February 19 2026, · 9:00 a.m. – 12:00 p.m.
Virtual Training

AKADEMIE HEIDELBERG

Pharmacovigilance Agreements

Interactive Training

- Practice-oriented introduction to pharmacovigilance contracts: when they are required and why they are crucial for compliance
- Overview of contract types and their use in different cooperation models within the pharmaceutical industry
- Key contractual elements including role allocation, reporting timelines, audit provisions, and safety data management
- Case studies to directly apply the acquired knowledge in practice

Speaker

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

Pharmacovigilance Agreements

Program

Introduction and Legal Framework

- Relevance of contracts in pharmacovigilance
- Overview of legal and regulatory foundations

When Are Pharmacovigilance Contracts Required?

- Typical use cases:
  - Contract manufacturers/service providers
  - Licensor/licensee relationships
  - Distribution and co-marketing partners
  - M&A and due diligence situations
- Legal and regulatory requirements
- Practical examples

Which Types of Contracts Exist?

- Differences between PVAs, Safety Data Exchange Agreements (SDEAs), and Technical Agreements
- Contract types by cooperation model (e.g. local vs. global, bilateral vs. multilateral)

What Should Be Included in a Pharmacovigilance Contract?

- Key elements:
  - Roles and responsibilities
  - Reporting timelines and communication pathways
  - Audits and inspections
  - Safety data and signal management
  - Accountability and escalation procedures
  - Contract duration, termination, and transition arrangements
- Best practices and common pitfalls

Challenges and Lessons Learned from Practice

- Frequent issues during implementation
- Collaboration with Legal, QA, and partners
- Risk minimization strategies

Reasons to Join

- Gain up-to-date know-how on specific requirements for pharmacovigilance contracts
- Receive immediately applicable implementation tips for your organization
- Clarify open questions relevant to your role or company directly with the
- Benefit from valuable practical insights through experience exchange

Aims and Objectives

The aim of this seminar is to provide participants with a practical introduction to the contractual fundamentals and requirements of pharmacovigilance. Contracts governing medicinal product safety—so-called Pharmacovigilance Agreements (PVAs)—are a central component of regulatory compliance in the pharmaceutical industry. During the seminar, participants will learn in which situations such contracts are required, which types of contracts exist, and how they are applied depending on the respective cooperation model (e.g. licensing agreements, contract manufacturing, co-marketing). In addition, the seminar provides a solid understanding of the typical contents of a PVA, including the allocation of roles and responsibilities, reporting timelines, provisions on signal management, audits, and other minimum contractual requirements in accordance with GVP. Through interactive exercises using realistic case studies and contract excerpts, the acquired knowledge is directly transferred into practice. Participants will thus be enabled to confidently classify, understand, and critically assess PVAs—both from an operational and a strategic perspective.

Who should attend

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

- Professionals working in pharmacovigilance, e.g. PV officers, QPPVs, safety scientists
- Specialists from Regulatory Affairs and Quality Assurance (QA)
- Contract managers who review or draft safety-related agreements
- Project managers, business development and alliance managers with cooperation responsibilities
- Professionals new to pharmacovigilance with an interest in regulatory and contractual fundamentals
- Other interested specialist or policy-related departments, managing directors/ board members, and external auditors

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

Pharmacovigilance Agreements

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

Thursday, February 19 2026
9:00 am to 12:00 pm
Online access from 8:45 am
Seminar code: 2602PS708W

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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01.26 / 26.02.PS708