COBBLESTONE

COURSE ID 2904

REVISED!

Pharmaceutical Technology Transfer and Project Management

CO-DIRECTED BY

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8 Hours

ACCREDITED COURSE

- Best Practices, Critical Issues, and Data Requirements
- Technology Transfer Teams and Project Management
- Scientific and Engineering Principles
- Relevant Regulatory Documents (FDA and ICH)
- Analytical Methods and Quality Control Transfers
- Dosage Form and Packaging Transfers
- Selection of Contract Development and Manufacturing Organizations

about the course

Participants will gain a fundamental comprehension of technology transfer in the pharmaceutical industry, including the transfer of analytical methods, quality control standards, packaging components/operations, and various dosage forms from R&D to manufacturing. The course provides an overview of scale-up and technology transfer of solid dosage forms, injectables, and semisolids.

This 8-hour accredited course will delve into the challenges of transfers within and outside a company, including transfers to/from international sites and third parties. Best practices to avoid common pharmaceutical technology transfer issues will be discussed.

The course will address issues affecting changes to batch size, formulation, packaging components, site of manufacture, manufacturing process, analytical methods, specifications, and processing equipment changes, with practical examples from experienced speakers. The importance of technology transfer teams and the roles and responsibilities of project managers and team members will be emphasized.

Additionally, participants will engage in interactive case studies, based on real-world examples, to develop collaborative strategies and plans to execute complex transfers with short timelines. The course is designed for professionals involved in technology transfer of prescription (innovator and generic) and over-the-counter drug products.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This online training is designed for professionals in the pharmaceutical industry. It will be especially valuable to the personnel and management, including senior management, in these areas:

- Project Managers and Operations Management
- Process Development/Validation
- Manufacturing, Logistics and Technical Support
- Quality Control/Assurance
- Package Development/Package Engineering
- Formulation Development
- CDMO Business Development
- Analytical Methods Development
- Regulatory Affairs
- Operation Management/Logistics

Participants, as well as their managers, will benefit by gaining a better understanding of the complexities of technology transfer in the pharmaceutical industry. The course covers transfers of small molecule drug products, not biotechnology, vaccines, or medical device products.

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 a wide variety of dosage forms
- Describe the critical issues surrounding technology transfer and how to plan for success
- Classify post-approval changes according to their potential impact on product quality and performance
- Use relevant regulatory guidance documents to develop research and regulatory strategies
- List key issues in internal and third-party transfers

course outline

Review of Learning Objectives

Overview of Technology Transfer

- Historical approaches to technology transfers and regulatory initiatives
- Underlying scientific principles
- Definition of terms
- Application of FDA/ICH guidance documents to planning and regulatory strategies

Dosage Forms and Packaging Transfers

- Quality-by-design (QbD) concepts
- Factors to consider for major types of dosage forms
- Equipment and engineering principles affecting scale-up
- Packaging component and process considerations
- Regulatory requirements for changes in site, batch size, and equipment

Quality System Transfers

- Analytical method transfers
- Document transfers and example transfer checklist
- Quality Agreements

Project Management of Internal and Third-Party Site Transfers

- Overview of technology transfer teams.
- Roles and responsibilities of project manager and team members

- Technology transfer timelines
- Risk management
- Project management tools
- Selection of and working with CDMOs

Interactive Technology Transfer Case Studies (team exercise)

- Third party product development and transfer in-house
- Manufacturing site shut down and international transfers

Question and Answer Session

Assessment Opportunity

co-course instructors

Walter G. Chambliss, Ph.D. is Professor Emeritus of Pharmaceutics and Drug Delivery, and Research Professor Emeritus in the Research Institute of Pharmaceutical Sciences at the University of Mississippi. He teaches graduate courses in pharmaceutical formulation development, manufacturing, and regulatory sciences. He also lectures in the post-graduate education courses, Hands-on Course in Tablet Technology (tabcourse.com) and the Advanced Hands-on Course in Tablet Technology (tabcourse.com). In addition to teaching, he managed the technology transfer operations of the university for 20 years. Dr. Chambliss received a B.S. in Pharmacy, a M.S. in Pharmaceutics, and a Ph.D. in Pharmaceutics from the University of Mississippi. He worked for 17 years in research and development in the pharmaceutical industry at G.D. Searle, Bristol-Myers, and Schering-Plough where he was Vice President of R&D for the HealthCare Products Division.

Dr. Chambliss has extensive experience in formulation development and process development of a wide variety of dosage forms. He is a Fellow of the American Pharmaceutical Association and a past-President of the Academy of Research and Science. He has authored or co-authored over forty publications including three book chapters in pharmaceutical reference books**.**

Mike Yelvigi is Principal and Managing Partner at Center for Pharmaceutical Integration LLC, which provides consultation 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 function at Pfizer/Wyeth Inc. NY. He had responsibility for co-ordination of CMC activities related to drug substance synthesis, drug product formulation, analytical development, and regulatory filing for several therapeutic areas. He has over thirty years extensive experience in pharmaceutical formulation, process development/scale-up, process validation, manufacturing and pre-approval inspections and has successfully launched several products globally. Earlier to this, he was Head of Process Development and clinical supply group at Hoffman-La Roche Company, New Jersey. Other companies he has worked include Parke Davis (USA), G.D Searle and Organon Inc. He obtained his undergraduate degree in Pharmacy from Bombay University and graduate degree in Pharmacy, from Philadelphia College of Pharmacy.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 8 contact hours, or .8 CEUs. For further information, visit www.iacet.org