DRUG REGULATORY AFFAIRS - update |

Training Course | 3 modules

MODULE 2 - 03.11.2023

Round Table Discussion - Hot Regulatory Issues |

In person event

SPEAKERS

BULGARIAN ASSOCIATION FOR DRUG INFORMATION

CELEBRATING 10 YEARS ANNIVERSARY

Rumyana Sharenkova, Chem. Eng., graduated the University of Chemical Technology and Metallurgy in Sofia in 1987 with Master's degree in Chemical Engineering and major in Organic Synthesis.

In 1995 she obtained also Master's degree in International Economic Relations at the University of National & World Economy in Sofia. Her professional experience started in the Chemical and Pharmaceutical Research Institute in Sofia in 1988 in the Department of Antibiotics.

In 1991 she obtained Research Associate IIIrd degree in Antibiotics. Since 1995 she has been working in the pharmaceutical business, gaining regulatory experience at the companies Zentiva (1997-2005) as Regulatory Manager and Actavis Bulgaria as Regulatory Affairs Director (2006-2014). In September 2014 she joined the team of Chemax Pharma Ltd as Head of Regulatory Affairs Department.

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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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Radoslava 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.

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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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Assoc. Prof. Lyubina Todorova, BDA

Lyubina Todorova, MD is a Head of Department for Marketing Authorisation of Medicinal Products at Bulgarian Drug Agency since 2010. Shed has more than 15 years experience in pharmaceutical regulatory affairs. She has been working at BDA since 2001 and took several different positions including clinical assessors and Head of Department for Control of Blood transfusion system. Her background is human medicine and has specializations in internal medicine and hematology. She was Bulgarian representative at CAT and CMDh 5 years ago and in 2017 was nominated as a member of Committee for Orphan Medicinal Products.

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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.