



**BULGARIAN ASSOCIATION FOR DRUG INFORMATION  
(BADI)**

**PROGRAM 2023 - Draft version**

**Pro bono event for members**

|                                |  |
|--------------------------------|--|
| <b>March 31, 2023 (online)</b> | <p><b>Cosmetics - COSING, NCPN, Cosmetovigilance</b></p> <p>HTA of Medical Devices and Logistic</p> <p>Authorisation of Medicinal Products with Established Recipe - Specifics in Bulgaria</p> |
|--------------------------------|--|

|                                      |  |
|--------------------------------------|--|
| <b>May 18 - 19, 2023 (in person)</b> | <p><b>Foundation Skills in Drug Regulatory Affairs</b></p> <p>Training course in Regulatory Affairs; Pricing, HTA and Reimbursement (introduction and methodology)</p> |
|--------------------------------------|--|

**Annual congress of BADI 2023 (some of the topics could be moved to the Autumn course)**

|  |   |
|--|---|
| <b>1 st of June (in person)<br/>Venue St. Ekaterina hospital</b> | <p>Pharmaceutical Strategy - update, Barbara Sickmueller</p> <p>Medical Devices - Implementation of the MDR,</p> <p>HTA - Implementation of Regulation 2021/2282</p> <p>Variations - Lesson Learnt from the Practice, CMHh practice</p> <p>Clinical Trial Regulation - CTIS</p> <p>Marketing Authorisation - global</p> |
|--|---|

**Drug regulatory affairs - update | Training course 2023 | 3 modules**

|                                  |   |
|----------------------------------|---|
| <b>October 06, 2023 (online)</b> | <p>Module 1 Pharmacovigilance - update</p> <p>PhV and Clinical Safety</p> <p>PhV - Audits</p> <p>Phv - Inspections</p> <p>ePIL - German Model</p> |
|----------------------------------|---|

|                                      |  |
|--------------------------------------|--|
| <b>November 03, 2023 (in person)</b> | <p>Round table Discussion - HTA and other hot regulatory issues</p> <p>Can HTA be useful tool in the hands of decision makers worldwide</p> <p>Collaborative work - Information sharing, Worksharing, Methods , Research Collaboration</p> |
|--------------------------------------|--|

|                                   |   |
|-----------------------------------|---|
| <b>December 01, 2023 (online)</b> | <p>Regulatory - update</p> <p>Regulatory update - DADI</p> <p>Import from 3rd countries -challenges</p> <p>Personalised Medicines</p> <p>Medical Information and Medical Statistic</p> <p>Data Protection in ISCR info</p> <p>Noninterventional Clinical Trials</p> |
|-----------------------------------|---|