



Fast Trak training and education

VWS1



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 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 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
- Chromatography resin lifespan
- Special validation issues for mAb and vaccine, examples for clinical phase 1
- Rapid development with regulatory compliance

2018 pricing

Fast Trak Center	List Price	Product Code
Japan, Tokyo	25000 (JPY)	28956292

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.

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