



BULGARIAN ASSOCIATION FOR DRUG INFORMATION

FOUNDATION SKILLS IN DRUG REGULATORY AFFAIRS MAY 30 - 31, 2024 | TRAINING COURSE

Format: in person

Venue: "Prof. Dr. Alexander Chirkov" Hospital
bul. "Pencho Slaveykov" 52, 1431 Sofia Center, Sofia, Bulgaria



Margarita Strokova, MD has master's degree in Medicine from Medical University, Sofia and Master of Business Administration from New Bulgarian University, Sofia. Joined Pharma Industry in 1997 and has extensive experience in pharmaceutical marketing, scientific communication, Medical Governance and Pharmacovigilance (for products both under clinical trials and marketed). Worked for over 13 years as local person responsible for Pharmacovigilance in GSK Bulgaria and 3 years as Local Country Medical Head. Margarita has experience in safety operations (MI and PV) and from September 2021 is part of PharmaLex team.



BULGARIAN ASSOCIATION FOR DRUG INFORMATION



Daniela Cherneva, PhD

graduated from Sofia University “St. Kliment Ohridski” in 2008 with a Bachelor’s degree in Russian philology. In 2011 she graduated from New Bulgarian University in Sofia with Master’s degree in International Business and in June 2015 she obtained a Master’s degree in Public Health and Healthcare Management from the Faculty of Public Health of the Medical University in Sofia. In April 2021 Daniela obtained a PhD in the Faculty of Public Health, Medical University in Sofia with a dissertation on “Challenges in front of the reference pricing of generic medicines in Europe”

She has 16 years of experience in the Regulatory Affairs, currently in the position of Regulatory Affairs Manager in Medochemie Ltd. Bulgaria.

During her professional life she gained broad experience not only in Regulatory Affairs, but also in pricing and reimbursement, market access, pharmacovigilance, life-cycle product management, etc. Daniela has more than 16 publications and conference participations in the field of Regulatory Affairs and is a Management Board Member of the Bulgarian Association for Drug Information (BADI) and the International Society for Pharmacoeconomic and Outcome Research (ISPOR).

danicherneva@gmail.com



BULGARIAN ASSOCIATION FOR DRUG INFORMATION



Radoslava Naydenova – Tunel holds a master's degree in Strategic management of the Pharmaceutical Industry from Medical University, Sofia as well as Bachelor's degree in Linguistics and International relations from Sofia University. She has extensive experience in different areas of pharmaceutical industry gained over the last 15 years in the fields of manufacturing and importation planning, pricing and reimbursement, sales analysis, and pipeline project management.

As a Regulatory Affairs professional she has in-depth knowledge of the local Bulgarian and EU legislation procedures and guidelines governing pharmaceutical products, GMP, GDP, food supplements, medical devices, and cosmetics. For the period of 14 years starting from 2008 until beginning of 2023, she has taken different expert and management positions at Nobel Pharma Bulgaria, last of which Regulatory Affairs Project manager.

Since February 2023 she has joined the pharmaceutical consultancy field as a Senior Manager Regulatory Affairs at PharmaLex with broad span of regulatory interactions with EMA, CMDh and EU national competent health authorities as well as Swissmedic.



BULGARIAN ASSOCIATION FOR DRUG INFORMATION



Valeria Sarbinova graduated Master's degree from the University of Chemical Technology and Metallurgy, Sofia in chemical engineering in 2005.

Her professional experience started as a research and development manager at Ficosota Syntez global department. She started working for Novartis Consumer Health in 2014 as a regulatory and pharmacovigilance manager.

Throughout her professional experience, she had to upgrade her knowledge, skills and qualities in order to adapt to new companies and situations. She worked for Bulgarian companies Salvis pharma, Meditrial internationals and GS Consult Ltd. Valeria has more than 15 years of experience in the pharmaceutical and pharma-related industries field from various perspectives. Since 2021 is working as a consultant in the sphere of regulatory and pharmacovigilance as well as a consultant in good distribution practice for many companies: Vianex S.A, SIFI S.p.A, Galenica S.A., Agarta CM Ltd., Referance Ofta Ltd. Pharma Trade BG, D&Fisher Ltd, Veamed and etc.



BULGARIAN ASSOCIATION FOR DRUG INFORMATION



Lyubina Todorova, MD, PhD in pharmacology

Head of Department for Marketing Authorisation of Medicinal Products at Bulgarian Drug Agency since 2010.

Started working at BDA since 2001 and took several different positions including clinical assessor and Head of Department for Control of Blood transfusion system.

Since 2017 has been working as a member of Committee for Orphan Medicinal Products.

Since September 2023, she is already a representative in the CHMP.



BULGARIAN ASSOCIATION FOR DRUG INFORMATION

Gergana Lazarova

Graduated from the National Gymnasium of Natural Sciences and Mathematics "Academician Lyubomir Chakalov" in 2013. In 2018 graduated Sofia University "St. Kliment Ohridski" as a Master of Pharmacy.

During the studies was part of an internship program in a pharmaceutical laboratory, a volunteer in a science project in the area of pharmaceutical technology that helped in finding the favorite part of the pharmaceutical profession in regulation.

Currently a senior expert in the Department for Marketing authorization of medicinal products at the BDA as well as an alternate member of CMDh and CHMP, and a member of the EDQM Borderline network. Also working on a PhD thesis in Pharmacology in the Medical University – Sofia.





BULGARIAN ASSOCIATION FOR DRUG INFORMATION



Prof. Tatyana Benisheva - Dimitrova, DSc., President of BADI is a professor in the Faculty of Public Health at Medical University, Sofia. After receiving an EC-CADREAC scholarship she completed master's degree in Drug Regulatory Affairs (2004/2005) at the University of Bonn and later in 2010 a Master degree in “Public Health” at the Medical University of 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). As the first president of the National Council on Prices and Reimbursement of Medicinal Products 2013-2014 she started an EU-project-OPAC for establishing of electronic database of medicinal product.

As a managing director of consulting in Bulgaria Betaconsult Pharma Ltd. (2007-2013) 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 medicinal product pricing in Serbia, in 2016. Prof. Benisheva is member of DIA and DGRA and Board member of the EAMEA, Advisory council at the DIA in Europe, since 2017. Her 25 years of experience in drug regulatory affairs (life cycle management and market access of medicinal product) is complemented by more than 100 publications in the regulatory science field of medicines.



BULGARIAN ASSOCIATION FOR DRUG INFORMATION

Prof. Valentina Petkova, DSc, PhD, MPharm., MPH

Prof. Valentina Petkova-Dimitrova, PhD is Vice-Rector for Science and Accreditation of MU-Sofia since 2016. She is Chair of the Council of medical Science. During the period 2012–2016 she was Deputy Dean for Academic Affairs for students studying in English at the Faculty of Pharmacy, MU-Sofia;

In 2015 she obtained the scientific degree of Doctor of Science after defending a dissertation on "Theoretical and applied aspects of the concept of" Pharmaceutical Care "in some specific groups of patients." In 2000 she successfully defended her PhD thesis on the topic "Study of the chronic patient's level of compliance" Master of Public Health and Health Management - PHC, MU-Sofia. She has acquired specialties in hospital pharmacy, clinical pharmacy, organization and economics of pharmaceutical production, organization and economics of pharmacy and distribution practice. Master in Marketing and Management at the Technical University, Sofia. Master of Pharmacy at the Faculty of Pharmacy, MU-Sofia.

She has more than 200 publication in Bulgarian and foreign scientific journals, 10 books and manuals and more than 75 participations in scientific meetings.

She has specialized in Germany (1998), Italy (1999, 2000) and the Netherlands (2006) in the sphere of Biostatistics, Epidemiology, Pharmacoepidemiology, Management and decision making in healthcare, and Pharmaceutical care.

petkovav1972@yahoo.com