Building the eCTD

Practical Solutions to Compile Electronic Submissions

Course #10545
September 23-24, 2010
Ramada Plaza Hotel, Basel, Switzerland

Course Instructor

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Course Overview

This course will offer insight into the compilation of the eCTD, share experience and best practice gained during eCTD submissions in the EU, and the eCTD review process. The focus will be on practical experience gained in preparing and submitting electronically.

Who Will Attend

Professionals in:

- Regulatory Affairs
- Dossier Management
- Document Management
- Data Management
- Compliance
- Electronic Publishing/Submissions
- IT/IS EDMS
- Medical Writing

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
- eCTD compilation and life cycle
- Document granularity and readiness
- Regulatory strategy facing technical issues
- Specifications and standards versus regions and procedures
- NeeS and its role in eSubmission

Learning Objectives

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

- Participate in the preparation of the eCTD including “submission ready documents”
- Recognise EU requirements on a regional basis
- Discuss the processes and procedures of compiling and reviewing an eCTD
- Prepare sponsors to move from a paper to eCTD process
- Describe technology used for eCTD compilation and review
- Discuss the difference between eCTD and NeeS submission

THURSDAY | SEPTEMBER 23, 2010

08:00 **Registration**

09:00 **Introduction, Logistics and Overview of Learning Objectives**

09:15 **Session 1**

eCTD BUSINESS FUNDAMENTALS

The purpose of this session is to give the participants an overview about the eCTD, the structure and relevance of modules, sections and documents and to learn about the differences between the eCTD and other electronic and paper based application formats.

- What is an electronic submission?
- eCTD history and progression
- Overview eCTD structure and purpose
- Additional eCTD components
- Relevant guidelines
- Current specifications
- Legacy documents (scanning)
- Differences from the NeeS specification

10:45 **COFFEE BREAK**

11:15 **Session 2**

eCTD REVIEW AND TECHNICAL VALIDATION

The objective of this session is to introduce the eCTD review process from sponsor to regulator and its impact on business process and working practice. It highlights the importance of "technical validation" and its consequences.

- What are the implications of reviewing electronically?
- Why are eCTD reviewing tools required?
- The EMEA review system and its state of implementation
- The eCTD technical validation procedure and requirements
- What are the consequences of submitting a non-compliant eCTD?
- NeeS requirements and validation

12:45 **LUNCH**

14:00 **Session 3**

eCTD READINESS

eCTD readiness is one of the challenges for sponsors and regulators, which are at various stages of implementation. What has to change, what is the impact and where are we now?

- eCTD readiness in Europe, US and the rest of the world
- Recognise regional requirements and handle differences
- Agency readiness on a country per country basis
- eCTD frontrunners – current problems in the EU
- ICH and regional guidelines and impact

15:30 **COFFEE BREAK**

16:00 **Session 4**

PRACTICAL EXERCISE - eCTD PREPARATION

This practical exercise gives the professional an overview on process changes required to move marketing applications from paper via electronic format to the eCTD. At the end of this session participants are able to identify and advice on processes and procedures of moving marketing applications to the eCTD.

- Strategic and logistic planning of your eCTD submission
- Changing business processes
- Preparing for successful eCTD compilation and submissions
- Processes, Procedures, Technology, and Infrastructure challenges
- The "submission ready document" and its impact on eCTD preparation
- Authoring eCTD ready documents and templates
- Internal and external document flow and control
- CTD and eCTD granularity

17:30 **END OF DAY ONE**

17:30 - 18:30 **RECEPTION**

FRIDAY | SEPTEMBER 24, 2010

09:00 **Introduction, Logistics and Overview of Learning Objectives**

09:15 **Session 5**

PREPARING YOUR COMPANY FOR eSUBMISSIONS

The purpose of this session is to share practical first hand experience with the participants and present challenges faced during actual submissions

- Practical issues from first hand experience
- Agency communications and mock submissions
- At what phase during product life cycle should I start submitting eCTDs?
- Timelines according to regulatory procedure
- Successful eCTD Project Management

10:45 **COFFEE BREAK**

11:15 **Session 6**

PRACTICAL EXPERIENCE

This session is focused on submitting in the Decentralised Procedure (DCP) using the eCTD format.

- Experience with the Decentralised Procedure (DCP) using eCTD
- Strategic and logistic planning - timelines
- Hurdles and pitfalls
- Preparing paper copies from the eCTD
- Exercise: eCTD Creation and Assembly

12:45 **LUNCH**

14:00 **Session 7**

eCTD LIFE CYCLE MANAGEMENT (VARIATIONS, RENEWAL etc.)

What do sponsors really need to know about XML? This session will give some insights into terminology used and presents some examples of eCTD Life Cycle.

- Understanding the general concept of XML, DTD, MD5 and Style Sheets
- Examining the role of XML in pharmaceutical business applications
- Understanding eCTD Life Cycle and its strategies
- Subsequent submissions following sequence 0000
- Concurrent Life Cycle
- Exercise: eCTD Life Cycle Management

15:30 **COFFEE BREAK**

16:00 **Session 8**

CHALLENGES AND BEST PRACTICE

The last session of the course highlights a number of challenges during eCTD submissions, gives guidance on best practice and presents some examples from real case studies.

- Top 10 reasons for getting a Refuse to File (RTF) on eCTD filings
- Document and dossier granularity
- Case study eCTD submissions
- Beyond eCTD: PIM, SPL, Pharmacovigilance
- Archiving
- eWorking with authorities (portals and on-line submissions)

17:30 **END OF TRAINING COURSE**

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the:

Ramada Plaza Basel Hotel
Messeplatz 12
4058 Basel
Switzerland
http://www.ramada.com/Ramada/control/Booking/property_info?propertyId=15756

Tel.: +41 61 560 40 00
Fax: +41 61 560 55 55

at the special rate of
CHF 249.00 single occupancy CHF 279.00 double occupancy
including breakfast, service and VAT but excluding CHF 3.20 city tax.

To reserve a room, please call the Reservations Department on +41 61 560 40 00 referring to the DIA Training Course on "eCTD" or use the hotel booking form on the DIA website.

IMPORTANT: To be assured of accommodation at Ramada Plaza Basel Hotel, registrants are recommended to complete their reservation by August 24, 2010 latest.

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by
the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD) at the European Medicines Agency
Courses throughout the year | European Medicines Agency, London, UK
For course details on EV, please visit www.diahome.org >
Educational Offerings > EudraVigilance > Click on Related Courses

Non-Clinical Research

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

Building the eCTD - Practical Solutions to Compile Electronic Submissions
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ID# 10545

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY	MEMBER			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 7.6%	TOTAL	FEE	VAT 7.6%	Membership	TOTAL	FEE	VAT 7.6%	TOTAL
Industry	€ 1'365.00	€ 103.74	€ **1'468.74** ❑	€ 1'365.00	€ 103.74	€ 115.00	€ **1'583.74** ❑	€ 1'480.00	€ 112.48	€ **1'592.48** ❑
Government/Academia (Full-Time)	€ 683.00	€ 51.91	€ **734.91** ❑	€ 683.00	€ 51.91	€ 115.00	€ **849.91** ❑	€ 798.00	€ 60.65	€ **858.65** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course

Please indicate your areas of professional interest:

10545DIA

- ❑ AH - Academic Health Centres
- ❑ AM - Alternative / Herbal Medicine
- ❑ BT - Biotechnology
- ❑ CD - Clinical Data Management
- ❑ CH - Chemistry / Drug Design
- ❑ CL - Clinical Laboratory Data
- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
- ❑ DE - Devices
- ❑ DM - Document Management
- ❑ FI - Finance
- ❑ EC - e-Clinical
- ❑ GC - GCP
- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
- ❑ IM - Information Management
- ❑ IMP - Impact
- ❑ IS - Investigator Site
- ❑ IT - Information Technology / e-Business
- ❑ LA - Legal Affairs
- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
- ❑ MH - Managed Healthcare
- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
- ❑ NC - Non-clinical Safety & Efficacy / Toxicology
- ❑ NH - Natural Health Products
- ❑ OS - Outsourcing / Virtual Development
- ❑ OT - Over the Counter
- ❑ PC - Pharmaceutics
- ❑ PD - Professional Development
- ❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
- ❑ PP - Public Policy / Law
- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
- ❑ ST - Statistics / Biostatistics / Mathematical Modelling
- ❑ TR - Training
- ❑ VA - Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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Last Name

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Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

PAYMENT METHODS

❑ **Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ **VISA** ❑ **MC** ❑ **AMEX**

Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 10545 as well as the invoice number to ensure correct allocation of your payment.
Payments must be net of all charges and bank charges must be borne by the payer.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Registrants who do not cancel five working days prior to the course start date and do not attend, will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.**

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA European Office Postfach, 4002 Basel, Switzerland