ICH Endorsed Pharmacovigilance Training Course

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

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.


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 SMEs 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

This course has limited capacity. Register early.
### Day One

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Topic</th>
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<tbody>
<tr>
<td>08:00</td>
<td>Registration</td>
<td>-</td>
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<tr>
<td>09:00</td>
<td>Session 1</td>
<td><strong>INTRODUCTION TO ICH PHARMACOVIGILANCE GUIDELINES</strong></td>
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<tr>
<td>10:30</td>
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<td><strong>COFFEE BREAK</strong></td>
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<tr>
<td>11:00</td>
<td>Session 2</td>
<td><strong>ICH E2A</strong>&lt;br&gt;<strong>PRE-MARKETING SAFETY</strong></td>
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<tr>
<td>12:30</td>
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<td><strong>LUNCH</strong></td>
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<tr>
<td>13:30</td>
<td>Session 3</td>
<td><strong>ICH E2D</strong>&lt;br&gt;<strong>DEFINITIONS &amp; STANDARDS FOR EXPEDITED REPORTING (POST-APPROVAL)</strong></td>
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<td>15:00</td>
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<td><strong>COFFEE BREAK</strong></td>
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<tr>
<td>15:30</td>
<td>Session 4</td>
<td><strong>ICH M1</strong>&lt;br&gt;<strong>MedDRA</strong></td>
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<td>17:00</td>
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<td><strong>END OF DAY ONE</strong></td>
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### Day Two

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<thead>
<tr>
<th>Time</th>
<th>Session 5</th>
<th>Topic</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Session 5</td>
<td><strong>ICH E2F</strong>&lt;br&gt;<strong>DEVELOPMENT SAFETY UPDATE REPORT</strong></td>
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<tr>
<td>10:30</td>
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<td><strong>COFFEE BREAK</strong></td>
</tr>
<tr>
<td>11:00</td>
<td>Session 6</td>
<td><strong>ICH E2C(R2)</strong>&lt;br&gt;<strong>PERIODIC BENEFIT RISK EVALUATION REPORT (PBRER) GUIDELINE</strong></td>
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<tr>
<td>12:30</td>
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<td><strong>LUNCH</strong></td>
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<tr>
<td>13:30</td>
<td>Session 7</td>
<td><strong>EU GVP MODULE V RISK MANAGEMENT PLAN</strong>&lt;br&gt;<strong>EU GVP MODULE IX SIGNAL MANAGEMENT</strong></td>
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<td>15:00</td>
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<td><strong>COFFEE BREAK</strong></td>
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<tr>
<td>15:30</td>
<td>Session 8</td>
<td><strong>Q&amp;A AND PRACTICAL EXERCISES RELATED TO THE LOCAL IMPLEMENTATION</strong></td>
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<td>17:00</td>
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<td><strong>END OF TRAINING COURSE</strong></td>
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### Training Course Location

Bytes Conference Centre<br>Bytes Business Park<br>Block C<br>241 Third Road<br>Midrand (Johannesburg)<br>South Africa<br>Tel.: +27 11 205 7151/2/3<br>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<br>14th Street, Noordwyk Ext. 20<br>Halfway House<br>Midrand (Johannesburg)<br>Gauteng<br>South Africa<br>Tel.: +27 11 318 1868<br>Fax: +27 11 318 2429<br>Email: info@proteamidrand.co.za<br>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

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### 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

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### RESPONSIBILITY/INTEREST AREA

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<tr>
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<th>__ CMC</th>
<th>__ Medical Writing</th>
<th>__ Professional Education &amp; Training</th>
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<tr>
<td></td>
<td>__ Clinical Data Management/eClinical</td>
<td>__ Non-clinical</td>
<td>__ Public Policy/Law</td>
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<tr>
<td></td>
<td>__ Clinical Research &amp; Development</td>
<td>__ Outsourcing</td>
<td>__ Quality Assurance/Quality Control</td>
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<td></td>
<td>__ Clinical Safety/Pharmacovigilance</td>
<td>__ Comparative Effectiveness/Health Technology Assessment/Evidence-based Medicine</td>
<td>__ Regulatory Affairs</td>
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<td>__ Document Management/eSubmissions</td>
<td>__ Pricing/Reimbursement</td>
<td>__ Statistics</td>
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<td>__ Medical Communications</td>
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<td>__ IT/Validation</td>
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### 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
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### 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 / 315.07 ZAR

Regrettfully, 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.

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

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**FEES**

- € 300.00
- ZAR 3'090.39

Exchange rate 1 EUR = 10.3013 ZAR

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**CONTACT**

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