

Course Topics Include:

- Current Status of Technology Transfer and Post-Approval Changes
- Analytical Methods and Quality Control Specification Transfers
- Dosage Forms Transfers
- Internal and Third Party Transfers
- Packaging Components and Process Transfers
- FDA Guidelines for Post-Approval Changes (SUPAC) & Transfers
- Post Approval Changes (labeling, packaging, manufacturing site, API, process)
- FDA Recommended Data to Support Post approval Changes
- New Emerging Trends In Post Approval Changes & Transfers Worldwide
- Interactive Case Studies

Who should attend

This course is intended for professionals from Pharmaceutical Industry involved in:

- Formulation and Process Development/Validation
- Regulatory Affairs, Quality Assurance and Quality Control
- Analytical Methods Development
- Package Development/Package Engineering
- Manufacturing and Technical Support
- Project Management and Planning
- Contract Research, Development or Manufacturing Organizations

Participants will benefit by gaining a better understanding of the complexities of technology transfer and post-approval changes of various dosage forms in the pharmaceutical industry.

Learning objectives

Upon completion of this course, you will be able to:

- Utilize the interactive processes involved in technology transfer and describe the approaches used to transfer packaging components, analytical methods and dosage forms
- Define the critical issues surrounding technology transfer and how to plan for success
- Use relevant regulatory guidance documents to develop research and regulatory strategies

- List key issues in the selection of third party development and manufacturing partners

Course description

This 2-day intensive, accredited course will provide a basic understanding of the technology transfer of analytical methods, quality control standards, packaging components/operations and various pharmaceutical dosage forms from R&D to manufacturing. It is designed to provide an understanding of the issues affecting the transfer within and outside a company. Topics will include transfer of technology to/from international sites as well as to /from third parties. This course will also provide an understanding of the FDA Scale-up and Post Approval Changes Guidelines & the FDA guideline on changes to an approved NDA or ANDA. The issues affecting batch size scale-up /scale-down, site of manufacturing changes, manufacturing process changes, and equipment changes will be addressed along with the issues affecting analytical methodology, packaging and labeling changes. The speaker will use practical examples to highlight issues critical to successful technology transfer in compliance with FDA regulations.

Interactive case studies based on real examples will allow participants to develop strategies and plans in a team environment.

Course Director

Course director: Mukund (Mike) Yelvigi is founder & principal at Center for Pharmaceutical Integration LLC, which provides consulting service to the industry in the area of CMC support & Technology Integration and Transfers (mergers & acquisitions). He retired as Sr. Director and Head of CMC Therapeutic Area Management at Pfizer/Wyeth Inc. NY. He has over 30 years extensive experience in formulation, process development/scale-up, and has successfully launched several products globally. He obtained his undergraduate degree in Pharmacy from

Bombay University and graduate degree from Philadelphia College of Pharmacy.

He is an adjunct Assistant Professor of Pharmaceutics at the School of Pharmacy, U of Mississippi and an active member of AAPS, ISPE, AAiPS, FIP. He was the Chairperson of the AAPS Manufacturing Science & Engineering section.

Co-Director: Walter G. Chambliss, Ph.D., Associate Vice Chancellor for Research and Professor of Pharmaceutics and Drug Delivery at the University of Mississippi.

FIRST DAY

8:30-9.00:

Registration

9.00-10:45:

Welcome and introduction to technology transfer

- Definitions
- Critical FDA & ICH guidelines
- Latest FDA & ICH initiatives
- Other Global initiatives (WHO, EMEA etc)
- Current status of technology transfer in the industry

11:00-12:45:

Coordination of activities and responsibilities for solid dosage forms

- Roles and responsibilities
- Documentation and reports
- Different approaches and models

14:00-15:30

Analytical methods transfer, quality systems & documentation

- Roles and responsibilities of the QC and Analytical units
- Regulatory requirements
- Checklists
- Intra- and inter-company transfers

15.45-17.30

Parenteral dosage forms:

- Factors to consider in parenteral dosage forms transfers
- Case Studies Discussion

SECOND DAY

9:00-10:45

Transfer of packaging components and packaging process

- Roles and responsibilities
- Factors to consider
- FDA SUPAC & Other Guidelines
- Site Transfer
- Scale-up considerations
- Risk based analysis

11:00-12:45

Semi-solid and liquid dosage forms

- Factors to consider in semi-solid and liquid transfers
- Case studies

13:45-15.45

Interactive case study 1 :

- 1a. Modified Release Dosage Forms
- 1b. Presentation and discussion of case studies by students

16.00-17.00

Interactive Case Study 2:

- 2a. Plant Shut Down
- 2b. Presentation and discussion of case studies by students

17.00-17.30

Discussion and Wrap-Up

TUITION AND PAYMENT

Early registration **:

(received before August 10, 2018) - Euro 1750+VAT/1575+VAT (group discount*)

Regular registration:

(received after August 10, 2018) - Euro 1950+VAT/1755+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks)
Participants are responsible for their own hotel reservations.

* Group discount is for two or more enrollments from the same company.
** Early Registration means: registrations forms received by the deadline and payments made within one week from invoice date. Otherwise regular registration fee will be applied

Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.

Registration

Name

Surname

Position

Organization

VAT

Address

Postal Code

City

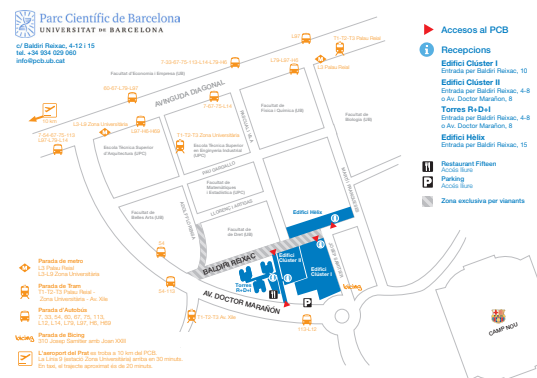
Country

Phone/Fax

Participant e-mail

Billing e-mail

PLEASE RETURN BY FAX OR E-MAIL



General information

Cancellations received after September 21, 2018 will be invoiced completely. All cancellations will be subject to euro 300 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

For Information please contact us at:

Office: +34 93 4487156
Cell: +34 691676055
Fax: +34 93 4037109
e-mail: info@sitec-pharmabio.com