Building the eCTD - Practical Solutions to Compile Electronic Submissions

Course #11581
16-17 May 2011
Novotel Nice Centre Acropolis, Nice, France

Course Instructors

Kent Briggs
Professional Services Director
LORENZ Life Sciences Group, Germany

Anastasia Iliadou-Hohls
Business Process Consultant
LORENZ Life Sciences Group, Germany

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 13 credits.

Course Overview

Participants of this course will create a validated eCTD Submission for a new drug product for Europe and the US. This course will offer insight into eCTD lifecycle management and global submission management practices combining hands on exercises with presentations on best practices and practical experience.

Who Will Attend

Professionals in:
- Regulatory affairs
- Regulatory operations
- Submission management
- Electronic publishing

Key Topics

- eCTD compilation
- eCTD publishing
- eCTD validation
- eCTD lifecycle management
- Compiling Study Tagging Files (STFs)
- Regulatory strategy
- Regional differences in eCTD requirements
- Co-ordinating global eCTD submissions

Learning Objectives

At the conclusion of this course participants should be able to:
- Compile a technically validated eCTD for various regions
- Maximise the reuse of compiled content
- Understand eCTD publishing and technical validation
- Understand the differences in the regional interpretations of electronic submissions
- Consider the impact of various regional interpretations of eCTD Specifications and Guidelines on global submissions strategy

This course is a hands on course full of practical work. It is necessary that you bring your laptop with you.

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MONDAY | 16 MAY 2011

08:00 REGISTRATION

08:45 WELCOME AND INTRODUCTION

09:00 SESSION 1

COMPILATION OF SUMMARIES AND OVERVIEWS AND QUALITY DATA (CMC)

Participants will compile content, merge compiled content, and fill in submission metadata.

10:30 COFFEE BREAK

11:00 SESSION 2

COMPILATION OF REGIONAL MODULE 1 FOR: EUROPE AND US

Participants will compile a Regional Module 1 for each the EU (Decentralised Procedure), Switzerland and the USA, filling in submission metadata appropriately.

12:30 LUNCH

13:30 SESSION 3

COMPILATION OF NON-CLINICAL AND CLINICAL STUDIES AS STF & NON-STF

Participants will compile Modules 4 and 5 as Study Tagging Files using content files and preassembled complex study reports. Participants will then adapt their STF compilation to non-STFs.

15:00 COFFEE BREAK

15:30 SESSION 4

MERGING, PUBLISHING, AND VALIDATION OF EU, CH, AND US SUBMISSIONS

Participants will assemble the appropriate pieces created thus far into a sequence 0000 for each the EU, Switzerland, and the USA. Participants will publish and validate each of these submissions.

17:30 DRINKS RECEPTION

18:30 END OF DAY 1

TUESDAY | 17 MAY 2011

09:00 SESSION 5

US eCTD LIFECYCLE MANAGEMENT

Participants will be introduced to eCTD lifecycle compilation by compiling, publishing, and validating sequence 0001 for the US.

10:30 COFFEE BREAK

11:00 SESSION 6

EU eCTD LIFECYCLE MANAGEMENT

Participants will create, compile, publish, validate, and correct sequences 0001 Response to List of Questions and 0002 Grouping Related Variations.

12:30 LUNCH

13:30 SESSION 7

REGIONAL DIFFERENCES IN eCTD REQUIREMENTS

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

15:00 COFFEE BREAK

15:30 SESSION 8

COORDINATING GLOBAL eCTD SUBMISSIONS

An interactive presentation on coordinating the simultaneous submission of eCTD globally.

17:30 END OF TRAINING COURSE

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.

HOTEL INFORMATION

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

Novotel Nice Centre Acropolis
8/10 Parvis de l'Europe
FR-06300 Nice - France

http://www.novotel.com/gb/hotel-1103-novotel-nice-centre/index.shtml

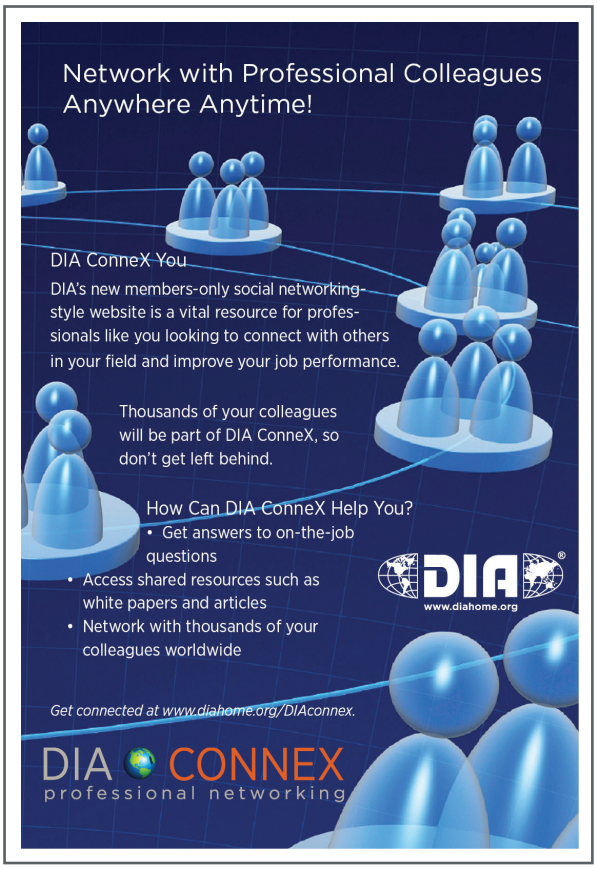
Tel (+33) 4 93 133093
Fax (+33) 4 93 130904

at the special rate of

EUR 106.20 for single occupancy
EUR 117.40 for double occupancy
including breakfast, service and VAT

To reserve a room, please fill in the booking form available on our website and fax it directly to the Novotel Nice at (+33) 4 93 130904.

IMPORTANT:
To be assured of accommodation registrants are recommended to complete their reservation form by 1 April 2011 latest.



DIA Upcoming Training Courses in Regulatory Affairs

Building the eCTD - Practical Solutions to Compile Electronic Submissions
16-17 May 2011 | Nice, France | ID 11581
October 2011 | Location to be confirmed | ID 11529

Comprehensive Training on European Regulatory Affairs: Keeping your finger on the pulse of Marketing Authorisations
27 February – 1 March 2011 | Abu Dhabi, United Arab Emirates | ID 11541

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
4-6 April 2011 | Basel, Switzerland | ID 11534
27-29 November 2011 | Abu Dhabi, United Arab Emirates | ID 11533

European Regulatory Affairs: In-depth Review of Current Registration Procedures in the European Union
24-25 February 2011 | Basel, Switzerland | ID 11535
3-4 November 2011 | Paris, France | ID 11546

Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe
4-6 May 2011 | Basel, Switzerland | ID 11519

Good Management of Medical Devices and In-vitro Diagnostics
9-12 May 2011 | Amsterdam, The Netherlands | ID 11539
November 2011 | Location to be confirmed | ID 11568

Quality by Design: A Hands-on Short Course for Pharma
November 2011 | Graz, Austria | ID 11572

US Regulatory Affairs
October 2011 | Location to be confirmed | ID 11582

REGISTRATION FORM

Building the eCTD - Practical Solutions to Compile Electronic Submissions
16-17 May 2011 | Novotel Nice Centre Acropolis, Nice France

ID # 11581

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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 FEE	VAT 19.6%	TOTAL	Non-Member (with optional membership) FEE	VAT 19.6%	Membership	TOTAL	Non-Member (without optional membership) FEE	VAT 19.6%	TOTAL
Industry	€ 1'365.00	€ 267.45	**€ 1'632.54** ❑	€ 1'365.00	€ 267.45	€ 115.00	**€ 1'747.54** ❑	€ 1'480.00	€ 290.08	**€ 1'770.08** ❑
Government/Academia (Full-Time)	€ 683.00	€ 133.87	**€ 816.87** ❑	€ 683.00	€ 133.87	€ 115.00	**€ 931.87** ❑	€ 798.00	€ 156.41	**€ 954.41** ❑

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 11581DIA

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.

__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

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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❑ 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# 11582 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.

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

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