Seminar

FORUM

Medical Devices in Russia, the Ukraine and in the EEC

Topics

- Current regulatory framework
- Explaining the complexity: How to register and certify your medical device
- Mandatory documents and certificates
- Management of changes and amendments of dossiers
- How to treat an authority in the right way

Focus:
Russia, Belarus, Kazakhstan, Ukraine

Your speakers

Dr. Edelgard Rehak
Dr Edelgard Rehak Consulting, Germany

Dr. Alexey Stepanov
Medical Device Expert, Russia

15 May 2019 in Berlin

Medical Devices in Russia, the Ukraine and in the EEC

Aims and objectives

Starting January 2016, common regulations set by the Eurasian Economic Union (EEC) for theregistration of medical devices came into force. And since 2013, a new highly complex law for medical devices was released in Russia.

The aim of the course is to give you a qualified overview of the legislation, different registration strategies in Russia and the EEC member states and how your business might be improved. Learn more about the highest Russian authority Roszdravnadzor and EEC mutual recognition procedure.

A second focus of this course is market access in the Ukraine and the regulation for medical devices. After having attended the course you will know how to currently handle registration and distribution in Russia, Belarus, Kazakhstan and the Ukraine and which legislation changes are still pending.

Who should attend?

This unique course addresses the needs of employees in the healthcare industry who intend to register, export, manufacture medical devices to or in Russia, in the EEC and the Ukraine or plan a market access. Those involved in:

- regulatory and quality affairs
- product management and marketing
- market access and sales
- export and business development

will particularly benefit from the speakers' first-hand expertise.

Your speakers

Dr. Edelgard Rehak

Dr Edelgard Rehak Consulting, Storkow, Germany

Dr Rehak is an expert on registration in Russia and Central and Eastern Europe.

Dr. Alexey Stepanov

Regulatory Affairs Manager Medical Devices and In vitro Diagnostics in Russia & the EEC

Dr Stepanov works at a major global healthcare company in Moscow.

Quality guaranteed!

IMI (Innovative Medicines Initiative) defined quality criteria for professional training and education.

We follow these criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards.

An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 10.2016 - 09.2017 produced a result of 1.6 (based on a school grading system of 1-6).

Your programme from 09:00 - 16:30

> 09:00 Welcome

> 09:15
The market for medical devices in Russia and its neighbouring countries: BY, KZ, UA
Dr Edelgard Rehak

- Economical overview about CIS countries
- What you should know about culture and cultural particularities
- Comparative summary about registration roles for medical devices in CIS countries

> 09:45
The Eurasian Economic Community (EEC) - an overview
Dr Alexey Stepanov

- History and economic potential
- Further important points: what you should know about the EEC
- Market access and customs for non-EEC members
- The Eurasian Economic Medical Device Registration Rules (EER)

> 10:30 Coffee break

> 10:45
Market authorization for medical devices in Russia
Dr Edelgard Rehak

- How does the Russian law for medical devices work?
- Nomenclature and classification of medical devices in type
  - risk class
  - GESN (OKP)
  - Impact of local Standards

> 12:30 Lunch break

> 14:00
Registration of medical devices in Russia
Dr Alexey Stepanov

- Registration documents and declaration of conformity (compulsory certification)
- The "refusal writing"
- Process and length of registration
- Documents for accreditation/ certification
- Change and amendments of registration dossiers
- Change or duplicate of a registration certificates
- Cancelation of a registration certificates
- Import of samples/prototypes
- Consequences of the increased VAT for foreign importers

> 15:30 Coffee break

> 16:00
Market access and registration in the Ukraine
Dr Edelgard Rehak

- Regulatory framework
- Authorized Representatives
- Self declaration
- Documentation and sample submissions required for registrations
- Manufacturing site inspections

> 16:30 End of the course

Registration recommended 30 days in advance

Registration under service@forum-institut.com or Fax +49 6221 500-555

Registration Form

Yes, I will attend the seminar

☐ Medical Devices in Russia, the Ukraine and in the EEC

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no.

E-mail

Contact person at office

Date, signature

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How to register

Registration: +49 6221 500-500
Conference no.: 19 05 921

Date and venue
Wednesday, 15 May 2019 in Berlin
Seminar: 09:00 -16:30 (08:30 registration)
Adina Apartment Hotel Checkpoint Charlie
Krausenstr. 35-36 · 10117 Berlin
Tel. +49 30 200 767 0 · Fax +49 30 200 767 599

Fee
€ 990.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Any Further Questions?

Please feel free to contact me if you have any questions.

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Cancellation Policy

Our general terms and conditions (as of 1 January 2016) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c