



**BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)**  
supported by BALI Eventteam

**FOUNDATION SKILLS IN DRUG REGULATORY AFFAIRS**

**MAY 18-19, 2023 | 2-DAY TRAINING COURSE**

**Limited Seating! In person**

**"Prof. Dr. Alexander Chirkov" Hospital (Hall 2)**

<b>TIME</b>	<b>TOPICS</b>	
<b>May 18, 2022</b>		
8.30 – 9.00 AM	<i>Registration &amp; Welcome Coffee</i>	<i>Moderators Prof. Tatyana Benisheva, Daniela Cherneva, PhD</i>
9.00 - 10.30 AM	Introduction In regulatory Affairs regulatory approaches of medicinal products, Regulatory requirements of Medical devices, Food supplements, Cosmetics;	Prof. Tatyana Benisheva, MDRA, MPH, DSci
	Types of Drugs; Molecule to medicine – basic understanding of Clinical trials phases, risk / benefit; Do – Do Not; Classifications, Categories and ATC Code	Margarita Strokova, MD  Rosalina Kulaksazova, M. Pharm.
10.30 -10.45 AM	<i>Networking Coffee Break</i>	
10.45 – 13.30 AM	Competent authorities and Marketing Authorization Procedures; Centralized Procedure (CP); Mutual Recognition Procedure (MRP) Decentralised procedure (DCP), National Procedure (NP)  Renewals, Variations, Authorisation of medicinal products with the established recipe - specifics in Bulgaria. Registration of traditional herbal and homeopathic medicines	Daniela Cherneva, PhD      Assoc. Prof. Lyubina Todorova
13.30 – 14.30	<i>Lunch Break &amp; Networking</i>	
14.30 -15.15	Advertisement – What is promotion, Off-label use; Ethical promotion – Q&A; Discussion	Prof. Valentina Petkova
15.15 – 16.00	Good distribution practice (GDP) and Good manufacturing practice – products complains	Valeria Sarbinova



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<b>May 19, 2022</b>		
9.00 – 10.35 PM	Pharmacovigilance - AE reporting; PSUR, EudraVigilance;	Margarita Strokova, MD
10.30 – 10.45 PM	<i>Networking Coffee Break</i>	
10.45 – 12.00 PM	Product complaints / MI inquiries; Handling enquires;	Daniela Cherneva, PhD
12.00 – 13.30 PM	Market Access – Introduction; Pricing and Reimbursement; HTA – Introduction	Elka Boncheva
13.30 – 14.30 PM	<i>Lunch Break &amp; Networking</i>	
14.30 – 15.30 PM	<i>Discussion &amp; Working in groups; Competency Quiz; Test &amp; Course Evaluation; Certificates;</i>	