MANAGEMENT forum

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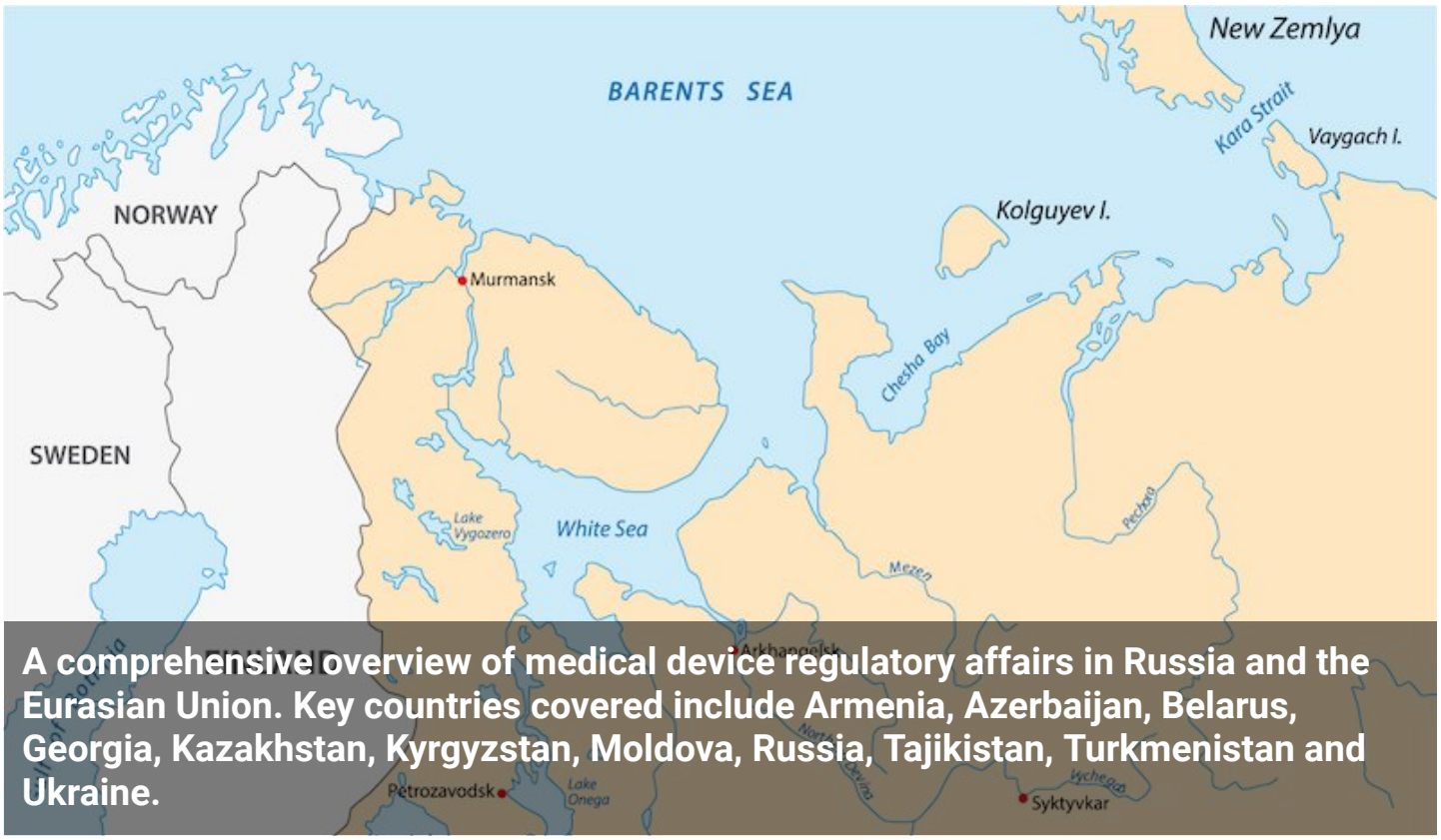
Medical Device Regulation in the Eurasian Union, Russia and the CIS

6-7 Oct 2021, London • 13-14 Oct 2021, London



A comprehensive overview of medical device regulatory affairs in Russia and the Eurasian Union. Key countries covered include Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan and Ukraine.

Programme at a glance:

- CIS – regional regulatory overview
- Common regional requirements in CIS
- Eurasian regulations for Medical Devices
- Registration of Medical Devices in Russia
- Registration of Medical Devices in other EAEU countries
- Registration of Medical Devices in other CIS countries
- Workshop: CIS Regional Regulatory Strategy

Full programme inside

★★★★★ *"My opinion is overall very positive. I liked how the content was delivered and the knowledgeable speaker."*

Monica Fabris, Regulatory Affairs Expert, Fidia Farmaceutici S.p.A.

★★★ *"Great"*

Helen Finn, Regulatory Affairs Coordinator, ArjoHuntleigh

★★★★★ *"Content is very good. Speakers are also well prepared and competent "*

Anette Hulstrøm, Specialist Regulatory Affairs, William Cook Europe ApS

Medical Device Regulation in the Eurasian Union, Russia and the CIS

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About this programme

The aim of this event is to provide a comprehensive overview of medical device regulatory affairs in Russia and the Eurasian Union. This interactive course will cover the regulatory requirements within these regions, focusing on practical aspects to assist in developing your regulatory strategy for product approval. The presentations will also give practical hints on the regulatory and registration process where possible.

Benefits of attending

Attending this programme will:

- Give you the full background to the CIS medical device market
- Ensure that you understand the full implications of the new regulations which will affect how you do business in the Eurasian Economic Union (EAEU)
- Help clarify the document requirements and timelines of national procedures and EAEU registration procedures
- Fully update you on the national regulations in Russia, Belarus, Kazakhstan, Ukraine and other CIS countries

Who should attend?

This seminar will be of particular interest to:

- Personnel working in medical device regulatory affairs in this region
- Anyone who is considering marketing a medical device in this region
- Those interested in an update on recent developments

Expert trainer

Anna Harrington-Morozova

Anna Harrington-Morozova is a regulatory, drug development and external relations professional with over 20 years' experience gained working in a Regulatory Authority, academia and industry. Anna graduated in Russia as a pharmacist. After working in the Russian Ministry of Health and the Clinical Pharmacology Department of Moscow Medical University, she held regulatory and external relation positions in the pharmaceutical industry and CROs in Russia and the UK, including senior regulatory affairs posts in GSK,EISAI, ICON and PRA. Anna currently acts a a Scientific and Reguatory director at Regem Consulting Ltd – a consultancy which focuses on drug development, global regulatory advice, professional trainings and flexible resourcing solutions for the pharmaceutical, biotech and medical device industries in emerging markets.

CIS – regional regulatory overview

- CIS and Russia Market Overview. Market protection policies
- CIS in regional and international Regulatory Harmonisation

Common regional requirements in CIS

- Administrative data, translations, FSC, dossier format, local normative document, samples, labelling

Eurasian regulations for Medical Devices

- Countries current members of EAEU and EAEU Official bodies
- Terms of transition period
- EAEU Registration Procedures. Application process
- EAEU submission documents and data Requirements
- QMS inspections

Registration of Medical Devices in Russia

- Regulatory authorities in Russia and key bodies
- Key regulations governing registration process
- Clinical trials for medical devices
- Registration procedures – what is required?
- Application dossier and data requirements
- Post-approval life cycle maintenance applications
- Safety reporting and market surveillance

Registration of Medical Devices in other EAEU countries

Kazakhstan, Belarus, Armenia, Kirgizstan

Registration of Medical Devices in other CIS countries

- EU sphere of influence: Ukraine, Moldova, Georgia,
- Independent National procedures: Azerbaijan, Uzbekistan, Tajikistan, Turkmenistan

Workshop: CIS Regional Regulatory Strategy

Medical Device Regulation in the Eurasian Union, Russia and the CIS

Schedule and prices

Three ways to book:

Online	Email	Telephone
management-forum.co.uk/2289	bookings@management-forum.co.uk	+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11166	**6-7 Oct 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**25 Aug**
11397	**13-14 Oct 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	**1 Sep**

Your choice of date & location

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

FEE

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE

Falconbury Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Falconbury will refund the registration fee and disclaim any further liability.

TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions