



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PROGRAM

FOUNDATION SKILLS IN REGULATORY AFFAIRS

Introduction in marketing authorization procedures, market access of medicinal products,
Pharmacovigilance;

Date: April 19, 2019

Moderators:

Prof. Tatyana Benisheva, President of BADI, MU – Sofia

Daniela Cherneva, MU – Sofia

TIME	TOPICS	SPEAKERS
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;	Prof. Tatyana Benisheva
	Types of Drugs;Molecule to medicine – basic understanding of Clinical trials phases, risk / benefit; Do – Do Not; Classifications &ATC Code	MargaritaStrokova Prof. Tatyana Benisheva
10.30 -10.45AM	<i>Networking Coffee Break</i>	
10.45 -12.15 AM	Competent authorities and Marketing Authorization Procedures;Centralized Procedure (CP); Mutual Recognition Procedure, Decentralised procedure, National Procedure (MRP, DCP, NP) Variations, Renewal Medical Information, SmPC;	Prof. Tatyana Benisheva Daniela Cherneva
12.15 – 1.00 PM	Advertisement – What is promotion, Off –label use; Ethical promotion – Q&A;	Prof. Valentina Petkova
1.00 – 1.30 PM	<i>Lunch Break</i>	
1.30 – 3.00 PM	Pharmacovigilance - AE reporting; PSUR, Eudravigilance; Product complaints / MI inquiries; Handling enquires; <i>Discussion &Working in groups</i>	MargaritaStrokova Valentin Kopanarov Daniela Cherneva
3.00 – 3.15 PM	<i>Networking Coffee Break</i>	
3.15 – 4.00PM	Market Access	ElkaBoncheva Prof. Tatyana Benisheva
4.00 – 4.30 PM	<i>Competency Quiz, Test& Course Evaluation, Certificates, Pictures;</i>	

Please note: You will get the certificate by providing your questioner!