



Bulgarian Association for Drug Information (BADI)

DRUG REGULATORY AFFAIRS - update | Training Course | 3 modules

PROGRAM MODULE 3 - 01.12.2023 | Regulatory - Update | Online event



9.45 - 10.00 **Open Registration**

Topics / Welcome & Opening and Moderator / Daniela Cherneva, PhD & Prof. Nadka Boyadzhieva

Session 1

10.00 - 10.30 **Regulatory update – ePIL and Product life management system (PMS);**
Prof. Tatyana Benisheva – Dimitrova – President of BADI

10.30 - 11.15 **Borderline products;**
Gergana Lazarova & Radoslav Ruitchev – Bulgarian Drug Agency

11.15 - 12.00 **Medical Information and Medical Statistic;**
Anna Peneva - Medical Affairs and PHV Expert

12.00 - 12.45 **Personalized medicine in the Clinical Practice;**
Assoc.Prof. Dragomira Nikolova, PhD - Department of Medical Genetics,
Medical Faculty, Medical University

12.45 – 13.30 **Lunch break**

Session 2

13.30 – 14.15 **Noninterventional Clinical Studies;**
Rozalina Kulaksazova - Bulgarian Drug Agency

14.15 – 15:00 **Data Protection in ICSR info;**
Margarita Strokova, MD

15.00 – 15:45 **Food and Drug Interactions;**
Assoc.Prof. Daniela Popova

Discussion

16 Hubcha Str., Office 2, Krasno Selo, 1618 Sofia, Bulgaria
Tel.: +359 2 955 85 86; Mobile: +359 889 919 655;
e-mail: office@badibg.org; <http://badibg.org/>