topics covered

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



Customized training and education

Training & education

Concept: Modular and tailor-made content

Duration: From days to weeks

Location: Fast Trak center/customer site

Equipment: Specific pool provided by Fast Trak

Trainer: Fast Trak, R&D/Application team, not from GE Healthcare

Language: English, French, Mandarin, German, and Spanish



Custom, on-demand courses

Upon request either at our facility or customer's site

Duration: Varies by scope agreed with customer

FlexFactory™ operator training

Duration: 8 to 10 days

This course provides training on FlexFactory equipment, consumables, and automation at your qualified FlexFactory site.

Training is focused on day-to day-operation of the various components of the FlexFactory platform. 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 platform.



Custom, on-demand courses

Equipment maintenance and trouble shooting

Duration: Varies by scope

Equipment maintenance training

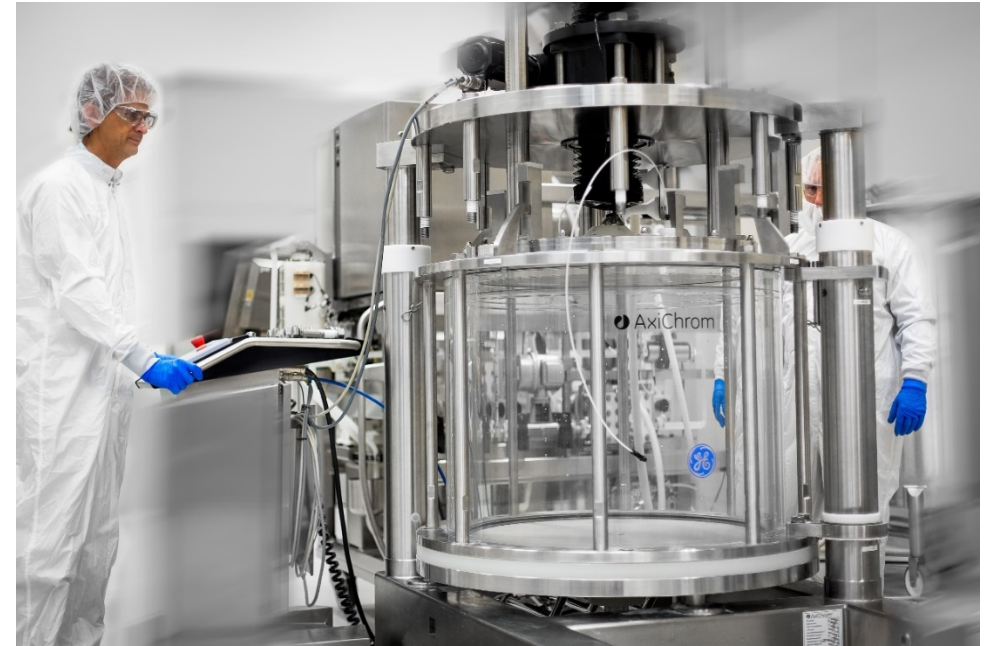
Enable faster resolution of equipment issues by improving communication between in-house service engineers and GE's field service engineers.

This course offers basic equipment level 1 training through both lectures and hands-on exercises. You will learn how to interpret error codes, resolve simple issues quickly and become more effective working with GE's engineers when needed.

Advanced equipment maintenance training

This training enables in-house engineers to carry out preventative maintenance.

Together with GE's documentation, this course will ensure you have the know-how to carry out service on GE-manufactured equipment.



Custom, on-demand courses

Bioprocessing using membrane separations (MEM1)

Duration: 3 days

Training & education

Learn about membrane separation techniques used in bioprocessing with emphasis on cross flow filtration (CFF) 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 on alternative filtration techniques
- Presentation and discussion of cross 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

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



Process consulting

Cell culture media & supplements

Upstream PD

Downstream PD

Clinical manufacturing

Analytical development/Quality control

Process transfer

Training & education

Our global team of bioprocessing experts can support you in the development, optimization and troubleshooting of existing unit operations or in the design of efficient and cost-effective 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



Fast Trak standard courses 2018 schedule

		US, Marlborough, MA	India, Bangalore	Sweden, Uppsala	Germany, Munich	Turkey, Istanbul	China, Shanghai	Singapore	South Korea, Songdo	Japan, Tokyo
Upstream processing										
CELL1	Advanced bioreactor cultivation technology	Mar 20–23	Mar 6–9 Jul 9–13	Apr 17–20	–	–	–	Apr 10–13	Mar 6–9 Sep 11–14	Jun 13–15 Dec 12–14
CELL2	Advanced bioreactor cultivation technology pilot scale	–	–	–	–	–	Jun 12–15 Dec 11–14	–	–	–
Downstream processing										
DEV1	Introduction to downstream techniques and bioprocessing	Apr 10–12 Aug 14–16	–	May 29–31	Jun 12–14	–	–	Mar 13–15	Jul 10–12	Sep 13–14
DEV2	Downstream bioprocess development	Jun 11–15 Nov 5–9	Sep 3–7	Sep 24–28	–	–	Jan 15–19 Jul 23–27	–	Nov 19–23	–
DEV4	Bioprocess scale-up and technology transfer	–	Dec 11–13	Nov 13–15	–	–	Mar 20–22 Oct 16–18	–	Aug 28–30	–
DOE1	Introduction to design of experiments	–	–	Oct 23–25	Apr 24–25	–	Apr 17–19	Dec 18–20	Oct 16–18	–
MAB1	Downstream bioprocessing of monoclonal antibodies	–	Apr 10–13	Mar 20–23	–	Oct 9–12	May 22–25	–	–	Oct 10–12
Techniques										
COL1	Large-scale column packing	Sep 18–20	–	Mar 13–15	–	–	–	–	Mar 27–29	Nov 8–9
COL2	Small-scale column packing	–	–	–	Feb 19–21 Oct 15–17	Jun 5–7	–	Oct 9–10	–	–
CELLT1	Advanced cell therapy technology	Jun 26–29 Oct 23–26	–	Nov 6–9	–	–	Sep 25–28	–	Sep 18–21	–
UNICORN™ system control										
UNI1	Advanced UNICORN system control for chromatography systems	May 8–10 Oct 16–18	–	May 15–17	Jul 3–5	–	–	–	Apr 24–26	–
Quality assurance										
VWS1	Validation—workshop	–	–	–	–	–	–	–	–	Jul 20

Please contact your regional Fast Trak center for custom courses and the latest calendar updates.

Early registration discount of 20% is available for participants who register 60 days prior to course start.

For further info and registration please visit: gelifsciences.com/FastTrakTraining



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For local office contact information, visit **www.gelifesciences.com/contact**

www.gelifesciences.com/fasttrak

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