

CRED

eCTD

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: eCTD-2



Advanced eCTD course

Key aspects of eCTD preparedness from a process and procedures perspective is a one day workshop between TOPRA and Lipient with the aim to prepare organisations for eCTD which becomes mandatory from 1st January 2010.

Overview

This workshop focuses upon the key aspects of eCTD implementation. The workshop is divided into 3 main sessions which will focus upon the technologies for eCTD, the authoring environment, and impact to organisations from a people and process perspective. During the workshop participants will learn about what is essential to success, best practices and the common pitfalls of eCTD implementation strategies from our industry-experienced trainers and will further explore these key aspects and how these may apply to their own organisation through participating in interactive small-group sessions facilitated by our trainers and using a mini-gap analysis tool.

Aspects of eCTD implementation is led by experienced trainers with expert knowledge of eCTD implementation and who have experience of submission delivery directly within the Pharmaceutical and Biotech Industry and worked with many organisations who have successfully implemented eCTD.

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 Document Management, IT and Data Management, Compliance, Publishing and Submission Management.



Lipient

Book online now at www.topra.org/eCTDadvancedbf

All data correct at time of print. For more information, please contact TOPRA via email: meetings@topra.org or tel: +44 (0) 207 510 2560 or go to www.topra.org/eCTDadvancedbf

Workshop Learning Objectives

- Understand the impacts and benefits of eCTD upon business processes, systems technology and skill sets
- Be able evaluate to the impact of eCTD implementation and to add value their organisational eCTD readiness activities
- Learn from best practices, successes and challenges encountered by other organisations
- Exchange ideas with other course participants
- Asks questions to Regulatory Operations experts with industry experience of eCTD implementation
- Receive a mini-gap analysis tool to use throughout the day to re-enforce learning, and to take back to your organisation and use for eCTD preparedness work.
- Hear about and discuss the impact of technologies that are used in successful eCTD preparation – understand what is a nice to have and what is essential
- Explore authoring, review and approval tools and processes and assess what changes your organisation may need to make to keep compliant and efficient throughout the eCTD lifecycle
- Assess the impact of eCTD on submission planning processes, timelines
- Understand the new skills needed by submission teams and regulatory operations staff to work within an electronic submissions environment.
- Working with CROs and outsourcing partners available for local, regional and global eCTD submissions

Topics include

- An introduction to the Gap analysis tool
- Technologies required to create a valid eCTD
- The authoring environment – processes, tools and submission readiness standards
- Resource considerations – timelines, people, knowledge and processes
- Outsourcing options to support eCTD submissions

One-day Course

Date:

Thursday
18 February 2010

Venue:

TOPRA office,
Bellerive House,
3 Muirfield Crescent,
London E14 9SZ

Member Price:

£581.63 = £495.00 +
£86.63 (GB VAT 17.5%)

Non-member Price:

£699.13 = £595.00 +
£104.13 (GB VAT 17.5%)



Lifelong learning

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

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