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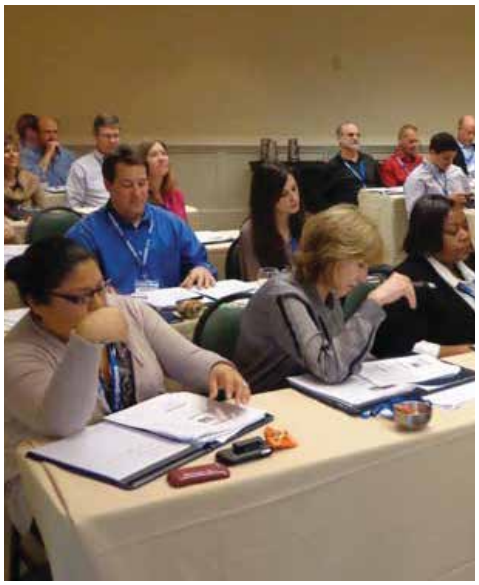
2-Day In-Person Seminar by Ex-FDA Official

eCTD Submissions of IND and NDA/BLA to the US FDA, EU and Canada

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

Location 01: Orlando, FL | February 1-2, 2018 **Location 02:** San Francisco, CA | May 31-June 1, 2018



SPEAKER

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

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). She 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).

WHO WILL BENEFIT

- 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

COURSE DESCRIPTION

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.

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 pre-publishing an eCTD.

AGENDA

Day One (8:30 AM - 4:30 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 Two (8:30 AM - 4:30 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.)**


Registration Form

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
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Seminar Topic: eCTD Submissions of IND and NDA/BLA to the US FDA, EU and Canada

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Attendee 2			
Attendee 3			
Attendee 4			

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