



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PROGRAM

DRUG REGULATORY AFFAIRS - UPDATE, TRAINING COURSE 2019

Module 2: Pharmacovigilance, Part II

Date: November 8, 2019

Venue: Forum Hotel Sofia, Central Hall

Moderator: Prof. Tatyana Benisheva, Medical University - Sofia, President of BADI

TIME	TOPIC	SPEAKERS
8:30 - 9:00 am	Registration and Welcome Coffee	
9:00 - 9:10 am	Welcome and Introduction	Prof. Tatyana Benisheva, MU - Sofia, BADI
Session 1		
9:10 - 9:40 am	Medicines under additional monitoring	Valentin Kopanarov, MPharm
9:40 - 10:10 am	Risk Minimisation Measures - Update	Dr. Vili Topalova
10:10 - 10:25 am	Safety - Update	Konstantin Kachulev, MScPharm, PhD
10:25 - 10:40 am	Signal management	Ekaterina Genova
10:40 - 10:50 am	Discussion	
10:50 - 11:20 am	Networking Coffee Break	
Session 2		
11:20 - 12:10 am	Audit-Proof Contracting	Joint team of experts from Berlin-Chemie, ComFit Europe, Gedeon Richter, PharmDedict, Sanofi
12:10 - 1:00 pm	Are you ready for an audit or inspection?	Joint team of experts from Berlin-Chemie, ComFit Europe, Gedeon Richter, PharmDedict, Sanofi
1:00 - 2:00 pm	Networking Lunch	
Session 3		
2:00 - 4:00 pm	Workshop Session <i>Two exercises to carry out in teams. They are related to the previous presentations of audit readiness and</i>	Joint team of experts from Berlin-Chemie, ComFit Europe, Gedeon Richter, PharmDedict, Sanofi
4:00 - 4:15 pm	Questionnaire, Test, Participants Photo	