DIA Training Course on

Clinical Aspects of Quality Risk Management and Quality by Design

Course #13560
19-20 September 2013
Dorint Hotel an der Messe, Basel, Switzerland

Faculty

Peter Schiemann
Managing Partner
Widler & Schiemann AG
Switzerland

Randy Ramin-Wright
QRM Consultant / QRM Business Unit Manager
ii4sm (International Institute for the Safety of Medicines Ltd.)
Switzerland

About DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.
The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.
DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.
For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

Continuing Education

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 eligible for these credits.

This course has limited capacity. Register early.

Overview

This course will deliver an in-depth overview of risk-based quality management and how to assess risk and improve quality in your organisation. As an introduction, general risk management concepts and methodologies will be presented as the basis for Quality by Design (QbD), Quality Risk Management (QRM) and Risk-based Monitoring, as applied to clinical development and pharmacovigilance. There follows a review of applicable and meaningful metrics for clinical development and pharmacovigilance processes, how these can be best applied and what change management challenges need to be considered.

Key Topics

- General risk management aspects
- QRM & QbD: Latest update on regulations
- QRM methodologies such as Failure Mode and Effects Analysis (FMEA)
- Key Risk Indicators (KRI) and other tools
- Case studies and practical exercises
- Implementation of QRM and change management aspects
- Proactive QbD methodologies
- QbD examples and exercises for protocol design and study set up
- Risk-based monitoring principles and implementation approaches

Who Will Attend

Clinical study managers, monitors, country study managers, clinical quality professionals, compliance and regulatory affairs professionals, project managers, risk management officers.

Level: Beginner to intermediate

Learning Objectives

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

- Define risk management and how it applies to clinical development
- Describe how risk management has been successfully applied
- Demonstrate the basic concepts and requirements for developing and implementing a QRM system
- Identify key tools and standards to use in risk management
- Evaluate how methodologies such as FMEA, etc. can be leveraged when introducing quality risk management in clinical development and pharmacovigilance
- Apply QbD principles when writing a protocol and setting up a clinical trial
- Understand the foundation of risk based monitoring and the tools and processes to set it up

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DAY 1

08:30 REGISTRATION

09:00 Session 1
RISK MANAGEMENT PRINCIPLES AND METHODOLOGIES

10:00 Session 2
REGULATIONS AND LATEST DEVELOPMENTS
REGULATORS' EXPECTATIONS

10:30 COFFEE BREAK

11:00 Session 3
RISK IDENTIFICATION EXERCISES

11:30 Session 4
THE JOURNEY FROM IDENTIFIED RISK TO THE FINAL INDICATOR(S) EXERCISES

12:30 LUNCH

13:30 Session 4 continued
THE JOURNEY FROM IDENTIFIED RISK TO THE FINAL INDICATOR(S) EXERCISES

14:00 Session 5
PRESENTATION OF RESULTS BY EACH GROUP

14:45 COFFEE BREAK

15:15 Session 6
IMPLEMENTATION OF A QRM APPROACH – POINTS TO CONSIDER – CHANGE MANAGEMENT ASPECTS

16:15 Session 7
QUALITY BY DESIGN PRINCIPLES

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

DAY 2

09:00 Session 7 continued
QUALITY BY DESIGN PRINCIPLES

09:15 Session 8
STUDY DESIGN ASSESSMENT - PRINCIPLES

10:00 COFFEE BREAK

10:30 Session 9
EXERCISES – QUESTIONS AND APPROPRIATE ANSWER OPTIONS

11:30 Session 10
PRESENTATION OF RESULTS BY EACH GROUP

12:00 LUNCH

13:00 Session 11
PROTOCOL DESIGN – RELATED TO CLINICAL OPERATIONS – POINTS TO CONSIDER

13:45 Session 12
EXAMPLE/EXERCISE

14:30 COFFEE BREAK

15:00 Session 13
RISK-BASED MONITORING – BASICS

15:45 Session 14
RISK-BASED MONITORING APPROACH AND IMPLEMENTATION

17:00 END OF TRAINING COURSE

HOTEL INFORMATION

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

Dorint Hotel an der Messe
Schoenaustrasse 10
4058 Basel
Switzerland

Tel.: +41 61 695 7000
Fax: +41 61 695 7100
Email: info.basel@dorint.com
Website: www.dorint.com

at the rate of:
CHF 230.00 per room inclusive of breakfast, service charge and VAT, exclusive of city tax of CHF 3.50 per day.

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

Cancellations of reservations are possible until +31 days prior to arrival.

IMPORTANT: Please complete your reservation by 19 August 2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

REGISTRATION FORM

DIA Training Course on Clinical Aspects of Quality Risk Management and Quality by Design | 19-20 September 2013 I Dorint Hotel an der Messe, Basel, Switzerland

ID #13560

FEES

	Member*	Non-Member*
Industry	€ 1'365.00 ❑	€ 1'480.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€ 683.00 ❑	€ 798.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

*All fees will be subject to the Swiss VAT at 8 %

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

TOTAL AMOUNT DUE: _____

Payment is due 30 days after registration and must be paid in full by commencement of the course.

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

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

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Course ID # 13560 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 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 or postponed, 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

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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.
Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland