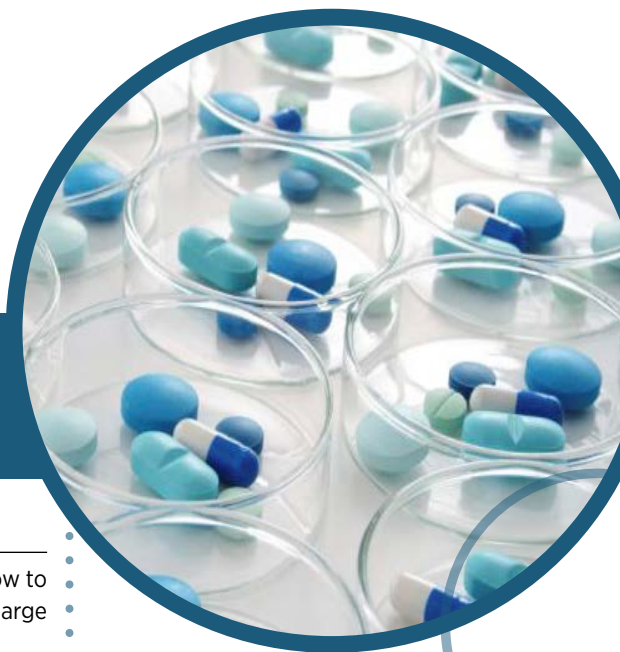


DIA Training Course on Signal Management in Pharmacovigilance

23-24 November 2016

Dorint An Der Messe hotel, Basel, Switzerland



OVERVIEW

This course will teach basic concepts of signal detection and signal management and how to apply them within the participants' functions, including the data mining techniques for large volume ADR data analysis, relevant EMA guidelines as well as a future outlook.

The entire course is 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.

Participants will be provided with preparatory material in order to better participate in the group exercises.

LEARNING OBJECTIVES

At the conclusion of this training course participants will be able to:

- Apply the basic concepts and principles of signal detection in pharmacovigilance, from simple visualisation and tabulation methods to sophisticated data mining techniques
- Design the signal management process for institutions and companies of various sizes, portfolios and geographical presence, based on the possibilities and limitations of their data and resources
- Understand key messages from the current European and US regulations on signal management, to best manage implications of signals for the future of pharmaceutical companies and products

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

- Signal detection - Theory, methods, data mining
- Signal management - Detection, triage, evaluation, further action
- Signal management - Regulatory expectations
- Signal management process: Strategy for implementation

WHO WILL ATTEND

This course is aimed at professionals who work in:

- Pharmacovigilance (including QPPVs)
- Drug safety and patient safety risk management
- Pharmacoepidemiology
- Information Technology
- Regulatory Affairs
- Pharmacovigilance consultancies
- Quality and Compliance
- Legal

Course level: Intermediate, for professionals with 2-3 years of experience in Pharmacovigilance, or related functions who are working with Pharmacovigilance around signal management.

Instructor

Jose Alberto Ayala Ortiz

Pharmacovigilance consultant

Pvpharm

Spain

DEVELOP.
INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION

09:00 SESSION 1

SIGNAL DETECTION - THEORY, METHODS, DATA MINING (1)

Jose Alberto Ayala Ortiz

Signal Detection is a key component of pharmacovigilance science – discovering new effects of medicines in their post-authorisation use. We will present concepts, definitions, data sources, traditional methods of detection, data mining and newest techniques. Participants will exercise the application of best practices in small teams.

10:30 COFFEE BREAK

11:00 SESSION 1 (continued)

SIGNAL DETECTION - THEORY, METHODS, DATA MINING (2)

12:00 LUNCH BREAK

13:00 SESSION 2

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION (1)

Jose Alberto Ayala Ortiz

Signal Management is one of the key pharmacovigilance processes; in this session we will review its position relative to other key processes. The different steps and quality requirements in the process will be explained, with the goal of clarifying the need for IT tools and resources for implementation in various contexts. Participants will work on real life examples in small groups.

14:30 COFFEE BREAK

15:00 SESSION 2 (continued)

SIGNAL MANAGEMENT – DETECTION, TRIAGE, EVALUATION, FURTHER ACTION (2)

16:30 SESSION 3

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (1)

Jose Alberto Ayala Ortiz

We will review the latest regulatory requirements on implementing and maintaining a signal management process. Again, practical exercises will allow participants to understand how they can develop a policy in signal management, and cope with any inspection on this topic.

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

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 DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

DAY 2

08:00 SESSION 3 (continued)

SIGNAL MANAGEMENT – REGULATORY EXPECTATIONS (2)

09:30 SESSION 4

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (1)

Jose Alberto Ayala Ortiz

This session reviews 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. We will discuss all of these critical issues during this final session, and look at the typical scenarios the industry and regulators face today.

10:00 COFFEE BREAK

10:30 SESSION 4 (continued)

SIGNAL MANAGEMENT PROCESS: STRATEGY FOR IMPLEMENTATION (2)

12:00 END OF THE TRAINING COURSE

Training Course Venue

The training course will take place at:

Dorint An Der Messe hotel

Schoenastrasse 10

4058 Basel, Switzerland

<http://hotel-basel.dorint.com>

Tel: +41 61 6957 000

Fax: +41 61 6957 100

Email: info.basel@dorint.com

DIA has blocked a limited number of hotel rooms at the rate of CHF 205.00 per standard room per night including breakfast and VAT, excluding City-Tax.

If you would like to make a booking, please fill in the booking form available on the DIA website and send it per email to info.basel@dorint.com with a reference "DIA".

The room rate is available until 20 October 2016 or until the room block is sold-out, whichever comes first.



Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 9.5 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9.5 credits.



DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

REGISTRATION FORM

Signal Management in Pharmacovigilance # 16549

23-24 November 2016 | Dorint An Der Messe hotel |Basel, Switzerland

REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'240.00 <input type="checkbox"/>	€ 1'395.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 <input type="checkbox"/>	€ 775.00 <input type="checkbox"/>

All registration fees are subject to applicable Swiss VAT

Please enter your company's Swiss VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

I do not want complimentary membership

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52

Email: EMEA@DIAGlobal.org Mail: DIA Europe, Middle East & Africa, Kuchengasse 16, 4051 Basel, Switzerland

Web: www.DIAGlobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks 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

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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 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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

Prof Dr Ms Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Fax Number

email (Required for confirmation)

Attendee email (Required for course material access)

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 # 16549 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, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on <http://www.diaglobal.org/EUTerms>

Date

Signature