

Fast Trak™ training and education

MAB1



Downstream bioprocessing of monoclonal antibodies

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

2019 pricing

Fast Trak Center	List Price	Product Code
Sweden, Uppsala	2839 EUR	29005242
China, Shanghai	20035.40 (CNY)	29012013
Japan, Tokyo	86300 (JPY)	28921808
India, Bangalore	120000 (INR)	29298320



General course information

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.

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 registered, 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 USA, 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.

gelifesciences.com/fasttraktraining

GE, the GE Monogram, and Fast Trak are trademarks of General Electric Company.

©2019 General Electric Company.

GE Healthcare Bio-Sciences AB, Björkgatan 30, 751 84 Uppsala, Sweden

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

KA2206220519FL