DIA Training Course on

Global CTD Dossier

Regulatory aspects and focus on quality documentation including concepts of Quality by Design

Course #13562 1-3 December 2013 Radisson Blu Hotel, Dubai Deira Creek, Dubai, United Arab Emirates



Faculty

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Overview

High quality of a registration dossier facilitates the registration procedure - Essential for Generics! This course provides a comprehensive description on the Common Technical Dossier structure - completely updated to reflect the latest changes in pharmaceutical regulatory affairs. The course provides an excellent opportunity to gain an overview of regulatory aspects and includes 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. Participants will be involved in case studies, group works and have to present the outcome.

Key Topics

- CTD, eCTD
- Regional requirements of EU Module 1
- Regulatory environment:
 - New applications
 - Past approval changes
- · Risk based approach
- Module 3
- Pharmaceutical development and Quality Risk Management
- Quality of active substance including purity issues (ASMF, CEP)
- Impurity testing
- Stability testing
- Setting of specifications
- Design space
- Control strategy

Who Will Attend

- Governmental institutions
- Pharmaceutical industry
 - Development managers and experts
 - QA and new manufacturing managers
- Regulatory experts

Course Level

Beginner to Intermediate

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

This course has limited capacity. Register early.

DIA meetings and training courses 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

Continuing Education

eligible for these credits.

PharmaTrain recognised
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SUNDAY | 1 DECEMBER 2013

08:00 REGISTRATION

09:00 WELCOME AND INTRODUCTION

09:05 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
- Content of CTD Module 2
- eCTD
- Current guidance documents
- Readyness to prepare and accept eCTD
- Future of the eCTD

DI Dr. Christa Wirthumer-Hoche, AGES, Austria

10:30 COFFEE BREAK

11:00 Session 2

DISCUSSION OF THE CONTENT OF MODULE 1 IN EUROPE

- Information relating to Pharmacovigilance
 - Pharmacovigilance Master File
 - Risk-management system
- Information relating to clinical trials
- Paediatric information

Dr. Peter Bachmann, BfArM, Germany

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
- Elements of Quality by Design
- What is a Design Space and Control Strategy
- Possibilities of the ICH Q8/Q9/Q10/Q11 Guidelines

Dr. Fritz Erni, Consultant, Switzerland

15:15 COFFEE BREAK

15:30 Session 3 (continued)

CTD - MODULE 3 QUALITY - DISCUSSION OF IMPORTANT CHAPTERS

- 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

Dr. Fritz Erni, Consultant, Switzerland

16:30 Session 4

INTRODUCTION TO THE QUALITY RISK MANAGEMENT CASE STUDY AND START WORKING IN GROUPS

Dr. Fritz Erni, Consultant, Switzerland

17:15 END OF DAY ONE

MONDAY | 2 DECEMBER 2013

09:00 Session 4 (continued)

DISCUSSION OF THE QUALITY RISK MANAGEMENT CASE STUDY

Dr. Peter Bachmann, BfArM, Germany Dr. Fritz Erni, Consultant, Switzerland DI Dr. Christa Wirthumer-Hoche, AGES, Austria

10:00 COFFEE BREAK

10:15 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
- Data protection period
- Information for Informed Consent Applications
- Specific provisions concerning the centralised procedure
 - Exceptional circumstances
 - Conditional Marketing Authorisation
 - Accelerated review

DI Dr. Christa Wirthumer-Hoche, AGES, Austria

12:00 LUNCH

13:15 Session 6

QUALITY OF ACTIVE SUBSTANCE AND IMPURITY TESTING

- Quality of Active Substance
- Active Substance
 - 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

Dr. Fritz Erni, Consultant, Switzerland DI Dr. Christa Wirthumer-Hoche, AGES, Austria

15:00 COFFEE BREAK

15:15 Session 7

STABILITY TESTING AND SETTING OF SPECIFICATIONS

- Stability testing
 - Discussion of the relevant guidelines
 - Practical examples
- Setting of specifications

Dr. Fritz Erni, Consultant, Switzerland

17:00 Session 8

CASE STUDY PRESENTATION AND START WORKING IN GROUPS

Dr. Peter Bachmann, BfArM, Germany Dr. Fritz Erni, Consultant, Switzerland DI Dr. Christa Wirthumer-Hoche, AGES, Austria

17:30 END OF DAY TWO

TUESDAY | 3 DECEMBER 2013

09:00 Session 8 (continued)

DISCUSSION OF THE CASE STUDY

Dr. Peter Bachmann, BfArM, Germany Dr. Fritz Erni, Consultant, Switzerland DI Dr. Christa Wirthumer-Hoche, AGES, Austria

COFFEE BREAK 10:00

10:15 Session 9

MARKETING AUTHORISATION PROCEDURES

- The European Network
- · Centralised Procedure
- Mutual Recognition Procedure
- · Decentralised Procedure

Dr. Peter Bachmann, BfArM, Germany

12:00 LUNCH

13:15 Session 10

CASE STUDY ON PLANNING AND ORGANISING A MEETING WITH AN AUTHORITY

Scientific advice, pre-submission meeting, oral hearing during a procedure

Dr. Peter Bachmann, BfArM, Germany Dr. Fritz Erni, Consultant, Switzerland

DI Dr. Christa Wirthumer-Hoche, AGES, Austria

14:15 Session 11

MAINTENANCE OF MARKETING AUTHORISATIONS

- Variations / Post-approval changes
 - New EU legal framework
 - Definition of Variations
 - Procedural & Classification Guideline
 - Post-Approval Management Protocol

Dr. Peter Bachmann, BfArM, Germany

DI Dr. Christa Wirthumer-Hoche, AGES, Austria

15:30 **COFFEE BREAK**

QUESTION AND ANSWER SESSION 15:45

Dr. Peter Bachmann, BfArM, Germany Dr. Fritz Erni, Consultant, Switzerland

DI Dr. Christa Wirthumer-Hoche, AGES, Austria

CLOSING REMARKS 16:45

17:00 **END OF TRAINING COURSE**

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham. Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China. www.diahome.org.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

HOTEL INFORMATION

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

Radisson Blu Hotel Dubai Deira Creek

P.O. Box: 476

Dubai, United Arab Emirates

Tel: +971 4 222 7171 Fax: +971 4 223 7615

info.deiracreek.dubai@radissonBlu.com

at the special rate of:

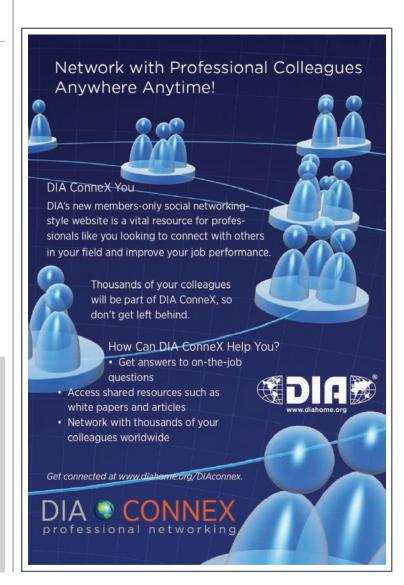
EUR 130.00 per room inclusive of breakfast, exclusive of 10% municipality tax and 10% service charge.

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

IMPORTANT: The room rate is available until 24 October 2013 or until the group block is sold-out, whichever comes first.

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

DIA Training Course on Global CTD Dossier 1-3 December 2013 | Radisson Blu Hotel, Dubai Deira Creek, Dubai, United Arab Emirates



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Postal Code City	correct allocation of your payment.
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• Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.

DIA reserves the right to include your name and affiliation on the attendee list.

- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = \in 100.00.
- Tutorial cancellation: € 50.00.

If you do not cancel five working days prior to the event 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.

Photography Policy

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The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.