



Bulgarian Association for Drug Information (BADI)

DRUG REGULATORY AFFAIRS - update | Training Course | 3 modules

PROGRAM - 04.10.2024 – 06.12.2024

Online event / In person



Module 1 - 04.10.2024 - Pharmacovigilance - Update | In person

11.45 - 12.20 - Registration and networking experience (coffee and gifts)
12.20-12.30 Topics / Welcome & Opening and Moderator / Prof. Tatyana Benisheva, MU-Sofia, President of BADI

Session 1

12.30 - 13.15 Audits and inspections of the PV/QA systems
13.15 - 14.15 Pharmacovigilance – Update
Signal Management; Discussion
14.15 - 14.45 Coffee break

Session 2

14.45 - 15.30 Attitude of medical doctors to adverse drug reactions reporting in Bulgaria.
15.30 - 16.15 Change of the prescription status
16.15 - 16.30 Discussion

MODULE 2 - 22.11.2024 - Round table Discussion - Hot Regulatory Issues | Online

12.50 - 16.00

12.50 -13.00 Topics / Welcome & Opening and Moderator / Prof. Tatyana Benisheva, MU-Sofia, President of BADI

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Bulgarian Association for Drug Information (BADI)

- 13.00 - 13.45** *Overview on the new EU Artificial Intelligence (AI) Act and regulatory consequences for healthcare products*
- 13.45 - 14.30** *Regulatory considerations in the development of new drugs? Would that work? Discussion*
- 14.30 - 15.15** *Pharmacovigilance of Biosimilars*
- 15.15 - 15.45** *Pharmacovigilance -Update*
- 15.45 - 16.00** *Discussion*

MODULE 3 - 06.12.2024 | Regulatory - update | Online event

10.45 - 11.00

Topics / Welcome & Opening and Moderator / Prof. Tatyana Benisheva, MU-Sofia, President of BADI

Session 1

- 11.00 - 11.45** *Regulatory Update*
- 11.45 - 12.30** *XEVMPD Update*
- 12.30 - 12.45** *GMP – Regulatory Update 2024 Discussion*
- 12.45 - 13.15** *Lunch Break*

Session 2

- 13.15 – 13.45** *Clinical Trials Transparency Policy for Drugs with a Focus on COVID-19*
- 13.45 – 14.30** *Regulatory Frame of Nonregistered Products in Bulgaria*
- 14.30 – 14.45** *Discussion*

Administration Team

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