

# Crisis Management: Focus on Pharmaceutical Product Crisis

Course #10563

3-4 June 2010

Mercure Hotel EUROPE, Basel, Switzerland



## Course Faculty

**Dr. Jan-Willem van der Velden**

Director

Mesama Consulting, Switzerland

**Dr. Michael Forstner**

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

## THURSDAY | 3 JUNE 2010

**08:00 Registration**

**08:45 Welcome & Introduction**

**09:00 Basic Principles of Crisis Management 1**

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*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**

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*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**

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*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**

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*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**

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*Workshop/Exercise*

**12:00 Lunch**

**13:00 Crisis Management**

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*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

<http://www.mercure.com/gb/hotel-5921-mercure-hotel-europe-basel/index.shtml>

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

## 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](http://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](http://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

ID# 10563



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 7.6%	TOTAL	FEE	VAT 7.6%	MEMBERSHIP	TOTAL	FEE	VAT 7.6%	TOTAL
Industry	€ 1'365.00	€ 103.74	€ 1'468.74	€ 1'365.00	€ 103.74	€ 115.00	€ 1'583.74	€ 1'480.00	€ 112.48	€ 1'592.48
Government/Academia (Full-Time)	€ 683.00	€ 51.91	€ 734.91	€ 683.00	€ 51.91	€ 115.00	€ 849.91	€ 798.00	€ 60.65	€ 858.65

## 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.

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- |  |   |   |   |
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| <input type="checkbox"/> CMC                                 | <input type="checkbox"/> Medical Writing  | <input type="checkbox"/> Pricing/Reimbursement                          | <input type="checkbox"/> Research & Development |
| <input type="checkbox"/> Clinical Data Management/ eClinical | <input type="checkbox"/> Nonclinical  | <input type="checkbox"/> Project Management                             | <input type="checkbox"/> Statistics             |
| <input type="checkbox"/> Clinical Research                   | <input type="checkbox"/> Outsourcing  | <input type="checkbox"/> Professional Education, Training & Development | <input type="checkbox"/> Strategic Planning     |
| <input type="checkbox"/> Clinical Safety/Pharmacovigilance   | <input type="checkbox"/> Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine | <input type="checkbox"/> Public Policy/Law/Corp. Compliance             | <input type="checkbox"/> IT/Validation          |
| <input type="checkbox"/> Document Management/ eSubmissions   |   | <input type="checkbox"/> Quality Assurance/Quality Control              |   |
| <input type="checkbox"/> Manufacturing                       |   |   |   |

## REGISTRANT

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

☐ Prof. ☐ Dr. ☐ Ms. ☐ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code

City

Country

Telephone

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., Elisabethen Anlage 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](http://www.diahome.org)

**Fax** +41 61 225 51 52

**Email** [diaeurope@diaeurope.org](mailto:diaeurope@diaeurope.org)

**Mail** DIA European Office  
Postfach, 4002 Basel, Switzerland