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

DRUG INFORMATION ASSOCIATION

November 1-3, 2009 - Dubai, United Arab Emirates

Faculty

Peter Bachmann, PhD
BfArM, Germany

Fritz Erni, Dr
Novartis, Switzerland

Danièle Giron, Dr
University of Basel, Switzerland

Christa Wirthumer-Hoche, PhD
AGES PharmMed, Austria

Course ID# 09556

This course has limited capacity. Register early!

Course Overview

High quality of a registration dossier facilitates the registration procedure!
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.

Key Topics

- CTD, eCTD
- EU Module 1
  - Cover Letter
  - Application Forms
  - 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

- 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

AUTHORIZED IACET PROVIDER

The Drug Information Association (DIA) has been approved as an 'Authorized Provider' by the International Association for Continuing Education and Training (IACET), 8405 Greensboro Drive, Suite 800, McLean, VA 22102.

DIA is authorised by IACET to offer 1.7 CEUs for this program.

If you would like to receive a statement of credit, you must attend the program, return your evaluation form and complete the online credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request.

Disclosure Policy
It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

REGISTER ONLINE! PLEASE VISIT OUR WEBSITE WWW.DIAHOME.ORG

Day 1

08:00 Registration

09:00 Welcome and Introduction

09:30 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
- 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
    - Standardisation
  - Application Forms
    - For new applications, variations, renewals
    - Electronic application forms
    - Discussion on a practical example for new application

12:00 Lunch

13:30 Session 2 continued

- Product Information
  - SPC, Labelling and Package Leaflet
    - Legal provisions and guidance documents
    - PIM-project
  - Readability Testing
    - Readability guideline
  - Braille
- Information about the Expert

15:00 Coffee Break

15:30 Session 3

- 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

17:30 End of Day 1

17:30 Reception
18:30

Day 2

09:00 Session 4

- 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

10:30 Coffee Break

11:00 Session 5

- 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

12:00 Lunch

13:30 Session 6

- CTD – Module 3 – 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

15:00 Coffee Break

15:30 Session 7

- Quality of Active Substance including Purity issues
  - Active Substance
    - Drug Substance properties and preformulation studies
    - Active Substance Master File
    - Certificate of Suitability
- Impurity Testing : Experience and New Trends
  - Impurities in drug substance
  - Degradation products in drug products
  - Residual solvents
  - Residual metals
  - Genotoxic impurities
  - Pharmacopoeal aspects

17:30 End of Day 2

Day 3

09:00 Session 8

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

10:15 Coffee Break

10:45 Session 8 continued

- Setting of Specifications

12:00 Lunch

13:30 Session 9

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

15:30 Coffee Break

16:00 Overall Discussion and Closing Remarks

17:00 End of Training Course

"Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association."

Register for upcoming DIA training courses in 2009

Clinical Research

Essentials of Clinical Study Management
February 18-20, 2009 / Madrid, Spain / ID# 09528
September 16-18, 2009 / Copenhagen, Denmark / ID# 09546
December 2-4, 2009 / Basel, Switzerland / ID# 09550

Practical GCP Compliance Auditing of Trials & Systems
October 7-9, 2009 / London, UK / ID# 09548

Clinical Statistics for Nonstatisticians
October 8-9, 2009 / London, UK / ID# 09549

Regulatory Affairs

European Regulatory Affairs
February 18-19, 2009 / Nice, France / ID# 09537
June 11-12, 2009 / Amsterdam, The Netherlands / ID# 09538
September 10-11, 2009 / Frankfurt, Germany / ID# 09539
November 19-20, 2009 / Paris, France / ID# 09540

Building the eCTD
February 19-20, 2009 / Madrid, Spain / ID# 09541
September 17-18, 2009 / Copenhagen, Denmark / ID# 09542

Comprehensive Training on European Regulatory Affairs: Expert Overview
May 6-8, 2009 / Basel, Switzerland / ID# 09544
November 25-27, 2009 / Lisbon, Portugal / ID# 09552

An Introduction to Product Information Management (PIM)
May 14-15, 2009 / London, UK / ID# 09534
October 15-16, 2009 / Berlin, Germany / ID# 09535

US Regulatory Affairs
October 19-22, 2009 / Basel, Switzerland / ID# 09525

Non-Clinical Sciences

Non-Clinical Safety Sciences and their Regulatory Aspects
May 4-8, 2009 / Basel, Switzerland / ID# 09543
November 23-27, 2009/Lisbon, Portugal / ID# 09551

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
February 9-13, 2009 / Paris, France / ID# 09526
October 12-16, 2009 / Berlin, Germany / ID# 09527

Medical Approach in Diagnosis and Management of ADRs
September 17-18, 2009 / Paris, France / ID# 09532

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
May 13-15, 2009 / London, UK / ID# 09545
November 18-20, 2009 / Paris, France / ID# 09547

EudraVigilance Information Day
July 1, 2009 / EMEA, London, UK / ID# 09529
November 4, 2009 / EMEA, London, UK / ID# 09530

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

REGISTRATION FORM

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module
November 1-3, 2009 - Dubai, United Arab Emirates

ID# 09556

DIA Drug Information Association

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. **Registration will be accepted by mail, fax, email or online at www.diahome.org**

CATEGORY	MEMBER FEE		NON-MEMBER (with optional membership)			NON-MEMBER (without optional membership)	
	FEE	TOTAL	FEE	Membership	TOTAL	FEE	TOTAL
Industry	€ 1'785.00	€ **1'785.00** ❑	€ 1'785.00	€ 130.00	€ **1'915.00** ❑	€ 1'915.00	€ **1'915.00** ❑
Government/Academia (Full-Time)	€ 893.00	€ **893.00** ❑	€ 893.00	€ 130.00	€ **1'023.00** ❑	€ 1'023.00	€ **1'023.00** ❑

TOTAL AMOUNT DUE: € _____

NOTE: Payment due 30 days after registration and must be paid in full by commencement of the event

All fees are shown excluding VAT which may be charged if applicable.

Please indicate your areas of professional interest:

09556DIAWEB

- ❑ 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

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Telefax (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# 09556 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 by 17:00 CET on October 23, 2009

Cancellations received by the date above are subject to an administrative fee:

Industry (Member/Non-Member) = EUR 200.00 / Government and Academia (Member/Non-Member) = EUR 100.00Registrants who do not cancel by the date above, and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel and travel reservations. If an event is cancelled, DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. DIA Europe reserves the right to alter the venue and dates if necessary.

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 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