CTD/eCTD content and format

November 7-8, 2016 | Montreal - Canada

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.

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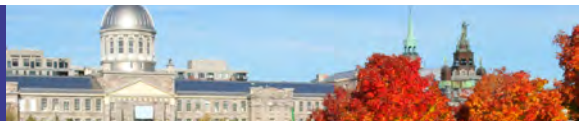
http://ipacanada.com/CTD_eCTD

About the course:



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.

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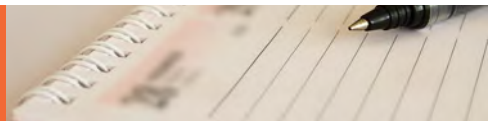
About the speaker:

Peggy J. Berry, MBA, RAC
President & CEO
Synergy Consulting LLC

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).

Course Agenda & Contents



Day 1 - Monday November 7, 2016 | Course Contents

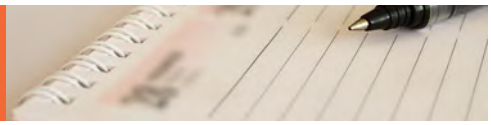
- Overview of the drug development program and source of relevant submission documents
- Discussion of the roles and responsibilities for CTD preparation
- Review of the CTD format requirements
- Discussion on the successful transition from other formats to the CTD
- Placement of content into the CTD 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

Day 1 - Course Agenda

8:30 AM – 9:00 AM **Registration and Continental Breakfast**
9:00 AM – 10:30 AM **Course begin**
10:30 AM – 10:45 AM **Mid-morning refreshment break**
10:45 AM – 12:15 AM **Course continue**
12:15 PM - 1:15 PM **Networking lunch**
1:15 PM - 2:30 PM **Course continue**
2:30 PM - 2:45 PM **Mid-Afternoon refreshment break**
2:45 PM - 5:00 PM **Course continue**
5:00 PM **Conclusion of day one**

Note: Agenda is subject to change without notice. Please check back regularly for updates.

Course Agenda & Contents



Day 2 - Tuesday November 8, 2016 | Course Contents

- Technical requirements for an eCTD submission
- Document naming requirements
- Building the folder structure
- Internal document requirements for the eCTD
- Performing "pre-publishing" work for each document
- Performing quality checks on the eCTD
- Updating content in the CTD and eCTD (amendments, supplements, variations, etc.)

Day 2 - Course Agenda

8:30 AM – 9:00 AM **Registration and Continental Breakfast**
9:00 AM – 10:30 AM **Course begin**
10:30 AM – 10:45 AM **Mid-morning refreshment break**
10:45 AM – 12:15 AM **Course continue**
12:15 PM - 1:15 PM **Networking lunch**
1:15 PM - 2:30 PM **Course continue**
2:30 PM - 2:45 PM **Mid-Afternoon refreshment break**
2:45 PM - 5:00 PM **Course continue**
5:00 PM **Conclusion of Program**

Note: Agenda is subject to change without notice. Please check back regularly for updates.

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Who Should Attend:

Regulatory Affairs, Quality Assurance, Pharmacovigilance, Project Management, Regulatory Operations, Anyone responsible for providing content for the CTD.

Industries:

- Biotech
- Pharma

Course Venue:

Holiday Inn Montreal Aeroport- Airport
6500 Cote De Liesse Montreal, Quebec H4T1E3 Canada
Tel: 1-514-739-6440

Website: http://www.ihg.com/holidayinn/hotels/us/en/montreal/yulcd/hoteldetail

Hotel Accommodation:

Guests are responsible for their own accommodations.

IPA has arranged a special room rate for attendees at the Holiday Inn Montreal Airport (Conference Venue). To reserve a room at our group rate, please call the hotel directly at 514-739-6440 and state that you are attending IPA event on February 25-26, 2016.

Complimentary shuttle available to and from **Pierre-Elliott Trudeau International(YUL) airport.**
Distance: 4.35 MI/7.0 KM WEST to Hotel. Complimentary Shuttle Available. 24 hour airport shuttle is available. Driving directions: from the airport follow signs for 520 East (Cote de Liesse EST/EAST). From the 520 EST/EAST, take exit 5 Hickmore. Stay on the Cote-de-Liesse service road and hotel will be on your right-hand side.

Nearby Hotel:

Crowne Plaza Montreal Airport

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Note: The Crowne Plaza Montreal Airport hotel offer a 10 km radius complimentary shuttle bus from 7AM - 9PM week-days. For more information, please call the hotel directly.

REGISTRATION FORM

CTD/eCTD content and format

November 7-8, 2016 | Montreal, Canada

Early Bird: Till July 31, 2016	CAD $888 +HST
Regular Price: August 01, 2016 to November 07, 2016	CAD $988 +HST
Academia / Government	CAD $688 +HST

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Substitution of delegate/s with the member/s of the same organization is permitted at any time with no penalty.

IPA reserves the right to postpone an event, prior to which time all the registered attendees will be notified a minimum of 2 weeks in advance. IPA shall not be responsible for any air fare, hotel or transportation costs incurred by registrant/s.