

CRED



eCTD

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: eCTD-1



Introduction to eCTD

Overview

This one-day workshop features discussions on eCTD topics and comes with an eCTD Workshop Guide that is also a handy reference manual for future use. Participants will understand the history and benefits of eCTD, the global regulatory context, high-level technical aspects, structure and granularity of documents, and basics of file placement and document lifecycle, compilation and review, and more.

Introduction to eCTD is led by field-experienced trainers who have expert knowledge of eCTD and regulatory submissions.

Who Should Attend

This workshop is designed for all industry professionals with little to no experience with eCTD, who are presently, or planning to be, involved with the development of eCTD submissions. This includes professionals in: Medical Writing, Regulatory Affairs, Dossier and Data Management, IT and Document Management, Compliance, Publishing and Submission Management.

One-day Course

Date:

Thursday
9 December 2010

Venue:

TOPRA Office,
Bellerive House,
3 Muirfield Crescent,
E14 9SZ, London, UK

Workshop Learning Objectives

- Review the process that led to the development of the eCTD.
- Understand the global regulatory context for the eCTD.
- Gain a thorough understanding of eCTD concept and structure.
- Become familiar with the underlying XML technology used in the eCTD.
- Understand how the eCTD organizes study files, including Node Extensions, Study Tagging Files, and the regional requirements for datasets and case report forms.
- Learn about lifecycle management advantages of the eCTD.
- Get a glimpse into the challenges and logistics of submission logistics.
- Ask questions to an eCTD specialist.
- Exchange ideas with other participants.
- Receive detailed reference tables on the granular content of each section of a submission.

Topics include

- CTD/eCTD Basics.
- Submission Structure and Document Granularity.
- Hyperlinking and Templates.
- Technical Elements of the eCTD.
- Working with Study Files.
- Lifecycle Management
- Overview of the differences in guidance from different regulators

**LIMITED
SPACES
AVAILABLE**

Book online now at www.topra.org/eCTDintro

All data correct at time of print.

For more information, please contact TOPRA via email: meetings@topra.org or tel: +44 (0) 20 7510 2560 or go to www.topra.org/eCTDintro



Lifelong learning

* For more information please visit www.topra.org/lifelonglearning

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