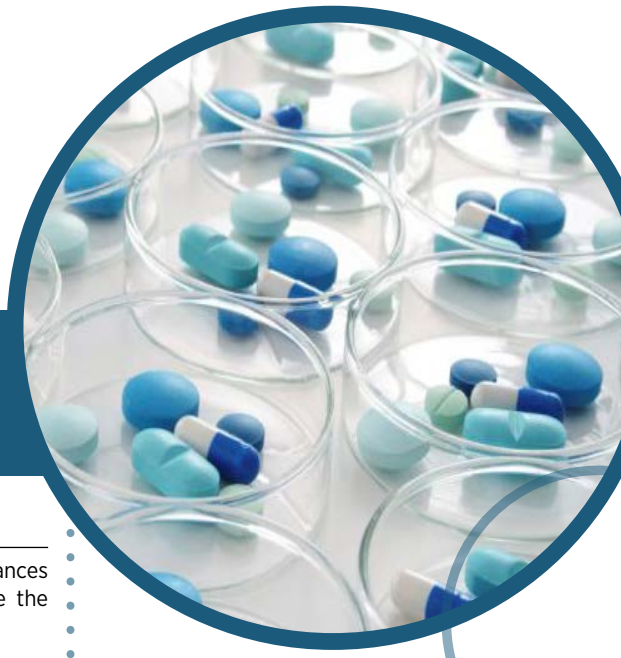
*DIA Training Course on*

# Benefit/Risk Management



**21-22 November 2016**
**Dorint an der Messe, Basel, Switzerland**

## 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 project 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 drafting key aspects of the regulatory submissions is included.

## 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 find all the necessary information and skills needed for successful benefit/risk management. Examples are presented for small as well as large organisations.

## 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 first three bullet points to key regulatory authorities and health technology assessment bodies
- Measure effectiveness of the planned actions – both risk minimisation and benefit optimisation

## CONTINUING EDUCATION

DIA meetings and trainings 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 11.5 credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available.

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 11.5 CPD credits.

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

This course has limited capacity. Register early.

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

## FACULTY

**Jan Petracek**

CEO, Consultant, PharmInvent,
Czech Republic
Former Head of Risk Management,
European Medicines Agency, EU

**Michael Forstner**

Managing Partner. Head of Risk Management & Business Process Management Practice
Mesama Consulting International,
Switzerland

## 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

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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 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*

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

**11:45 SESSION 3**

### SAFETY SPECIFICATION

*Michael Forstner*

- Non-clinical
- Clinical
- Epidemiology
- Construction of important risks and missing information

**12:15 LUNCH**

**13:15 SESSION 4**

### FAILURE MODES AND EFFECTS ANALYSIS

*Jan Petracek*

**13:45 SESSION 5**

### DOS AND DON'TS IN SAFETY SPECIFICATION

*Jan Petracek*

**14:00 SESSION 6**

### PHARMACOVIGILANCE PLAN

*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**

### RISK MITIGATION

*Michael Forstner*

- Risk minimisation toolbox
- Matching safety concerns with the risk minimisation tools
- Measuring effectiveness of risk minimisation

**17:00 DRINKS RECEPTION**

**18:00 END OF DAY ONE**

## DAY 2

**08:20 SESSION 9**

### BENEFIT OPTIMISATION

*Jan Petracek*

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

**08:45 SESSION 10**

### BENEFIT/RISK MANAGEMENT PLAN - CASE STUDIES

*Jan Petracek*

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

**09:45 COFFEE BREAK**

**10:15 SESSION 10 (continued)**

### BENEFIT/RISK MANAGEMENT PLAN - CASE STUDIES

**11:00 SESSION 11**

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

*Jan Petracek*

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

**12:15 LUNCH**

**13:15 SESSION 15**

### USE OF BENEFIT/RISK MANAGEMENT PLANS IN CRISIS MANAGEMENT

*Michael Forstner*

**13:15 SESSION 12**

### BENEFIT/RISK COMMUNICATION

*Michael Forstner*

- Importance of communication
- Communication channels and tools
- Communication planning

**14:15 SESSION 13**

### INTERACTIVE SESSION

*Michael Forstner*

- Practical aspects of Risk identification and prioritisation
- Risk Minimisation planning and implementation
- Evaluation of effectiveness of risk minimisation

**15:15 END OF TRAINING COURSE**



## Training Course Venue

The training course will take place at:

**Dorint an der Messe**

Schoenaustrasse 10
4058 Basel, CH
Tel: +41 61 6957 000
info.basel@dorint.com
www.hotel-basel.dorint.com

DIA has blocked a limited number of rooms at the rate of CHF 205.00 per single room per night including breakfast and W-lan internet. Upon arrival all guests will receive a Mobility Ticket, which allows them to use public transport in Basel during their stay free of charge. The City-Tax of CHF 3.50 per person and night will be charged additionally. A cancellation free of charge is possible until+31 days prior to arrival.

The room rate is available until 24 October 2016 or until the room block is sold-out, whichever comes first.

## About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

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# REGISTRATION FORM

## Benefit Risk Management # 16547
## 21-22 November 2016 | Dorint an der Messe | Basel, Switzerland

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### REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course 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 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, Küchengasse 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 # 16533 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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