



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 - 12.30

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 - 14.00 *Pharmacovigilance – Update*
Signal Management

14.00 - 14.15 *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 *Pharmacovigilance of Biosimilars*

16.15 - 16.30 *Discussion*



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

13.00 - 16.00

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

- 13.00 - 13.45 *Overview on the new EU Artificial intelligence (AI) Act and regulatory consequences for healthcare products*
- 13.45 - 14.30 *Change of the prescription status*
- 14.30 - 15.15 *Pharmacovigilance -Update*
- 15.15 - 15.45 *Strategic management in Pharmaceutical industry*
- 15.45 - 16.00 *Discussion*

MODULE 3 - 06.12.2024 | Regulatory - update | Online event

10.45 - 11.00

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Session 1

- 11.00 - 11.45 *Regulatory Update*
- 11.45 - 12.30 *Worksharing + XEVMPD;*
- 12.30 - 12.45 *Discussion*
- 12.45 - 13.15 *Lunch Break*

Session 2

- 13.15 - 14.00 *GMP – Regulatory Update 2024*
- 14.00 - 14.45 *Variations - Update*
- 14.45 - 15.30 *Regulatory Frame of Nonregistered Products in Bulgaria*
- 15.30 - 15.45 *Discussion*

Contacts:

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