



FOUNDATION SKILLS IN DRUG REGULATORY AFFAIRS

MAY 12 - 13, 2022 | TRAINING COURSE

Format: in person | Venue: Central Hall, Forum Hotel Sofia (41 Tsar Boris III Blvd)

Moderators: Prof. Tatyana Benisheva & Daniela Cherneva, PhD

| TIME | TOPIC | SPEAKER |
|---------------------|--|---|
| May 12, 2022 | | |
| 8.30 - 9.00 AM | <i>Registration & Welcome Coffee</i> | |
| 9.00 - 10.30 AM | Introduction in Regulatory Affairs, regulatory approaches of medicinal products, Medical devices, Food supplements, Cosmetics; Types of Drugs; Molecule to medicine – basic understanding of Clinical trials phases, risk / benefit; Do – Do Not; Classifications & ATC Code; | Prof. Tatyana Benisheva Margarita Strokova, MD |
| 10.30 - 10.45 AM | <i>Networking Coffee Break</i> | |
| 10.45 - 13.00 AM | Competent authorities and Marketing Authorization Procedures; Centralized Procedure (CP); Mutual Recognition Procedure, Decentralised procedure, National Procedure (MRP, DCP, NP); Variations, Renewal; | Daniela Cherneva, PhD Lubina Todorova, MD |
| 13.00 - 13.30 PM | <i>Lunch break</i> | |
| 13.30 - 15.10 PM | Introduction in market assess, Pricing, Reimbursement, HTA - Introduction; Clinical data transparency; | Prof. Tatyana Benisheva Daniela Cherneva, PhD Elka Boncheva Dimitar Dimitrov |
| 15.10 - 15.30 PM | <i>Q&A; Discussion</i> | |
| May 13, 2022 | | |
| 8.30 - 9.00 AM | <i>Registration & Welcome Coffee</i> | |
| 9.00 - 11.15 AM | Pharmacovigilance - AE reporting; PSUR, EudraVigilance; | Margarita Strokova, MD Valentin Kopanarov |
| 11.15 - 11.30 AM | <i>Networking Coffee Break</i> | |
| 11.30 - 13.00 PM | Medical information, SmPC; Product complaints/MI inquiries; Handling enquires; | Daniela Cherneva, PhD |
| 13.00 - 13.30 AM | <i>Lunch break</i> | |
| 13.30 - 14.30 PM | Advertisement - What is promotion, Off –label use; Ethical promotion; | Prof. Valentina Petkova |
| 14.30 – 15.00 PM | Good distribution practice (GDP) | Valeria Sarbinova |
| 15.00 – 15.30 PM | Good manufacturing practice (GMP) | Valeria Sarbinova |
| 15.30 – 16.00 PM | <i>Test/working in groups & Certificates;</i> | |