



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

DRUG REGULATORY AFFAIRS - update | Training Course 2022 | 3 modules

PROGRAM | MODULE 2 Pharmacovigilance Regulatory Update, Part II November 04, 2022 | In-person event

Venue: Forum Hotel Sofia, 41 Tsar Boris III Blvd./on the corner with "Sofiiski geroi" str.

Moderators: Prof. Tatyana Benisheva, Dr. Daniela Cherneva

Timing	Topic	Speaker
9:00 - 9:50 AM	Registration & Welcome coffee & Networking	
9:50 - 10:00 AM	Welcome & Opening	Prof. Tatyana Benisheva, MU-Sofia, President of BADI
	Session 1	
10:00 - 10:45 AM	Drug shortages - regulatory activities in preparation for and during a public health emergency <i>Discussion (10 mins)</i>	Teodora Chachevska, Woerwag
10:45 - 11:30 AM	Responsibilities of the actors in Medical devices sector. Post market surveillance and vigilance	Todor Darakchiev, Head of division "Medical devices", BDA Margarita Strokova, MD, Pharmalex Vladislav Mirchev, MD
11:30 - 12:15 PM	Pregnancy prevention programs (as part of risk minimization activities) <i>Discussion (10 mins)</i>	
12:15 - 1:15 PM	Lunch break Session 2	
1:15 - 2:00 PM	Signal Management <i>Discussion (10 mins)</i>	Dr. Monika Boos, BoosConsulting
2:00 - 2:45 PM	Artificial intelligence in Pharmacovigilance	Sriram Venkateswaran, Senior Safety Data Scientist, Roche
2:45 - 3:30 PM	Pharmacoepidemiology of COVID-19 <i>Discussion (10 mins)</i>	Prof. Nadka Boyadzhieva
3:30 - 4:15 PM	<i>Test presentation & Answer discussion</i>	Prof. Tatyana Benisheva, Dr. Daniela Cherneva