

Risk Minimisation Measures

Virtual Live Training Course

27-29 October 2026 | 13:00-17:30 CEST



Overview

The proactive planning of risk minimisation measures (RMMs) in the context of optimizing the benefit-risk profiles of medicinal product is a challenging task. RMMs should be commensurate to the risk in relation to the clinical benefit of the product and should work for the intended patient population without adding undue burden on the healthcare systems.

After the recent updates to GVP XVI, it's clear that they should also allow for rapid evaluation of their effectiveness to enable evidence-based adaptation to achieve their objectives or align to a changing healthcare environment, if and when necessary.

In this course, we will share experiences and challenges in designing, implementing, and evaluating RMMs in different regulatory settings and different therapeutic areas, as well as presenting an outlook on what may be the next generation of RMM tools.

Learning Objectives

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

- Design a risk management strategy
- Select the appropriate tools for risk minimisation
- Choose the right measures to evaluate effectiveness

Who Will Attend

This intermediate level virtual live training course is intended for professionals working within the pharmaceutical industry in pharmacovigilance, drug safety, risk management and regulatory affairs.

Ideally, participants should have experience in risk management.

Key Topics

- Introduction and overview of changes to risk management
- Regulatory framework for risk management
- Designing global risk management strategy
- Tools for risk minimisation
- Implementation of risk minimisation measures
- Measuring effectiveness
- Risk minimisation measures findings from an assessor's perspective
- Evolving landscape and future outlook

Faculty

Omar Aimer

President of the ISoP North American Chapter
ISoP, Canada

Mark Perrott

Managing Partner
Axian Consulting, United Kingdom

Anita Volkers

Pharmacovigilance Assessor
Medicines Evaluation Board, Netherlands

Schedule-At-A-Glance

DAY 1

13:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS, INTRODUCTION TO GROUP WORK

13:45 SESSION 1

INTRODUCTION AND OVERVIEW OF CHANGES TO RISK MANAGEMENT

Anita Volkers

- Risks classifying for inclusion RMP (evolvment)
- New challenges in risk management

14:15 SESSION 2

REGULATORY FRAMEWORK FOR RISK MANAGEMENT

Anita Volkers and Omar Aimer

- Updates in GVP Module XVI Rev 3
- Different country/region requirements in the EU, UK, US and brief overview of other regions
- Harmonisation initiatives

15:45 BREAK

16:15 SESSION 3

DESIGNING GLOBAL RISK MANAGEMENT STRATEGY

Mark Perrott and Anita Volkers

- Aligning risk management strategy and structured benefit-risk assessment
- Defining strategic goals of risk minimisation
- Prioritising risks and defining risk management objectives
- Requested (features of) aRMM (regulator view)

17:30 END OF DAY 1

DAY 2

13:00 SESSION 4

TOOLS FOR RISK MINIMISATION

Omar Aimer and Mark Perrott

- Turning risk management objectives into customer-focussed tools
- Engaging with internal colleagues and the customer
- Examples of 'traditional' paper-based approaches and digital tools designed to achieve various outcomes
- Group Work Part 1

14:30 SESSION 5

IMPLEMENTATION OF RISK MINIMISATION MEASURES

Omar Aimer

- Key updates on RMM implementation in GVP Mod XVI Rev 3
- Practical considerations in planning RMM implementation and strategy
- Working with health care systems in different countries
- Oversight of RMM implementation and compliance

16:00 BREAK

16:30 SESSION 6

MEASURING EFFECTIVENESS

Mark Perrott and Anita Volkers

- The effectiveness measurement challenge
- Do the FDA and EMA approaches conflict or align
- Aligning risk management objectives with measures of effectiveness
- What are the regulatory expectations at submission and beyond

17:30 END OF DAY 2

DAY 3

13:00 SESSION 6 CONT.

MEASURING EFFECTIVENESS

Anita Volkers and Mark Perrott

- PASS Studies
- Potential for digital tools to provide new approaches
- Specific interventions and their measurement, e.g. Valproate

13:30 SESSION 7

RISK MINIMISATION MEASURES FINDINGS FROM ASSESSOR'S PERSPECTIVE

Anita Volkers

- Digital access/dissemination
- RM control tools
- Barriers and enablers of effectiveness (qualitative data)

14:30 BREAK

15:00 SESSION 8

EVOLVING LANDSCAPE AND FUTURE OUTLOOK

Anita Volkers, Omar Aimer and Mark Perrott

- Future trends in RMM implementation
- Common implementation barriers
- Future digital approaches / platforms for risk management and implications
- Open forum for participant insights and experiences

16:00 SESSION 9

GROUP WORK PART 2

17:00 Q&A

17:30 END OF VIRTUAL LIVE TRAINING COURSE

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REGISTRATION FORM

RMMs Virtual Live Training Course # 26550
27-29 October 2026 | 13:00-17:30 CEST

DIA LEARNING

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