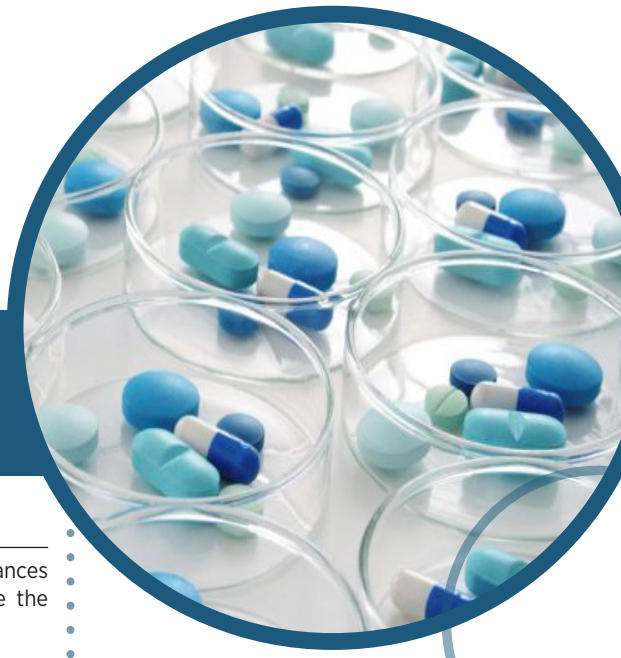
DIA Training Course on

Benefit/Risk Management



10-11 March 2016
Hotel Grand Majestic, Prague, Czech Republic

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.

DIA DEVELOP INNOVATE ADVANCE

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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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 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 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:

Hotel Grand Majestic Plaza
Truhlarska 16 110 00
Prague 1
Czech Republic
Tel: +420 211 159 100
Website: www.hotel-grandmajestic.cz

DIA has blocked a limited number of hotel rooms for the course participants from 9-11 March 2016 at the rate of EUR 70.00 per single room per night including breakfast, taxes and internet connection.

In order to book a hotel room, please contact the hotel directly and quote the booking reference "130477". The room rate is available until 9 February 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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