BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PROGRAM

DRUG REGULATORY AFFAIRS - UPDATE e - Conference | DIGITAL EVENT ONLY | via Cisco Webex

Date: June 4, 2021 | 9:30 AM - 4:00 PM (CET)

Moderators

Session 1 - Prof. Tatyana Benisheva, President of BADI, Dr. Birka Lehmann;

Session 2 - Prof. Tatyana Benisheva, President of BADI, Prof. Dr. Barbara Sickmueller;

Working language: English & Bulgarian		
TIME	**TOPICS**	**SPEAKERS/LECTURERS**
9:00 - 9:30 AM	**Event Logging**	
	Welcome and Opening of the Drug Regulatory Affairs - Update e-conference and Introduction to Sessions	Prof. Tatyana Benisheva, MU - Sofia, President of Bulgarian Association for Drug Information
	Session 1	
9:30 - 10:10 AM	**Covid-19 – Updates – All Safety Measures**	Margarita Strokova, MD
	Discussion	
10:10 - 10:50 AM	**Electronic Product Information (ePI) / Mobile Technologies / Procedures and Possibilities**	Prof. Dr. Barbara Sickmueller - Senior Scientific Advisor, Bundesverband der Pharmazeutischen Industrie e. V (BPI), President of German Association for Drug Information DGRA e.V.
	Discussion	
10:50 11:30 AM	**SPOR: EMA's new data base on all medicinal products authorised in the EU – impact and challenges for pharmaceutical industry**	Karl-Heinz Loebel, Director, Principal Consultant Regulatory Operations, Industry/Agency Liaisons PharmaLex GmbH
	Discussion	
11:30 - 12:30 AM	**Break**	
	Session 2	
12:30 - 1:10 PM	**Clinical Trials – are we nearly there?** **Implementation of Regulation (EU) No. 536/2014** **Challenges: New requirements** **New timelines** **Transition period**	Dr. Birka Lehmann, Senior Expert Drug Regulatory Affiars, Lehrbeauftragte der Universität Bonn
	Discussion	
1:10 - 1:50 PM	**Clinical Trials with vulnerable group of patients**	Veska Gergova, Bulgarian Drug Agency
	Discussion	
1:50 - 2:30 PM	**Current stage of the European MDR and IVDR implementation - Chances and challenges**	Prof. Dr. Folker Spitzenberger Centre for Regulatory Affairs in Biomedical Sciences - CRABS; Technische Hochschule Lübeck University of Applied Sciences
	Discussion	
2:30 - 3:00 PM	**Introduction to clinical evaluation under the MDR**	Dr. Marta Swierczynska, SFL Regulatory Affairs & Scientific Communication Ltd.
	Discussion	
3:00 - 3:30 PM	**Summary of EU Pharmaceutical Strategy - Challenges for the Industry and Competent authorities**	Daniela Cherneva, Medochemie Bulgaria
	Discussion	
3:30 - 4:00 PM	**Closing Remarks**	