DIA Learning

# Benefit-Risk Management

28-29 November 2017
Mercure Paris La Défense Grande Arche, Paris, France

## OVERVIEW

This intensive course explores current opportunities made possible by the legislation, advances in information technology and a new scientific methodology to enhance and modernise the approaches in the product lifecycle management.

The course starts with the current regulatory thinking about the benefit-risk methodology, including the relevant projects of the European Medicines Agency (EMA) / Committee for Medicinal Products for Human Use (CHMP). It gives a basis for the second part of the course, exploring the new European benefit-risk management planning - a notion stemming from the experience gathered over the past ten years with the EU Risk Management Plans (EU-RMPs). Participants will learn how to take advantage of the efficacy follow-up options given by the EU law and guidelines. A practical training in solving key aspects of the Benefit-Risk management based on real-life examples is included.

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

## LEARNING OBJECTIVES

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

- Describe safety, efficacy, and effectiveness profiles of drugs
- Plan safety and efficacy follow-up systems, including the best choice of study designs and available registries
- Optimise benefits and minimise risks of products, including the best use of an evidence-based toolbox
- Present the Benefit-Risk documents to regulatory authorities and health technology assessment bodies
- Measure effectiveness of the planned actions – both risk minimisation and benefit optimisation

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

## WHO WILL ATTEND

Professionals most likely to benefit from this training have experience in pharmacovigilance, drug safety, regulatory affairs, quality assurance, risk management, medical affairs or similar positions within the pharmaceutical industry. Those in charge of the design and maintenance of risk management systems, pharmacovigilance auditing or inspecting, Qualified Persons for Pharmacovigilance (QPPVs) and heads of benefit-risk management, patient safety, or lifecycle management will learn all the essential aspects needed for successful Benefit-Risk management. Examples are presented for small as well as large organisations.

## FACULTY

**Michael Forstner**
Managing Director, Head of Risk Management & Business Process Management Practice
Mesama Consulting International, Switzerland

**Jan Petracek**
CEO, PharmInvent and PrimeVigilance, Czech Republic
Former Head of Risk Management, European Medicines Agency, EU

## KEY TOPICS

- Legal possibilities for benefit optimisation and risk minimisation of products in the EU
- Designing benefit-risk management systems using current regulatory tools, including EU Risk Management Plans (EU-RMPs), Development Safety Update Report (DSUR), Periodic Safety Update Report (PSUR)
- Best study designs for safety and efficacy follow-up, and how to measure their effectiveness

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

## DAY 1

**08:00 REGISTRATION**

**08:30 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS**

**08:45 SESSION 1**

### INTRODUCTION TO BENEFIT-RISK MANAGEMENT

*Jan Petracek*

- Key concepts and terminology
- Essential principles for benefit-risk management
- Foreseeable developments

**10:30 COFFEE BREAK**

**11:00 SESSION 2**

### INTRODUCTION TO BENEFIT-RISK METHODOLOGIES

*Michael Forstner*

- The concept of risk
- Overview of qualitative and quantitative methods
- Use of the methodology by US and EU regulators

**11:45 SESSION 3**

### EXAMPLES OF APPLICATION OF BENEFIT-RISK METHODOLOGIES

*Michael Forstner*

- ZHA, FMEA, FTA
- BR frameworks, Conjoint analysis, MCDA
- QALYs, NNTH/NNTB

**12:15 LUNCH**

**13:15 SESSION 4**

### DESIGNING RISK MANAGEMENT SYSTEMS

*Jan Petracek*

**13:45 SESSION 5**

### DOS AND DON'TS IN SAFETY SPECIFICATION

*Jan Petracek*

**14:00 SESSION 6**

### TOOLBOX FOR PHARMACOVIGILANCE PLANNING

*Michael Forstner*

- Pharmacovigilance toolbox
- Design of studies and registries used in pharmacovigilance planning
- Matching safety concerns with appropriate pharmacovigilance tools

**14:45 COFFEE BREAK**

**15:15 SESSION 7**

### EFFICACY SPECIFICATION AND FOLLOW-UP PLAN

*Jan Petracek*

- Creation of efficacy specification and relevant regulatory discussions in EU-RMPs and PSURs(PADERs)
- Design of studies and registries used in the efficacy follow-up planning
- Matching efficacy concerns with the efficacy follow-up planning

**16:00 SESSION 8**

### OPTIONS FOR RISK MINIMISATION

*Michael Forstner*

- Risk minimisation toolbox
- Matching safety concerns with the risk minimisation tools
- Safety communication

**17:00 NETWORKING RECEPTION**

**18:00 END OF DAY ONE**

## DAY 2

**08:20 SESSION 9**

### EVALUATION OF RISK MINIMISATION EFFECTIVENESS

*Michael Forstner*

- Tools and methodologies available
- Levels of metrics
- Required evaluation levels and examples of satisfactory results

**09:45 COFFEE BREAK**

**10:15 SESSION 10**

### BENEFIT-RISK MANAGEMENT PLAN – CASE STUDIES

*Jan Petracek*

- Small molecules and generics
- Biologics and biosimilars
- Advanced therapies
- Combination therapies

**12:15 LUNCH**

**13:15 SESSION 11**

### BENEFIT OPTIMISATION

*Jan Petracek*

- Benefit management toolbox
- Matching efficacy/effectiveness concerns with the benefit management tools
- Measuring success of benefit optimisation

**14:15 SESSION 12**

### USE OF BENEFIT-RISK MANAGEMENT PLANS IN REGULATORY SUBMISSIONS

*Jan Petracek*

- Pre-authorisation – DSUR
- Post-authorisation – REMS, EU-RMP and PSUR
- EU-RMP

**15:15 END OF TRAINING COURSE**

## Training Course Venue

**PARIS LA DÉFENSE GRANDE ARCHE**

17/20 Esplanade Ch. de Gaulle - Rue des Trois Fontanot
92000 Nanterre/Paris, France

Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 150.00 per standard room per night including breakfast and VAT, excl. 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 H1982@accor.com with a reference "DIA".
The room rate is available until 20 October 2017 or until the room block is sold-out, whichever comes first.
Note: As hotel is located right above the train station, it is a bit noisy.

**HOW TO GET THERE**

From Charles de Gaulle airport take the Blue train line B towards city centre and get off at Chatelet.
Change there to Red train line A towards Cergy/Poissy/St. Germain en-Laye and get off at Nanterre Prefect.
The hotel is located right next to the train station.

## About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

## Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 11.25 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.25 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

## Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact EMEA@DIAglobal.org for a custom group rate.

# REGISTRATION FORM

**Benefit-Risk Management # 17564**
**28-29 November 2017 | Mercure Paris La Defènse Grande Arche | Paris, France**

DIA Learning

## REGISTRATION FEES

Registration fee includes refreshment breaks, lunches 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 | MEMBER | NON-MEMBER |
|---|---|---|
| INDUSTRY | € 1'450.00 ❑ | € 1'605.00 ❑ |
| ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME) | € 725.00 ❑ | € 880.00 ❑ |

**All registration fees are subject to applicable French VAT**

Please enter your company's French 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, 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 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 AND VIDEO 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

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 #17564 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 |
|---|---|
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