## Pharmaceutical Regulatory Affairs in Russia, the Eurasian Union and the CIS

To book online go to: **management-forum.co.uk/2279** W

### Date and venue

1-2 March 2018 **Ref: 10186**

The Rembrandt Hotel
11 Thurloe Place
London
SW7 2RS
Tel: +44 (0)20 7589 8100

### Programme schedule

Registration and refreshments: 09.00

| | Day one | Day two |
|---|---|---|
| Start | 09.30 | 09.00 |
| Close | 17.00 | 16.30 |

### Accommodation


We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact **reservations_rembrandt@sarova.co.uk** and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment. For information on alternative accommodation please visit our website: **management-forum.co.uk/accommodation**

### Three ways to book

**management-forum.co.uk** **+44 (0)20 7749 4730**
**info@management-forum.co.uk**

### Fees and payment

**EARLY BOOKING DISCOUNT Book BEFORE 12 January 2018**
**£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80**

**FULL PRICE Book AFTER 12 January 2018**
£1499.00 + VAT = £1798.80 • €2099 .00 + VAT = €2518.80

**Multiple booking discount for 2nd or subsequent delegates - 15%**
£1274.15 + VAT = £1528.98 • €1784.15 + VAT = €2140.98

**Payment options**

1. Invoice which can be paid by bank transfer or credit / debit card
2. Online through our secure website when registering

### In-house training

This course is also available in-house and can be tailored to your specific needs. Our expert comes to you, saving you time and money. For more information contact **Customer Services** on **+44 (0)20 7749 4730** or email: **inhouse@management-forum.co.uk**

**The small print**

**FEE**: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements please advise customer services when booking.

**HOW TO REGISTER AND PAY:** A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit/debit card, by bank transfer (for bank account details please see payment details section on our website). VAT no GB 341232109. Any questions please contact Customer Services on +44 (0)20 7749 4730. **ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.**

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

| Delegate | Up to 28 days before course | 27 to 14 days before course | 13 to 0 days before course |
|---|---|---|---|
| Cancellation | 10% admin fee | 100% admin fee | 100% admin fee |
| Transfers | Free | 10% admin fee | 100% admin fee |
| Substitution | Free | Free | Free |

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses. All cancellations must be received in written form.

**For event cancellation policy and T&Cs see our website**



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MANAGEMENT forum

# Pharmaceutical Regulatory Affairs in Russia, the Eurasian Union and the CIS

**Countries covered include Armenia, Azerbaijan. Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan**

**1-2 March 2018 London**


## Topics to be covered:

**After attending this programme you will:**

- **Understand** the competitive landscape of the growing markets in CIS region
- **Discover** the essential information on the new regulations and registration procedures in the Eurasian Customs Union
- **Discuss** national requirements and guidance for drug approval in core CIS markets of Russia, Kazakhstan, Belarus, Ukraine and Azerbaijan
- **Develop** your CIS Regional Submission Plan and place it within the global regulatory strategy
- **Gain** practical advice from industry experts working in CIS region

Expert trainer:

**Anna Harrington-Morozova**, MPharm, MTOPRA
Scientific and Regulatory Director, Regem Consulting Ltd, UK

***Includes:*** **Practical and interactive workshop**

CPD CERTIFIED
The CPD Certification Service

# Pharmaceutical Regulatory Affairs in Russia, the Eurasian Union and the CIS 1-2 March 2018, London

## Why you should attend

The aim of this meeting is to provide an overview of recent regulatory developments in pharmaceutical regulatory affairs in Russia and the Eurasian Union. This interactive meeting will discuss the regulatory requirements within these regions, and discuss the implications of the new joint Eurasian Union regulation, which came into force in 2016. The focus will be on practical aspects to assist in developing your regulatory strategy for product approval in these countries and the presentations will also give practical hints on the regulatory process where possible.

## Who should attend?

**This seminar will be of particular interest to:**

- Anyone working in pharmaceutical regulatory affairs in this region
- Anyone interested in an update of recent developments

## Benefits of attending

**Attending this programme will:**

- **Give** you the full background to the CIS pharmaceutical market
- **Ensure** that you understand the full implications of the new regulations which will effect 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

## Speaker

**Anna Harrington-Morozova** is a regulatory, drug development and external relations professional with over 20 years' experience gained in regulatory authority, academia, clinical and industry environment. Anna graduated in Russia as a pharmacist. After working in the Russian Ministry of Health and the Clinical Pharmacology Department of Moscow Medical University Anna 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 as a Scientific and Regulatory Director at Regem Consulting Ltd - a regulatory and drug development consultancy with a focus on global regulatory and drug development strategies, advocacy and registrations in emerging markets.



**A certificate of attendance for professional development will be available to each participant who completes the seminar**

# Programme

### Introduction and welcome

### Russia - competitive landscape
- Current market and projected growth
- Pharma-2020 and Health-2020 State programmes
- Pricing and reimbursement
- Patent and data protection

### Clinical trials in Russia and CIS
- Russia and CIS in global clinical research
- Clinical trial requirements
- Local registrations trials in Russia, CIS and the Eurasian Union

### Marketing authorisations in Russia
- Regulatory authorities in Russia
- Key regulations governing the MAA process
- Registration procedures
- Application dossier requirements

### CIS - regional regulatory overview
- CIS pharmaceutical market
- CIS regional regulation co-operation – the Eurasian Union
- CIS regulatory barriers for Market Access

### Marketing authorisations in CIS
- New Eurasian MAA procedure
- Common regional requirements in CIS:
  - administrative data
  - translations
  - CPP
  - Dossier format
  - local normative documents
  - samples
  - labelling
- Country specific requirements for MAAs:
  - Ukraine, Kazakhstan, Belarus, Moldova, Georgia, Armenia, Azerbaijan, Uzbekistan, Tajikistan, Turkmenistan, Kirgizstan
- Regional regulatory strategy

### Workshop - CIS Regional Regulatory Strategy

### Discussion will take place throughout the two days



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