ICH Endorsed Pharmacovigilance Training Course

22-23 October 2012
Bytes Conference Centre, Bytes Business Park, Block C,
241 Third Road, Midrand (Johannesburg), South Africa

Faculty

Prof Shabir Banoo
Pharmacovigilance Committee
Medicines Control Council (MCC)
South Africa

Oppel B W Greeff, MBChB, FCFP (SA), MPharmMed, FFPM (RCP), MD
Head, Department of Pharmacology
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South Africa

Marzelle Haskins
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South Africa

Natalia Kocankova, MD, MBA
Director, Drug Safety Europe
Sucampo AG
Switzerland

Gavin Steel
Systems for Improved Access to Pharmaceuticals and Services (SIAPS)
Deputy Chairman, Pharmacovigilance Committee
Medicines Control Council (MCC)
South Africa

Continuing Education

The Faculty of Health Sciences, University of Pretoria has accredited this training course with 12 CPD credits.

This course has limited capacity. Register early.

Overview

This course focuses on ICH international standards related to pharmacovigilance (ICH E2 series). It covers the principles, logic, and practical implementation of the guidelines in the international environment, and includes some examples of their implementation. ICH E2 series covers both pre-authorisation and post-authorisation pharmacovigilance standards. The course has been prepared by experienced pharmacovigilance professionals. Participants will get a very solid grounding in international approaches to pharmacovigilance as well as the understanding necessary for successful local application of those approaches.

Key Topics

ICH

- ICH E2A – Pre-marketing safety
- ICH M1 – MedDRA
- ICH E2C(R2) – Periodic Benefit Risk Evaluation Report (PBRER) Guideline
- ICH E2D – Definitions & standards for expedited reporting (post-approval)
- ICH E2F – Development Safety Update Report

EU

- EU GVP Module V Risk Management Plan
- EU GVP Module IX Signal Management

Enjoy comprehensive training in different pharmacovigilance areas, from pre-marketing safety, to all legal requirements for reporting in the post-marketing environment, including an overview of MedDRA coding.

Take advantage of new possibilities of benefit optimisation and risk minimisation of products, including Risk Management Plan (RMP), Development Safety Update Report (DSUR) and Periodic Safety Update Report (PSUR) - Periodic Benefit-Risk Evaluation Report (PBRER).

Who Will Attend

- 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 basic principles of case reporting in pre- and post-marketing pharmacovigilance, including SMQs and data analysis
- Optimise and plan the submission of aggregate safety reports PBRER and DSUR
- Describe safety, efficacy and effectiveness profiles of a drug
- Understand the principles of different tools for signal management

ICH harmonisation for better health

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DAY ONE

08:00 REGISTRATION

09:00 Session 1
INTRODUCTION TO ICH PHARMACOVIGILANCE GUIDELINES

10:30 COFFEE BREAK

11:00 Session 2
ICH E2A
PRE-MARKETING SAFETY

12:30 LUNCH

13:30 Session 3
ICH E2D
DEFINITIONS & STANDARDS FOR EXPEDITED REPORTING (POST-APPROVAL)

15:00 COFFEE BREAK

15:30 Session 4
ICH M1
MedDRA

17:00 END OF DAY ONE

DAY TWO

09:00 Session 5
ICH E2F
DEVELOPMENT SAFETY UPDATE REPORT

10:30 COFFEE BREAK

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

12:30 LUNCH

13:30 Session 7
EU GVP MODULE V RISK MANAGEMENT PLAN
EU GVP MODULE IX SIGNAL MANAGEMENT

15:00 COFFEE BREAK

15:30 Session 8
Q&A AND PRACTICAL EXERCISES RELATED TO THE LOCAL IMPLEMENTATION

17:00 END OF TRAINING COURSE

TRAINING COURSE LOCATION

Bytes Conference Centre
Bytes Business Park
Block C
241 Third Road
Midrand (Johannesburg)
South Africa

Tel.: +27 11 205 7151/2/3
Web: www.bytes.co.za

HOTEL INFORMATION

Attendees are requested to make their own bookings.

The recommended hotel close to the Bytes Conference Centre:

Protea Hotel Midrand
14th Street, Noordwyk Ext. 20
Halfway House
Midrand (Johannesburg)
Gauteng
South Africa

Tel.: +27 11 318 1868
Fax: +27 11 318 2429
Email: info@proteamidrand.co.za
Web: http://www.proteahotels.com/protea-hotel-midrand.html

REGISTRATION FORM

ICH Endorsed Pharmacovigilance Training Course

22-23 October 2012 | Bytes Conference Centre, Midrand (Johannesburg), South Africa

PIASA
Pharmaceutical Industry Association of South Africa

FEE	❑ € 300.00	❑ ZAR 3'090.39	Exchange rate 1 EUR = 10.3013 ZAR

TOTAL AMOUNT DUE:	€_____	NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ CMC
__ Clinical Data Management/eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'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 (Required for confirmation)

Email

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

PAYMENT METHOD

Payment can only be accepted by bank transfer.

Standard Bank
Account Number: 022277439
Branch: Hyde Park
Branch No: 006605
Type of Account: Cheque
Name of Account: Pharmaceutical Industry Association of South Africa

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

By signing below, I confirm that I agree with PIASA's Terms and Conditions of booking.

Date | Signature

CANCELLATION POLICY

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

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: € 50.00 / 515.07 ZAR
Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you will be responsible for the full registration fee. PIASA reserves the right to alter the venue and dates if necessary. If an event is cancelled PIASA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees 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 but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the PIASA office of any such substitutions as soon as possible.

Pharmaceutical Industry Association of South Africa (PIASA) | **Tel.** +27 11 805 5100 | **Fax** +27 11 805 5105 | **Online** www.piasa.co.za