Training Course for eCTD Submissions in Switzerland

Course #11590
8 December 2011
Hotel Courtyard by Marriott, Zurich, Switzerland

Faculty

Swissmedic Representative
Swissmedic - Swiss Agency for Therapeutic Products, Switzerland

Olaf Schoepke, PhD
Managing Director, Extedo Ltd., United Kingdom

Who will attend

Professionals in:
- Regulatory Affairs
- Dossier Management
- Document Management
- Data Management
- Compliance
- Electronic Publishing/Submissions
- IT/IS EDMS
- Medical Writing
- Project Management
- Quality

Continiung Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 6 credits.

This course has limited capacity. Register early.

Overview

Since January 2010, Swissmedic accepts electronic-only submissions in eCTD-format. This course will offer insight into the compilation of the eCTD, share experience and best practice gained during eCTD submissions in Switzerland, and the eCTD review process. The focus will be on practical experience gained in preparing and submitting eCTDs to Swissmedic.

Session 1 – eCTD Fundamentals
- eCTD structure and XML backbone
- Envelope information, meta data, and checksums
- Submission ready documents and granularity
- eCTD life cycle

Session 2 – eCTD Submissions in Switzerland
- Swissmedic‘s experiences with eCTD submissions
- Swiss specifications and guidelines
- The Swiss Module 1 for eCTD

Session 3 – Case Studies
- Applications according to §13 TPA
- Baseline submissions
- Life cycle management with variations
- Technical correctness

Session 4 – Practical
- eCTD creation and assembly
- Hyperlinking and publishing process
- eCTD life cycle

Key Topics

- Basic information about the eCTD
- Impact of the eCTD on regulatory processes and procedures
- eCTD compilation and life cycle
- Document granularity and readiness
- Regulatory strategy facing technical issues
- Swissmedics eCTD programme (staggered approach)
- The use of the Swiss specifications and guidelines for eCTD
- Preparation of the Swiss Module 1 for eCTD
- Technical correctness of Swiss eCTDs
- 1:1 creation of a Swiss eCTD

Learning Objectives

At the conclusion of this course, participants should be able to:
- Understand the structure and the technical aspects of eCTDs
- Prepare an eCTDs including “submission ready documents”
- Be familiar with the Swiss requirements for eCTD submissions
- Understand the processes and procedures of compiling and reviewing an eCTD
- Support the transition from a paper process to an eCTD process
- Describe technology used for eCTD compilation and review

Level

This course can be attended by participants with all levels (beginners, intermediate to advanced)

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THURSDAY | 8 DECEMBER 2011

08:00 REGISTRATION

09:00 Session 1

eCTD FUNDAMENTALS

The purpose of this session is to give the participants an overview about the eCTD, the dossier structure and different (technical) aspects as well as submission ready documents and eCTD life cycle.

- eCTD file/folder structure
- Envelope information, meta data, and checksums
- Document type definition, XML and style sheets
- Submission ready documents and templates
- Document granularity
- Hyperlinking and bookmarks
- eCTD life cycle and it's operators

10:30 COFFEE BREAK

11:00 Session 2

eCTD SUBMISSIONS IN SWITZERLAND

The eCTD Swissmedic Programme
- Swissmedic's eSubmission strategy
- Staggered approach
- Swissmedic's processes with eCTD submissions

Swiss Specifications and Guidelines
- Overview information for industry
- Questions and answers on Swissmedic's eCTD implementation
- Swiss guidance for industry on providing regulatory information in eCTD-format
- Swiss module 1 specification for eCTD
- Swiss eCTD validation criteria

Swissmedic's Experiences
- Preferred application types with eCTD
- Experiences with announced submissions
- Experiences with technical correctness
- Experiences with content validation
- Experiences review

12:30 LUNCH BREAK

13:30 Session 3

CASE STUDIES - CREATING A SWISS eCTD - WHAT YOU MAY NEED TO KNOW ABOUT IT!

Experience with Applicants
- Success factors for timely submissions
  - Examples for different approaches by applicants:
  - Project oriented approaches
- Coordination of the work between headquarters and affiliates
- Information flow HQs – affiliates - Swissmedic

Preparation of Swiss Module 1 for eCTD
- Handling of galenic forms
- Cover letter
- Dealing with path lengths
- Hyperlinks from module 1 to other modules
- Handling of empty sections
- Use of bookmarks in module 1

Technical Correctness of Swiss eCTDs
- Why Swissmedic validates eSubmissions
- How do we interpret the validation reports?
- Examples of frequent technical errors with different severities (A, B, C)
- Differentiating between technical issues and formal control issues (hyperlinks, bookmarks, life cycle management and others)

15:00 COFFEE BREAK

15:30 Session 4

PRACTICAL - eCTD CREATION AND ASSEMBLY

The purpose of this session is to give the participants the opportunity to compile compliant eCTDs, experience the challenges faced during dossier assembly and provide practical information about different eCTD life cycle stages.

- Create valid Swiss eCTD structure
- Edit Swiss envelope information/meta data
- Swiss Module 1 specifics
- Compile eCTD using submission ready documents
- Setting and maintaining hyperlinks
- Publish compliant Swiss eCTDs
- eCTD life cycle management

17:30 END OF TRAINING COURSE

HOTEL INFORMATION

The DIA has blocked a number of rooms at the:

Hotel Courtyard by Marriott Zurich Nord
Max-Bill-Platz 19
8050 Zurich, Switzerland

http://www.marriott.com/hotels/travel/zrhcy-courtyard-zurich-north

at the special rate of:
CHF 259.00 single room, inclusive of breakfast and VAT,
excluding City Tax CHF 2.50

To make your reservation please
Tel: +41 44 564 04 10
Please quote the booking reference: DIA TRAINING COURSE eCTD SUBMISSIONS

Important: Please complete your reservation by 9 November 2011. Reservations received after this date will be subject to hotel availability and room rate may vary.

In case of cancellation:
Cancellation of the hotel booking must be made in writing directly to the hotel 48 hours prior to the arrival date. Cancellations made at least 48 hours prior to arrival will not incur any cancellation charges.

DIA UPCOMING TRAINING COURSES IN 2011

Clinical Research

Advanced GCP Study Monitoring
19 September 2011 | Paris, France | ID 11531

Clinical Project Management – Part I
Date to be confirmed | Vienna, Austria | ID 11528

Clinical Statistics for Non-Statisticians
6-7 October 2011 | Vienna, Austria | ID 11566

Essentials of Clinical Study Management
2-4 November 2011 | Paris, France | ID 11536

Practical GCP Compliance Auditing of Trials & Systems
26-28 October 2011 | London, United Kingdom | ID 11538

Regulatory Affairs

Building the eCTD - Practical Solutions to Compile Electronic Submissions
October 2011 | Location to be confirmed | ID 11529

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

eCTD Submissions in Switzerland
8 December 2011 | Zurich, Switzerland | ID 11590

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

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and Practical Aspects as used in Personalised Medicine
November 2011 | Location to be confirmed | ID 11568

Quality by Design: New Concepts for Development & Manufacturing - A Hands-on Course for Pharma
3-4 November 2011 | Vienna, Austria | ID 11572

US Regulatory Affairs: A Comprehensive Review of Regulatory Procedures for INDs and NDAs in the US
14-16 November 2011 | Paris, France | ID 11582

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing
3-7 October 2011 | Zagreb, Croatia | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections
November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance
November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs
19-20 September 2011 | Paris, France | ID 11530

EudraVigilance Information Day at the European Medicines Agency
15 November 2011 | London, United Kingdom | ID 11522

Information Day on the Development Safety Update Report (DSUR) Guidelines ICH E2F
04 July 2011 | London, United Kingdom | ID 11591

IDMP Information Day at the European Medicines Agency
22-23 September 2011 | London, United Kingdom | ID 11524

ICSR Information Day at the European Medicines Agency
16 November 2011 | London, United Kingdom | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency
17 November 2011 | London, United Kingdom | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
13 September 2011 | London, United Kingdom | ID 11552
6 December 2011 | London, United Kingdom | ID 11553

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
21-25 November 2011 | Lisbon, Portugal | ID 11567

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.

REGISTRATION FORM

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ID # 11590

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 FEE	Member VAT 8%	Member TOTAL	Non-Member (with optional membership) FEE	Non-Member (with optional membership) VAT 8%	Non-Member (with optional membership) Membership	Non-Member (with optional membership) TOTAL	Non-Member (without optional membership) FEE	Non-Member (without optional membership) VAT 8%	Non-Member (without optional membership) TOTAL
Industry	€ 770.00	€ 61.60	**€ 831.60** ❑	€ 770.00	€ 61.60	€ 115.00	**€ 946.60** ❑	€ 885.00	€ 70.80	**€ 955.80** ❑
Government/Academia (Full-Time)	€ 385.00	€ 30.80	**€ 415.80** ❑	€ 385.00	€ 30.80	€ 115.00	**€ 530.80** ❑	€ 500.00	€ 40.00	**€ 540.00** ❑

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 11590DIAWEB

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

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

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.

❑ VISA ❑MC ❑ AMEX

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ 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# 11590 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 www.diahome.org | **Fax** +41 61 225 51 52 | **Email** diaeurope@diaeurope.org | **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland