



## BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

### PROGRAM 2019

DATE	EVENT
<b>I. WORKSHOP - Free for BADI members 2019</b>	
29.03.2019 (Friday)	Bulgarian Drug Legislation - Update; Advanced therapy medicinal products - Types, EU Regulatory Framework and challenges; Certification by a Qualified Person and Batch Release of medicinal products manufactured outside the EU; Manufacturing: QP main responsibilities and challenges, PIC - Update; Most common GMP non-compliance in Bulgaria;
<b>II. ONE DAY TRAINING COURSE</b>	
08.04.2019 (Monday)	GMP (Good Manufacturing Practice – Добра Производствена Практика), One Day Face to Face Training Course 2019
<b>III. ONE DAY TRAINING COURSE</b>	
19.04.2019 (Friday)	Foundation Skills in Regulatory Affairs, Introduction in marketing authorization procedures, Market access of medicinal products, One Day Face to Face Training Course
<b>IV. CONFERENCE</b>	
06.06.2019 (Thursday)	Patents and Data Exclusivity of Medicinal Products;
	Variations: ▪ View of Industry - Update; ▪ View of Competent Authorities - Update;
	Document Management System of Medicinal Products;
	Oncology development of Medicinal Products – Challenges;
	Medical Devices – Regulation EU 2017/745 - Update;
	HTA changes in Bulgaria and HTA EU Landscape;
<b>V - VII. DRUG REGULATORY AFFAIRS UPDATE TRAINING COURSE</b>	
04.10.2019 (Friday)	<b>Module 1 - Pharmacovigilance - Update</b> ▪ Audits and Inspections
08.11.2019 (Friday)	<b>Module 2 - Pharmacovigilance - Update</b> ▪ Safety - Update ▪ Signal Management - Update ▪ Risk Minimisation Measures - Update
22.11.2019 (Friday)	<b>Module 3 - Regulatory Affairs - Update</b> ▪ Medical Devices - Regulation EU 2017/745 - Update; ▪ Marketing authorisation procedures - variations ▪ Market Access - Pricing, Reimbursement and HTA ▪ Clinical Trials in the EU - Update