6-Hour Virtual Seminar on eCTD Submissions of IND/NDA to the US FDA,

Date : May 24, 2021 - 11:00 AM - May 25, 11:00 AM

Event URL : http://www.BostonEventsList.com/events/6-hour-virtual-seminar-on-ectd-submissions-of-ind-nda-to-the-us-fda-may-2019

Organizer : WCS

Venue : online

Location : WCS Consulting Inc.3190 Stirling Rd, Unit K4 ,Hollywood, FL 33021,
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Overview
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. Beginning in May 2017, the eCTD will be required in the US for all marketing applications.

Why you should attend
This webinar will provide you with information to ensure that you are ready for implementing the mandated requirements of the CTD/eCTD. This webinar will provide you with information to ensure that you are ready for implementing the mandated requirements of the CTD/eCTD.

Lecture 1 - CTD > eCTD

- 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 content & format requirements
- Implementing tools for the project management of CTD preparation and publishing

Lecture 2 - eCTD Prepararation

- Technical requirements for an eCTD submission
- Document naming requirements
- Building the folder structure
- Publishing each document, module & submission
- Tools for tracking and managing eCTD content
- Performing quality checks on the eCTD
- Lifecycle management: Updating content (amendments, supplements, variations, etc.)

Who Will Benefit

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

Event Categories :