



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 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 and Prof. Dobriyana Sidgimova, Margarita Strokova PhD and Daniela Cherneva PhD (Board Members)

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| 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 -Update |
| 15.15 - 15.45 | Pharmacovigilance of Biosimilars |
| 15.45 - 16.00 | Regulatory Frame of Nonregistered Products in Bulgaria Discussion |



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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 Overview of EUPATHI

14.30 – 14.45 Discussion

Administration Team

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