Drug Safety Research Unit

DSRU Education & Training

Courses and Symposia
2016

Experts in Pharmacovigilance Education

www.dsru.org
Welcome to the latest Drug Safety Research Unit (DSRU) Course and Symposia programme in pharmacovigilance, which should give all the information you need to make your choice for study during 2016.

The DSRU is one of Europe’s leading providers of outstanding education and training in pharmacovigilance. Our courses, and the qualifications attained by our delegates, are highly regarded by organisations and professional bodies within this field.

All courses have been carefully developed by experts to deliver high quality, affordable programmes that help delegates achieve esteemed professional and academic standards. Our experienced staff and respected international speakers have a wealth of expertise gained over many years’ practical experience in drug safety and ensure the content of every course is regularly revised to reflect regulatory, industry and scientific developments and feedback from delegates. All courses to date have been awarded Continuing Professional Development credits by the Faculty of Pharmaceutical Medicine.

The DSRU is grateful for the support it receives from the many organisations that encourage their staff to attend our courses and, in turn, we remain committed to providing high quality pharmacovigilance training at a low cost. We continue to welcome suggestions for new courses or ideas on how we can further improve our current programme; please contact our team with your comments.

If you would like to be added to our mailing list to ensure you receive this free brochure every year, please contact us. In the meantime, we look forward to welcoming you to the DSRU courses in 2016.

Location
Courses are generally held in the Southampton area which is just over one hour from central London by train. In addition, Southampton airport has regular flights to and from Europe. A few courses are held in central London. The venues are carefully chosen to provide pleasant accommodation and excellent travel accessibility.

Postgraduate qualifications
The DSRU provides postgraduate awards in pharmacovigilance in association with the University of Portsmouth. This flexible, part-time programme allows you to study for a postgraduate certificate, diploma or masters in pharmacovigilance.

If you are interested in accredited training please contact us to request a brochure or visit us at www.dsru.org

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Fees
The DSRU is a registered independent medical charity (No. 327206) and not-for-profit organisation, any funds generated from the DSRU’s courses are used to support the public health work of the DSRU to protect patients from the hazards of medicines.

Updates
For updates on all DSRU Education and Research meetings and to find out about newly developed courses and symposia, please visit our website www.dsru.org

To register
Please visit our website www.dsru.org to book and pay for courses online. Alternatively you can contact the Education Team (details below).

Contact us
For further information or to discuss your training needs please contact Fiona Coxsell, Course Administrator at fiona.coxsell@dsru.org or telephone +44 (0)2380 408621.
Monitoring Safety in Clinical Trials and Drug Development

Aimed at:
- Pharmaceutical industry personnel from areas including clinical research, medical writing, regulatory affairs, medical information, post-marketing product support or safety
- Staff from regulatory authorities
- Clinicians and academic staff
- Pharmacists or other professions allied to medicine

Background:
Adverse Drug Reactions (ADRs) are a major clinical problem. An understanding of the clinical aspects of ADRs is a fundamental requirement for any professional in the field of pharmacovigilance. This course provides the opportunity to acquire concentrated instruction on the strategy of therapeutics, medical diagnosis and all medical aspects of ADRs. It is divided into individual body systems and general concepts of ADRs. This course benefits from inter-professional learning across clinical practice, industry and academia where experts from each sector offer interactive sessions with practical examples on a range of aspects of ADRs.

Outline:
- Principles of medical diagnosis
- Comprehensive and up-to-date understanding of medical and scientific aspects of ADRs
- ADR examples
- Overview of ADRs and interactions
- ADRs by body system: Cardiovascular, Dermatological, Endocrinological, Gastrointestinal, Haematological, Hepatic, Neurological, Psychiatric, Renal, Respiratory, plus Teratology and issues in Pregnancy
- Pharmacogenetic and metabolic basis of ADRs
- Immunological aspects of ADRs

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal

- £1290.00 + VAT – Standard registration fee
- £885.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

Back to Basics in Pharmacovigilance

Aimed at:
- Pharmaceutical industry personnel from areas including pharmacovigilance, clinical research, medical affairs, medical writing, regulatory affairs and medical information
- Staff from regulatory authorities

Background:
Monitoring drug safety is very important to public health. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. Those working in pharmacovigilance must have good working knowledge of the principles of drug safety, its regulations and proactive strategies for risk management. This course provides solid practical foundations for those working in drug safety, and an update for experienced staff. This course will be valuable to a broad range of staff across the pharmaceutical industry and regulatory authorities.

Outline:
- Historical aspects and evolution of drug safety
- Basic terminology and key concepts
- Principles of causality
- Regulatory aspects, including the Clinical Trials Directive and PDUFA III
- International Conference on Harmonisation
- Collecting and reporting drug safety information
- Pharmacovigilance planning

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal

- £1190.00 + VAT – Standard registration fee
- £775.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

Medical Aspects of Adverse Drug Reactions

Southampton

Aimed at:
- Pharmaceutical industry personnel from areas including clinical research, medical writing, regulatory affairs, medical information, post-marketing product support or safety
- Staff from regulatory authorities
- Clinicians and academic staff
- Pharmacists or other professions allied to medicine

Background:
Adverse Drug Reactions (ADRs) are a major clinical problem. An understanding of the clinical aspects of ADRs is a fundamental requirement for any professional in the field of pharmacovigilance. This course provides the opportunity to acquire concentrated instruction on the strategy of therapeutics, medical diagnosis and all medical aspects of ADRs. It is divided into individual body systems and general concepts of ADRs. This course benefits from inter-professional learning across clinical practice, industry and academia where experts from each sector offer interactive sessions with practical examples on a range of aspects of ADRs.

Outline:
- Principles of medical diagnosis
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- Immunological aspects of ADRs

Fee:
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- £1290.00 + VAT – Standard registration fee
- £885.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

** An Assessment Support Fee of 10% will be added for those participating in PMST.
Periodic Safety Reports: PSURs/PBRERs

9 – 10 March 2016
Southampton area

Aimed at:
• Pharmaceutical industry personnel from areas including drug safety, clinical research, medical affairs, medical writing, regulatory, and medical information.
• Staff from regulatory authorities

Background:
This course will cover the evolution of Periodic Safety Update Report (PSUR) and into the new Periodic Benefit-Risk Evaluation Report (PBRER) format. Through their content PBRERs serve to provide succinct summary information together with a critical evaluation of the benefit-risk balance of the product in the light of new or changing information. Participants will gain an understanding of the new ICH guideline and EU legislation for writing these documents intended to provide an update of the worldwide safety experience of a medicinal product to Competent Authorities. Group sessions and workshops will discuss the practical application of the guidelines to emerging data on drug products. Practical issues, such as the planning and writing of reports and the evaluation of the emerging data will be addressed. This course has been developed for those who have no previous training in writing PBRERs as well as those who have a basic knowledge which they wish to improve.

Outline:
• Development of Good Pharmacovigilance Practices (GVP)
• Timetable for implementation and requirements of GVP
• Use of pharmacoepidemiology in the detection and investigation of signals
• Pharmacovigilance and risk management planning

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal

£1190.00 + VAT – Standard registration fee
£775.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

Introduction to Pharmacoepidemiology*

13 – 14 April 2016, repeated 2 – 3 November 2016
Southampton area

Aimed at:
• Pharmaceutical industry personnel from areas including pharmacoepidemiology, clinical research, medical affairs, medical writing, regulatory affairs and medical information
• Pharmaceutical physicians completing the Drug Safety Surveillance module of Pharmaceutical Medicine Specialty Training (PMST)
• Staff from regulatory authorities
• NHS, NHS R&D and other research organisations, doctors, nurses, medical information pharmacists, pharmaceutical advisors or other professions allied to medicine

Background:
Pharmacoepidemiology is a key discipline for understanding the safety of medicines. It is also being increasingly recognised as a practical tool for supporting risk management and in planning safety activities at the time medicines are authorised. The course focuses on development of practical skills and it would benefit staff across industry, regulatory authorities and academia. This introduction will be suitable both for those with no previous experience in pharmacoepidemiology, as well as those with basic knowledge that they wish to expand.

Outline:
• Principles of epidemiology and pharmacoepidemiology
• Study methods and data resources
• Interpretation of pharmacoepidemiological data
• Use of pharmacoepidemiology in the detection and investigation of signals
• Pharmacoepidemiology and risk management planning

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal

£1190.00 + VAT – Standard registration fee
£775.00 + VAT** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

Note:
This course is one of the three DSRU courses which comprise the Drug Safety Surveillance module of the PMST and can be used by pharmaceutical physicians as part of that training if required.

Periodic Safety Reports: PSURs/PBRERs

11 – 12 May 2016
Southampton area

Aimed at:
• Pharmaceutical industry personnel from areas including drug safety, medical affairs and regulatory affairs
• Staff from regulatory authorities
• Medical writers
• Others with an interest in learning more about periodic updates

Background:
In 2012 new pharmacovigilance legislation, Directive 2010/84/EU, became effective in Europe replacing the former Volume 9A of the rules governing Medicinal Products in the EU. This forms the foundations of practice and pharmacovigilance in both the pharmaceutical industry and regulatory authorities. This course will cover the development and requirements of Good Pharmacovigilance Practices (GVP) as well as other aspects of the new legislation and give attendees a professional working knowledge of requirements and an overview of the processes and procedures necessary to ensure compliance.

Outline:
• Rationale for writing PSURs/PBRERs
• Format and content of PSURs/PBRERs
• Planning, writing and reviewing of PSURs and PBRERs

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal

£1070.00 + VAT – Standard registration fee
£695.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities
Pharmacovigilance Planning and Risk Management

Aimed at:
• Experienced colleagues working in the pharmaceutical industry, for regulatory authorities or research organisations

Background:
A proactive approach to risk management of drug safety is vital throughout the whole life-cycle of a medicinal product. In this course we critically explore existing and developing strategies to plan and optimise risk management activities for known and potential risks of a newly approved product and for extending safety knowledge post-authorisation. Understanding the drivers and relationships between safety specification, pharmacovigilance plans, risk minimisation programmes and pharmacoepidemiology will be a central theme. Experts will share their personal experiences in managing the risk of bringing new medicines to market, and outline new approaches to mitigating risk and improving decision making. Group interactive sessions will analyse ‘real-world’ challenges faced by marketing authorisation holders and regulators.

Outline:
• Current regulations and guidance relevant to global risk management
• Safety specification and pharmacovigilance planning
• Risk management activities and the drug development programme
• Stakeholder perspectives on construction and execution of risk management plans
• Workshops to analyse recent challenges in the implementation of risk management plans
• Development of best practice techniques
• Management of drug safety after reclassification

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal
£1190.00 + VAT – Standard registration fee
£775.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

Reviewing and Understanding Clinical Papers

Aimed at:
• Pharmaceutical industry personnel from areas including pharmacovigilance, clinical research, medical affairs, medical writing, regulatory affairs, medical information, post-marketing product support and safety
• Candidates about to sit postgraduate exams with assessment of critical appraisal skills as a component eg. in pharmaceutical medicine
• Staff from regulatory authorities
• General practice or public health personnel
• NHS, NHS R&D and other research organisations and agency staff including researchers, doctors, nurses, medical information pharmacists, pharmaceutical advisors or other professions allied to medicine

Background:
The practice of evidence-based medicine means integrating the current best research evidence with clinical decision making. Research evidence is one of many factors that are important when making healthcare decisions. A systematic and objective examination of research evidence in terms of its quality, validity, and relevance of results to specific situations give insight into the strength of a paper. It provides a balanced assessment of the benefits and strengths of research against its flaws and weaknesses. As well as incorporating the theoretical foundation, the programme includes interactive sessions with practical techniques to enable participants to draw strong evidence based conclusions.

Outline:
• Awareness of key study design and basic statistical concepts
• Understanding of the critical appraisal process
• Practical experience in applying critical appraisal
• Gain additional skills in drawing conclusions on research findings
• An appreciation of the rationale behind evidence based medicine

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal
£764.00 + VAT – Standard registration fee
£495.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

Global Pharmacovigilance Regulatory Requirements: What’s New?

Aimed at:
• Pharmaceutical industry personnel from areas including drug safety, clinical research, medical affairs, medical writing, regulatory affairs and medical information.
• Staff from regulatory authorities

Background:
Legislation requires that Marketing Authorisation Holders have an acceptable pharmacovigilance system in place and that all aspects comply with the requirements of the appropriate regulatory authority. This course brings together a panel of international experts from industry, regulatory and legal backgrounds to provide up-to-date information on all aspects of compliance in pharmacovigilance (both pre-marketing and post-marketing) for Europe, the USA and Japan including inspection and legal implications.

Outline:
• Compliance in the US – how to satisfy the FDA
• Compliance in the EU – a regulator’s perspective
• Good Pharmacovigilance Practices and other on-going implications related to the EU pharmacovigilance legislation
• The QPPV in the EU
• Legal aspects
• Effects of Japanese regulations on EU compliance
• African pharmacovigilance regulations and impact
• Latin American regulations and their impact on pharmacovigilance
• Differences globally in product information and labelling requirements

Fee:
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal
£1190.00 + VAT – Standard registration fee
£775.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities
**Risk Benefit Assessment in Pharmacovigilance**

**19 - 20 October 2016**  
**Southampton area**

**Aimed at:**  
- Pharmaceutical industry personnel from areas including pharmacovigilance, clinical research, medical affairs, medical writing, regulatory affairs and medical information  
- Pharmaceutical physicians completing the Drug Safety Surveillance module of Pharmaceutical Medicine Specialty Training (PMST)  
- Staff from regulatory authorities

**Background:**  
All risks must be considered in the context of benefits. Assessment of the balance of risk and benefit is vital throughout the whole life cycle of a medicine. The underlying principles of assessment are the same whether pre- or post-marketing. For each medicine there is a balance between risk and benefit, but the perspective of different stakeholders (regulator, marketing authorisation holder, academic, patient, or prescriber) may vary. This course enables delegates to explore the relationship between risk and benefit, plus review the integration of appropriate strategies within risk management plans.

**Outline:**  
- Principles of risk benefit assessment and management  
- Implications of the EU PV Legislation

**Fee:**  
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal  

**£1190.00 + VAT ** – Standard registration fee  
**£775.00 + VAT ** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

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**Pharmacovigilance in Products Subject to Licensing Agreements**

**30 November - 1 December 2016**  
**Central London**

**Aimed at:**  
- Pharmaceutical industry personnel from areas including pharmacovigilance, drug safety, regulatory affairs, clinical research and legal departments  
- Staff from regulatory authorities

**Background:**  
At a time when company strategies increasingly look to strengthen their portfolios through in-licensing, co-development, co-marketing or co-promotion opportunities this course aims to help pharmacovigilance professionals understand the impact of such arrangements on pharmacovigilance activities. The course covers the nature and types of relationships where agreements may be required, the approaches required for different types of relationship and what such agreements should contain. The course will be a balanced mix of presentations and workshops facilitated by people with experience in these areas.

**Outline:**  
- Nature and type of relationships  
- Due diligence activities  
- Content of safety agreements  
- Challenges with international sales teams  
- Perspectives from a small pharma company  
- Managing relationships  
- Legal aspects  
- Compliance and audit  
- Regulatory expectations

**Fee:**  
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal  

**£1190.00 + VAT ** – Standard registration fee  
**£775.00 + VAT ** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

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**Assessment and Medical Evaluation of Individual Case Safety Reports**

**12 - 13 October 2016**  
**Southampton area**

**Aimed at:**  
- Pharmaceutical industry personnel from areas including pharmacovigilance, clinical research, medical affairs, medical writing, regulatory affairs and medical information  
- Staff from regulatory authorities

**Background:**  
This new interactive course is designed to provide the necessary skills and knowledge required to assess individual case reports. Assess reports from various sources both from a regulatory and a clinical perspective. Evaluation of a cluster of reports or case series will be discussed, in addition to guidance regarding the coding of certain types of events such as off label use. The course covers the current and future requirements for the production of case narratives, at an individual level and also within regulatory submissions such as periodic benefit risk evaluation reports. Practical coaching takes place in small groups where delegates have the opportunity to discuss individual cases and receive feedback from expert tutors.

**Outline:**  
- Assessment of reports from various sources both from a regulatory and a clinical perspective  
- Evaluation of a cluster of reports/ case series  
- Coding of atypical events  
- Current and future requirements for the production of case narratives

**Fee:**  
The registration fee includes course materials, refreshments, lunch and a complimentary evening meal  

**£1190.00 + VAT ** – Standard registration fee  
**£775.00 + VAT ** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

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An Assessment Support Fee of 10% will be added for those participating in PMST.
Monitoring the Effectiveness of Risk Minimisation

November 2016
London

We will be holding our ever popular Risk Minimisation meeting, building on the success of the last two years. Following the implementation of GVP Module XVI, this annual conference has caught the imagination of our pharma delegates.

The mix of practical implementation advice, real-world case studies, great networking opportunities, and top pharma and regulatory speakers has ensured that this meeting is a key event in the training calendar for successful pharmacovigilance staff.

Please check the up to date programme and fees on our website: http://www.dsru.org/courses/course-calendar/monitoring-the-effectiveness-of-risk-minimisation

Speakers

Invited international speakers who participated in 2014 courses included:

Glyn Belcher, PV Consultancy
Vicki Edwards, AbbVie
Shelley Gandhi, NDA Regulatory Services
David Lewis, Novartis Pharma AG
Anne Ruth van Troostenburg, Gilead Sciences International Ltd
Thomas Paternoster, European Medicines Agency
Karen Pattenden, Gilead Sciences International Ltd
John Poustie, Novartis
Kristina Strutt, Ipsen
Elspeth McIntosh, Castle Pharmacovigilance Ltd
Jefferson Guillon, Alliance Pharmaceuticals Ltd
Inspectors from the MHRA

Venues

Courses are generally held in the Southampton area which is just over one hour from central London by train. In addition, Southampton airport has regular flights to and from Europe. A few courses are held in central London. The venues are carefully chosen to provide pleasant accommodation and excellent travel accessibility.

Accommodation

Details of accommodation will be provided when delegates register.
Registration

To register please visit our website www.dsru.org where you can book and pay for courses online. Alternatively please contact Fiona Coxsell, Course Administrator, for a registration form or for further details.

Email: fiona.coxsell@dsru.org
Tel: +44 (0)23 80408621

Payments can be made by debit or credit card, cheque, or electronic bank transfer.

Cancellations

Cancellations must be received in writing. Cancellation charges are as follows: more than 28 days prior to the date of the course – 10% of the course fee; less than 28 days, but more than eight days – 25% of the course fee; less than eight days – the full course fee will be charged. Delegate substitutions can be made at any time.

Discounts

The DSRU offers reduced rates for representatives from academic units, public sector organisations or registered charities and, in some cases, when booking as a group or registering for multiple courses. Please contact Fiona Coxsell, Course Administrator, fiona.coxsell@dsru.org for details.

Testimonials

“Very informative course with a good range of information that meets the needs of delegates irrespective of their background. Good presenters who are experts in their area. I really enjoyed the interactive sessions.”

Medical Aspects of ADRs delegate 2015

“Good competent speakers with a wealth of experience. Interesting and experienced participants who contributed relevant questions and interesting discussion.”

Monitoring Safety in Clinical Trials delegate 2015

“This course gave me a great broad overview of pharmacovigilance and the opportunity to meet and interact with delegates from other companies and roles. I wanted to get a practical, big picture view of pharmacovigilance and this course fulfilled that.”

Back to Basics in Pharmacovigilance delegate 2015

“I really enjoyed the training. I liked the interaction between speakers and audience. There was opportunity to share experience, best practice, concerns, etc. Brilliantly organised.”

EU Regulations and Guidelines for Pharmacovigilance delegate 2015

“Many new scientific concepts, philosophic and mathematic thinking which adjust my clinical thinking to what pharmacovigilance and pharmacoepidemiology require.”

Introduction to Pharmacoepidemiology delegate 2015

“Excellent course that met all my learning needs. A lot of useful information was provided and the practical sessions were very helpful. The speakers were very knowledgeable and approachable.”

Periodic Safety Reports delegate 2015

“Excellent balance between the world view and a full range of topics along with up to date information.”

Global Pharmacovigilance Regulatory Requirements delegate 2015

Postgraduate programme in Pharmacovigilance (PgC, PgD, MSc)

We also run a flexible part-time postgraduate programme in pharmacovigilance in collaboration with the University of Portsmouth built around our short courses.

To find out more see our website http://www.dsru.org/courses/pgc-pgd-and-msc-in-pharmacovigilance

This is what one student said about the programme:

“The DSRU courses allow me to step back and see how pharmacovigilance is evolving, and how what we do fits in to the global picture. That is brilliant…. This is why I’m doing what I’m doing and this is what I can contribute”

Postgraduate student 2014 - 2015