



Bulgarian Association for Drug Information (BADI)

DRUG REGULATORY AFFAIRS - update | Training Course | 3 modules

PROGRAM MODULE 1 - 06.10.2023

Pharmacovigilance - update | Online event



9.45 - 10.00

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

Session 1

10.00 - 10.45

PhV and clinical safety – Update | part 1

Prof. Dr. Barbara Sickmueller - Senior Scientific Advisor, Bundesverband der Pharmazeutischen Industrie e. V (BPI), President of German Association for Drug Information DGRA e.V

10.45 - 11.30

PhV - Hybrid Audits - (combination of remote and online)

Valentin Kopanarov

11.30 - 12.15

10 years from the extensive reforms of the PHV rules in 2010(in force from 2012) – what has to change

Marya Popova, MD | BDA | BG member of PRAC - EMA committee



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12.15 - 12.30 *Discussion*

12.30 - 14.00 *Lunch break*

Session 2

14.00 - 14.45 *PhV and clinical safety reporting, based on Regulation (EC) 536/2014 – Update | part 2*

Konstantin Kachulev, PhD

14.45 - 15.30 *PhV - Inspections (Update)*

Margarita Strokova, MD

15.30 - 16.15 *Most common findings at audits and inspections - practical examples*

Axel Thiele

16.15 - 16.30 *Discussion*

Contacts:

Administration Team

Mobile: +359 889 919 655

Office tel.: +359 2 955 85 86;
Bulgarian Association for Drug Information
16 Hubcha Str., Office 2
1618 Sofia
Bulgaria

E-mail: office@badibg.org
Website: www.badibg.org