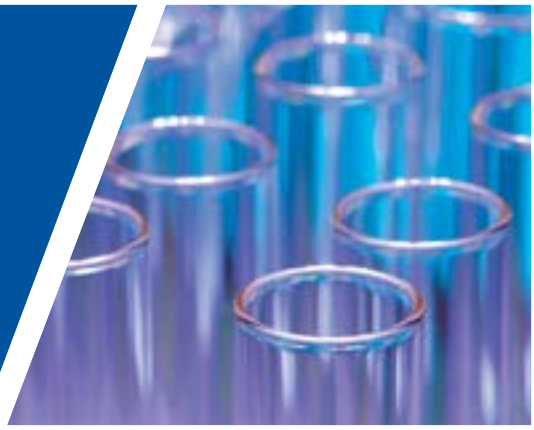
DIA Training Course on

Signal Management in Pharmacovigilance



Course #13557
10-11 June 2013
NH Nice Hotel, Nice, France

Instructor

Jan Petracek
Director of Pharmacovigilance, EU-QPPV,
PharmInvent, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

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

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

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MONDAY | 10 JUNE 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**

TUESDAY | 11 JUNE 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**

HOTEL INFORMATION

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

NH Nice Hotel
2-4, Parvis de l'Europe
FR-06300 Nice - France
http://www.nh-hotels.fr/nh/fr/hotels/france/nice/nh-nice.html

Tel (+33) 4 92 00 1814
Fax (+33) 4 93 821 77 42 96

at the special rate of
EUR 145.00 for standard room single occupancy
EUR 160.00 for standard room double occupancy
including breakfast, VAT plus city tax of EUR 1.50 per person/night

In order to make your reservation please use the hotel booking form available on the DIA website.

IMPORTANT: To be assured of accommodation registrants are recommended to complete the booking by 13.05.2013

REGISTRATION FORM

DIA Training Course on Signal Management in Pharmacovigilance
10-11 June 2013 I NH Nice Hotel, Nice, France

ID #13557

FEES

	Member*	Non-Member*
Industry	€ 1'155.00 ❑	€ 1'270.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€ 578.00 ❑	€ 693.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

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

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 event.

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 #13557 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