July 14 2026, · 9:00 a.m. – 12:00 p.m.
Virtual Training

AKADEMIE HEIDELBERG

Beyond the Risk Management Plan

Additional Risk Minimisation Measures and Due Diligence

Interactive Training

- Risk minimisation across the product lifecycle
- Routine vs. additional RMMs: European regulatory background
- Types and implementation of aRMMs: Educational materials, checklists, patient agreements; design, approval, distribution, and oversight
- Governance and regulatory roles: Responsibilities of MAHs and authorities, monitoring, and effectiveness evaluation
- Examples: Thalidomide analogues, endothelin receptor antagonists

Speaker

Dr. Marion Müller
Scientific Advisor
AH Akademie für Fortbildung Heidelberg GmbH
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Program

Introduction to Risk Minimisation in Pharmacovigilance

- Role and relevance of risk minimisation throughout the medicinal product lifecycle
- Regulatory framework in the EU: GVP Module V (RMP) and Module XVI (aRMMs)
- Purpose, structure and limitations of the Risk Management Plan

Routine vs. Additional Risk Minimisation Measures

- Definition and examples of routine risk minimisation measures
- Criteria and regulatory triggers for additional risk minimisation measures
- Distinction between regulatory documentation and operational implementation

Types and Implementation of Additional Risk Minimisation Measures

- Overview of aRMMs: educational materials, checklists, patient agreements, controlled access tools
- Design, approval and distribution requirements
- Practical considerations for implementation and compliance

Governance, Roles and Oversight

- Responsibilities of Marketing Authorisation Holders, healthcare professionals and patients
- Role of authorities (EMA, PRAC, national competent authorities)
- Monitoring, control mechanisms and effectiveness evaluation

Case Study: Pregnancy Prevention Programmes (PPPs) and Controlled Distribution Systems (CDS)

- Regulatory expectations and guidance
- Structure of PPPs, including obligations for prescribers, pharmacists and patients
- Examples: Thalidomide, lenalidomide, pomalidomide and endothelin receptor antagonists

Aims and Objectives

The aim of this seminar is to provide participants with a solid understanding of the regulatory requirements and practical implementation of risk minimisation measures (RMMs) within pharmacovigilance. In addition to routine RMMs, such as the Summary of Product Characteristics and Package Leaflet, the seminar focuses on additional risk minimisation measures (aRMMs), which are often required for higher-risk medicinal products.

A particular emphasis is placed on the complex implementation of Pregnancy Prevention Programmes (PPPs) for teratogenic substances. Using a case study based on thalidomide analogues and endothelin receptor antagonists, the seminar illustrates regulatory expectations, practical challenges, and effective solutions for designing and implementing PPPs.

The objective is to enable participants to systematically identify risks, plan appropriate risk minimisation measures, implement them in a regulatory-compliant manner, and evaluate their effectiveness.

Worth Knowing

Who should attend

From practice, for practice!
This seminar is specifically aimed at:

- Professionals in pharmacovigilance, regulatory affairs, and quality assurance
- Medical specialists, e. g., Drug Safety Physicians
- Staff in Market Access, Medical Affairs, and Patient Advocacy
- Individuals involved in the planning, implementation, or evaluation of risk minimisation measures
- Beginners interested in practical safety communication
- Other relevant departments or functions, including senior management, board members, and external auditors

Reasons to Join

- Gain up-to-date knowledge on specific requirements for risk minimisation in pharmacovigilance
- Receive immediately applicable guidance and practical tips for your organisation
- Discuss open questions relevant to your team or company directly with the trainer
- Benefit from valuable practical insights through experience sharing and peer exchange

Our Speaker

Dr. Marion Müller
Scientific Advisor AH Akademie für Fortbildung Heidelberg GmbH Heidelberg

Dr. Marion Müller is a pharmacist with several years of experience at the Federal Institute for Drugs and Medical Devices (BfArM), where she worked as a pharmacovigilance scientist while completing an experimental doctoral thesis with a regulatory focus. Subsequently, Dr. Müller worked as a consultant in the fields of pharmacovigilance and medical information, collaborating with pharmaceutical companies, contract research organisations (CROs), universities, recruitment agencies, and IT service providers.
From 2018, Dr. Müller joined Novartis, where she led global risk minimisation strategies for teratogenic phthalimides and played a key role in establishing an independent generics safety organisation. She also contributed her expertise to the IMI ConcePTION project.
Currently, Dr. Müller serves as a Scientific Advisor at the Heidelberg Academy, supporting strategic initiatives in regulatory science, pharmacovigilance, and interdisciplinary training.

Pharmarecht kompakt: Praxiswissen für Zulassung, Sicherheit und Vertrieb
4./5. Februar 2026, Online-Veranstaltung

Klar, souverän und selbstbewusst
9. Februar 2026, Online-Veranstaltung

Rechtliche Grundlagen für KI-basierte MedTech-Lösungen
11. Februar 2026, Online-Veranstaltung

Pharmacovigilance in Clinical Trials: A European and DACH Perspective
20. Februar 2026, Online-Veranstaltung

Verträge in der klinischen Forschung: Arzneimittel und Medizinprodukte
24./26. Februar 2026, Online-Veranstaltung

MedDRA – Hands-on
6. März 2026, Online-Veranstaltung

Programme aus dem EMA-Dschungel mit PV-Relevanz
19. März 2026, Online-Veranstaltung

▶ This and other seminar offers can be found online on our website: *www.akademie-heidelberg.de/online-seminare*

Further Information

I am happy to answer your questions about this seminar, in-house trainings and our entire program.

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Registration form

Beyond the Risk Management Plan

First name

Name

Position / Department

Company

Adress

Postal Code / City

Telefone

E-Mail

Assistant's name

Date / Signature

Kindly send your regsitration to: **anmeldung@akademie-heidelberg.de**

Date and Time

Tuesday, July 14 2026
9:00 am to 12:00 pm
Online access from 8:45 am
Seminar code: 2607PS707W

Fee

€ 490,– (plus VAT)

The fee includes access to the seminar as well as the presentation as a PDF file. After the seminar, you will receive a certificate confirming your attendance.

General Terms and Conditions

Our general terms and conditions apply (as of 01.01.2010). If you wish, we can send these to you. An English version is available upon request.You can also view our general terms and conditions at any time on our website: www.akademie-heidelberg.de/agb

Procedure

- One day prior to the seminar you will receive an email with a link giving you direct access to the online seminar.
- In order to participate, you do not need to download and install any program. You can dial in directly via Zoom using your internet browser.
- You can ask questions at any time and discuss them with the speakers and other participants via your microphone and camera. Alternatively, you can use the chat to communicate.

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