CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3

Course #10529
26-28 April 2010
Austria Trend Hotel Savoyen Vienna, Vienna, Austria

Faculty

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This course has limited capacity. Register early!

Course Overview

High quality of a registration dossier facilitates the registration procedure - Essential for Generics!
This Module provides a comprehensive description on the Common Technical Dossier structure - completely updated to reflect the latest changes in pharmaceutical regulatory affairs. The course is focusing on the specific regional EU requirements for Module 1 including discussion of the relevant legislation.
The requirements for the Quality documentation (Module 2.3 & 3) will be presented in detail, taking into account the recent ICH-Q guidelines.
The course is for new developments, but is also very much attractive for Generics. In addition, this training course addresses **Quality by Design** aspects and issues.

Key Topics

- CTD, eCTD
- EU Module 1
  - Cover Letter
  - Application Forms
    - New Applications
    - Variations
  - Product Information
  - Environmental Risk Assessment
  - Information relating to Orphan Market Exclusivity
  - Risk-management System
  - Paediatric Information
- Module 3
  - Pharmaceutical Development and Quality Risk Management
  - Quality of Active Substance including Purity Issues
  - Impurity Testing
  - Stability Testing
  - Setting of Specifications
  - Pharmaceutical Quality System
  - Development and Validation of Analytical Methods

Learning Objectives

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

- Identify the recent requirements for developing drug substance and drug products and setting up a registration dossier - especially for generics
- Define the requirements for developing a product and discuss how to prepare the regional EU Module 1 and the Quality documentation
- Discuss the legal background of the dossier requirements and identify the relevant guidelines
- Demonstrate optimal presentation of information and justifications

Who Will Attend

- Governmental Institutions
- Pharmaceutical Industry
  - Development Managers and Experts
  - QA and New Manufacturing Managers

Level: Beginner to Intermediate

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DAY ONE

08:00 Registration

08:45 Welcome and Introduction

09:00 Session 1

- Introduction to the Common Technical Document Structure of the Licensing Dossier – In general
  - Structure of the CTD (Module 1 – 5)
    - Relevant guidance documents
- Administrative information in Module 1
- Content of CTD-Module 2
  - 2.3 Quality Overall Summary
  - 2.4 Nonclinical Overview
  - 2.5 Clinical Overview
  - 2.6 Nonclinical Summaries
  - 2.7 Clinical Summaries
- eCTD
  - Current guidance documents
  - Readiness to prepare and accept eCTD
  - e-submission mandatory?

10:30 Coffee Break

11:00 Session 2

- Discussion of the content EU-Module 1:
  - Cover Letter
  - Application Forms
    - For new applications, variations, renewals
    - Electronic application forms
- Different EU-licensing procedures – brief overview:
  - National procedure
  - MRP/DCP
  - Centralised procedure
- Product Information
  - SPC, Labelling and Package Leaflet
    - Legal provisions and guidance documents
    - PIM-project
  - Readability Testing
    - Readability guideline
  - Braille

12:30 Lunch

13:30 Session 3

- CTD – Module 3 Quality – Discussion of important chapters
  - What is necessary in the quality section of the CTD
  - What are the optional possibilities and opportunities
- Pharmaceutical Development and Quality Risk Management
  - Possibilities of the new ICH 8 guideline on pharmaceutical development
  - Interaction with ICH Q8 pharmaceutical development
  - How to implement quality risk management in a dossier
  - The ICH Q9 guideline on quality risk management
  - Elements of quality risk management
  - Application of quality risk management

15:30 Coffee Break

16:00 Session 4

- Quality of Active Substance including Purity Issues
  - Active Substance
    - Drug substance properties and preformulation studies
    - Active substance master file
    - Certificate of suitability

17:30 End of Day 1

17:30-18:30 Reception

DAY TWO

09:00 Session 5

- Specific Requirements for Different Types of Applications
  - Information for bibliographical applications
    - Legal provisions concerning well established use applications
  - Information for
    - Generic,
    - "Hybrid" or
    - Bio-similar applications
    - Legal provisions concerning generics
  - Information for Informed Consent Applications
  - Specific provisions concerning the centralised procedure
    - Exceptional circumstances
    - Conditional marketing authorisation
    - Accelerated review
- Environmental Risk Assessment
  - Non-GMO
  - GMO

10:30 Coffee Break

11:00 Session 6

- Information relating to Orphan Market Exclusivity
  - Similarity
  - Market exclusivity
- Information Relating to Pharmacovigilance
  - Pharmacovigilance system
  - Risk-management system
- Information Relating to Clinical Trials
  - PIP-details
- Paediatric Information

12:00 Lunch

13:00 Session 7

- Impurity Testing: Experience and new trends
  - Impurities in drug substance
  - Degradation products in drug products
  - Residual solvents
  - Residual metals
  - Genotoxic impurities
  - Pharmacopoeal aspects

15:00 Coffee Break

15:30 Session 8

- Stability Testing
  - Discussion of the relevant guidelines
  - Practical examples
- Setting of Specifications

17:00 Case study presentation and start working in groups

17:30 End of Day 2

DAY THREE

09:00 Session 9

- Discussion of the case study

10:15 Coffee Break

10:45 Session 10

- Variations
  - New provisions
    - Grouping
    - Worksharing

12:00 Lunch

13:30 Session 11

- Pharmaceutical Quality System and GMP
- Development and Validation of Analytical Methods

15:30 Coffee Break

16:00 Session 12

- Overall Discussion and Closing Remarks

17:00 End of Training Course

Hotel Information

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

Austria Trend Hotel Savoyen Vienna
Rennweg 16
1030 Vienna
Austria

Tel.: +43 (1) 206 33 0
Fax: +43 (1) 206 33 9110
Website: www.austria-trend.at/sav
e-mail: reservierung.savoyen@austria-trend.at

at the special rate of EUR 150.00 for a single and EUR 160.00 for a double room including breakfast, service and VAT.

To reserve a room, please send an email to the hotel or use the booking form that you find on the DIA website.

IMPORTANT: To be assured of accommodation at the Austria Trend Hotel Savoyen, registrants are recommended to complete their reservation by January 26, 2010 at the latest.

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
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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

The New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2 Information Day at the European Medicines Agency
25 June 2010 | London, United Kingdom | ID 10568

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)
Courses throughout the year | European Medicines Agency, London, UK 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
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

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
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ID# 10529

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			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 20%	TOTAL	FEE	VAT 20%	Membership	TOTAL	FEE	VAT 20%	TOTAL
Industry	€ 1'785.00	€ 357.00	€ **2'142.00** ❑	€ 1'785.00	€ 357.00	€ 115.00	€ **2'257.00** ❑	€ 1'900.00	€ 380.00	€ **2'280.00** ❑
Government/Academia (Full-Time)	€ 893.00	€ 178.60	€ **1'071.60** ❑	€ 893.00	€ 178.60	€ 115.00	€ **1'186.60** ❑	€ 1'008.00	€ 201.60	€ **1'209.60** ❑

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

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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.

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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.

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