IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmaceutical Regulatory Affairs in Russia and the Eurasian Union

2-3 October 2025

This interactive course will discuss the regulatory requirements for human pharmaceuticals within these regions, and discuss the implications of the new joint Eurasian Union regulation.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

The pharmaceutical markets in Russia, the Eurasian Union and the CIS are of growing commercial importance and companies looking to take advantage of the opportunities available need to be fully up to date with the evolving regulatory landscape for human pharmaceuticals, including the potential for market access offered by the latest legislation.

This interactive course will guide you through national procedures as well as exploring the implications of and updates on the Eurasian Union regulation.

The focus of the programme is to offer practical advice in developing your regulatory strategy for product approval in these countries and you will get the full benefit of our trainer's experience and expertise in the region.

Benefits of attending:

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

Why you should attend

Attending this programme will:

- **Give** you the full background to the CIS pharmaceutical market
- **Ensure** that you understand all the implications of the latest 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
- **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 all those who need to learn about successful marketing authorisation applications and regulatory compliance in this region. The seminar will be useful either as an introductory or refresher course.

Please note this course will only cover human pharmaceuticals not animal (veterinary) pharmaceuticals.

Programme

Day 1

CIS – regional regulatory overview

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

Common regional requirements in CIS

- Administrative data, translations, normative document, samples, labelling, etc

Eurasian economic area

- Countries current members of EAEU and EAEU Official bodies
- History of EUAE, scope of products, available experience
- Terms of transition period for medicines

Eurasian Regulations for Medicines

- Overview of EAEU regulatory framework
- Registration Procedures and Application process
- EAEU submission documents and data requirements
- GMP inspections
- PhV requirements

Day 2

Registration of Medicine in Russia

- Regulatory authorities in Russia
- Key regulations governing registration process
- Clinical trials

National Regulatory Procedures in Russia

- Application dossier and data requirements
- Post approval life cycle maintenance applications
- Safety reporting and market surveillance
- Price and reimbursement
- Patent data protection

Registration in other EAEU countries

- Kazakhstan, Belarus, Armenia, Kirgizstan

Registration in other CIS countries

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

Workshop – CIS Regional Regulatory Strategy

Presenter

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.

Course date

2-3 October 2025

Live online
09:00-17:00 **UK (London)** (UTC+01)
Course code 14967

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 28 Aug

How to book

Online:
ipi.academy/2279

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

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
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

My expectation was to gain as much knowledge as possible about EAEU regulations. It was very helpful and useful to get EAEU region overview and understand regulatory approach in each country.

Maryna Orudzheva
Regulatory Manager CIS
Accord Healthcare Polska Sp. z o.o.
Feb 6 2025

★★★★☆

I found this webinar really helpful and informative. Thank you for organising this webinar and a very special thanks to the speaker.

Ayse Gulden Oztekin
International Markets Regulatory Affairs Coordinator
Recordati Ilac Sanayi ve Ticaret Anonim Sirketi
Oct 3 2024

★★★★★

The workshop was very useful. I really liked the presentation and the content. The experience has been very rewarding.

Monica Fabris
Regulatory Affairs Expert
Fidia Farmaceutici S.p.A.
Feb 4 2021

★★★★☆

My goal was to obtain a clear picture of the situation in the Eurasian countries and the changes that we can find in the legislation for the registration of medicinal products in comparison to the national legislations and yes, I accomplished this.

Silvia Santano Hernandez
Regulatory Affairs Technician
Grifols S.A.
Feb 4 2021

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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