# Risk Management

17 May 2019 Park Plaza Amsterdam Airport Hotel, Netherlands



# **FACULTY**

Paul ten Berg Pharmacovigilance Assessor Medicines Evaluation Board (MEB), Netherlands Jan Petracek CEO PrimeVigilance, Czech Republic

Remy Francisca Assessor Pharmacovigilance Medicines Evaluation Board (MEB), Netherlands

## **OVERVIEW**

This Module is part of the MEB/DIA Excellence in Pharmacovigilance training course

This module aims also to provide the background for understanding drug-related risks, and to present recent developments regarding risk communication.

In accordance with the GVP Module V on Risk Management System, risk management plans (RMPs) should be submitted by companies to propose activities aiming to identify, characterise or minimise risks associated with medicinal products. Given the potential public health implications and costs of such interventions, RMPs should be based on robust epidemiological methods.

08:00 REGISTRATION

08:30

**RISK MANAGEMENT** 

08:30 Risk Communication in EU – Challenges and Possibilities

Jan Petracek

10:00 COFFEE BREAK

10:30 Risk Management Plans: An Industry Perspective

Jan Petracek

12:00 LUNCH

13:00 Harmonisation of RMP (HaRP) in Europe Paul ten Berg, MEB

14:30 COFFEE BREAK

14:45 Effectiveness of Risk Minimisation Measures

Jan Petracek

Remy Francisca, MEB

16:00 END OF MODULE 4





### REGISTRATION FORM

#### Risk Management #19154

## 17 May 2019 | Amsterdam, The Netherlands

#### **REGISTRATION FEES**

Registration fee includes refreshment breaks, lunch and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	LENGTH	INDUSTRY		GOV/ACA/CHAR	
		MEMBER	NON- MEMBER	MEMBER	NON- MEMBER
MODULE 1: DEFINITIONS AND METHODS IN PHARMACOVIGILANCE	1 day	€ 800.00 □	€ 955.00 🗖	€ 400.00 □	€ 555.00 🗖
MODULE 2: REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES	2 days	€ 1′450.00 🗖	€ 1′605.00 🗖	€ 725.00 □	€ 880.00 □
MODULE 3: SIGNAL DETECTION AND SIGNAL MANAGEMENT	1 day	€ 800.00 □	€ 955.00 🗖	€ 400.00 □	€ 555.00 🗖
MODULE 4: RISK MANAGEMENT	1 day	€ 800.00 □	€ 955.00 🗖	€ 400.00 □	€ 555.00 🗖

A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information

Please enter your Company's European VAT number:

If DIA cannot verify your membership upon receipt of your registration form, you will be charged the non-member fee. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.

### **DIA MEMBERSHIP**

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at <u>DIAglobal.org/Membership</u>.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at <a href="DIAglobal.org">DIAglobal.org</a>. If you would like to decline complimentary membership, please indicate your preference below.

☐ I would like to decline a one year complimentary DIA membership.

The DIA 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: <a href="mailto:Basel@DIAglobal.org">Basel@DIAglobal.org</a> Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

# TERMS AND CONDITIONS

### **Cancellation Policy**

All cancellations must be made in writing and be received at the DIA 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 nonmember fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

#### **Event Stream and recording**

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click <a href="here">here</a>.

#### **Privacy Policy**

DIA respects the privacy of all of its members and customers. To view our privacy policy, click <u>here</u>. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS	PAYMENT METHODS			
Please complete in block capital letters or attach the attendee's business card here.	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.			
□ Prof □ Dr □ Ms □ Mr	☐ Please charge my ☐ VISA ☐ MC ☐ AMEX			
Last Name	Card N°			
First Name	Exp. Date			
Job Title	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 #19154 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.			
Company				
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Country	By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on <a href="http://www.diaglobal.org/EUTerms">http://www.diaglobal.org/EUTerms</a>			
Telephone Number	Date Signature			
Attendee email required for course material access				

<sup>\*</sup>All fees are subject to the applicable Dutch VAT.