

# CRED

# eCTD

## Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: eCTD-3



## eCTD regional differences

An in depth workshop on the differences between the US, EU, Canadian and Japanese eCTDs. Regional eCTD differences and efficiencies are explored from a process and procedures perspective within a one day workshop provided jointly by TOPRA and Datafarm. This program has the aim to prepare organisations to understand and maximize the benefits of the eCTD which became mandatory on 1st of January 2010.

### Overview

This workshop focuses upon regional aspects of eCTD implementation. The workshop is divided into 3 main sessions which will focus upon the eCTD regions unique requirements, how to maximise the common aspects of the eCTD to minimise regionally unique eCTD components and the process and people considerations for developing and delivering eCTDs across regions. During the workshop participants will learn about what is essential to success, best practices and the common pitfalls for multi-regional eCTD implementation strategies from our industry-experienced trainers. Additionally, these key aspects and how these may apply to their own organisation will be explored through participating in interactive small-group sessions facilitated by our trainers and illustrated via eCTD assembly tools. Aspects of eCTD implementation are 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, Regulatory Operations, Dossier and Document Management, IT and Data Management, Compliance, Publishing and Submission Management.



**Book online now at [www.topra.org/eCTD3bf](http://www.topra.org/eCTD3bf)**

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

### Workshop learning objectives

- Overview of each regions unique eCTD components unique naming and location. Regional information overview – US, EU, Japan, Health Canada and Switzerland.
- EU the DCP, CP, MRP and National delivery methods and their impact on life-cycle maintenance
- Switzerland has joined the eCTD party – a first look at the differences to consider
- US STF, CRF and SDTM Datasets requirements overview
- Canadian Hybrid eCTDs and unique life-cycle maintenance methods
- Japanese unique life-cycle method and excel deliverables. When must the components be in Japanese?
- How to leverage regional commonality to facilitate a more simultaneous delivery to all eCTD accepting regions
- Learn from best practices, successes and challenges encountered by other organisations
- Understand the impacts and benefits of eCTD upon business processes, systems technology and skill sets
- Assess the impact of regional eCTD deliverables on submission planning processes and timelines
- Understand the new skills needed by submission teams and regulatory operations staff to work within an electronic submissions environment
- Exchange ideas with other course participants
- Asks questions to Regulatory Operations experts with industry experience of eCTD implementation
- Working with outsourcing partners available for local, regional and global eCTD submissions

### Topics include

- An introduction to the unique components found within the various regional eCTDs
- Technologies required to create a valid regionally specific eCTDs
- Resource considerations – timelines, people, knowledge and processes
- Outsourcing options to support eCTD submissions

One-day  
Course

### Date:

Wednesday  
12 May 2010

### Venue:

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



Lifelong learning

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