BULGARIAN ASSOCIATION FOR DRUG INFORMATIO (BADI)

REGULATORY AFFAIRS UPDATE COURSE 2017

DRAFT PROGRAMME

13.10.2017 г.	
MODULE 1 - Regulatory Update: Falshified Medicines, Medical Devices – New Legislation, Update of Clinical Trials	
Moderators: prof. Tatyana Benisheva, prof. Dobriana Sidjimova	
Time	**Theme**
09:00 - 11:15	Falshfied Medicines - Regulatory Update
	Medical Devices Regulation from 25.05.2017 Update
	Analysis Methods - biochemical and genetics
	Holistic marketing
11:15 - 11:30	**Coffee break**
11:30 - 14:00	Update of Clinical Trials legislation
	Drug development success rates. Medical statistics made easy
	Reference pricing in EU
	Biosimilarals, exchangebility, HTA
	Brexit and consequences for CAs and MAHs

03.11.2017 г.	
MODULE 2 - Pharmacovigilance - Part I	
Moderator - Prof. Dr. Barbara Sickmuller	
Time	**Theme**
09:00 - 09:45	**Regulatory authorities and requirements**
	Pharmacovigilance system
	Pharmacovigilance master file system
	QPPV
	Role of the Regulatory authorities.
09:45 - 10:15	**PRAC - role and functions - update**
10:15 - 10:45	**Collection and management of pharmacovigilance data after receipt of a marketing authorisation**
	EMA Guidance on Medication errors
	Off label Use - EMA Guideline - Module VI
10:45 - 11:00	**Coffee break**
11:00 - 13:00	**Assessment of pharmacovigilance information**
	Ongoing safety evaluation
	Regulatory requirements relating to signal detection
	Assessment of signals and benefit/risk ratio
	Risk management systems and risk management plans
	Intensified monitoring
	Referral procedures
13:00 - 14:00	**Lunch break**
14:00 - 15:00	**New Pharmacovigilance requirements for marketed products in the EU**
	PASS/PAES
	PSUR/PBRER
	Educational material
15:00 - 15:30	**Procedural documentation, quality system and pharmacovigilance**
	Pharmacovigilance System Master File – update
	Signal Detection
	Updated pharmacovigilance topics for discussion
15:30 - 16:00	**Coffee break**
Moderator - Prof. Dr. Barbara Sickmuller	
16:00 - 17:00	**Pharmacovigilance inspections**
	Purpose and scope of inspections in the EU
	Preparation for a pharmacovigilance inspection (Inspection readiness)
	Conducting a pharmacovigilance inspection
	When things are not going well
	Corrective actions after a regulatory pharmacovigilance inspection, CAPA handling

24.11.2017	
MODULE 3 - Pharmacovigilance - Part II	
Time	**Theme**
09:00 - 10:30	**Collection and management of pharmacovigilance data after receipt of a marketing authorisation**
	Literature monitoring - MLM Service (0.5 h)
	PSURs (0.5 h)
	PV in pre – approval - DSUR
	Regulatory reporting requirements
	PV agreements. Safety management plan and responsibilities
	PV in Clinical Trials , Medication Errors & Off Label Use - pre clinical examples
10:30 - 11:00	**Coffee break**
11:00 - 13:00	**Pharmacovigilance and contractual interrelations with third parties**
	Scope of contractual agreements as regards pharmacovigilance
	Regulatory requirements relating to contractual agreements
	Contractual agreements between pharmaceutical companies
	Contractual agreements with service suppliers regarding to pharmacovigilance
	Drawing up and maintenance of pharmacovigilance agreements
	Collection and management of pharmacovigilance data after receipt of a marketing authorisation
	MedDRA Dictionary (0.5)
	EV and signal detection by MAHs (0.5h)
	GVP Updates (45 min.)
13:00 - 14:00	**Lunch break**
14:00 - 15:30	**The Role of Pharmacovigilance Department within the Company**
	Interactive sessions - Simulation of crisis (case in situ) and selfinspections (*0.5 h)*