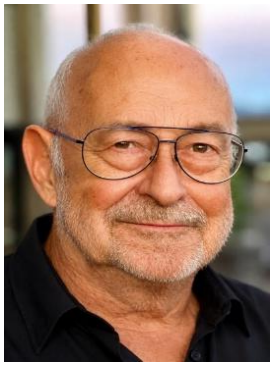
DRUG REGULATORY AFFAIRS UPDATE

TRAINING COURSE 2026 in 2 MODULES /Online

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

MODULE 1 - SPEAKERS & MODERATORS



Dr. rer. nat. Axel Thiele is a chemist and internationally recognized expert in pharmacovigilance, risk management, and regulatory inspections, with decades of experience at Germany's Federal Institute for Drugs and Medical Devices (BfArM) and its predecessor, the Federal Health Authority. He served as Director and Professor, Head of the Unit for Risk Management Procedures and Pharmacovigilance Inspections, and Deputy Head of the Pharmacovigilance Department. He also represented Germany in the European Pharmacovigilance Inspectors Working Group and has contributed extensively to the development and implementation of national and European pharmaceutical legislation.

Dr. Thiele has more than 25 years of experience in pharmacovigilance training and has provided expert support to pharmaceutical companies, national competent authorities, and international regulatory cooperation programmes across Europe and the Middle East. He has performed more than 100 pharmacovigilance inspections as German lead inspector and more than 150 pharmacovigilance audits worldwide involving marketing authorisation holders and pharmacovigilance service providers. In addition to his work as a senior pharmacovigilance expert, consultant, and auditor, he has served as an assistant lecturer at several leading German universities,

including the University of Bonn, Humboldt University of Berlin, Beuth University Berlin, and Philipps University Marburg.

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

Prof. Tatyana Benisheva is a president of Bulgarian Association for Drug Information (BADI) . She is a medical doctor and graduated from the Bulgarian Medical University – Sofia, Bulgaria. Since 2010 and she is a professor in the Faculty of Public Health at Medical University – Sofia, Bulgaria. After receiving an EC-CADREAC scholarship she completed Master' degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn/Germany and later in 2010 a Master degree in "Public Health" at the Medical University - Sofia, Bulgaria.

She was a Director of the "Drug Policy" Department at the Ministry of Health (2000-2005) and has over 10 years of experience at the Bulgarian Drug Agency (BDA) and 3 years experience at the Health Committee and Sport at the Bulgarian Parliament (38 National Assembly in Bulgaria).

As the first president of the National Council on Prices and Reimbursement of Medicinal Products (national competent authority on prices, HTA and reimbursement) 2013-2014 she started an EU-project-OPAC for establishing of electronic database of medicines..

Managing director of pharma consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) where she developed activities at the global regulatory database IDRAC of the Thompson Reuters (2006-2012).

She was involved like an expert in the project of the European Commission - PLAC assignment of medicinal product for pricing in Serbia, in 2016 and in EU project for pricing and reimbursement in Bulgaria. (2019-2021).

Her 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal products) is complemented by more than 100 publications in the regulatory science field of medicines.

At the moment she is full time professor at the Medical Universiry – Sofia Bulgaria in drug regulatory affairs in Masters – Pharmaceutical Management and Management of Clinical Trials.

Since 2023 she has been a member of the Central Ethic Committee for Clinical Trials at the Ministry of Health and is a member
of MedEthics EU.

Prof. Benisheva was a member of the EAMEA, Advisory council at the DIA in Europe. She is stil a member of DGRA and many national organisations.