Crisis Management: Focus on Pharmaceutical Product Crisis

Course #10564
14-15 October 2010
SAS Radisson Hotel Boulogne, Paris, France

Course Faculty

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Director
Mesama Consulting, Switzerland

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Integrated Safety Risk Manager

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the following training course on 'Crisis Management: Focus on pharmaceutical product crisis' with 15 credits.

This course has limited capacity. Register early.

Course Overview

This is a **highly interactive** training course.

Crisis prevention is extremely important in the drug development community and proper management of a crisis is crucial for the reliability of the company or regulator.

Learning Objectives

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

• Recognise a potential crisis on time and to approach a crisis appropriately when it happens

Key Topics

• Issue to risk – risk to crisis: Understanding the difference when an issue becomes a crisis
• Hands on experience with a crisis
• Basic principles
• Examples
• Internal organisation
• Dealing with the media
• Exercises
• Behaviour
• Set up of a "Crisis Management Team"

Who Will Attend

Professionals who work in:

• Regulatory institutions
• Pharmaceutical industry
• Medical affairs
• Marketing department
• Drug safety department
• Legal affairs

Level of course

Intermediate - advanced

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THURSDAY | 3 JUNE 2010

08:00 Registration

08:45 Welcome & Introduction

09:00 Basic Principles of Crisis Management 1

Lecture and exercises in groups

In this introductory session the participant learns the definition of a crisis and to understand which processes could be vulnerable for possible crises. Examples are given and attendees are invited to join an exercise to learn which parties are involved within and outside of their own organisation.

10:30 Coffee Break

11:00 From an Issue to a Crisis

Lecture and exercises in groups

Issues, risks and crises are many times incorrectly used as interchangeably. This session teaches the clear differences between the three and how one follows the other. Examples and exercises will show how one's problems get deeper when this process is not recognised or acted upon.

13:00 Lunch

14:00 Basic Principles of Crisis Management 2

Lecture and exercises in groups

In this session the participant learns how to organise for a potential crisis and how to build a preventive strategy. The roles of the Crisis Management Team members are shown and examples are given how to do right and wrong, including attitude towards the media.

15:30 Coffee Break

16:00 Issue Management and Crisis Prevention

Workshop

In this interactive workshop several tools are shown how to manage an issue, a crisis to then return to standard procedures. Attendees are invited to share their experiences and thoughts.

18:00 Drinks Reception

19:00 End of Day 1

FRIDAY | 4 JUNE 2010

In the second day of the Crisis Management Course, participants are allocated to different roles and they will be confronted with an issue that quickly escalates to a crisis. They will be requested to analyse the situation, implement strategies and respond to internal and external persons, departments and organisations.

Refreshment breaks on Day 2 if time permits.

08:30 Crisis Management

Workshop/Exercise

12:00 Lunch

13:00 Crisis Management

Workshop/Exercise cntd.

16:00 Wrap up

17:00 End of Day 2

Hotel Information

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

SAS Radisson Hotel Boulogne
Av. Edouard Vaillant 33
92660 Boulogne-Billancourt cedex
France
Tel: +33 1 46 08 85 00
Fax: +31 1 46 08 87 29
Email: reservations.boulogne@radissonsas.com

at the special rate of:
Single Room EUR 190.00
Double Room EUR 190.00

This rate is per room, per night, VAT, service, taxes and buffet breakfast included.

To reserve a room, please call the hotel referring to the DIA Training Course on "Crisis Management".

IMPORTANT: To be assured of accommodation at the SAS Radisson Hotel Boulogne, registrants are recommended to complete their reservation by 13 September 2010 the latest. Reservations received after that date are subject to availability.

DIA UPCOMING TRAINING COURSES IN 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

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

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.

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REGISTRATION FORM

Crisis Management: Focus on Pharmaceutical Product Crisis
14-15 October 2010 - SAS Radisson Hotel Boulogne, Paris, France

ID# 10564

DIA www.diahome.org

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			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 19.6%	TOTAL	FEE	VAT 19.6%	MEMBERSHIP	TOTAL	FEE	VAT 19.6%	TOTAL
Industry	€ 1'365.00	€ 267.54	**€ 1'632.54** ❑	€ 1'365.00	€ 267.54	€ 115.00	**€ 1'747.54** ❑	€ 1'480.00	€ 290.08	**€ 1'770.08** ❑
Government/Academia (Full-Time)	€ 683.00	€ 133.87	**€ 816.87** ❑	€ 683.00	€ 133.87	€ 115.00	**€ 931.87** ❑	€ 798.00	€ 156.41	**€ 954.41** ❑

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

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line. **10564DIA**

__ Advertising & Promotion
__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/Health Technology Assessment/Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

PAYMENT METHODS - CREDIT CARD PAYMENT IS PREFERRED

❑ **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# 10564 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 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.

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