SmartPharma Group

Management and operation of pharmacovigilance system in EAEU. Critical aspects

«Pharmacovigilance: more clarity – fewer difficulties!»

Who should attend:

- Manufacturers/MAHs of medicines on the territory of the EAEU
- QPPVs
- Directors / Managers / Drug Safety Specialists
- (Global / local)
- Medical Directors / Heads of Medical Departments
- Director s of Global Regulatory Affairs
- Regulatory Managers
- Specialist responsible for development of PV system documentation
- Heads of Clinical Research Departments
- Specialist responsible for development й
- Specialist responsible for development of clinical research documentation, PILs, SmPCs

20-21 of February 2020
Vilnius, Lithuania
Margis Trakai Hotel

Registration:

info@smart-pharma.group

We can reach your goals

Speaker – Ivan Vorobiev

Member of International Society ISOP. Participated in the development of the EAEU PV quality system, developed an original algorithms and documents within the framework of the quality system of the PV. Experienced pharmacovigilance expert fulfilling the responsibilities of QPPV of six companies on the territory of the EAEU and a LPPV of the foreign companies in the EAEU.
Qualification has been confirmed by numerous certificates and implemented in the successful development and operation of the pharmacovigilance system in the EAEU.

During the course you will learn about:

- peculiarities of mutual recognition procedure in the EAEU countries
- models of quality system (QS)
- quality system of pharmacovigilance system
- peculiarities of the PV QS and relevant responsibilities of MAH
- preparation of system's master file depending on the QS model
- critical processes and procedures of quality systems
- important features of development / improvement of pharmacovigilance procedures
- critical aspects of the pharmacovigilance system audit / inspection
- pharmacovigilance during clinical trials
- storage and archiving of pharmacovigilance information
- interaction with distributors as a part of PV QS operation

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Participation

Registration fee – 830 euro (+ VAT, if applicable)

For 2 or more representatives of the Company - *7% discount*

The fees include:

- participation in a two-day workshop
- learning materials (hard / soft copy)
- coffee breaks / dinners during the event
- supper in a friendly atmosphere on the 1st day of the workshop for informal communication with the speaker and participants

Additional 10% discount for hotel accommodation from the Company!

For registration or any additional information contact us:

info@smart-pharma.group
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We will be glad to see you!

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