



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

9.45 - 10.00

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

Session 1

10.00 - 10.45 *Audits and inspections of the PV/QA systems*

10.45 - 11.30 *Pharmacovigilance*

11.30 - 12.00 *Discussion*

12.00 - 13.30 *Lunch break*

Session 2

13.30 - 14.15 *Attitude of medical doctors to adverse drug reactions reporting in Bulgaria.*

14.15 - 15.00 *Pharmacovigilance of Biosimilars*

15.00 - 15.30 *Discussion*



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

13.00 - 15.30

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

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|----------------------|---|
| 13.00 - 13.45 | <i>New Pharmaceutical (EU) Legislation – Discussion</i> |
| 13.45 - 14.30 | <i>Change of the prescription status</i> |
| 14.30 - 15.15 | <i>Overview on the new EU AI Act and regulatory consequences for healthcare products</i> |
| 15.15 - 15.30 | <i>Discussion</i> |

MODULE 3 - 06.12.2024 | Regulatory - update | Online event

9.45 - 10.00

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

Session 1

- | | |
|----------------------|---|
| 10.00 - 10.45 | <i>Regulations in Paediatric clinical trials</i> |
| 10.45 - 11.30 | <i>Regulatory - Update</i> |
| 11.30 - 12.15 | <i>Worksharing + XEVMPD</i> |
| 12.15 - 12.30 | <i>Discussion</i> |
| 12.30 - 14.00 | <i>Lunch break</i> |

Session 2

- | | |
|----------------------|--|
| 14.00 - 14.45 | <i>GMP – Regulatory Update 2024</i> |
| 14.45 - 15.30 | <i>Variations Update</i> |
| 15.30 - 16.15 | <i>Nonregistered Products</i> |
| 16.15 - 16.30 | <i>Discussion</i> |

Contacts:

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