

15th

BULGARIAN ASSOCIATION FOR DRUG INFORMATION



Under the motto **“MEET THE REGULATORS“**
Regulatory Affairs Update Congress
09 October 2025

**Grand Hotel Millennium - Sofia, Bulgaria, Hall
daVinci, 89B Vitosha Blvd.**

SPEAKERS
MODERATORS



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SPEAKERS



Bogdan Kirilov

Executive Director of the Bulgarian Drug Agency from August 2018

Deputy Executive Director of the Bulgarian Drug Agency from November 2017 to August 2018.

Master degree in Pharmacy from Faculty of Pharmacy, Medical University, Sofia. Master degree in Public Health from Faculty of Public Health Medical University, Sofia.

PhD of Medical University, Varna.

Eight years' experience in Pharmaceutical industry in different positions



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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Emer Cooke, Executive Director of the European Medicines Agency (EMA)



Emer Cooke began her mandate as Executive Director of EMA on 16 November 2020.

Ms Emer Cooke has over 30 years of experience in international regulatory affairs, with more than 18 of these in leadership roles. Before taking up her current role, she was the Director responsible for all medical product related regulatory activities at the [World Health Organization](#) (WHO) in Geneva between November 2016 and November 2020.

Ms Cooke worked at EMA between 2002 and 2016. She joined the Agency as Head of Inspections and became Head of International Affairs in 2009.

Prior to that, she was Principal Administrator in the Pharmaceuticals Unit of the European Commission between 1998 and 2002, with responsibility for inter alia, inspections, international activities including enlargement of the EU and selected legislative initiatives.

Ms Cooke worked for the [European Federation of Pharmaceutical industries and Associations](#)

(EFPIA) as Manager of Scientific and Regulatory Affairs from 1992 to 1995 and part time from 1996 to 1998. She also worked part time as an independent pharmaceutical policy advisor, based in the Czech Republic, from 1996 to 1998. Ms. Cooke held a number of roles within the Irish pharmaceutical sector between 1985 and 1990 including two years as a pharmaceutical assessor at the Irish medicines regulatory authority.

Ms. Cooke holds a degree in pharmacy and two master's degrees in science and in business administration from Trinity College Dublin, Ireland. She is an Irish national.



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SPEAKERS



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 University – 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 still a member of DGRA and many national organisations.



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Christa Wirthumer-Hoche

Former **Head of the Austrian Medicines and Medical Devices Agency, and former Chair EMA Management Board**

Dipl. Ing. Dr Christa Wirthumer-Hoche studied biochemistry and graduated at the Technical University, Vienna in 1981, she did her doctoral thesis at the Institute for Medical Physiology, graduating in 1983. She joined the Austrian National Institute for Quality Control of Drugs in 1983 until May 1998, focusing on the assessment of quality documentation. From June 1998 until December 2005 she was the Head of the Licensing Division for medicinal products at the Austrian Federal Ministry of Health and Women. With the foundation of the new Austrian Agency for Medicinal Products 1 January 2006, her position was Head of the Unit for Marketing Authorisation and Lifecycle Management of Medicinal Products, and from 2013 - 2023 she was Head of the Austrian Medicines and Medical Device Agency at AGES Austrian Agency for Health & Food Safety. She retired from this position on April 1, 2023.

Since her retirement, she is an external expert for the Ministry of Health on questions in relation to the Pharmareview.

She is a member of the Scientific Advisory Board of the BfArM, and for the period (01/2022 - 12/2025) elected chair of the group. Since 1994 she has been involved in different European committees and working groups (Quality Working Party, the Committee for Human Medicinal Products CHMP, MRFG, Notice to Applicants Group, in the PERF project). She was the Austrian delegate for the Coordination Group – Mutual Recognition and Decentralised Procedure human (CMDh), and also the chair of the Joint Working Group on ASMF- procedures. In Dec.1999 she was appointed by the European Commission as Co-ordinator for the CTD Implementation in Europe (ICH-IWG).

As Head of the Austrian Agency she was a member of the Heads of Medicines Agency Group (HMA), member of the EMA-Management Board - and from 2016 - 2022 elected chair of the EMA-MB. Together with EMA she was co-chairing the EU-Network Training Centre (2014 - 2023). She was and is a frequent speaker at numerous international and European meetings. Further she is a lecturer for post-graduate studies "Master of Regulatory Affairs" at the University in Vienna (Austria), in Bonn (Germany) and Copenhagen (Denmark), and for the Master study "Development and life cycle management of medicinal products" at the University in Innsbruck (Austria).





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Prof. Barbara Sickmueller



President of the German Society for Regulatory Affairs (DGRA) is a pharmacist. She studied and obtained her doctorate at the Philipps University in Marburg - Germany (1967-1974).

From 1977 she worked as a scientific executive at the Association of the German Pharmaceutical Industry (BPI) and took over the section "Drug Safety" of BPI in 1979. 1984/1985 she had a sabbatical year in the USA with training into US drug legislation. From 1988 she was appointed as head of the department "Medical affairs" and from 1997 Director of the Medicines and Pharmacy Division of BPI. In 2000 she was appointed as Deputy Director General of BPI.

Since 1987 until 2011 she gave yearly lectures in the department of Pharmacy, University of Marburg, and was appointed honorary Professor of the University of Marburg/Lahn (Januar 2000). In addition, she gave lectures for the Master of Drug Regulatory Affairs at the University in Bonn. She had further teaching assignments at the Universities of Frankfurt and Heidelberg on Pharmacovigilance and clinical trials, and has published numerous publications and book contributions in these regulatory areas.

The German Ministry of Health appointed her as Member of the Advisory Committee on prescription of pharmaceutical products, the Commission on Medicines for Children and Adolescents (KAKJ) and member of the Board of Trustees of the Institute for Quality and Efficiency in Health Care (IQWiG) and a member of the Board of Trustees of the German Agency for Health Technology Assessment (HTA) at DIMDI.

She was member of several Working Groups of the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization of Marketing Authorization Requirements (ICH) in the areas of pharmacovigilance and clinical trials.

Since March 2012 she has retired and is now active as Senior Scientific Advisor for BPI. Furthermore, she gives lectures on Pharmacovigilance and clinical trials at the Universities in Bonn, Heidelberg and Marburg.

In July 2014 she was appointed President of the German Association for Regulatory Affairs (DGRA) in Bonn and in October 2014 as member of the university council of the University of Applied Sciences of Central Hesse (THM) in Gießen.

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Harald Enzmann, Head of Executive Department: EU and International Affairs, BfArM, and former Chair of CHMP, (EMA)

Dr. Harald Enzmann is a leading figure in European medicines regulation, currently serving as Head of European and International Affairs at the German Federal Institute for Drugs and Medical Devices (BfArM). With a background in medicine from Heidelberg University and advanced training in experimental pathology in the U.S., Dr. Enzmann has held senior roles at BfArM for over two decades, particularly in preclinical pharmacology, licensing, and regulatory strategy. He has been deeply involved in the European Medicines Agency's (EMA) work, having served as Vice-Chair and later Chair of the Committee for Medicinal Products for Human Use (CHMP) between 2016 and 2024. His expertise spans oncology, immunology, toxicology, and international regulatory cooperation.

Beyond his institutional leadership, Dr. Enzmann is recognized for bridging science and regulation, co-authoring over 100 publications and actively contributing to shaping EU regulatory science policy. During his tenure at EMA, he played a central role in evaluating and approving key medicines, including during the COVID-19 pandemic. He is widely respected for his scientific rigor and commitment to harmonizing regulatory standards across Europe, and remains a prominent voice in advancing transparent and efficient medicine approval processes on both national and EU levels.

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Lyubina Todorova

Director of Marketing Authorisation Department of Medicinal Products; Bulgarian Drug Agency (BDA) CHMP Member. Since 2010. Started working at BDA since 2001 and took several different positions including clinical assessors and Head of Department for Control of Blood Transfusion System. Member of COMP 2017 – 2023.

Member of CHMP since September 2023 and Rapporteur /Co-Rapp for several procedures.

Scientific background: Human medicine (1991), Certified Physician in Internal diseases (1997) and Clinical Haematology (2001).

PhD in Pharmacology in 2018 (Sofia Medical University, Department of Pharmacology and Toxicology)

Commencing 2021 is an Associate Professor in Pharmacology at Burgas University "Prof. Assen Zlatarov".



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MODERATORS

Dr. Birka Lehmann

Senior Expert Drug Regulatory Affairs

Head of Executive Department EU and International Affairs of the Federal Institute for Drugs and Medical Devices (BfArM) since October 2011 till March 2016.

Study of Human Medicines at the Free University Berlin (MD, PhD) and training at the Kinderklinik Norderney.

My working experience includes 9 years preclinical assessment in the division 'Pharmacology and Toxicology' of Federal Health Office. I served as head of unit 'Decentralised Procedure'

(1996-2002) Federal Institute for Drugs and Medical Devices and as deputy head of EU Division (2000-2002) and supported the Committee Human Medicines Products of the European Medicines Agency (EMA) as expert.

From 2002 – 2006 I joined the European Commission, Directorate-General Enterprise and Industry as expert on secondment to in the unit 'Pharmaceuticals' responsible for inter alia Marketing Authorisation and implementation of Clinical Trials Directive.

From September 2006 till October 2011 I was head of the division 3 Marketing Authorisation procedure at the BfArM. Since 2007 I was member of the Paediatric Committee at the European Medicines Agency till end of 2015.

Lecturer: Friedrich-Wilhelm-University Bonn (Master of Drug Regulatory Affairs) since 1999




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MODERATORS

Ekaterina Genova



Ekaterina Genova is a Doctor of Medicine, holding a degree from the Medical University of Sofia. She specialized in Ophthalmology and Neuro-ophthalmology. Dr Ekaterina Genova is a member of the Bulgarian Medical Association since 1999. After several successful years in the Military Medical Academy of Sofia, she joined the pharmaceutical industry, the German company Asta Medica in 1999.

Ekaterina Genova has a long and successful career in the healthcare and pharma industries through which she built an extensive network across the Bulgarian and Eurasian Markets. Since 2007 she has been responsible for the Business Development and Growth of Ecopharm - initiating cooperation with potential partners and building the product portfolio of the company. In 2014 Ekaterina took a year-long course at the Pharmaceutical Faculty in Sofia, which enhanced her knowledge in disciplines such as analysis, testing, pharmaceutical chemistry and technology which helped her to understand the end-to-end process of drug manufacturing. She was leading both the Business Development and Regulatory Departments of Ecopharm, and built the pharmacovigilance department of Ecopharm, including the whole pharmacovigilance system and processes.

Since 2014, Ekaterina has been a QPPV of Ecopharm. She is legally responsible for the safety of all medical products that the company sells and also acts as a single point of contact for EMA.

Throughout the years, Ekaterina has been both a participant and a lecturer at various courses and events related to the regulation of drugs and medical devices held by BADI, EMA, DIA and as well as other organizations. In 2016 she gained a Diploma in Health Management from the Medical University of Sofia. In 2017, after years of experience both as a doctor and a lead in the pharmaceutical industry, Ekaterina decided to set up her own consultancy company. She has been advising start-ups and working on transformational projects for other companies, focusing innovation and technology in the healthcare sector. She has the ability to build the “big picture” and be seen as a trusted advisor.



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Lena Gebert, M.D.R.A.
Regulatory Affairs Consultant

Lena Gebert is a Clinical Regulatory Strategist with 20+ years of experience in drug development and deep expertise in oncology, immuno-oncology, and hematology. She has held senior leadership roles, including Vice President and Head of Global Regulatory Affairs at Full-Life Technologies GmbH and Global Regulatory Program Lead at Merck Healthcare KGaA. Earlier in her career, she worked at Wyeth Pharma and Germany's Paul-Ehrlich-Institut, where she represented the agency at key EU regulatory bodies. Today, she consults globally on clinical development and regulatory strategy for pharmaceutical and biotech companies.

Lena holds a pharmacy degree from Heinrich Heine University Düsseldorf, a Master's in Drug Regulatory Affairs from the University of Bonn, and additional qualifications in Clinical Pharmacology and Drug Information.




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MODERATORS

Brigitte Franke-Bray



Brigitte Franke-Bray (MD PhD), FFPM RCP UK, GFMD (IFAPP), Board Member and Treasurer of IFAPP (ifapp.org), Member of the Advisory Boards of the IFAPP Academy (ifappacaemy.org) and of ECPM (ecpm.ch) Basel, CH, is an independent consultant and a board-certified specialist in Pharmaceutical Medicine (PM, FMH/Switzerland). After her medical studies she worked for several years in a German hospital (Internal Medicine, Pneumology, Allergology). After 10 years' work as an international medical expert for respiratory diseases in Ciba-Geigy/Sandoz, Basel, Switzerland, she became the first office head/medical director for Quintiles in Switzerland and also headed two more Quintiles offices in Germany.

After about 8 years Brigitte worked as Medical Director for two Swiss companies before she joined the DIA (Drug Information Association) as the Director Europe, Middle East, Africa where she was also responsible as the global Training Director for the development of scientific congresses and training courses in Pharmaceutical Medicine which she designed in collaboration with virtually all regulatory medicines agencies on a global level. Eight years later she became a clinical reviewer with the Swiss Medicines Regulatory Agency, Swissmedic, and finally a globally acting Medical Director in Novartis Basel, responsible for the development of medicines in respiratory diseases.

For 22 years Dr Franke-Bray was a board member of the two Swiss societies in Pharmaceutical Medicine, SGPM and SwAPP, and organised their annual symposium for 20 years. Dr Franke-Bray is also a member of the examination committee of the University of Basel, Switzerland, for the board certification of physicians in PM as well as of various other related Basel University diplomas and certificates, e.g. for ECPM, the European Course in PM.

Dr Franke-Bray collaborated in two of the EU Commission's IMI (Innovative Medicine Initiative) projects, PharmaTrain and EUPATI, where she deepened her knowledge of training course development in PM.




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Anne-Louise Kirkegaard



is a seasoned Regulatory Affairs expert with over 25 years of experience in the life sciences industry. Currently, she serves as the Director of Regulatory Affairs and Principal Pharma Consultant at Pharma IT in Copenhagen. Throughout her career, she has held various leadership roles, including Director of Regulatory Affairs at FluoGuide A/S and VP of Regulatory Affairs at Cyxone AB. Her expertise encompasses regulatory strategic and operational support for startup biotech companies, where she has successfully managed teams and led projects that have advanced drug development and market access.

Anne-Louise holds a Master of Drug Regulatory Affairs from the University of Bonn and an MSc in Pharmacy from the Royal Danish School of Pharmacy. Her academic background is complemented by her extensive practical experience, including significant positions at Novozymes, Galenica AB, and LEO Pharma A/S. Her work has focused on regulatory compliance and pharmacovigilance, ensuring that companies navigate complex regulatory landscapes effectively to bring innovative therapies to market.



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MODERATORS



Deyan Denev CEO

Association of Research-based Pharmaceutical Manufacturers Bulgaria (ARPharM Bulgaria)
Deyan Denev is heading the Association of Research-based Pharmaceutical Manufacturers in Bulgaria since October 2003. He has a legal education from SoWa University and is an expert in pharmaceutical legislation and pharmaceutical policy. As Director of the association he is leading the advocacy activities of R&D pharmaceutical industry in Bulgaria on key issues regarding pharmaceutical policy, regulatory environment, intellectual property, pharmaceutical market development.

He was a member of the Supervisory Board of the National Health Insurance Fund on behalf of the Confederation of Employers and Industrialists in Bulgaria from January 2014 to January 2015. He was a representative of the pharmaceutical industry in the Transparency Commission, which is an appeal body for all pricing and reimbursement decisions in Bulgaria. He is a co-chair of the Central and Eastern European Task Force of EFPIA (European Federation of Pharmaceutical Industries and Associations).