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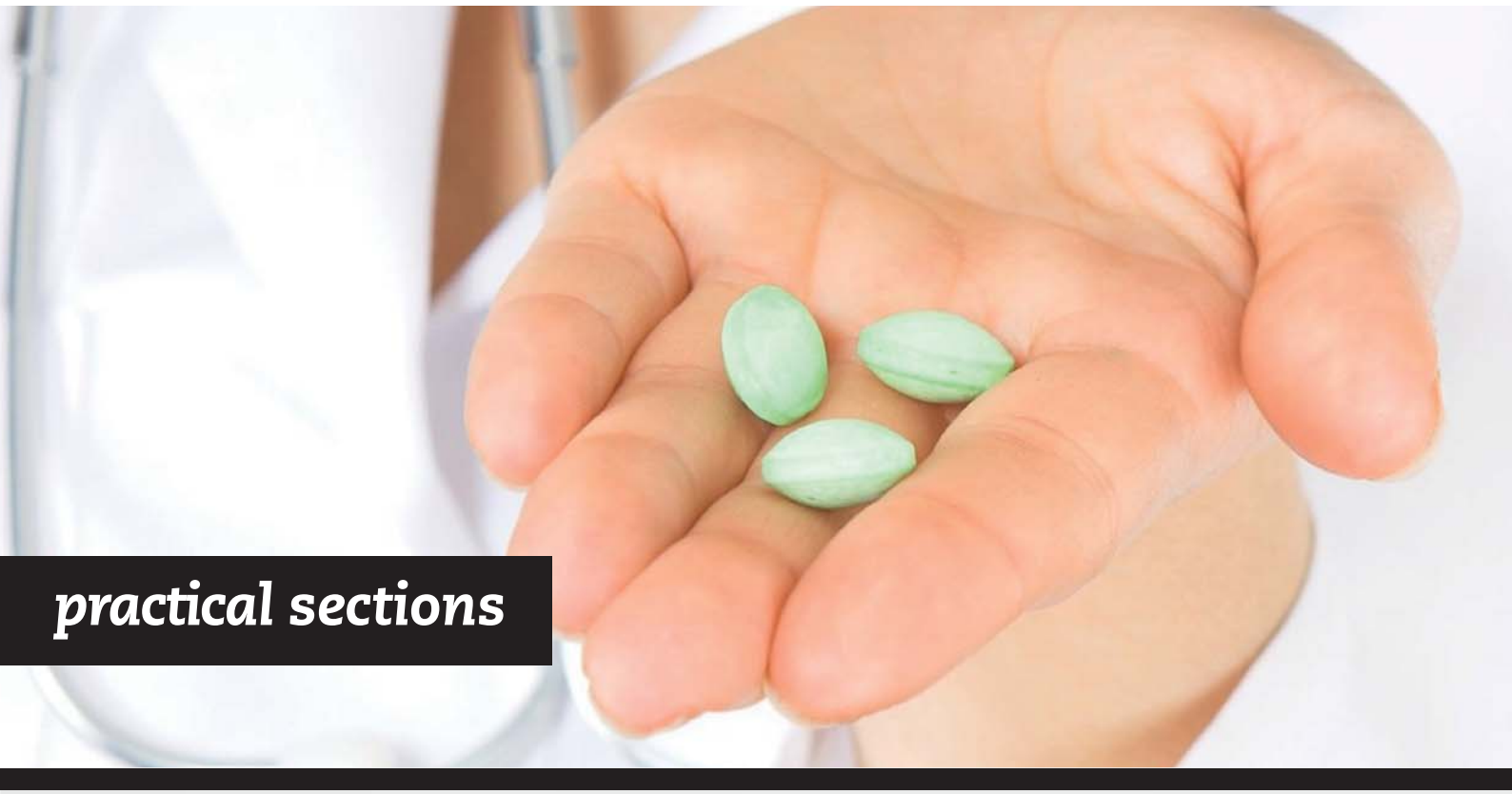
LIFE SCIENCE ACADEMY

PHARMACOVIGILANCE
BASIC TRAINING COURSE 2011
Daily practice in pharmacovigilance



practical sections

20th and 21st October 2011

PRAGUE (CZ)

9:00 am - 5:00 pm

Save 100 Euro if you send the participation form before 30/09/2011

For Further Information, please contact :

ENRICO PEDRONI

tel. (+39) 035.515684
fax: (+39) 035.4501262
mobile: (+39) 338.8422561
e-mail: enrico.pedroni@lsacademy.it

VALERIA QUINTILY

tel. (+39) 035.515684
fax: (+39) 035.4501262
mobile: (+39) 328.4987130
e-mail: valeria.quintily@lsacademy.it

www.lsacademy.it

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***20th and 21st October 2011* - Prague (CZ)**

Pharmacovigilance is a discipline designed to evaluate all information related to drug safety, in development as well as in commerce, on an ongoing basis and to ensure the consistency of a risk / benefit ratio favourable for the population. For this reason the operators of this discipline are required to have medical and regulatory knowledge.

There is a need to train people entering this discipline or retrain and update those who already work in the field. Pharmacovigilance regulations require highly qualified personnel who are up-to-date on the latest changes. The objective of this course is to understand the goals and objectives of Pharmacovigilance, examine the current regulations, interpret and manage information on drug safety and raise awareness of the responsibilities of those working in the field. The participant should be able to acquire the necessary tools to handle daily operations relying on an adequate knowledge base.

At the end of each of the two days, theoretical presentations will be followed by practical sections

Who should attend?

- *Qualified Person Responsible for Pharmacovigilance (QPPV)*
- *Pharmacovigilance Manager*
- *Pharmacovigilance Assistant*
- *Degree in :*
  - *Biology*
  - *Pharmacy*
  - *Medicine*
  - *Chemistry*
  - *Other scientific discipline*

Belonging to:

- *Pharma company*
- *Biotech*
- *CROs*
- *Regulatory Offices*
- *Academic Institution*

LECTURERS

Enrico Marchesi

Pharmacovigilance Consultant

Gian Nicola Castiglione

Drug Safety Corporate Director, Chiesi Farmaceutici S.p.A.

Natalia Kocankova

Head of Corporate Pharmacovigilance Department, EU QPPV, Pharmaswiss

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First Day: 20th October, h. 9:00am – 5:00pm

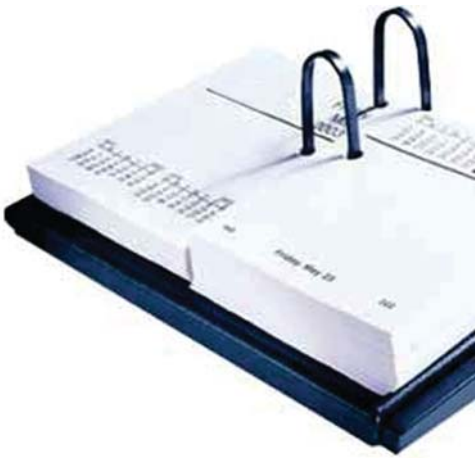
- Historical hints
- Pharmacovigilance aim
- Definitions
  - Guidelines
  - Highlights for the future
- Qualified Person Responsible For Pharmacovigilance (QPPV)
- Adverse Event /Adverse Drug Reaction classification:
  - Seriousness and severity
  - Causality Assessment
  - Expectedness
  - Reference document (SmPC and IB)
- MedDRA dictionary
- How to manage a safety report:
  - Recording
  - Clinical evaluation
  - Reporting
  - Follow up
  - Safety database
  - Archiving and preservation of documents
- Report forms
- Case narrative
- Practical section (CIOMS preparation)

Second Day: 21th October, h. 9:00am – 5:00pm

- The regulatory basis of pharmacovigilance in clinical trials:
  - European Regulation
  - Guidelines
  - Highlights for the future
- Non interventional trials
- Eudravigilance
- The quality system and procedures for pharmacovigilance
- The regulatory documents:
  - Pharmacovigilance System (DDPS)
  - Periodic Safety Update Report (PSUR)
  - Development Safety Update Report (DSUR)
  - Risk Management Plan (RMP), some hints
- Pharmacovigilance Inspections
- Behaviour during inspections
- Organization of pharmacovigilance in a pharmaceutical company
- Practical section (expedited report selection and description of a case narrative)

AGENDA

9.00 am	***Welcome and registration***
9.30 am	***Course start***
11.15 am – 11.30 am	***Coffee Break***
1.00 pm – 1.45 pm	***Lunch***
3:30 pm – 3.45 pm	***Coffee Break***
5.00 pm	***Discussion and closure***



PHARMACOVIGILANCE BASIC TRAINING COURSE 2011

Daily practice in pharmacovigilance

***20th and 21st October 2011* - Prague (CZ)**

Lecturer:

Enrico Marchesi - Pharmacovigilance consultant

Enrico holds a degree in Biological Sciences from the Pavia University.
Since 1969 he has worked in major pharmaceutical companies such as Hoechst, Polichimica and Recordati, holding a variety of roles in various departments as assistant in the International Department and then in the Medical Department. In 1982 he moved to Schering-Plough assuming the position of Project a Leader in clinical research. In 1993 he created the Italian pharmacovigilance unit of Schering-Plough. In 1998 he was promoted to European Safety Director for Schering-Plough Europe and he moved to the UK holding this position until retirement. As a Qualified Person of Pharmacovigilance at European level (QPPV), Enrico has organized international meetings on an annual basis aimed at all those responsible for pharmacovigilance for international, European and non-European affiliates.
Since 2003 he has been teaching Master in Pharmacovigilance at the University of Milan and since 2004 has been the official instructor for courses on EMEA Eudravigilance.
Author of numerous publications, he is now a consultant working for national and international clients conducting audits of system and providing support for pharmacovigilance system implementation. As a Eudravigilance instructor, he holds courses for members of pharmaceutical companies and health authorities for the EMEA in London, Italy and other places worldwide.

Gian Nicola Castiglione - Director of Drug Safety Corporate, Chiesi Farmaceutici SpA

Gian Nicola graduated with a degree in Medicine in 1988 from Bologna University . After experience as a Medical representative for Eli Lilly, he worked for the Medical Direction of Chiesi Farmaceutici S.p.A since 1991 in the role of Clinical Research Assistant and then as Clinical Project Manager . In September 1997 he bocome responsible for pharmacovigilance. He currently holds the role of European Qualified Person Responsible for Pharmacovigilance and Drug Safety Director for the Corporate Group, Chiesi Farmaceutici SpA. He is also a Professor of Pharmacoepidemiology and Pharmacovigilance (since 2001) and Professor for Master in Technology and Regulatory Affairs (since 2007) at the University of Parma. Finally he is a member of the Pharmacovigilance Working Party Ad Hoc Group of EFPIA (July 2008).

Natalia Kocankova - Head of Corporate Pharmacovigilance Department, EU QPPV, Pharmaswiss

Since 2008 she holds the position of Head of Corporate Pharmacovigilance Manager and EU QPPV of PharmaSwiss where she built up whole pharmacovigilance system for whole company including EU and non EU countries. In 2004-2008 worked at sanofi-aventis for the position of Affiliate Pharmacovigilance Head.
She graduated from 2nd Medical Faculty of Charles University in Prague. From 1996-2003 she worked at AstraZeneca as a Medical representative and Product specialist within the different therapeutically areas.
In 2005 completed MBA studies at the City University of Seattle, College of Finance and Administration in Prague. It is a member and active international speaker of the International Society of Pharmacovigilance – ISOP, member of DIA, BARQUA. She did several presentation of pharmacovigilance in Czech Republic for International Institute of Research, DUX Training and Consulting and 1st Medical Faculty of Charles Univesity.

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REGISTRATION FEES:

Euro 940 before 30th September 2011 (early bird)
Euro 1040 on or after 1st June 2011
Euro 540 for Academy and Public Administration personnel *

The fee includes: seat at the course, educational material, copy of lecturers' presentations, networking lunch, coffee breaks, organisational assistance leading up to the event, certificate of attendance.

** The early bird discount of € 100 does not apply to the Academy and P.A. fee.*

Packaged rates for multiple enrolment

2 pax: Euro 1664 (Euro 1504 before 30th September 2011)
3 pax (2 + 1 free) : Euro 2080 (Euro 1880 before 30th September 2011)

In order to attend the course the registration form should be completed and faxed to (+39) 035 4501262 or emailed to: segreteria@lsacademy.it
Please use one form for each participant.

Payment

Payment should be made ***online*** *(http://www.easy-b.it/events.html) or by* ***bank transfer*** *(please see details below), along with the registration form. Upon receipt of payment, the registration will be confirmed. Invoice will be sent following receipt of payment. We can't accept late registrations due to limited course place available.*

Bank transfer: *(Please send proof of bank transfer via fax or email)*

EasyB S.r.l.
Via Roma, 25 - 24022
Alzano Lombardo (BG)
P. IVA 03633040161
Banca Popolare di Vicenza - Filiale di Nese
IBAN:
IT27H0572852521820570697999

REGISTRATION FORM - PLEASE FILL IN AND SEND VIA FAX: (+39) 035.4501262 OR E-MAIL: segreteria@lsacademy.it

On line ☐ Bank Transfer ☐
Surname Name
Company Job Title
Address
City Post Code
Tel. Fax.
E-mail
Special dietary requests

INVOICING DETAILS

Company name
Address
Mail address (if different) Post Code
City VAT number
I would like to receive information on accomodation: ☐

Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received before October 13th, 2011. Cancellations will only be valid if made in writing.
Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event.
EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the adevrtised speakers for an event.EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

THE COURSE WILL PROCEED WITH A MINIMUM OF 20 PARTICIPANTS.

Information collection and use *- Participants information is collected and utilised by EasyB s.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.*

Date ..... Signature .....

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:
Enrico Pedroni tel. (+39) 035.512804 Fax: (+39) 035.4501262 mobile: (+39) 338.8422561 e-mail: enrico.pedroni@lsacademy.it
Valeria Quintily tel. (+39) 035.515884 mobile: (+39) 328.4987130 e-mail: valeria.quintily@lsacademy.it
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