PHARMIG ACADEMY AM PULS.

Foundations of Drug Safety and Pharmacovigilance (PV)

22.09.2026 | 09:00-18:00 UHR
23.09.2026 | 09:00-17:45 UHR

PROGRAM DAY ONE 22.09.2026

09:00-09:20	**Welcome & Introduction**	*Lisbeth Andersen*
09:20-10:15	**Regulation & Guidelines** This session provides an overview of the European and Austrian pharmacovigilance regulatory framework, key legislation, and current guidelines governing medicinal product safety monitoring.	*Jan Neuhauser*
10:15-10:30	**Coffee Break**	
10:30-12:00	**QPPV Role and Responsibility, PV System Master File** This session focuses on the role of the QPPV and the importance of the PSMF within a company's pharmacovigilance system.	*Martina Friedl*
12:00-13:15	**Lunch**	
13:15-14:25	**Handling of Individual Case Safety Report (ICSR), MedraCoding** This session introduces participants to the principles of ICSR processing, including regulatory definitions, MedDRA Coding principles, and practical case examples.	*Lisbeth Andersen*
14:25-15:30	**Product Safety Information** This session provides an overview of the key documents, tools, and regulatory procedures used to communicate safety-related information about medicinal products to healthcare professionals and patients.	*Sabine Rußler*
15:30-15:45	**Coffee Break**	
15:45-16:45	**Workshop: ICSR Case Processing in Groups** A practical workshop where participants work in small groups on real-life case scenarios to apply the knowledge acquired during the ICSR session.	*Lisbeth Andersen*
16:45-17:30	**Wrap-up & Questions** Summary of key takeaways, discussion, and open Q&A session.	*Lisbeth Andersen*
17:30-18:00	**Networking**	

PROGRAM DAY TWO

23.09.2026

	Summary of Day One	*Lisbeth Andersen*
09:00-09:30	**The PHARMIG Network PV** Overview of the PHARMIG Pharmacovigilance Network and its role in facilitating collaboration and knowledge exchange within the PV community.	*Michael Kunze*
09:30-10:45	**Introduction to Safety in Clinical Trials, Performance Studies, and Medical Devices** Introduction to safety responsibilities related to Investigational Medicinal Products (IMPs), In Vitro Diagnostics (IVDs), Medical Devices (MDs), and Combination Products, including the applicable regulatory requirements.	*Marianne Kaniak*
10:45-11:00	**Coffee Break**	
11:00-12:00	**Periodic Safety Update Reports (PSURs)** This periodic re-evaluation of the benefit-risk ratio of medicinal products represents one of the fundamental pillars of drug monitoring. The procedure is presented using practical examples and relevant guidelines are discussed.	*Jan Neuhauser*
12:00-13:00	**Signal Management** Practical introduction to signal management, including signal detection, validation, assessment, prioritization, and regulatory processes for managing potential safety risks.	*Britta Kuhn*
13:00-14:15	**Lunch**	
14:15-15:10	**PV Interfaces** Overview of the cross-functional collaboration between Pharmacovigilance and key departments such as Regulatory Affairs, Quality, Medical Affairs, and Commercial.	*Marianne Kaniak*
	PV Partnerships & Agreements Introduction to different types of pharmacovigilance partnerships and agreements, including key elements, responsibilities, and best practices for PV Agreement management.	*Regina Lauer*
15:10-15:20	**Coffee Break**	
15:20-16:25	**PV Inspections: RA Perspective & Industry Preparation** This session provides practical guidance on pharmacovigilance inspection readiness, including regulatory expectations, inspection processes, and effective management of inspection findings and CAPAs.	*Elena Rodionova*
16:25-17:30	**Introduction to Artificial Intelligence in Pharmacovigilance** Insights into the use of Artificial Intelligence in pharmacovigilance, including practical examples and responsible AI implementation in daily PV activities at Pfizer.	*Sergiy Kryvych*
17:30-17:45	**Wrap-up & Questions** Summary of key takeaways, discussion, and open Q&A session. Lisbeth Andersen / Pfizer Corporation Austria	*Lisbeth Andersen*

SPEAKERS

Lisbeth Andersen
Country Safety Lead, Pfizer Corporation Austria Gesellschaft m.b.H.

Martina Friedl
Head of PHV, EU-QPPV,
Gebro Pharma GmbH,

Marianne Kaniak
Global Safety Manager,
Amgen GmbH

Sergiy Kryvych
Senior Drug Safety Officer, Medical Advisor, and Deputy Graduated Plan Officer,
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Britta Kuhn
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Regina Lauer
Head of International Pharmacovigilance,
QPPV, EVER Neuro Pharma GmbH

Jan Neuhauser
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Elena Rodionova
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Sabine Russler
RA Manager,
AOP Orphan Pharmaceuticals GmbH

KEYFACTS:

- Hybrid Event (onsite at Pharmig Academy Vienna & online)
- Intensive 2-day training programme
- Course language: English
- Ideal for professionals new to Pharmacovigilance
- 9+ expert speakers from industry & authorities
- Hand-on Workshop & AI Insights
- Pharmig-Member: EUR 1.719,00 p.p.
- Regular Fee: EUR 1.889,00 p.p.

All prices excl. MwSt

YOUR BENEFITS:

- Build a strong foundation in PV and Drug Safety
- Gain practical knowledge you can immediately apply in your daily work.
- Navigate European and Austrian PV requirements with greater confidence.
- Learn from leading experts from industry and regulatory authorities
- Enhance your inspection readiness through real-world examples and best practices.
- Discover innovative approaches, including the use of AI in PV

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