

DIA Training Course on Building the eCTD: Practical Approaches to Compiling Electronic Submissions

Course #12564
8-9 March 2012
Novotel, Barcelona, Spain



Faculty

Representative from LORENZ Life Sciences Group,
Germany

Overview

During this interactive workshop participants will learn about the Electronic Common Technical Document (eCTD), its components and history, preparing submission ready documents, as well as best practices for changing your business processes in preparation for moving towards electronic submissions. Participants will then apply this information and compile a two-sequence submission for a single country EU national procedure using LORENZ DocuBridge®, as well as repurpose the EU compilation for Switzerland.

Key Topics

- eCTD components and history
- eCTD vs. non-eCTD electronic Submissions (NeeS)
- Creating submission ready documents
- Regional differences in eCTD requirements
- eCTD compilation
- eCTD publishing
- eCTD validation
- eCTD lifecycle management
- Regulatory strategy and best practices
- Co-ordinating global eCTD submissions

Who Will Attend

Professionals in:

- Regulatory affairs
- Regulatory operations
- Submission management
- Electronic publishing

Level: Beginner to intermediate

Learning Objectives

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

- Demonstrate a general understanding of the eCTD
- Compile a technically validated eCTD for various regions
- Explain how to maximise the re-use of compiled content
- Describe the eCTD publishing and technical validation
- Explain the differences in the regional interpretation of electronic submissions
- Evaluate the impact of various regional interpretations of eCTD specifications and guidelines on global submissions strategy

Continuing Education

DIA meetings and trainings are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available

This course has limited capacity.
Register early.

THURSDAY | 8 MARCH 2012

08:00 REGISTRATION

09:00 WELCOME AND INTRODUCTION

09:15 Session 1 – Lecture

eCTD - AN INTRODUCTION

An overview about the eCTD principles and key guidance documents provides insight to the eCTD benefits, structure, document granularity, technical specification and implementation status. Participants learn about the scope and relevance of the eCTD.

10:00 COFFEE BREAK

10:30 Session 2 – Lecture

COMPILATION OF REGIONAL MODULE 1

An in-depth look at regional information for Module 1. Learning about the different requirements and specifications for the different regions within the EU as well as in Switzerland. Participants will also be introduced to the United States and Canada regional Module 1.

11:15 Session 3 – Lecture

BUSINESS PROCESSES – GOING ELECTRONIC EFFICIENTLY

This session will look at the requirements for efficiently managing electronic submissions with focus on document authoring processes (“eCTD ready documents”). We will examine the business case for moving to electronic submissions and especially the eCTD and making a smooth transition from paper to electronic.

12:00 Morning session questions and discussions

12:15 LUNCH

13:15 Session 4 – Hands-on

CREATION OF AN eCTD AND COMPILATION OF MODULE 1

Participants will compile a Regional Module 1 for the EU (National Procedure), filling in the appropriate submission metadata.

14:00 Session 5 – Hands-on

COMPILATION OF eCTD MODULES 2 & 3

Participants will compile Modules 2 and 3 in their submissions. Participants will also be made aware of submission metadata and their use in these modules as well as the relationship between the two modules.

14:45 COFFEE BREAK

15:15 Session 6 – Lecture

eCTD REVIEW AND TECHNICAL VALIDATION

Participants will be introduced to the eCTD review process as well as the importance of technical validation and the different validation criteria in different regions.

16:00 Session 7 – Hands-on

SUBMISSION PROCESSING, PUBLISHING, AND VALIDATION

Participants will create, compile, publish and validate their EU submission.

16:45 Afternoon session questions and discussions

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

FRIDAY | 9 MARCH 2012

09:00 WELCOME AND INTRODUCTION

09:15 Session 8 – Lecture

EU eCTD LIFECYCLE MANAGEMENT

Participants will be introduced to eCTD lifecycle including the technical background, typical lifecycle submission scenarios and potential challenges.

10:00 COFFEE BREAK

10:30 Session 9 – Lecture

REGIONAL DIFFERENCES IN eCTD REQUIREMENTS

An interactive presentation on how regions differ in their interpretation of the eCTD specifications.

11:15 Session 10 – Lecture

COORDINATING GLOBAL eCTD SUBMISSION

An interactive presentation on coordinating the simultaneous submission of eCTD globally

12:30 Morning session questions and discussions

12:45 LUNCH

13:45 Session 11 – Hands-on

EU eCTD LIFECYCLE MANAGEMENT

Participants will create a new sequence of their submission using globally defined Life Cycle Operations. They will then review and publish their 0001 EU submission.

14:30 COFFEE BREAK

15:00 Session 12 – Hands-on

RE-USING YOUR EU SUBMISSION FOR OTHER REGIONS

Participants will have an opportunity to make the most of the re-usability of the eCTD and re-purpose their submissions for other regions.

15:45 Afternoon session questions and discussions

16:00 END OF DAY TWO

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

REGISTRATION FORM

Building the eCTD: Practical Approaches to Compiling Electronic Submissions
8-9 March 2012 | Novotel, Barcelona, Spain

ID# 12564



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. * All fees are subject to local Spanish VAT of 8%

CATEGORY	Member Fee*		Non-Member Fee*
Industry	€ 1'365.00 <input type="checkbox"/>	Industry	€ 1'480.00 <input type="checkbox"/>
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TOTAL AMOUNT DUE: € _____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION

12564DIA

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

ATTENDEE DETAILS

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

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PAYMENT METHODS - Credit cards are the preferred payment method.

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.

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Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, 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# 12564 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.

HOTEL INFORMATION

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

Novotel Barcelona City

Avenida Diagonal 201 (Entrada por Ciutat de Granada)

08018 BARCELONA, SPAIN

Tel (+34)933262499 - Fax (+34)933208779

E-mail h5560@accor.com

<http://www.novotel.com/de/hotel-5560-novotel-barcelona-city/index.shtml>

at the special rate of EUR 120 per single use and night inclusive of breakfast and 8% VAT.

To make your reservation please use the hotel booking form available on our website.

Important: Please complete your reservation by 6 February 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

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

Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you 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 registered attendees. Registered attendees 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 attendees 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 Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe 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

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