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

Course #11533
27-29 November 2011
Radisson Blu Hotel, Abu Dhabi, United Arab Emirates

Faculty

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Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 18.5 credits.

This course has limited capacity. Register early!

Course 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 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

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Speakers and agenda are subject to change without notice.
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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:

Radisson Blu Hotel, Abu Dhabi Yas Island
Golf Plaza, Yas Island
P.O. Box 93725
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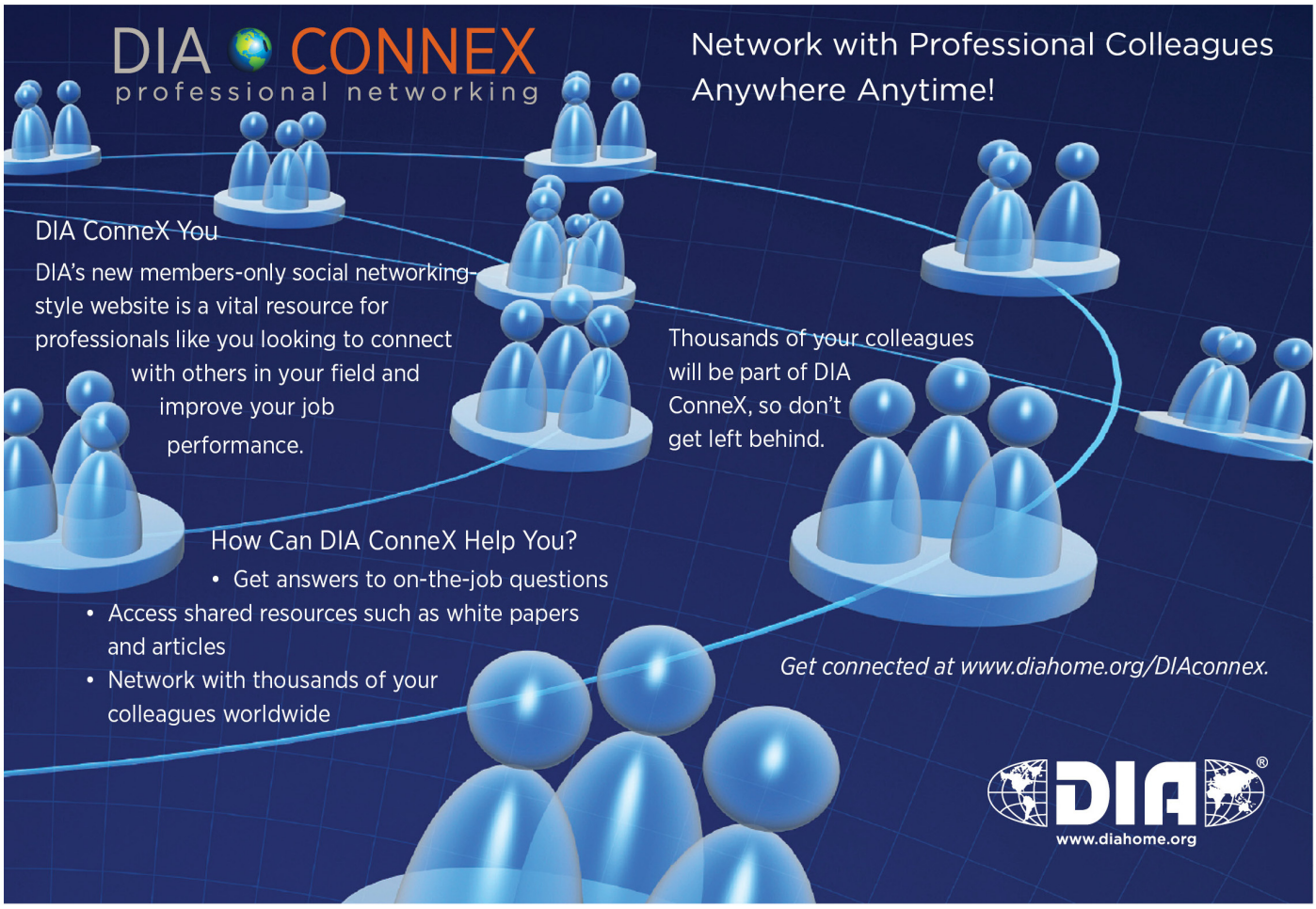

REGISTRATION FORM

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

ID# 11533

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	FEE	Membership	TOTAL	FEE
Industry	€ 1'785.00 ❑	€ 1'785.00	€ 115.00	€ 1'900.00 ❑	€ 1'900.00 ❑
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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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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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