ICH Endorsed Pharmacovigilance Training Course

Course #13569
28-29 November 2013
HALMED (Agency for Medicinal Products and Medical Devices)
Zagreb, Croatia

Faculty

Natalia Kocankova
Director, Drug Safety Europe
Sucampo AG
Switzerland

Viola Macolic Sarinic
Head of the Agency
HALMED (Agency for Medicinal Products and Medical Devices)
Croatia

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 12 CPD credits. The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 12 credits.

Training Course Location

HALMED (Agency for Medicinal Products and Medical Devices)
Ulica Roberta Frangeša Mihanovića 9 (Sky Office)
Zagreb
Croatia

This course has limited capacity. Register early.

Overview

This training course focuses on ICH international standards related to pharmacovigilance (ICH E2 series). It covers both pre- and post-authorisation pharmacovigilance standards and practical implementation of the ICH guidelines in the international environment. The course includes case studies and examples of challenges and practical solutions. The course is prepared and taught by experienced pharmacovigilance experts. Participants will gain solid knowledge and a clear understanding of international approaches to drug safety pharmacovigilance, as well as the best practices for successful local and global regulatory applications.

Key Topics

- ICH E2A Pre-marketing safety
- ICH E2D Definitions and standards for expedited reporting (post–approval)
- ICH E2B (both pre-and post-authorisation) Data elements for electronic submission
- ICH E2F Development Safety Update Report
- ICH E2C(R2) Periodic Benefit Risk Evaluation Report (PBRER) Guideline
- ICH E2E Pharmacovigilance planning

Who Will Attend

Professionals with background in the following areas:
- Clinical Research
- Clinical Safety/Pharmacovigilance
- Information Technology/Document Management
- Public Policy/Law/Compliance
- Regulatory Affairs
- Research & Development
- Risk Management

Learning Objectives

At the conclusion of this course, participants should be able to:
- Understand the international history, the principles and regulatory framework for pre- and post-approval clinical safety/pharmacovigilance
- Recognise the need for international safety surveillance and understand the regulatory requirements
- Understand the basic definitions of terms, scope of work, and purpose of pharmacovigilance used in day-to-day work
- Demonstrate an awareness of risk management and optimal risk minimisation methods

ICH harmonisation for better health

DIA®

DAY 1

08:00 REGISTRATION

08:45 **Opening remarks**

09:00 **Session 1**
INTRODUCTION OF ICH PHARMACOVIGILANCE GUIDELINES

09:30 **Session 2**
ICH E2A PRE-MARKETING SAFETY
Local perspective

10:50 COFFEE BREAK

11:20 **Session 3**
ICH E2D DEFINITIONS & STANDARDS FOR EXPEDITED REPORTING (POST-APPROVAL)
Local perspective

12:40 LUNCH

13:40 **Session 4**
ICH E2B (BOTH PRE- AND POST-AUTHORISATION) DATA ELEMENTS FOR ELECTRONIC SUBMISSION
Local perspective

15:30 COFFEE BREAK

16:00 **Session 5**
ICH E2F DEVELOPMENT SAFETY UPDATE REPORT
Local perspective

17:30 END OF DAY ONE

DAY 2

09:00 **Session 6**
ICH E2C (R2) PERIODIC BENEFIT RISK EVALUATION REPORT (PBRER) GUIDELINE
Local perspective

10:30 COFFEE BREAK

11:00 **Session 6 continued**
ICH E2C (R2) PERIODIC BENEFIT RISK EVALUATION REPORT (PBRER) GUIDELINE
Local perspective

11:45 **Session 7**
ICH E2E PHARMACOVIGILANCE PLANNING
Local perspective

13:15 LUNCH

14:15 **Session 8**
Case studies of practical exercises related to the ICH implementation in EU and US
Case studies and discussion on local aspects

15:45 END OF TRAINING COURSE

HOTEL INFORMATION

A limited number of rooms has been blocked at the following hotel:

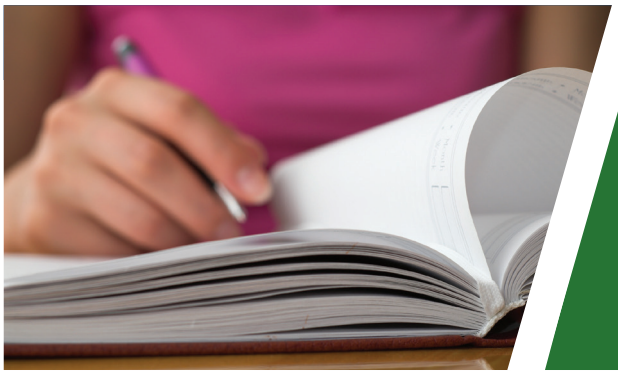
Hotel Antunovic
Zagrebačka Avenija 100 A
100 90 Zagreb
Croatia

Tel.: +385 1 2041 121 - Fax: +385 1 2041 762 - Website: http://www.hotelantunovic.com/en/

at the rate of:
single room: EUR 95.00 per person per day incl. breakfast
double room: EUR 60.00 per person per day incl. breakfast
exclusive of city tax of EUR 1.00 per person per day

The hotel is situated approximately 15 min. walking distance from HALMED.

Important: The room rate is available until 30 October 2013 or until the group block is sold-out, whichever comes first.
Cancellation policy: Hotel reservations are subject to one night cancellation fee if you cancel 14 days prior to the course start date and no shows will be responsible for the full hotel charges.



DIA EUROPE TRAINING PROGRAMME 2013-2014

Chemistry, Manufacturing and Controls (CMC) / Quality

- **Global CTD Dossier – Regulatory aspects and focus on quality documentation including concepts of Quality by Design**
  1-3 December 2013 | Dubai, United Arab Emirates | ID 13562
- **Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators**
  11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research

- **Advanced GCP Study Monitoring**
  Next recurrence of this course to be announced
- **Clinical Project Management – Part I**
  18-20 September 2013 | Basel, Switzerland | ID 13572
- **Clinical Project Management – Part II**
  25-27 November 2013 | Zurich, Switzerland | ID 13501
- **Clinical Statistics for Non-Statisticians**
  24-25 October 2013 | London, United Kingdom | ID 13551
- **Essentials of Clinical Study Management**
  20-22 November 2013 | Paris, France | ID 13554
- **Practical GCP Compliance Auditing of Trials and Systems**
  23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences

- **Non-Clinical Safety Sciences and Their Regulatory Aspects**
  February 2014 | Lisbon, Portugal

Regulatory Affairs

- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
  18-20 September 2013 | Basel, Switzerland | ID 13546
- **European Regulatory Affairs: In-depth review of current registration procedures in the European Union**
  21-22 November 2013 | Paris, France | ID 13553
- **Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices**
  Next recurrence of this course to be announced
- **Health Authority Interactions – Preparation, consultation and implementation**
  15-16 October 2013 | Vienna, Austria | ID 13575
- **Health Technology Assessment (HTA)**
  26-27 November 2013 | Zurich, Switzerland | ID 13561
- **Paediatric Investigation Plans (PIP)**
  November 2013 | Location to be confirmed
- **The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)**
  2-4 October 2013 | Basel, Switzerland | ID 13532
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
  6-8 November 2013 | Paris, France | ID 13552

Safety and Pharmacovigilance

- **Benefit/Risk Management**
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  19-20 September 2013 | Paris, France | ID 13563
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  7–8 November 2013 | Paris, France | ID 13556
- **ICH Endorsed Pharmacovigilance**
  22-23 September 2013 | Muscat, Sultanate of Oman | ID 13568
  28-29 November 2013 | Zagreb, Croatia | ID 13569
- **Pre-Marketing Clinical Safety**
  Next recurrence of this course to be announced
- **Signal Management in Pharmacovigilance**
  6–7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

- **Benefit/Risk Management**
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  19-20 September 2013 | Paris, France | ID 13563
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  7–8 November 2013 | Paris, France | ID 13556
- **ICH Endorsed Pharmacovigilance**
  22-23 September 2013 | Muscat, Sultanate of Oman | ID 13568
  28-29 November 2013 | Zagreb, Croatia | ID 13569
- **Pre-Marketing Clinical Safety**
  Next recurrence of this course to be announced
- **Signal Management in Pharmacovigilance**
  6–7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses

- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  18-22 November 2013 | London, United Kingdom | ID 13522
- **MedDRA Information Day**
  22 October 2013 | London, United Kingdom | ID 13542
- **EudraVigilance Information Day**
  10 December 2013 | London, United Kingdom | ID 13530
- **EudraVigilance courses:**
  - EudraVigilance – Electronic reporting of ICSRs in the EEA
  - eXtended EudraVigilance Medicinal Product Dictionary
  - Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

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DIA Tailored Training is available to both public and private institutions and is delivered by instructors with no conflict of interest.

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Call DIA Europe on +41 61 225 51 51 or email: diaeurope@diaeurope.org

MAY 2013

REGISTRATION FORM

ICH Endorsed Pharmacovigilance Training Course

28-29 November 2013 | HALMED (Agency for Medicinal Products and Medical Devices), Zagreb, Croatia

ID# 13569

SEND YOUR COMPLETED REGISTRATION FORM TO OBZOR PUTOVANJA, Teslina 5, 10000 Zagreb, Croatia: FAX +385 1 6160 240 ; TEL. +385 1 6160 242 OR EMAIL TO: vladimir.mitic@croatiaairlines.hr

Registration fee (The registration fee includes training course material, lunch and coffee breaks)	Fees*
Industry	1'100 EUR ❑
Industry, Croatian participants	8'250 HRK ❑
Academia/Charitable/Non-profit (Full-time)	500.00 EUR ❑
Academia/Charitable/Non-profit (Full-time), Croatian participants	3'750.00 HRK ❑
Government	400.00 EUR ❑
Government, Croatian participants	3'000.00 HRK ❑

***ALL FEES ARE SUBJECT TO THE CROATIAN VAT AT 25 %. EXCHANGE RATE 1 EUR = 7.50 HRK.**
PAYMENT OF REGISTRATION FEES MUST BE RECEIVED BEFORE COMMENCEMENT OF THE COURSE.

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

LAST NAME

FIRST NAME

COMPANY

JOB TITLE

STREET ADDRESS / P.O. BOX

POSTAL CODE

CITY

COUNTRY

TELEPHONE

FAX

E-MAIL

OIB or VAT (Required for Croatian participants)

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

ADDITIONAL SERVICES

Would you like Obzor putovanja to provide additional services, please mark if required:

❑ **Airplane ticket (OBZOR will contact you with their proposal)**

From: To:

❑ **Transfer arrival (30.00 EUR per person per way)**

Flight: Date: Arrival time:

❑ **Transfer departure (30.00 EUR per person per way)**

Flight: Date: Arrival time:

PAYMENT METHODS

AFTER RECEIVING YOUR REGISTRATION, OBZOR WILL SEND YOU A CONFIRMATION/INVOICE WITH DETAILS FOR YOUR PAYMENT WHICH SHOULD BE MADE BY BANK TRANSFER.

Bank transfer only:
Payments should be made to:
OBZOR PUTOVANJA d.o.o.
Teslina 5
10000 Zagreb
Croatia

❑ Payments of participants from the EEA shall be made in EURO to:
ZAGREBACKA BANKA ZAGREB
2360000 - 1000000013 - 2500 - 0490555 - 978
SWIFT CODE ZABAHR2X BY ZAGREBACKA BANKA
IBAN HR33 2360 0001 1016 22374

❑ Payments from Croatian participants shall be made in HRK to
Kunski racun kod PRIVREDNE BANKE ZAGREB HR48 2340 0091 1001 8258 0

Payments should include your name, company, Meeting ID#13569 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be done by the payer.

ACCOMMODATION RESERVATION

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Hotel Antunovic - Zagrebačka Avenija 100 A - 100 90 Zagreb - Croatia
at the rate of:
single room: EUR 95.00 per person per day incl. breakfast
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❑ SINGLE ROOM
❑ DOUBLE ROOM (sharing with)

Arrival date: Departure date:

Notice (allergies, disabilities etc.):

CANCELLATION POLICY

Cancellations must be made in writing and be received at the OBZOR office five working days prior to the course start

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Standard EUR 200.00 / HRK 1'500.00 - Reduced EUR 100.00 / HRK 750.00. Hotel reservations are subject to one night cancellation fee.
Registrants who do not cancel five working days prior to the course start date and do not attend, will be responsible for the full registration fee. OBZOR reserves the right to alter the venue and dates if necessary. If an event is cancelled OBZOR is not responsible for airfare, hotel or other costs incurred by registrants. Registrants are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event. Please notify the OBZOR office of any such substitutions as soon as possible.

IMPORTANT: If registrants want to make their own hotel and travel reservations, they should be made ONLY after receipt of written registration confirmation from OBZOR. If you have not received your confirmation within five working days, please contact OBZOR.