



# Fast Trak training and education

## DEV4



### 바이오횰약품 정제 공정 스케일업 및 기술이전 (DEV4)

기간: 3일

#### 코스 소개

Fast Trak DEV4 코스는 크로마토그래피 공정 스케일업 및 기술이전을 위한 심화 과정으로, 생산 스케일 공정 개발을 위한 공정 설계, 최적화 및 밸리데이션에 초점을 두며 실제 기술이전 시 발생할 수 있는 이슈에 대한 해결책을 제시합니다.

실습을 통해 연구용 컬럼으로 최적화된 크로마토그래피 공정을 파일럿 생산용과 상업 생산용 컬럼 규모로 스케일업 하며, 이를 통해 스케일업 시 핵심이 되는 주요 인자를 파악하고 논의함으로써 실제 스케일업을 위한 역량을 강화합니다.

#### 코스 일정

- 날짜: 2020년 7월 8일 - 10일 (3일 과정)
- 장소: GE Healthcare APAC Fast Trak 센터
- 주소: 인천광역시 연수구 송도1동 송도 미래로 9 BRC 2동 2층 GE Healthcare APAC Fast Trak Center
- 식사: 점심식사 제공

#### 강좌 목표

- 스케일업 가능한 크로마토그래피 공정 설계, 최적화 및 기술이전
- 생산용 크로마토그래피 공정 관리를 위한 GMP의 이해 및 공정 밸리데이션
- 생산 공정 및 최종 산물의 경제성 향상을 위한 방안 모색
- 실습: Desalting 및 이온 교환 크로마토그래피 공정 스케일업을 통한 효모 유래 효소 분리

#### 수강 대상

- 스케일업, 스케일다운 및 생산 현장에서 크로마토그래피 작업을 수행해야 하는 연구원 또는 엔지니어
- 기술이전 책임자, 생산 현장의 작업자 및 QA/QC를 포함한 크로마토그래피 공정에 대한 이해가 필요한 모든 인원

#### 등록 방법

APAC Fast Trak 웹사이트 ([www.bit.ly/fasttrak-kr](http://www.bit.ly/fasttrak-kr))를 통해 직접등록 또는 담당 GE 영업사원에게 문의 주시기 바랍니다.

#### 코스 가격 (2020년 기준)

Fast Trak Center	List Price	Product Code
Korea, Songdo	2,300,000 (KRW)	29244579

#### 강의 내용

- 크로마토그래피 공정 설계 및 최적화
- 크로마토그래피 공정의 스케일업 및 기술 이전
- 전반적인 공정 관리 및 경제성 향상
- 적격성 검사와 밸리데이션
- 실험실 및 파일럿 규모의 공정 검증 및 생산 규모 공정 수행
- 스케일업 사례 분석



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## 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

### 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

### 2020 pricing

Fast Trak Center	List Price	Product Code
Korea, Songdo	2,300,000 (KRW)	29244579

# 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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