

❖ **The training course will take place at the Belarusian Medical Academy of Post-Graduate Education, Minsk, Republic of Belarus**

❖ **Time**

The course will start on 26 May at 9.00 through to 17.30 (1 hour lunch) and continue on 27 May at 8.30 through to 17.00 (1 hour lunch)

❖ **Practical information, Programme and Registration forms** available from

the ISoP Administration office:

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# ISoP

## Training course

### Minsk, Belarus

### 26 & 27 May 2011

**Risk Management and  
Regulatory inspections**

First Announcement



# **ISoP Training course – Minsk, 26 & 27 May 2011**

## **Risk Management and Regulatory inspections**

Risk management lies at the heart of modern pharmacovigilance and is now supported by a strong regulatory framework within the EU and elsewhere. This two day-seminar will be dedicated to the principles and practice of safety risk management, both from a company and a regulatory authority perspective, beginning with basic PV system requirements and covering risk identification, management and communication.

**This course is targeted at all interested healthcare professionals and in particular industry and MAHs with a strong focus on practical examples and real-life solutions.**

There will be ample opportunity to exchange views and ideas in discussions both following individual presentations, after the panel discussion at the end of the seminar, and during coffee breaks.

The aim is to increase participants' proficiency in the understanding and daily practice of safety and risk management.

### **The programme will include the following topics:**

- Principles of Risk Management
- PSURs as a risk management tool
- Pharmacovigilance Planning and the EU-RMP
- Product risk-benefit profile – what are 'risks' and how can you manage them?
- Risk communication – labeling documents, DHCP communications, special prescriber training programmes
- Regulatory Inspections – what you need to know

The faculty for this seminar consists of international and local experts in pharmacovigilance, representing academia, government and industry.

This course will be held in the city of Minsk, one of the most modern and unique cities of the former USSR.