Registration Information

C4163 C R

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From the Lab to FDA Submission

Technology/Product Evaluation, Regulatory Strategy, Project Planning, Document Control and Design Control

You will learn how to

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- Avoid pitfalls and identify areas for improvement in managing the transfer process in your organization

Course Instructor:

Cynthia G. Pritchard, Ph.D.
CEO
BioTechnology Transfer, LLC

Dates and Locations:

September 21-22, 2006 • Boston, MA
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Benefits of Attending:

- Understand the FDA submission process: learn key regulatory requirements, submission categories, and steps for each product type
- Gain appreciation of FDA-mandated design control requirements and learn how to properly integrate these with project management and document control
- Gain insight, practical tips and techniques from industry veterans on designing, implementing, and managing these systems to efficiently guide transfer of your technology from R&D through agency clearance
- Receive system outlines and documentation examples that you can use as a guide for development of your products and for effective technology transfer through each design phase
- Learn pitfalls to avoid and how to identify areas for improvement in managing the transfer process in your organization
- A comprehensive course binder with examples of the systems discussed and a CD with templates and Links to applicable FDA regulations and guidance documents

Who Should Attend:

Individuals participating in the tactical and strategic development of biotechnology products: medical devices, diagnostics, cell therapy or biologics.

Scientific, regulatory, quality, and management personnel who need a practical, working knowledge of agency submission requirements, design control, documentation and project managemen.

Important Course Information

- Registration begins at 8:15 a.m. on the first day. Please check in at the IBC Registration Desk to receive your badge and materials.
- Course Schedule: Each day the course will begin at 9:00 a.m. and conclude at 5:00 - 5:30 p.m. Continental breakfast is served from 8:15 - 9:00 a.m. There will be two refreshment breaks at approximately 10:00 a.m. and 3:00 p.m. Lunch will be served each day at approximately 12:00 p.m. Refreshment breaks, lunches, and meeting conclusion times may vary slightly based on delegate interaction and the instructor(s) discretion.
- Audio tape and/or video recordings are not permitted.
- Certificate of Attendance: All participants completing the course will receive a certificate of attendance at the meeting. Please see the IBC staff person at the IBC Registration Desk.

Course Description:

There is no manual to guide entrepreneurs in the transfer of a technology from the lab to the marketplace. The road is filled with potholes but can be more easily navigated if one knows the route. A new company can 'learn as it goes' but with limited time and money, this option is not the best. The optimal solution is a proactive, planned approach that realistically determines a technology's true potential to be developed and manufactured into a marketable product. Early implementation of FDA-mandated design control, documentation and project management systems allow efficient capture of R&D data that can be used to support and speed agency submissions and clearance to market.

To learn the steps required to save time and effort, and to meet FDA and European agency mandates in developing clinical devices, diagnostics, and biologic products, attend this in-depth, two-day advanced course on transferring your technology. You will learn how to evaluate your technology for potential pitfalls to development, manufacturing, marketability, and how to determine the best design for potential products. You will learn the requirements for developing a correct regulatory strategy, the first key to designing a detailed project plan. You will also learn how to set up integrated design control, documentation, and project management systems. Real-life case studies will be discussed and practical, simple techniques for implementation and management will be given throughout the course.

Course Instructor:

Cynthia G. Pritchard, Ph.D., CEO of BioTechnology Transfer, LLC

Dr. Pritchard has over 25 years in the medical industry, and has helped bring more than 30 products from research into development through clinical trials and manufacturing to market launch. She began her career as a clinical microbiologist. Her graduate and postdoctoral training were in virology, molecular biology and biochemistry. She served in positions of increasing responsibility at both small and large companies, integrating various assay chemistries with instrumentation, and developing biologics and cell-based therapies. She has a strong regulatory and quality assurance background, with extensive experience in GTP/GCP/GMP, ICH and ISO requirements, clinical project management, design control, and documentation, and has written over 25 successful submissions (510(k), IDE, DMF, IND) to CDRH and CBER divisions of FDA. She currently heads a company of medical industry veterans that was started to provide practical help to start-up biotech companies.

In-House Training

All IBC Training Academy courses can be offered at your company site. We bring the information to you. You choose the topic and location. Call Kerry Patterson at 508-614-1423 or visit www.IBCLifeSciences.com/courses

Course Agenda

- Evaluating a technology: product design, development, manufacturing, market, regulations; pitfalls to avoid
- Alphabet Soup: Defining Regulatory Strategy
  - Which type of submission?
  - Product Codes
  - Product Classes
  - Where do we Send it?
  - Agency
  - Division
  - Office
- FDA regulations and guidance concerning design control, documentation
  - Design Control Basics
  - Phases
  - Steps
  - Documents
  - Reviews
  - Document Control
  - Quality System
  - Document Types
- Examples
- Uses
- Implementation
- Project Management in Practice
  - Responsibilities
  - Planning
  - Regulatory Strategy
  - Design Link
  - Document Link
  - Management
- Basics of Regulatory Submissions
  - Submission Elements
  - Writing and Filing Tips
  - What to Expect After the Submission is Filed

Furnished Resources: A comprehensive course binder with examples of the systems discussed and an electronic copy on CD containing:

- Design Control Templates
- Project Management Templates
- Document Templates
- Links to applicable FDA regulations, guidance documents

Register Today! Call: 800-858-4881 or Fax: 941-365-0104

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