

DRUG REGULATORY AFFAIRS UPDATE

TRAINING COURSE 2026 in 2 MODULES /Online

DRA Course - Online, 09 of October 2026 - Start 1 PM



MODULE 1 - **SPEAKERS & MODERATORS**



Galyna Cordero, MD QPPV & Head of Pharmacovigilance, Farmak JSC (Ukraine)

Galyna Cordero is a medical doctor and experienced pharmacovigilance professional with over 15 years of expertise in drug safety. Since 2011, she has served as Qualified Person Responsible for Pharmacovigilance (QPPV) and Head of Pharmacovigilance at Farmak JSC, one of Ukraine's leading pharmaceutical companies. She specializes in establishing, managing, and auditing pharmacovigilance systems in compliance with EMA, FDA, and EAEU requirements. She has conducted more than 20 pharmacovigilance audits, covering regulatory compliance, risk management, corrective and preventive actions (CAPA), and inspection readiness.

Galyna is also an expert in applying artificial intelligence and machine learning to pharmacovigilance. She has implemented validated AI solutions for adverse event processing, signal detection, literature monitoring, and regulatory medical writing, including PSURs, PBRERs, RMPs, and DSURs. Her work focuses on AI validation, regulatory compliance, data integrity, human oversight, and inspection readiness under EU and international guidelines. Her guiding principle is "AI accelerates, the QPPV remains accountable." She is fluent in English, Ukrainian, and Russian.



Viola Macolic Sarinic is a medical doctor specializing in clinical pharmacology, with a PhD in Pharmacogenomics applied to Biosciences and a master's degree in clinical pharmacology (pharmacokinetics). With over 20 years of experience, she has held various roles in clinical pharmacology and pharmacovigilance. Viola has worked in university hospitals and the Croatian medicines regulatory authority, HALMED, serving as a clinical and pharmacovigilance assessor, Head of the pharmacovigilance department, national PRAC and CHMP member, and director of HALMED, overseeing its integration into the EU medicines network upon Croatia's accession to the European Union.

Following her tenure at HALMED, Viola spent two years as a national expert on secondment at the European Medicines Agency (EMA) in London, primarily in the scientific advice office. She then joined the World Health Organization (WHO) headquarters in Geneva, Switzerland, where she contributed to strengthening pharmacovigilance activities within the regulatory systems of low and middle-income countries (LMICs).

Returning to the EMA in 2019, now based in Amsterdam, Viola serves as the PRAC Scientific Committee Lead and Scientific Adviser on the safety of medicines in the Pharmacovigilance office. Her extensive expertise spans clinical pharmacology, pharmacovigilance, and regulatory affairs.



Dessislava Ilieva -Tonova is a highly experienced pharmaceutical regulatory professional and pharmacist with extensive expertise in pharmacovigilance, clinical trials, market surveillance, pharmaceutical analysis, and regulatory inspections. She currently serves as Head of the Pharmacovigilance and Clinical Trials Control and Inspections Division at the Bulgarian Drug Agency, following senior roles as Chief Inspector and Chief Expert within the Agency. She holds a PhD in Pharmaceutical Analysis and a Master of Pharmacy from the Medical University of Sofia.

Her professional expertise is complemented by significant involvement in European and national regulatory bodies. She represents Bulgaria in the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH), the Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care, and the Good Clinical Practice Inspectors Working Group. She is also a member of the Expert Council on Narcotic Drugs at the Bulgarian Ministry of Health and has authored and co-authored numerous scientific publications in the fields of pharmaceutical quality control, clinical trials regulation, medicinal product surveillance, and pharmaceutical analysis.



Valentin Kopanarov, MPharm holds a Master of Science in Pharmacy from the Medical University in Sofia, Bulgaria. Building on a three-year foundation as a pharmacist, he has more than eight years of pharmacovigilance experience, both with clinical trials and with marketed products. His therapeutic expertise spans nervous system, digestive system, dermatology, hematology, infectious/parasitic diseases, oncology and rare diseases. Valentin joined a leading global contract research organization in 2012 as a Drug Safety Specialist. Through a series of increased levels of responsibility including the roles of Senior Safety Specialist, Principal Safety Specialist, Manager Pharmacovigilance, Senior Manager Pharmacovigilance, Valentin assumed his current role of Associate Director Pharmacovigilance in Aug 2018