DIA Learning

Building the eCTD in the Middle East - Practical Solutions to Compile Electronic Submissions

12-13 October 2019
Royal Maxim Palace Kempinski, New Cairo, Egypt

OVERVIEW

This course will offer insight into the compilation of eCTDs, share experience and best practice gained during eCTD submissions around the world, and explain the eCTD review and lifecycle process. Especially eCTD submissions in the GCC region and Jordan will be addressed in detail.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Participate in the preparation of the eCTD including creating "submission ready documents"
- Recognise eCTD requirements on a regional and ICH basis
- Discuss the processes and procedures of compiling and reviewing an eCTD
- Create and submit technically valid GCC eCTDs
- Prepare to move from a paper to eCTD process
- Describe technology used for eCTD compilation, validation and review
- Understand the difference between eCTD and NeeS submission
- Have an overview on future eSubmission development

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

- Overview of eCTD readiness at the agencies
- Impact of the eCTD on regulatory processes and procedures
- Practical experience of submitting an eCTD in the EU and GCC
- eCTD compilation and life cycle management
- Document granularity and readiness
- Regulatory strategy facing technical issues
- Specifications and standards versus regions and procedures
- A global approach to electronic submissions

WHO WILL ATTEND

Professionals working in:

- Regulatory Affairs
- Dossier Management
- Document Management
- Data Management
- Compliance
- Electronic Publishing/Submissions
- IT/IS EDMS
- Medical Writing
- Regulatory Affairs Agency eSubmission processing and review

FACULTY

Karl-Heinz Loebel
Director, Principle Consultant Regulatory Operations
PharmaLex GmbH, Germany

Olaf Schoepke
Director of Strategic Development
Samarind, Ltd., United Kingdom

DAY 1

08:30 REGISTRATION

09:00 INTRODUCTION, LOGISTICS AND OVERVIEW OF LEARNING OBJECTIVES

09:15 SESSION 1

INTRODUCTION TO ICH, CTD AND ECTD

Karl-Heinz Loebel

- Background on the ICH
- Outline the basic CTD format
- Brief Overview on CTD Content
- ICH guidance documents
- Key terms and definitions
- Differences between CTD and eCTD
- eCTD basics and terminology
- eCTD specifications, submission structure and organization
- Process overview: eCTD generation, validation, submission and review

10:45 COFFEE BREAK

11:15 SESSION 2

ECTD GENERATION AND SUBMISSION - BASICS

Olaf Schoepke

- Document requirements/document preparation
- Modularity of submission components
- Document granularity and documentation standards
- Submission-ready files
- Format templates, content templates, and submission templates
- PDF specifications and requirements
- Bookmarking and intra-document hyperlinking
- Exercise 1: eCTD document preparation and compilation

12:45 LUNCH

14:00 SESSION 3

SUBMISSION STANDARDS INSIDE AND OUTSIDE ICH - OVERVIEW

Karl-Heinz Loebel

- General and regional requirements
- Region specific peculiarities of eCTD / Regional differences: EEA, US, JP, CH, CA, AUS, GCC, JO and post-Brexit UK
- Submitting in the GCC region: status and specifics
- GCC & JO Module 1 specification
- Current requirements in GCC countries & Jordan
- Study tagging files vs Node extensions
- Future eCTD implementors

15:30 COFFEE BREAK

16:00 SESSION 4

ECTD VALIDATION AND REVIEW - BASICS

Olaf Schoepke

- Validation tools and validation criteria
- Good practice for 'technical validation'
- Corrections of invalid eCTDs
- Basics of submission review
- Agency-Applicant communication
- Exercise 2: Technical validation

17:30 END OF DAY ONE

DAY 2

09:00 INTRODUCTION, LOGISTICS AND OVERVIEW OF LEARNING OBJECTIVES

09:15 SESSION 5

PREPARING YOUR COMPANY FOR ESUBMISSION

Karl-Heinz Loebel

- Practical issues from first-hand experience
- Agency communications and pilot/test submissions
- Switching to eCTD during product lifecycle
- Baseline Submissions, consolidation and closing sequences
- Handling of multiple strengths, presentation forms, substances and manufacturers in a single eCTD

10:45 COFFEE BREAK

11:15 SESSION 6

ECTD NAVIGATION AND CROSS-REFERENCING

Olaf Schoepke

- Good Hyperlinking Practise
- Authors' and publishers' responsibilities
- Tools in producing linked cross-references
- Supportive documentation and literature references
- Broken hyperlinks – analysis and resolution
- Exercise 3: Hyperlinks/Bookmarks/Navigation

12:45 LUNCH

14:00 SESSION 7

ECTD LIFECYCLE MANAGEMENT

Olaf Schoepke

- Lifecycle management concept
- Basics of eCTD life cycle
- Variations and eCTD life cycle
- Sequence numbers and meta data in eCTD-Lifecycle
- Lifecycle operators
- Document and eCTD version control
- Exercise 4: eCTD compilation – Life Cycle

15:30 COFFEE BREAK

16:00 SESSION 8

GCC ECTD COMPILATION. FURTHER DEVELOPMENT OF ELECTRONIC SUBMISSIONS

Karl-Heinz Loebel

- Exercise 5: Compiling and publishing a GCC eCTD
- Portals and online submissions
- eCTD 4.0, RPS and ISO IDMP

Summary and Conclusions
Discussion

17:40 END OF TRAINING COURSE