Risk Management

6 October 2017 The Crystal, London, United Kingdom

COURSE DIRECTORS

Gaby Danan Pharmacovigilance Expert, France Phil Tregunno Signal Management Unit Manager

Medicines & Healthcare products Regulatory Agency (MHRA), UK

OVERVIEW

This Module is part of the MHRA/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 14:00 **COFFEE BREAK** 08:30 14:30 **Post-authorisation Development Plan (PASS/PAES) RISK MANAGEMENT** Jan Petracek, CEO, PharmInvent 08:30 **Risk Communication in EU – Challenges and Possibilities** 15:00 **Effectiveness of Risk Minimisation Measures** Jan Petracek, CEO, PharmInvent Jan Petracek, CEO, PharmInvent 10:00 **COFFEE BREAK** 16:00 **END OF MODULE 4** 10:30 An Overview of the Risk Management Process & the PRAC. The main components of the RMP Julie Williams, Expert Assessor, MHRA LUNCH 12:00 13:00 **Risk Management Plans: An Industry Perspective** Jan Petracek, CEO, PharmInvent





REGISTRATION FORM

Risk Management # 17154

6 October 2017 | The Crystal | London, United Kingdom

REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course 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 🗆

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 <u>www.diaglobal.org</u> and click on Membership for more details.

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

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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: <u>EMEA@DIAglobal.org</u> Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

ATTENDEE DETAILS **PAYMENT METHODS** Credit cards: Payments by VISA, Mastercard or AMEX can be made by Please complete in block capital letters or attach the attendee's business completing the details below. Please note that other types of credit card card here. cannot be accepted. Please charge my VISA MC AMEX Prof Dr DMs DMr Card N° Last Name Exp. Date First Name Cardholder's Name Job Title Bank transfers: When DIA completes your registration, an email will be Company 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 # Address 17154 as well as the invoice number to ensure correct allocation of your payment. Postal Code 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. City By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on Country http://www.diaglobal.org/EUTerms Telephone Number Fax Number Date Signature Attendee email required for course material access

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 nonmember 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.

