Fast Trak
Training and education

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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.

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. In addition to our standard courses, customized training programs can be created according to your needs. The courses can be held in a number of languages.

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 a large proportion of hands-on training as well as classroom education.

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

The course facilities are located across the world with convenient access to local knowledge. They are equipped with teaching labs furnished with our latest products and equipment. The Fast Trak regional centers are located in the US, Sweden, Korea, India, and China. Satellite centers are found in Turkey, Germany, Japan, and Singapore. While each contributes its own area of expertise, they also serve as a common training and education center for local operations.
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
- 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 be able to:
- Have a detailed theoretical background about process control strategies in bioreactors and culture scale-up
- Be trained in controlling and evaluating fed-batch and perfusion cultures
- 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 kLa
- Aseptic fluid transfer
- Process control in bioreactors
- Inoculate fed-batch and perfusion cultures
- Development of cell culture media
- Cell metabolism
- Inoculate a microcarrier 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

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

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 microcarrier 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
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 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

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

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 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

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 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 and 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
Downstream bioprocessing of monoclonal antibodies (MAB1)

Duration: 4 days

Course description
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

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:
- Communicate the usefulness of different techniques dependent on source material
- Define a platform process for mAb purification suitable to the process objectives
- Develop optimization methods and understand regulatory concerns unique to mAb manufacturing processes

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

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
- Guidelines for writing standard operating procedures (SOPs)
- 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 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/resin considerations
- Column evaluation
- Column and resin cleaning and maintenance
- Troubleshooting
- Sanitization of resin and equipment
Small-scale column packing (COL2)

Duration: 3 days

Course description
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 small-scale columns, with different design features and dimensions, using several types of chromatography resins.

- Hands-on practice for preparing and maintaining lab- or pilot-scale chromatography columns
- Column packing-lectures and exercises
- Column testing and troubleshooting
- Guidelines for writing standard operating procedures (SOPs)
- 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 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- and pilot-scale column packing based on your own practical experience
- Pack and test lab- and pilot-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 and maintenance
- Troubleshooting
- Sanitization of resin and equipment

Advanced cell therapy technology (CELTL1)

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 Procedures (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.

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
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.

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 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

Quality assurance

Japan: Validation—workshop (VWS1)

Duration: 1 days

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 workshop, 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™
• 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
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: 8 to 10 days

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 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.

Technical 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 technical 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 equipment manufactured by GE.

For more information on our Fast Trak trainings please visit gelifesciences.com/fasttraktraining

Biacore basics

Duration: 2 days

Course description

Biacore basics is a course both for users new to surface plasmon resonance (SPR), those who have never been formally trained, or users with prior experience that want to familiarize themselves with a new platform type. In this class, we cover the technologies behind Biacore systems, assay development, best practices in basic experimental design, and the most common applications run on today’s Biacore systems. The course uses both lecture and hands-on exercises to instruct you on the optimal methods for designing and optimizing Biacore assays, with a focus on kinetics.

After of the course, you will be able to:

- Design binding assays
- Operate the Biacore control software to set up automated runs
- Use the Biacore evaluation software to determine kinetics and affinity

Kinetic and affinity analysis

Duration: 2 days

Course description

This course is intended for users interested in binding kinetics who have already attended Biacore basics. The course is available for Biacore T100/T200, 3000, S200, and X100 systems. This is a two-day instructor lead course that is conducted in a computer lab. The course includes theory (lectures), and hands-on data analysis with the evaluation software that corresponds to the user’s own instrument. We do not do experiments, but spend a majority of time analyzing data. We focus on the design and optimization of kinetic and affinity experiments, and evaluation of kinetic and affinity data using the Biacore evaluation software. Different analysis models will be also discussed. In addition, we will include the use of BIAsimulation software for design of kinetic and affinity experiments.

After of the course, you will be able to:

- Properly set up and analyze kinetic, steady-state affinity, solution affinity, and thermodynamic assays
- Correctly apply complex binding models to appropriate experimental data, and modify existing models in the evaluation software

Topics covered

- Study a wide range of biomolecules in different sample environments
- Define structure/function relationships
- Understand the dynamics of molecular pathways
- Measure the concentration of active protein
- Define kinetics, affinity, and specificity
Biocore system training

The Biocore training portal provides a comprehensive range of learning opportunities to expand your expertise and get the most out of your Biocore system. Teaching materials such as kits, courses, laboratory guidelines, and handbooks are available.

- Self-training tools—getting started kit, e-learning courses, and educational lecture package
- Classroom courses—practical and theoretical courses with support and course literature
- Application support tools—tech tips, interactive tutorials and tools, lab guides, and handbooks

For more information on Biocore training please visit gelifesciences.com/bctraining

Biotechnology group leader

"I have been in the pharmaceutical industry for more than 15 years in Turkey. Currently, we are focused on monoclonal antibody development and production. This course improved our understanding on downstream development and had valuable impact for developing efficient purification steps and getting higher yields. GE’s Fast Trak laboratory is very well equipped and the trainers are very experienced."

R. Serdar Alpan, MD, PhD, MSc., Turgut Pharmaceuticals

Bioprocessing using membrane separations (MEM1)

Duration: 3 days

Course description

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

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 purity 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

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

There are hands-on training courses on column packing, basic chromatography, optimization and scale-up for both pilot and production scales. Courses on validation issues and chromatography theory are also given.

The courses are run at our regional Fast Trak centers or customized at your premises. To view our Fast Trak course schedule, please visit gelifesciences.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. GE Healthcare 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. GE Healthcare 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, Turkey, India, Singapore, and Korea, unless otherwise specified. In China, most courses are in Chinese with occasional courses in English. The courses in Germany are held in German and courses in Japan are held in Japanese. Customized courses can be presented in other languages. Please contact the 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 safety level S1 (L1) 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.

General course information
Marlborough, Massachusetts, US
Email: fasttrak.americas@ge.com
Mail: Fast Trak Center North America
GE Healthcare Bio Sciences Corp.
100 Results Way
Marlborough, MA 01752
US
Phone: +1 508 683 3766

Istanbul, Turkey
Email: fasttrak.europe@ge.com
Mail: Fast Trak Istanbul
Yeditepe University
Research & Development
and Analysis Center
Acibadem Mah. Bağ S. No:8
34718
Kadıköy, Istanbul, Turkey
Phone: +90 (0) 212 3980888

Shanghai, China
Email: fasttrak.cn@ge.com
Fax: +86 21 5080 6339
Mail: Fast Trak Center China
GE Healthcare
1800 CaiLun Road
Zhangjiang High-tech Park, Pudong
ShangHai 210203
China
Phone: +86 21 3877 2600

Munich, Germany
Email: fasttrak.europe@ge.com
Mail: GE Healthcare Training Laboratory
Oskar-Schlemmer-Straße 11
80807 Munich
Germany
Phone: +49 (0) 761 45 43 683

Bangalore, India
Email: fasttrak.india@ge.com
Fax: +91 80 2526 8423
Mail: Fast Trak Center India
John F. Welch Technology Centre
Whitefield Road, Hoodi Village
Bangalore, Karnataka, 560 066
India
Phone: +91 80 4088 1674

Songdo, Korea
Email: FastTrak.APAC@ge.com
Fax: +82 32-822-8228
Mail: Fast Trak Center APAC
BRC 2-Dong 2F
9, Songdomirae-ro, Yeonsu-gu
Incheon, 21988
Korea
Phone: +82 32-822-8330

Uppsala, Sweden
Email: fasttrak.europe@ge.com
Mail: GE Healthcare Europe GmbH
Swedish branch
Björkgatan 30
751 84 Uppsala
Sweden
Phone: +46 18 675854

Singapore
Email: lifesciences.sg@ge.com
Fax: +65 6773 7302
Mail: Fast Trak Singapore
GE Healthcare Pte Ltd
1 Maritime Square #13-01
HarbourFront Centre
Singapore 099253
Singapore
Phone: +65 6773 7303

Tokyo, Japan
Email: fasttrak.japan@ge.com
Fax: +81 (0) 3 5331 9372
Mail: Fast Trak Japan
GE Healthcare Japan Corporation
Sanken Bldg, 3-25-1
Hyakunincho, Shinjuku-ku
Tokyo 169-0073
Japan
Phone: +81 (0) 3 5331 9316