Crisis Management: Focus on Pharmaceutical Product Crisis

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

Explore real-life case studies of crises in clinical trials and biopharmaceuticals. Learn from interactive sessions; hand-on practical methods of crisis management.

Course Faculty
Dr. Jan-Willem van der Velden
Director
Mesama Consulting, Switzerland

Dr. Michael Forstner
Integrated Safety Risk Manager
F. Hoffmann-La Roche Ltd., Switzerland

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.

About the Drug Information Association (DIA)
DIA serves more than 30,000 biopharmaceutical professionals from industry, academia and regulatory agencies worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes.

Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team. For more information, visit www.diahome.org or call DIA in Europe +41 61 225 51 51.

This course has limited capacity. Register early.
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:

Mercure Hotel EUROPE Basel
Clarastrasse 43
4005 Basel
Switzerland

Tel.: +41 61 690 80 80
Fax: +41 61 690 88 80

at the special rate of
CHF 210.00 single occupancy
including breakfast, service and VAT but excluding CHF 3.20 city tax.

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

IMPORTANT: To be assured of accommodation at Mercure Hotel EUROPE Basel, registrants are recommended to complete their reservation by May 19, 2010 latest.

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

Speakers and agenda are subject to change without notice.

Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.
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

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

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 | Basel, Switzerland | ID 10563
14-15 October 2010 | Paris, France | ID 10564

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.
REGISTRATION FORM
Crisis Management: Focus on Pharmaceutical Product Crisis
3-4 June 2010 - Mercure Hotel EUROPE, Basel, Switzerland

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.

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TOTAL AMOUNT DUE: € ____________

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- __ Advertising & Promotion
- __ CMC
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- __ Clinical Research
- __ Clinical Safety/Pharmacovigilance
- __ Document Management/ eSubmissions
- __ Manufacturing
- __ Medical Communications
- __ Medical Writing
- __ Nonclinical
- __ Outsourcing
- __ Comparative Effectiveness/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 Affairs
- __ Research & Development
- __ Statistics
- __ Strategic Planning
- __ IT/Validation

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[ ] 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 # 10563 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

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