Risk Management and Minimisation Workshop

26 October 2018 | Doubletree by Hilton London Docklands Riverside, London, United Kingdom

PROGRAMME COMMITTEE

Steve Mayall
Principal Consultant, Huron, UK

Jan Petracek
CEO, PrimeVigilance, Czech Republic

Patrick Batty
PRAC UK Alternate delegate, MHRA, UK

FACULTY

James Milligan, Vice President Patient Safety, AstraZeneca, UK

Catarina Martins, Global Risk Management Plan Group Head, Novartis, Switzerland

Michael Forstner
SVP, Pharmacoepidemiology and Risk Management, PrimeVigilance, Switzerland

Randip Kahlon
Global Risk Management Implementation Lead, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Joanne Treacy, Independent Pharmacovigilance Risk Management Consultant, UK

Zuzana Vinterova
Director, Medical Writing, PrimeVigilance, Czech Republic

Overview

Risk Management, including risk minimisation, is receiving more and more attention from regulators and industry. It is a point of interest for the stakeholders to have a better understanding on this topic.

This hands-on workshop will explore in more detail the practical implications.

Topics have been carefully selected from the feedback received by past attendees from EMA Infodays and DIA RMP events. The agenda will explore in detail topics covered at the EMA Risk Management Plan Information Day on 25 October.

The interactive format will reinforce learnings and illustrate how to apply them to the development and implementation of EU-RMPs, involving case studies and worked examples

Key Topics

- EU-RMP for different types of marketing authorisation
- Special populations impact the content of an EU-RMP
- Risk Minimisation Measures
- Communicating risks effectively
- Burden of risk minimisation

Target Audience

Professionals working within the pharmaceutical industry in pharmacovigilance, drug safety, regulatory and medical affairs or similar positions, who are involved in in risk management planning, risk minimisation development or risk communication at small to medium enterprises (SMEs), MAAs / MAHs for generic products, MAAs / MAHs for innovator products and Contract Research Organisations (CROs)

Also, attendees of the EMA Risk Management Plan Information Day and others who wish to practically apply the topics covered to the development of EU-RMPs.

RMM WORKSHOP | FRIDAY, 26 OCTOBER

08:30 REGISTRATION

08:45 WELCOME

09:00 SESSION 1

RISK MANAGEMENT FOR DIFFERENT TYPES OF MARKETING AUTHORISATION AND SPECIAL POPULATIONS IMPACT ON THE CONTENT OF AN EU-RMP

Topic lead:
Jan Petracek, CEO, PrimeVigilance, Czech Republic

GVP Module V specifies which sections of an EU-RMP are needed for different types of marketing authorisation application (MAA), including biosimilars. This session will cover some of the key challenges that arise when developing an EU-RMP for a product that doesn't require a full initial MAA and will offer the opportunity to ask questions related to the Special populations impact the content of an EU-RMP.

Facilitators:
Zuzana Vinterova, Director, Medical Writing, PrimeVigilance, Czech Republic
Michael Forstner, SVP, Pharmacoepidemiology and Risk Management, PrimeVigilance, Switzerland

10:30 COFFEE BREAK

11:00 SESSION 2

MEASURING THE EFFECTIVENESS OF RISK MINIMISATION MEASURES

Topic lead:
Patrick Batty, PRAC UK Alternate delegate, MHRA, UK

Assessing the effectiveness of risk minimisation measures (RMM) after they are implemented is an important aspect of risk management. This session will cover key principles of measuring RMM effectiveness, and provide an opportunity to discuss the challenges faced and approaches to address these.

Facilitators:
James Milligan, Vice President Patient Safety, AstraZeneca, UK
Catarina Martins, Global Risk Management Plan Group Head, Novartis, Switzerland
Joanne Treacy, Independent Pharmacovigilance Risk Management Consultant, UK

12:30 LUNCH

13:30 SESSION 3

COMMUNICATING RISKS EFFECTIVELY

Topic lead:
Steve Mayall, Principal Consultant, Huron, UK

The clear communication of important risks (and more generally, the benefit-risk balance) of a medicinal product is challenging. Risk minimisation activities typically involve education for healthcare professionals and patients/caregivers. This session explores approaches to effectively communicate with these audiences and what to include in an EU-RMP for risk education.

Facilitator:
Steve Mayall, Principal Consultant, Huron, UK
Randip Kahlon, Global Risk Management Implementation Lead, Bristol-Myers Squibb Pharmaceuticals Ltd, UK

15:00 COFFEE BREAK

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15:30 SESSION 4

BURDEN OF RISK MINIMISATION

Topic lead:
Jan Petracek, CEO, PrimeVigilance, Czech Republic

Although the analysis has been suggested by CIOMS IX and mandated by EU GVP Module XVI, no methodology has been described in the regulatory guidelines yet. Regulatory practice is evolving, and the inclusion of the Burden Analysis is not consistent across the industry. The session will explore published literature in this respect and share couple of practical hints from the real life cases.

Facilitators:
Michael Forstner, SVP, Pharmacoepidemiology and Risk Management, PrimeVigilance, Switzerland
Jan Petracek, CEO, PrimeVigilance, Czech Republic

16:30 END OF WORKSHOP

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NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with the presentation. Updated versions of the slides will be made available shortly after the conference.

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A Certificate of Attendance will be sent electronically fter the conference . Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.

Evaluation

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference and can also be accessed through the following link: https://bit.ly/2pUyxDa

Hotel Information

Doubletree by Hilton London Docklands Riverside
265 Rotherhithe Street
London, SE16 5HW, UK

Tel (+44)207 2311001
Airport: London City Airport (20min)
The hotel's complimentary ferry provides access to Canary Wharf.

View Directions

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SwAPP Swiss Association of Pharmaceutical Professionals

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