Quality, Regulatory Affairs, Medical Device & IT

mediteq FORUM

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Mediteq Forum

- How to conquer EURASIA?

Mediteq Forum is welcoming Alexey Stepanov from Raifarm in Moscow who will guide us through the requirements in the medical device regulation for Eurasian Economic Union. The regulation is planned to replace the local legislations and registration processes in the five countries forming Eurasian Economic Union - Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan.

The regulation, that is already in force with transitional rules, will from the 1st of January 2022 apply to all medical and in vitro diagnostic device submissions in the Eurasia region.

During this Mediteq Forum activity Alexey will share his knowledge and experience about the requirements in the new Eurasian regulation, the transition period and how to avoid delays and bottlenecks. Practical implications on future registrations in the Eurasia region like local representatives, documentation required, and database registration will also be discussed.

Date: 28 of September 2021 from 9-11 o'clock
Digital: Zoom link will be sent closer to the date
Sign up: here

The presentation will be held in English and cover the Eurasia regulation as described above and there will also be a chance for the participants to ask questions.

Please send in your questions ahead of time if you have specific issues, you'd like the expert to cover.

Welcome!

Helen Sandelin
Facilitator, Mediteq Forum

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Presentation of today's guest

Alexey Stepanov is Director Regulatory Affairs in the medical devices department at the consultant company Raifarm.

Alexey has more than 10 years' experience in regulatory affairs for medical devices and IVD for Russia and CIS countries, from working both in consultancy and global healthcare companies such as Stryker and Abbott.

He has a medical doctors' degree and is an author of the blog about medical device regulations in Russia and the Eurasian Union www.MedicalDevicesInRussia.com