

Novotel Hotel, Calea Victoriei 37B, sector 1,  
010061 Bucharest, Romania

## **Pharmacovigilance Conference** **Bucharest, 12-14 May 2015**

Pharmacovigilance Conference on risk management, electronic reporting,  
XEVMPPD updates, audits, inspections and periodic reporting.

### **Faculty**

Calin Lungu, MD, DDCS S.A., Luxemburg  
Jan Petracek, MD, Pharminvent, Czech Republic  
José Ortiz, PhD, Spain

### **Agenda**

#### **Day one, May 12<sup>th</sup>**

<b>08:30 – 9:00</b>	<b>Welcome and registration</b>
<b>09:00 – 9:15</b>	Introduction and overview of the agenda (C. Lungu)
<b>09:15 – 10:15</b>	Introduction to ICH and EU pharmacovigilance (J. Petracek)
<b>10:15 – 10:40</b>	Coffee break
<b>10:40 – 11:10</b>	Signal detection in EudraVigilance (C. Lungu)
<b>11:10 – 11:40</b>	Update on the XEVMPD requirements and ongoing activities of data maintenance (C. Lungu) – Part I
<b>11:40 – 12:15</b>	Data quality of ICSRs (C. Lungu)
<b>12:15 – 12:30</b>	Questions and answers
<b>12:30 – 13:30</b>	Lunch break
<b>13:30 – 15:00</b>	Signal Management in the EU (Module IX) (J. Petracek)
<b>15:00 – 15:30</b>	Coffee break
<b>15:30 – 16:45</b>	GVP Module VII – PSUR (J. Ortiz)
<b>16:15 – 17:00</b>	GVP Module VII – PSUR Practical examples (J. Ortiz)
<b>17:00</b>	End of Day 1

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**Day two, May 13<sup>th</sup>**

<b>9:00 – 10:00</b>	<b>Update on the XEVMPD requirements and ongoing activities of data maintenance (C. Lungu) – Part II</b>
<b>10:00 – 10:30</b>	Risk Management Plans in the EU – requirements and practice (J. Petracek) (Part I)
<b>10:30 – 11:10</b>	Coffee break
<b>11:10 – 11:40</b>	Safety Communication as result of Signal Management (Module XV) (J. Petracek)
<b>11:40 – 12:15</b>	Electronic reporting in the EEA member states (C. Lungu)
<b>12:15 – 12:30</b>	Questions and answers
<b>12:30 – 13:30</b>	Lunch break
<b>13:30 – 14:15</b>	EudraCT (J. Ortiz)
<b>14:15 – 15:00</b>	A word on children, pediatric studies (J. Ortiz)
<b>15:00 – 15:30</b>	Coffee break
<b>15:30 – 16:15</b>	Risk Management Plans in the EU – requirements and practice (J. Petracek) (Part II)
<b>16:15 – 17:00</b>	Preparing audits and inspections using EudraVigilance (C. Lungu)
<b>17:00</b>	End of Day 2

**Day three, May 14<sup>th</sup>**

<b>9:00 – 10:00</b>	<b>Clinical trials perspective SUSARs and ASR/DSUR (J. Ortiz)</b>
<b>10:00 – 10:30</b>	SUSARs and ASR/DSUR practical examples (J. Ortiz)
<b>10:30 – 11:10</b>	Coffee break
<b>11:10 – 11:40</b>	GVP Module I – Quality Systems (C. Lungu)
<b>11:40 – 12:15</b>	Risk Minimisation Planning based on GVP Module XVI and CIOMS IX (J. Petracek)
<b>12:15 – 12:30</b>	Questions and answers
<b>12:30 – 13:30</b>	Lunch break
<b>13:30 – 14:15</b>	GVP Module III – IV – PV audits and inspections (C. Lungu)
<b>14:15 – 15:00</b>	Benefit-Risk Management in regulatory submissions (DSUR, PSUR, PBRER, DRMP, RMP) (J. Petracek)
<b>15:00 – 15:30</b>	Questions
<b>15:30</b>	End of Day 3

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## **REGISTRATION FORM**

Pharmacovigilance Conference on risk management, electronic reporting,  
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Fax or email your completed registration form to Business Travel Turism S.R.L. Fax: +4021 3126708,  
Phone: +4021 2315615, email: [madalina.nedelciu@businesstravel.ro](mailto:madalina.nedelciu@businesstravel.ro).

### **FEES**

Standard fee **ron 3.589 + VAT (ron 4.450)**

Early booking fee (before March 8<sup>th</sup>) **ron 2.991 + VAT (ron 3.709)**

\*the registration fee includes training course material, lunches and refreshments

\*the rate doesn't include VAT 24%

\*payment of registration fees must be received before commencement of the course

\*courses may be cancelled if number of participants are not sufficient

### **ATENDEE DETAILS**

Please complete with capital letters

Prof  Dr  Ms  Mrs

Last name \_\_\_\_\_

First name \_\_\_\_\_

Company \_\_\_\_\_

Job Title \_\_\_\_\_

Address \_\_\_\_\_

Postal code \_\_\_\_\_ City \_\_\_\_\_

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\*participants from Romania will be charged in RON; participants from other counties will be charged in euro,  
exchange rate at the date of invoice issue

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**CANCELTATION POLICY**

If the minimum of 25 persons is not reached by April 15<sup>th</sup> prices and conditions will be reconfirmed.