SPEAKER:- PEGGY J. BERRY.

2 Days eCTD Submissions of IND and NDA/BLA to the US FDA, EU and Canada (COM)

02 - 03 -NOV -2017
Location | Philadelphia, PA

Single Attendee
$ 1295
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An event by:
World Compliance Seminars

COURSE SUMMARY

World Compliance Seminars WCS is known all over the world for high quality of professional training programs it offers to members of the global bio pharmaceutical community. We commit to bring you quality webinars from industry experts in a timely fashion. Ensuring your business strategy is on the right track to face the future bounties.

Topic:- 2017 workshop eCTD Submissions of IND and NDA/BLA to the US FDA, EU and Canada (COM)

An Interative Workshop Presented BY WCS & Peggy J. Berry, MBA, RAC, (Synergy Consulting)

The international agreement to assemble all Quality, Safety and Efficacy information for a drug or biologic product into a common format (called the CTD- Common Technical Document) has improved the speed and efficiency for companies working in global development programs and clarified expectations by regulatory bodies.

Reformatting for multiple submissions is substantially limited. The CTD has improved the regulatory review processes and enabled implementation of good review practices. The eCTD has increased efficiency for reviewers and improved submission times.

Key Topics

This two day workshop will provide you with an in-depth review of the content and format requirements of the CTD/eCTD. Hands-on activities will include organizing specific study reports and other documents into the CTD, using tools for the project management of the CTD preparation, and prepublishing
an eCTD

Areas Covered

- Overview of the drug development program and source of relevant submission documents
- Discussion of the roles and responsibilities for CTD preparation
- Review of the CTD format requirements
- Discussion on the successful transition from other formats to the CTD
- Placement of content into the CTD format; including less obvious items
- Review of different requirements across regions (US, EU, Canada)
- Implementing tools for the project management of CTD preparation and publishing
- Technical requirements for an eCTD submission
- Document naming requirements
- Building the folder structure
- Internal document requirements for the eCTD
- Performi

Industries who can attend

- Regulatory Affairs
- Quality Assurance
- Pharmacovigilance
- Project Management
- Regulatory Operations
- Medical and Technical writers
- Professionals preparing IND, DMFs, NDAs and other submissions
- IT Professionals
- Anyone responsible for providing content for the CTD

SPEAKER

Peggy J. Berry.
MBA, RAC,President & CEO, Synergy Consulting
(Ex-FDA Official)

PEGGY J. BERRY

Peggy J. Berry, MBA, RAC, is the President & CEO at Synergy Consulting where she provides consulting services to companies in all aspects of drug development. She also provides group and one-on-one training in drug development, regulatory affairs and project management topics. Prior to founding Synergy Consulting in 2015, she was Vice President of Regulatory Affairs at Insmed (2/2015-5/2015) where she was responsible for the development and implementation of global regulatory strategies and the management and oversight of the regulatory affairs department. Prior to Insmed, she was Vice President of Regulatory Affairs and Quality at Amarin (3/2009-2/2014).

Peggy J. Berry has also held a variety of senior level positions at Dyax (5/2006-3/2009), MGI Pharma (now Eisai; 7/2005-5/2006), AstraZeneca (10/2001-7/2005), and Dey Pharma (now Mylan; 12/1997-10/2001). She has also held Regulatory Affairs roles within two clinical contract research organizations (ILEX Oncology and Cato Research Ltd; 1992-1997) and has worked in review divisions at the FDA (1985-1992). In addition, Ms. Berry consults for a number of companies in the regulatory and quality area, conducts a number of training courses, and is active in the Regulatory Affairs Professionals Society. She is the editor of the 2010 book "Choosing the Right Regulatory Career" (RAPS, MD) and author of the 2011 book "Communication & Negotiation" (RAPS, MD).

Our Testimonials

David QU, senior Analytical Chemist Dalton Pharma Services.

"I learned a lot from the instructor and trainee good."

Nicola Mootoo, Senior Validation Engineer Shire Pharmaceuticals.

"Well placed, a lot of good information. Good interaction between participants.Held at a good location"

Evelyn Chang, Corporate manager Genzyme.

"Well delivered seminars, right place, good contents."

Mary Beird, Regulatory Compliance Manager
Charles River laboratories International, Inc.

"I thought the contents of the presentation and the discussion was very good"

Sajan B. Balabhadran, Watson Pharma Pvt Ltd.

"A Very Well organized event. The Speaker was just marvellous in driving to a depth of my understanding of Data Integrity and 21 CFR Part 11 aspects."

Course Outline:

Day 1 9:00 AM - 5:00 PM

- Registration Process - (8:30 am till 8:45 am)
- Lecture 1: Overview of the drug development program and source of relevant submission documents
- Lecture 2: Discussion of the roles and responsibilities for CTD preparation
- Lecture 3: Review of the CTD format requirements
- Lecture 4: Discussion on the successful transition from other formats to the CTD
- Lecture 5: Placement of content into the CTD format; including less obvious items
- Lecture 6: Review of different requirements across regions (US, EU, Canada)
- Lecture 7: Implementing tools for the project management of CTD preparation and publishing

Day 2 9:00 AM - 5:00 PM

- Lecture 8: Technical requirements for an eCTD submission
- Lecture 9: Document naming requirements
- Lecture 10: Building the folder structure
- Lecture 11: Internal document requirements for the eCTD
- Lecture 12: Performing "pre-publishing" work for each document
- Lecture 13: Tools for tracking and managing eCTD content
- Lecture 14: Performing quality checks on the eCTD
- Lecture 15: Updating content in the CTD and eCTD (amendments, supplements variations, etc.)

Register Now

PACKAGE	Single Attendee	Special Group Discount
2 days Workshop 02,03 -NOV -2017 Location | Philadelphia, PA	$ 1295	$ 3885

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""Each attendee will receive 2-Day workshop materials by the speaker. Seminar Also Includes Certificate, Complimentary Breakfast, Lunch & High Tea/Coffee provided by WCS""

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