Education & Training

Courses and Symposia 2019

EXPERTS IN PHARMACOVIGILANCE EDUCATION

www.dsru.org
“Very enjoyable, informative and thought provoking course. Lovely venue. Excellent presenters. Very well organised and everyone very approachable.”

2018 delegate

“Well organised as always! Very informative and a good introduction to the field. Lots of content covered!”

2017 delegate

“The DSRU courses gave me a really good insight into what pharmacovigilance is about. Not only from the conference speakers and course lecturers, but from the other participants who are from all across the industry and have different perspectives on things and different approaches.”

Bina Patel

“What you are getting is real and valid experience and not just a regurgitation of the regulations. Therefore you also get a good attendee base who participate and discuss the topics together, and share their own views and experience.

DSRU are constantly scrutinising and changing and updating the content they present, and their speakers and presenters are actively engaged in pharmacovigilance work”.

Karen Pattenden
DSRU Course Leader
Welcome to the latest Drug Safety Research Unit (DSRU) Course and Symposia programme in pharmacovigilance, which will give you all the information you need to make your choice for study during 2019.

RESPECTED
The DSRU is one of Europe’s leading providers of outstanding education and training in pharmacovigilance. With our high quality, affordable and flexible training courses, you’ll expand your skills and achieve the esteemed professional qualifications that will allow you to excel in your role and go further in your career.

All DSRU courses are highly regarded by organisations and professional bodies within the pharmaceutical field and they’ve been awarded Continuing Professional Development (CPD) credits by the Faculty of Pharmaceutical Medicine.

KNOWLEDGEABLE
Carefully developed by experts, the content of every course is regularly revised to reflect regulatory, industry and scientific developments and delegate feedback.

Respected international speakers deliver our courses with a wealth of expertise gained over many years in drug safety, giving your learning the valuable benefit of their practical experience.

The DSRU also provides flexible, part-time postgraduate awards in pharmacovigilance in association with the University of Portsmouth, recently awarded a Gold Rating in the Teaching Excellence Framework.

COLLABORATIVE
Well-connected with today’s Pharmacovigilance and Pharmacoepidemiology community, our training supports and encourages best practice throughout the industry.

By attending our interactive courses, not only will you have an opportunity to gain expertise from speakers and get a better understanding of ever-changing regulations, you’ll grow a valuable network of contacts that will serve you well, today and into the future.

Location
Courses are held in London or the Southampton area, UK. The venues are carefully chosen to provide pleasant accommodation and excellent travel accessibility.

Fees
We’re grateful for the support we receive from the many organisations that encourage their staff to attend our courses and, in turn, we remain committed to providing you with high quality pharmacovigilance training at a low cost.

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.

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

Contact us
If you’d like to discuss your training needs, provide feedback on our courses or join our mailing list, please contact us at EandT@dsru.org or telephone +44 (0) 2380 406621
## Overview

### Courses

#### 30 – 31 Jan 2019

**Monitoring Safety in Clinical Trials and Drug Development**

The implementation of the Clinical Trials Directive was a critical event for clinical research and pharmacovigilance, which impacted on all those working in this area. This course is aimed at providing delegates with an overview of some of the challenges companies faced in implementation of safety standards and best practice in managing their implementation.


**Back to Basics in Pharmacovigilance**

This course is designed to provide solid practical foundations for those working in drug safety and will benefit staff working in the pharmaceutical industry and regulatory authorities.

#### 20 – 21 Mar 2019

**EU Regulations and Guidelines in Pharmacovigilance**

This course will cover the development and requirements of Good Pharmacovigilance Practices (GVP) as well as other aspects of the new legislation.

#### 3 – 4 Apr 2019 & 30 – 31 Oct 2019

**Introduction to Pharmacoepidemiology**

Pharmacoepidemiology is a key discipline for understanding the safety of medicines. This course is aimed at introducing delegates to the core concepts of this scientific discipline.

#### 8 – 9 May 2019

**Periodic Safety Reports: PSURs/PBRERs**

This course will cover practical issues, such as planning and writing of reports, and the evaluation of the emerging data will be addressed, particularly the challenges of writing the benefit-risk assessment section of the report.

#### 5 – 7 Jun 2019

**Medical Aspects of Adverse Drug Reactions**

An understanding of the clinical aspects of ADRs is a fundamental requirement for any professional in the field of pharmacovigilance. This course covers recognition and interpretation of adverse drug reactions and their underlying toxopathology and pharmacology.

#### 19 – 20 Jun 2019

**Global Pharmacovigilance Regulatory Requirements: What’s New?**

This symposium 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.

#### 10 – 11 July 2019

**Medication Errors**

An interactive course designed to provide delegates with the necessary skills and knowledge required to collect, assess and report medication error information in line with the recommendations from the European Medicines Agency.
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<tr>
<th>Date</th>
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<tr>
<td>25 – 26 Sept 2019</td>
<td>Pharmacovigilance Planning and Risk Management</td>
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<td>9 – 10 Oct 2019</td>
<td>Risk Benefit Assessment in Pharmacovigilance</td>
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<td>16 – 17 Oct 2019</td>
<td>Assessment and Medical Evaluation of Individual Case Safety Reports</td>
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<td>27 – 28 Nov 2019</td>
<td>Pharmacovigilance in Products Subject to Licensing Agreements</td>
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**Courses for GP's**

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<tr>
<td>1 May 2019, 18 Sept 2019 &amp; 13 November 2019</td>
<td>GP Masterclass</td>
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**Conferences**

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<tr>
<td>11 - 13 Jun 2019</td>
<td>10th Biennial Signal Detection and Signal Management Conference</td>
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<tr>
<td>11 - 12 September 2019</td>
<td>2nd Big Data for Pharmacovigilance Conference</td>
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Speakers

The DSRU’s experienced staff and invited international speakers have a wealth of expertise gained over many years in drug safety, and each training programme is carefully developed by experts. Course content is regularly revised to reflect developments and feedback from delegates.

All courses and symposia have traditionally been awarded Continuing Professional Development points by the Faculty of Pharmaceutical Medicine.

Invited international speakers who participated in 2017/18 courses included:

- Kristina Strutt, Sanofi
- Glyn Belcher, PV Consultancy
- Shelley Gandhi, NDA Regulatory Science Ltd.
- Vicki Edwards, AbbVie
- David Lewis, Novartis Pharma AG
- Thomas Paternoster-Howe, EMA
- Joanne Webbe, Gilead Sciences Intl.
- Martin Menke, CSL Behring
- Jane Knight, MedDRA
- Jane Feron, AstraZeneca
- Jean Kilgour-Christie, Consultant
- Elspeth McIntosh, Castle Pharmacovigilance Ltd.
- Anne-Ruth van Troostenburg de Bruyn, Arvant Ltd.
- Tony Fox, Kings College London
- Heike Schoepper, Merck Serono
- Lesley Wise, Wise PV & Risk Management Ltd.
- Nicholas Rees, AbbVie
- Maria Diedrick, Roche Products Ltd.
- Beatriz Bustillo, Roche Products Ltd.
- Inspectors from the MHRA

Professor Saad Shakir MB ChB LRCP&S FRCP FFPM MRCGP
Director Drug Safety Research Unit

Saad Shakir is a pharmacoepidemiologist and drug safety physician. He has worked in the fields of pharmacovigilance, pharmacoepidemiology and risk management for 30 years, initially at the UK Regulatory Authority, then the international pharmaceutical industry and as the Director of the Drug Safety Research Unit in Southampton.

The DSRU is an academic unit associated with the University of Portsmouth. At the DSRU Saad leads a research team with an active programme for monitoring and studying the safety of medicines in populations. He has led many important drug safety studies and has worked and advised on many drug safety issues including product withdrawals, major restrictions and important safety hazards. Saad serves as a Chairman or member of Safety Advisory Boards and Data Safety Management Committees. He is an author of many book chapters and publications in scientific journals on pharmacovigilance, pharmacoepidemiology and risk management and is a member of the editorial boards for the journals Drug Safety and Pharmacoepidemiology and Drug Safety.

Saad Shakir has led and co-ordinated many post graduate educational and training programmes including the MSc programme in Pharmacovigilance at the DSRU. He supervises post graduate students for higher degrees and has been involved with a number of international initiatives to promote and develop pharmacovigilance and pharmacoepidemiology.

Saad Shakir is a Fellow of the Royal Colleges of Physicians in Glasgow, Edinburgh and London; a Fellow of the Faculty of Pharmaceutical Medicine; a Fellow of the International Society of Pharmacoepidemiology and a Member of the Royal College of General Practitioners in the UK.
Conferences

10th Biennial Signal Detection and Signal Management Conference
Aimed at:
• Pharmaceutical industry personnel from areas including pharmacovigilance departments, clinical research, and epidemiology
• Staff from regulatory authorities
• Academic researchers
• Those with an interest in data analysis and statistics in large epidemiological databases

Background:
Since its inception in 2001, the DSRU Biennial Conference on Signal Detection has established itself as one of the most important meetings in the pharmacovigilance calendar and has built up a loyal following. The conference delivers the best available knowledge and new developments, featuring internationally renowned experts in signal detection and pharmacovigilance. Programme highlights this year cover benefit-risk assessment, large observational data sets and signal detection in patient-generated data. In addition delegates have the opportunity to attend a pre-conference workshop which features practical sessions and case studies.

Outline:
• The potential value of patient-level predictions and models in screening spontaneous reports
• Update on large observational data sets, including OMOP: development, testing and implementation of data mining approaches
• Incorporation of benefit-risk assessment in the analysis of observational medical data
• The ongoing challenges of terminology in drug safety surveillance and evaluation
• The potential value of full predictive models in screening spontaneous reports
• Social media, both as a tool in internet searching and for patient generated data
• How to evaluate spontaneous and longitudinal individual cases
• Real-world case studies

Early Registration - Save 20%
Register before 28 February 2019 and receive a 20% discount on the registration fee.

2nd Big Data for Pharmacovigilance Conference
Aimed at:
• Pharmaceutical industry staff from pharmacovigilance, epidemiology, regulatory affairs
• Those with an interest in large datasets
• Regulatory authority staff
• Academic researchers
• Those with an interest in analysis of large epidemiological or health databases

Background:
The scale of available health data is increasing rapidly and as the age of Big Data is established, and following success of the first conference we will be holding the second "Big Data for Pharmacovigilance" event. Join us to hear how Big Data is revolutionising Pharmacovigilance from a panel of international experts from medicines regulators, industry and academia.

Outline
Pharmacovigilance is increasingly characterised by extremely large data sets from populations, individuals, disease registries, social media, pharmacogenomics and more. While big data can be messy, efforts are underway to establish strategies for ordering and structuring the data in order to put it to the best use in pharmacovigilance and ultimately public health. We will consider how best to link these large data sets and identify data clusters, the challenges and rewards of such large scale data analysis, ways to protect data security and patient confidentiality, and many other pertinent issues.

Early Registration - Save 20%
Register before 31 May 2019 and receive a 20% discount on the registration fee.
Monitoring Safety in Clinical Trials and Drug Development

**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:**
The implementation of the Clinical Trials Directive was a critical event for clinical research and pharmacovigilance in Europe. Its standards have influenced regulatory expectations worldwide which, together with ICH standards, such as the Development Safety Update Report and pharmacovigilance planning, bring new challenges to safety personnel. The directive continues to evolve, challenging the traditions of approaches to clinical trials with respect to safety data management and protocol designs. Join colleagues and share experiences in a series of presentations and workshop scenarios that aim to provide useful insights and practical considerations to help you manage the new and existing challenges of safety in clinical trials.

**Outline:**
- Pharmacovigilance planning and monitoring in drug development, including communication to trial subjects
- Development of labelling – the developmental core safety information through to the core data sheet and SPC
- Risk management in drug development – planning and risk minimisation
- Monitoring safety in clinical trials
- Data Safety Monitoring Boards
- Clinical Trials Directive – current requirements, challenges and future changes
- Producing a Developmental Safety Update Report
- Reporting to EudraVigilance Clinical Trials Module – practicalities and challenges
- Future drug safety regulatory challenges on the horizon for clinical trials and drug development

**Fee:**
The registration fee includes course materials, refreshments, lunch.
- £1190.00 + VAT – Standard registration fee
- £775.00 + 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
- Pharmaceutical physicians completing the Drug Safety Surveillance module of Pharmaceutical Medicine Specialty Training (PMST)
- 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
- International Conference on Harmonisation
- Collecting and reporting drug safety information
- Pharmacovigilance planning

**Fee:**
The registration fee includes course materials, refreshments, lunch.
- £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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* 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.

** An Assessment Support Fee of 10% will be added for those participating in PMST.
EU Regulations and Guidelines in Pharmacovigilance  
**20 - 21 March 2019**  
London

**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:**
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 current legislation and give attendees a professional working knowledge of requirements and an overview of the processes and procedures necessary to ensure compliance. Consideration will also be given to the effects on pharmacovigilance requirements of the UK leaving the EU.

**Outline:**
- Development of Good Pharmacovigilance Practices (GVP)
- Timetable for implementation and requirements of GVP
- Pharmacovigilance System Master Files
- Reporting of adverse drug reactions; reporting requirements, procedures and roles of stakeholders
- Update of PBRERs, Risk Management Plans and PASS
- Inspections; demonstration of compliance

**Fee:**
The registration fee includes course materials, refreshments, lunch.
£1190.00 + VAT*  
£775.00 + VAT ** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities.

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Introduction to Pharmacoepidemiology*  
**3 – 4 April 2019, repeated 30 – 31 October 2019**  
Southampton

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

* 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.

** An assessment Support Fee of 10% will be added for those participating in PMST.
Courses

**Periodic Safety Reports: PSURs/PBRERs**

**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:**
This course will cover the evolution of Periodic Safety Update Report (PSUR) 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:**
- 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.
- **£1070.00 + VAT** – Standard registration fee
- **£695.00 + VAT** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

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**Medical Aspects of Adverse Drug Reactions**

**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 interprofessional 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:**
- 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, Oncology, 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.
- **£1290.00 + VAT** – Standard registration fee
- **£885.00 + VAT** – Reduced registration fee for delegates from academic units, public sector organisations or registered charities
Global Pharmacovigilance Regulatory Requirements: What's New?

19 – 20 June 2019
London

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 Asia 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
• Legal aspects
• Effects of Japanese regulations on EU compliance
• African pharmacovigilance regulations and impact
• Latin American regulations and their impact on pharmacovigilance
• Differences globally (Australia, New Zealand and the Middle East, an overview) in product information and labelling requirements
• PV in Asia – Getting ready for the future
• Russian Pharmacovigilance; is Russia moving in the same direction as Europe

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

Medication Errors

10 – 11 July 2019
London

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:
Our Medication Errors course is an interactive course designed to provide delegates with the necessary skills and knowledge required to collect, assess and report medication error information in line with the recommendations from the European Medicines Agency.

You will have the opportunity to exchange experience on the new good practice guides on medication errors, increase your awareness of the requirements and discuss operational aspects of the implementation of the guidance.

Outline:
• Assessment of medication error reports and MedDRA coding
• Practical aspects of implementation in Global, Affiliate, Medical Information and Product Quality teams
• Medication error signal detection and data presentation in PBRERs
• Risk management strategies tailored to medication errors

Fee:
The registration includes course materials, refreshments, lunch.
£1190.00 + VAT – Standard registration fee
£775.00 + 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.
£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*

**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 authority 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
- Evaluating signals
- Reporting and summarising safety data at registration and for the periodic safety report
- Variations, urgent safety restrictions, licence suspension and withdrawal
- Regulations and guidelines governing risk benefit
- Methods and tools for formal risk benefit assessment
- SPCs and PILs

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

* 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.

** An Assessment Support Fee of 10% will be added for those participating in PMST.
Assessment and Medical Evaluation of Individual Case Safety Reports

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

Pharmacovigilance in Products Subject to Licensing Agreements

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

**GP Masterclass – Effective Prescribing in General Practice**

The DSRU aims to protect patients in primary and specialist care from unwanted adverse effects of newly marketed medicines using unique methods of monitoring patients during the lifecycle of products. The Unit conducts this research in primary care using data on possible side effects obtained from hundreds of GPs across England.

**Learning objectives:**
1. To provide an overview of effective prescribing and explain why it is important in general practice
2. To provide detailed examples of application of effective prescribing in different scenarios
3. To provide practical advice for GPs to improve the effectiveness of their prescribing
4. To explain how effective prescribing can contribute to GP appraisal.

**Recent speakers have included:**
- Prof David Taylor, lead author of the Maudsley Prescribing Guidelines, Maudsley Hospital
- Dr Paul Gallagher, Cork University Hospital and University College
- Dr Klaus Green, GP, Appraiser, CCG clinical lead for Diabetes
- Dr Susie Cooper, GP
- Dr Helen Carr, GP, Appraiser and Research Fellow DSRU
- Dr Neal Maskrey

**Background:**
An educational day for GPs, looking at various aspects of prescribing, accredited by the RCGP. Join us for a chance to think more about your prescribing decisions and to hear from the experts. There will be opportunities for discussion and professional interaction.

This is a very practical training day intended to be directly applicable to practice. The sessions include scenarios which GPs are likely to encounter frequently (including prescribing for depression, children and the elderly) and potential sources of help (including pharmacists or technology) in order to ensure that the knowledge gained can be fully and immediately used in the day-to-day work.

**Outline:**
- Prescribing for osteoporosis
- Prescribing for the elderly
- Prescribing for diabetes
- Therapeutic challenges: case studies
- Prescribing evidence for appraisal
- Prescribing for depression and anxiety

**Fee:**
The registration fee includes course materials, refreshments and lunch.

£125.00 + VAT – For GPs
£85.00 + VAT – For GP Registrars

**“Interactive, small groups, compelling speakers” GP Masterclass 2018 delegate**

**“Good topics and very relevant for common prescribing dilemmas and appropriate prescribing” GP Masterclass 2017 delegate**

**Accommodation**

Details of accommodation will be provided when delegates register.

**Registration**

**Registration**
To register please visit our website www.dsru.org where you can book and pay for courses online. Alternatively please contact the Education & Training Team, for a registration form or for further details.

Email: EandT@dsru.org
Tel: +44 (0)2380 408621

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 the Education & Training team, EandT@dsru.org, for further details.
We also run a flexible part-time postgraduate programme in pharmacovigilance in collaboration with the University of Portsmouth built around our short courses.

### Key Features of our Flexible Study Programme

Three awards are available:
- **PgC** – Three compulsory units with a further unit chosen from eight optional units (60 credits)
- **PgD** – Three compulsory units plus five from eight optional units (120 credits)
- **MSc** – Three compulsory units plus five from eight optional units plus MSc research project (180 credits)

Students will undertake 60 credits in the form of part-time study over a period of one or two years for the PgC, a further 60 credits over the next one or two years for the PgD and then undertake a research project over one to three years for a further 60 credits for the MSc. The duration of each award depends on whether Fast-track or Standard route is selected.

The University operates a system through which you can gain recognition of prior learning (certified/experiential). This is applicable to PgD and MSc awards.

Assessments - The short taught courses are supplemented with pre and post-course assignments.

Intake dates for 2018 - 2019: 3 September 2018; 7 January 2019, 3 June 2019

Intake dates for 2019 - 2020: 2 September 2019; 6 January 2020, 1 June 2020

### Overview of units for PgC, PgD and MSc in Pharmacovigilance

<table>
<thead>
<tr>
<th>Unit Title</th>
<th>Credit Points</th>
<th>Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back to Basics in Pharmacovigilance</td>
<td>15</td>
<td>PgC/PgD - Compulsory</td>
</tr>
<tr>
<td>Introduction to Pharmacoepidemiology</td>
<td>15</td>
<td>PgC/PgD - Compulsory</td>
</tr>
<tr>
<td>Medical Aspects of Adverse Drug Reactions</td>
<td>15</td>
<td>PgC/PgD - Compulsory</td>
</tr>
<tr>
<td>Assessment and Medical Evaluation of Individual Case Safety Reports</td>
<td>15</td>
<td>PgC/PgD - Compulsory</td>
</tr>
<tr>
<td>Monitoring Safety in Clinical Trials and Drug Development</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>Risk Benefit Assessment in Pharmacovigilance</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>Global Pharmacovigilance Regulatory Requirements: What’s New?</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>Periodic Safety Reports (PSURs/PBRERs)</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>EU Regulations &amp; Guidelines in Pharmacovigilizance</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>Pharmacovigilance in Products Subject to Licensing Agreements</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>Pharmacovigilance Planning &amp; Risk Management</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>MSc Research Project</td>
<td>60</td>
<td>MSc</td>
</tr>
</tbody>
</table>