

DIA Training Course on

# Signal Management in Pharmacovigilance

Course #13558

6-7 November 2013

Hotel Mercure Paris la Villette, France



## Instructor

**Jan Petracek**

Director of Pharmacovigilance, EU-QPPV,

PharmInvent, Czech Republic

Former Head of Risk Management, European Medicines Agency, EU

## About DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

For more information, visit [www.diahome.org](http://www.diahome.org) or call DIA Europe +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

Signal Management is a critical process of Pharmacovigilance required by EU Good Pharmacovigilance Practice. It is the scientific component that underpins Pharmacovigilance, and the very reason why Pharmacovigilance was created in the first place.

The entire course has been updated in line with the latest guidelines on EU Good Pharmacovigilance Practices (GVP): Module IX - Signal management, Commission Implementing Regulation (EU) No. 520/2012, and CIOMS VIII.

Time has been set aside for exercises, questions and discussions.

## Who Will Attend

Professionals who work in:

- Pharmacovigilance (including QPPV)
- Drug safety and patient safety Risk Management
- Pharmacoepidemiology
- Information Technology
- Regulatory Affairs
- Pharmacovigilance consultancy
- Quality and Compliance
- Legal

## Course Level

For professionals with 2-3 years of experience in Pharmacovigilance. This course will be at intermediate level.

## Learning Objectives

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

- Explain and design the signal management process for companies of various sizes, portfolios and geographical presence
- Explain and apply the basic concepts and principles of signal detection in Pharmacovigilance, including the role and differences of classical and statistical signal detection in the ongoing safety surveillance of medicinal products
- Outline how to apply signal detection within their function based on the possibilities and limitations of methodology, data and resources
- Employ data mining techniques to analyse large volumes of adverse event report data
- Discuss key messages from the EMA Guideline on the uses of statistical signal detection methods in the Eudravigilance Data Analysis System, Module IX of EU GVP and CIOMS VIII
- Understand and manage implications of Pharmacovigilance signals for the future of pharmaceutical companies and products

PharmaTrain recognised



## WEDNESDAY | 6 NOVEMBER 2013

09:30 REGISTRATION

10:00 Session 1

### SIGNAL DETECTION – THEORY, METHODS, REGULATORY BASIS

Signal Detection is a key component of Pharmacovigilance science – discovering new effects of medicines in their post-authorisation use. The choice of the best methodology suitable for divergent portfolios, company sizes and regions will be presented.

12:00 LUNCH

13:00 Session 2

### SIGNAL DETECTION – APPLICATION AND WORKSHOP

Application of the best practices will be practised in small teams, tasked with the typical scenarios the industry and regulators face today.

15:00 COFFEE BREAK

15:30 Session 3

### DATA MINING – THEORY AND METHODS

Data Mining methodologies are used in big databases, and outcomes are accessible to all players in industry. Examples of data visualisation and interpretations will be presented.

17:30 END OF DAY ONE

## THURSDAY | 7 NOVEMBER 2013

08:30 Session 4

### DATA MINING – APPLICATION

Options for implementation and use by small and big companies and regulators will be discussed and problem solving practised in small working groups.

10:00 COFFEE BREAK

10:30 Session 5

### SIGNAL MANAGEMENT PROCESS, METHODS, REGULATORY EXPECTATIONS

How regulators, big companies and small companies should design their signal management process, the expected timelines, resources and outcomes from this process, and how the communication of signals should be performed. All of those critical issues will be discussed during the last session of the training.

12:00 END OF TRAINING COURSE

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe. Speakers and agenda are subject to change without notice. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.

## HOTEL INFORMATION

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

### Mercure Paris la Villette

216 Avenue Jean Jaurès  
75019 Paris  
France

Tel:+33 (0) 1 44 84 18 18

Fax:+33 (0) 1 44 84 18 20

Email: [mercureparisv@alliance-hospitality.com](mailto:mercureparisv@alliance-hospitality.com)

Website: <http://www.mercure.com/fr/hotel-8816-mercure-paris-la-villette/index.shtml>

at the rates of EUR 180.00 per room inclusive of breakfast and VAT.

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

**Important:** The room rate is available until 22 September or until the group block is sold-out, whichever comes first.

### Cancellation policy

No change or cancellation can be made after booking.

The client acknowledges that first night of the stay will be charged when the booking is made. This amount is non-refundable.

## Network with Professional Colleagues Anywhere Anytime!

### DIA ConneX-You

DIA's new members-only social networking-style website is a vital resource for professionals like you looking to connect with others in your field and improve your job performance.

Thousands of your colleagues will be part of DIA ConneX, so don't get left behind.

### How Can DIA ConneX Help You?

- Get answers to on-the-job questions
- Access shared resources such as white papers and articles
- Network with thousands of your colleagues worldwide



Get connected at [www.diahome.org/DIAconnex](http://www.diahome.org/DIAconnex).

**DIA CONNEX**  
professional networking

# REGISTRATION FORM

DIA Training Course on Signal Management in Pharmacovigilance  
6-7 November 2013 | Hotel Mercure Paris la Villette, France



ID #13558

## FEES

	Member*	Non-Member*
Industry	€ 1'155.00 <input type="checkbox"/>	€ 1'270.00 <input type="checkbox"/>
Academia/Charitable/Government/Non-profit (Full-time)	€ 578.00 <input type="checkbox"/>	€ 693.00 <input type="checkbox"/>
Join DIA now to qualify for the member rate	€ 115.00 <input type="checkbox"/>	

\*All fees will be subject to the French VAT at 19.6 %

Please advise your European VAT number: \_\_\_\_\_

**TOTAL AMOUNT DUE:** \_\_\_\_\_

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 availability – please contact DIA Europe for more information.

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

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 # 13558 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:

- 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](mailto:diaeurope@diaeurope.org) Tel. +41 61 225 51 51 Fax +41 61 225 51 52 Web [www.diaeurope.org](http://www.diaeurope.org) Mail DIA Europe, Postfach, 4002 Basel, Switzerland © DIA 2013