DRUG REGULATORY AFFAIRS - update | Training Course | MODULE 2 | November 04, 2022

Pharmacovigilance Regulatory Update, Part II | In-person event

SPEAKERS

BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

Dr. Monika Boos holds a doctor's degree in human medicine (MD, PhD) and a master's degree in pharmaceutical laws (LL.M.). She is an independent consultant with long-time professional experience in pharmacy, hospital, medical practice and the pharmaceutical industry.

Monika's more than 18 years of pharmacovigilance experience have been based on ten years of permanent employments in international pharmaceutical companies comprising extensive hands-on experience and several years of leadership positions (national & international teams, matrix structures, forums including worldwide PV responsibility for established products and development compounds), lastly as German Graduated Plan Officer, Deputy EU QPPV and Head of Corporate Pharmacovigilance.

Monika is founder and owner of BoosConsulting, a company that provides independent, tailored and flexible services for pharma and biotech companies - from short-term support due to sudden resource constraints up to long-term services for products, projects and customers. Based on a proven track record in this area, the special focus is on drug safety / pharmacovigilance; further key areas concern medical devices and pharma law matters.

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Teodora Chachevska
Head of Regulatory Affairs, Quality Assurance and Pharmacovigilance at Woerwag Pharma Bulgaria EOOD.

I have more than 15 years of experience in the field of Regulatory Affairs. I am experienced in the new registrations, maintenance and life-cycle of the medicinal products, food supplements and cosmetics worldwide with emphasis on Europe, non-EU countries, CIS, etc.
My field of expertise is also extended to pharmacovigilance, quality assurance (QA), including wholesale distribution of medicinal products and food supplements.
The experience in the Regulatory affairs field started for me in 2007 at Sopharma AD as Expert Regulatory coordination (CMC and administrative) and was promoted to Manager Regulatory Coordination the same year.
I joined Woerwag Pharma GmbH & Co. KG, branch office in 2012 as Regulatory Affairs Manager, where later widened my skills and expertise in the field of Pharmacovigilance and QA. I developed myself by participating in different international projects within the Pharmaceutical industry.
I have a Master's degree in Chemistry and chemical technologies (2001) from Plovdiv University ang hold a Specialization of Ecology and Pedagogy. After that I completed a Master's degree in Finance at Veliko Tarnovo University (2008) and have a post-graduation Certificate in Pharmacy for non-pharmacists from Medical University Sofia (2009).

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M. Pharm. Todor Darakchiev is a Head of Division "Trade control and supervision" in Department "Market supervision and Inspections" at the Bulgarian Drug Agency (BDA). He has been working in the field of medical devices regulation for more than 18 years after going to work for BDA in 1999. During his career in BDA he gained regulatory experience as a chief expert for issuing of marketing authorizations of medical devices (till 2006) and a chief inspector for medical devices and medicinal products (since 2007). Todor Darakchiev is a member of working groups for medical devices (MDEG and Borderline & Classification) at the European Commission, DG SANCO since 2008. During the same period he participated in the meetings of the Competent Authorities for Medical Devices as a BDA representative. In the period 2005 – 2017 attended at several workshops for medical devices organized by TAIEX. In the beginning of Bulgarian membership in EU he was a member of a working group responsible for transposition of the European legislation for medical devices. In 2011 – 2012 Darakchiev participated in an interdepartmental project ''Creation of digital database of medical devices payed with public resources" as a coordinator.

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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.

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Daniela Cherneva, PhD

Daniela Cherneva 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 13 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 member of the Bulgarian Association for Drug Information (BADI) and the International Society for Pharmacoeconomic and Outcome Research (ISPOR).

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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.