Management and operation of pharmacovigilance system in EAEU. Critical aspects

20-21 of February 2020
Vilnius, Lithuania

Training session 1 20.02.2020	
9:00 – 9:15	Registration of participants
9:15 - 10:00	Features of mutual recognition in the EAEU countries. The EAEU Electronic Submission Format and its difference from eCTD. Pharmacovigilance documents as part of eCTD
10:00 - 11:00	Pharmacovigilance (PV) quality system (QS). Models of QS and their features
11:00 – 11:15	Coffee break
11:15 - 12:15	The main documents of pharmacovigilance quality system. Differences based on the model of PV quality system and its functions with regards to MAH
12:15- 13:00	Critical processes and procedures of the PV quality system. Are there a penalty for the absence of any procedures? The basic requirements for the procedure in the PV quality system
13:00 – 14:00	Lunch
14:00 – 16:00	Analysis of the procedure in the PV quality system: • The procedure for delegation of the PV and QPPV functions; • Collection and reporting of spontaneous signals on the EAEU territory. Requirements. Procedure, including addresses, request forms. Validation documents; • The procedure for weekly monitoring of literary and internet sources. Lists of sites. Selection criteria. The quality system of literary and online searches.
16:00 – 16:15	Coffee break
16:15 - 18:00	Analysis of the procedure in the PV quality system: • Procedure for assurance the continuity of PV system. • Procedures for assessing information on the safety profile, minimizing risk, maintaining relevant information in SmPC
19:00	Dinner The possibility of informal communication with the speaker and other participants

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Training session 2 21.02.2020	
9:00 - 9:45	Features of QPPV activities in the EAEU. Delegation of the PV and QPPV functions. Local representative of QPPV. Requirements, and peculiarities
9:45 – 10:45	Key documents generated through pharmacovigilance activities. Preparation and presentation of PSUR, DSUR, RMP, ACO in the EAEU
10:45 – 11:00	Coffee break
11:00 – 12:00	Overview of PV databases. Selection and work with databases of spontaneous signals. Their role and necessity. The role of MS Office (Excell, Access). Economic expediency. Validation of databases and applications. Requirements and validation process.
12:00 – 13:00	Pharmacovigilance inspections and audits. The principle of the continuous development of the PV quality system. The main sensitivity points of PV system. Documentation of the PV system in the view of inspector. Self-Inspection.
13:00 – 14:00	Lunch
14:00 – 15:00	Pharmacovigilance system master file. The structure and required elements. Local PSMF.
15:00 – 16:00	PV in clinical studies in the EAEU. PV sections in protocol and report of clinical study. Requirements for DSUR. The minimum package of procedures for PV assurance in CS.
16:00 – 16:15	Coffee break
16:15 – 17:00	Nomenclature of PV cases. Storage and archiving of pharmacovigilance information
17:00 – 17:30	SDEA with distributors. Basic principles and problems. SDEA Template

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