



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

**FOUNDATION SKILLS IN DRUG MARKETING AUTHORISATION
PROCEDURES OF MEDICINAL PRODUCTS IN THE EU,
WORKSHARING OF MPS, GMP, GDP**

MAY 30-31, 2024 | 2-DAY TRAINING COURSE

Limited Seating! In person
"St. Ekaterina" Hospital (Hall 2)

TIME	TOPICS
May 30, 2024	
8.30 – 9.00	<i>Registration & Welcome Coffee</i>
9.00 - 10.00	Regulatory affairs approaches of medicinal products, main documents and sources. Types of Drugs; Molecule to medicine – basic understanding of Clinical trials phases, risk / benefit; Do – Do Not; Classifications, Categories and ATC Code.
10.00 – 11.00	Competent authorities and Marketing Authorization Procedures; Centralized Procedure (CP).
11.00 – 11.15	<i>Networking Coffee Break</i>
11.15 – 12.15	Mutual Recognition Procedure (MRP); Decentralised procedure (DCP); National Procedure (NP).
12.15 - 13.30	Decentralised procedure (DCP); Mutual Recognition Procedure (MRP); (Practical experience) Application form for MAS; Worksharing Procedures.
13.30 – 14.00	<i>Lunch Break & Networking</i>
14.00 - 14.45	Good distribution practice (GDP) and Good manufacturing practice – products complains.
14.45 – 15.30	Product complaints / MI inquiries; Handling enquires;



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May 31, 2024	
8.30 – 9.00	<i>Registration & Welcome Coffee</i>
9.00 – 9.45	Pharmacovigilance - AE reporting; PSUR, EudraVigilance;
9.45 – 10.45	Renewals, Variations; Authorisation of medicinal products with the established recipe - specifics in Bulgaria; Registration of traditional herbal and homeopathic medicines.
10.45 – 11.00	<i>Networking Coffee Break</i>
11.00 – 12.00	EMA – Committees – how they work; Orphan Designation.
12.00 – 13.00	Pricing Reimbursement and Market access.
13.00 - 13.30	<i>Lunch Break & Networking</i>
13.30 - 14.30	Advertisement – What is promotion; Off-label use; Ethical promotion; Q&A; Discussion.
14.00 - 15.00	<i>Discussion & Working in groups; Competency Quiz; Test & Course Evaluation; Certificates;</i>