

**BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)****DRAFT AGENDA 2019****DATE****EVENT****I. WORKSHOP - Free for BADI members 2019**29.03.2019  
(Friday)Bulgarian Drug Legislation - Update;  
BDA Drug Database - Update;Manufacturing: QP - Introduction, main responsibilities and  
challenges, ICH guidelines, PIC - Update;**II. WORKSHOP**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;

HTA changes in Bulgaria and HTA EU Landscape;

Medical Devices – Regulation EU 2017/745 - Update;

**III - V. DRUG REGULATORY AFFAIRS UPDATE TRAINING COURSE**04.10.2019  
(Friday)**Module 1 - Pharmacovigilance - Update**

- Audits and Inspections

8.11.2019  
(Friday)**Module 2 - Pharmacovigilance - Update**

- Safety - Update
- Signal Management - Update
- Risk Minimisation Measures - Update

22.11.2019  
(Friday)**Module 3 - Regulatory Affairs - Update**

- Medical Devices - Regulation EU 2017/745 - Update;
- Variations - Update
- Market Access - Pricing, Reimbursement and HTA
- Clinical Trials in the EU - Update