DIA Learning

Benefit-Risk Management

11 - 12 November 2019
Hotel Berlin Mitte, Berlin, Germany

OVERVIEW

This intensive course explores current opportunities made possible by legislation, advances in information technology and new scientific methodologies to enhance and modernise approaches for benefit-risk management in the product lifecycle.

The course starts with key concepts and current regulatory thinking about benefit-risk methodologies, including relevant projects of the European Medicines Agency (EMA) / Committee for Medicinal Products for Human Use (CHMP). It provides a basis for the second part of the course, exploring benefit-risk management planning - a notion stemming from the experience gathered over the past 15 years, e.g. with EU Risk Management Plans (EU-RMPs). Participants will learn how to develop optimal safety and efficacy follow-up options consistent with regulatory guidelines. A practical training in solving key aspects of benefit-risk management based on real-life examples is included.

LEARNING OBJECTIVES

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

- Describe benefits, risks and benefit-risk 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
- Communicate benefit-risk profiles to key stakeholders (regulators, healthcare professionals,...)
- 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, 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
Senior VP - Head of Risk Management and Pharmacoepidemiology
PrimeVigilance
Switzerland

Steve Mayall
Principal Consultant
Huron, United Kingdom

KEY TOPICS

- Approaches 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

Michael Forstner

- 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

Steve Mayall

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

11:45 SESSION 3

EXAMPLES OF BENEFIT-RISK METHODOLOGIES

Michael Forstner

- ZHA, FMEA, FTA
- BR frameworks, Conjoint analysis, MCDA
- QALYs, NNTH/NNTB
- Designing Risk Management Systems

12:15 LUNCH

13:15 SESSION 3 - CONTINUED

EXAMPLES OF BENEFIT-RISK METHODOLOGIES

14:00 SESSION 4

TOOLBOX FOR PHARMACOVIGILANCE PLANNING

Steve Mayall

- 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 5

OPTIONS FOR RISK MINIMISATION

Steve Mayall

- Risk minimisation toolbox
- Matching safety concerns with the risk minimisation tools
- Implementing risk minimisation measures

16:15 SESSION 6

EVALUATION OF RISK MINIMISATION EFFECTIVENESS

Michael Forstner

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

17:30 END OF DAY ONE

DAY 2

08:30 SESSION 7

EFFICACY SPECIFICATION AND FOLLOW-UP PLAN

Michael Forstner

- Creation of efficacy specification and relevant regulatory discussions in EU-RMPs and PSURs
- Design of studies and registries used in the efficacy follow-up planning
- Matching efficacy concerns with the efficacy follow-up planning
- Real-World Evidence in Pharmacovigilance

08:30 SESSION 8

BENEFIT-RISK MANAGEMENT PLAN – CASE STUDIES

Michael Forstner & Steve Mayall

- Small molecules and generics
- Biologics and biosimilars

10:30 COFFEE BREAK

11:00 SESSION 9

BENEFIT-RISK MANAGEMENT PLAN – CASE STUDIES

Michael Forstner & Steve Mayall

- Advanced therapies
- Combination therapies

12:00 LUNCH

13:30 SESSION 10

EFFECTIVE BENEFIT-RISK COMMUNICATION

Steve Mayall

- Important factors when designing benefit-risk communications
- Choice of channels, including digital approaches
- Rolling out benefit-risk communications

14:30 SESSION 11

NEW DEVELOPMENTS

Michael Forstner

Latest Updates and best practices to prepare for

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

15:00 END OF TRAINING COURSE

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

Training Course Venue

HOTEL BERLIN MITTE (MANAGED BY MELIA)

Chausseestrasse 33
10115 Berlin, Germany
Tel: +49 30 41 47 230
Email: hotel.berlin.mitte@melia.com

Participants are kindly requested to contact hotel directly for the best available rate.

HOW TO GET THERE

The closest U-Bahn station is "Naturkundemuseum" on line U6 Alt-Tegel - Alt-Mariendorf.
From Tegel Airport take the bus TXL 128 towards Osloer Strasse, and get off at Kurt-Schumacher-Platz U-Bahn station. Change there to U-Bahn line 6 towards Alt-Mariendorf and get off at Naturkundemuseum (8 stops).

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 11.00 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.00 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 Basel@diaglobal.org for a custom group rate.