



BULGARIAN ASSOCIATION FOR DRUG INFORMATION (BADI)

PRELIMINARY PROGRAM

DRUG REGULATORY AFFAIRS - UPDATE, TRAINING COURSE 2021

Format of the events: TBA

MODULE 1 October 08, 2021 Pharmacovigilance, Pharmacoepidemiology, Regulatory Update
Main Topics
Post - authorization Safety Studies (PASS) - Overview
Covid-19 - Drug Safety - Update, Part I
Pharmacovigilance of the Regulatory Issues - update
RMP and Signal Detection - update
Pharmacovigilance Inspections / Audits, 20 years worldwide experience
MODULE 2 November 05, 2021 Pharmacovigilance, Pharmacoepidemiology - from Regulatory Practice
Main Topics
Pharmacovigilance of Biosimilars - update
Covid-19 - Drug Safety - Update, Part II
Literature Search - update
Drug Safety in Pediatric Studies
CHMP - Experience and Challenges
Self-medication Attitudes and Safety
MODULE 3 December 03, 2021 Regulatory Affairs – Update, Bulgarian and EU Regulatory procedures, Procedures of Life Cycle Management
Main Topics
Variations - Update from Industry
Product Information (ePI) / Procedures and Possibilities - experience of BDA
Early Market Access
Pharmaceuticals in the environment/Green Deal EU - Pharmastrategy
Promotion of Medical Products - update
Medical Devices - update

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