Drug Safety Research Unit

Education & Training Courses and Symposia 2021

Celebrating 20 years of DSRU training

DEVELOP YOUR SKILLS

EXPAND YOUR KNOWLEDGE

REALISE YOUR POTENTIAL

IMPROVE YOUR CAREER

EXPERTS IN PHARMACOVIGILANCE EDUCATION

www.dsru.org
“Interesting speakers, who are extremely knowledgeable”

2020 delegate

“Very enjoyable, informative and thought provoking course. Lovely venue. Excellent presenters. Well organised and everyone approachable.”

2018 delegate

“Your course was very well organized and the speakers were fantastic. Everything went smoothly in terms of connectivity and access. Thank you so much!!!”

2020 online course delegate

“Without the Masters in Pharmacovigilance behind me it would have been difficult to get into the industry as I did not have pharmaceutical industry experience. The qualification has been a talking point in all of my interviews and it has helped me immensely with my career journey thus far.”

Masters in Pharmacovigilance graduate
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, a programme validated by the University of Portsmouth, 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
At the time of going to press, we plan to run all courses online until the end of March 2021. We will restart to face-to-face training (in London or Southampton) once it is safe to do so, according to UK government advice.

How online courses work
We’ll send you a link in advance to enable you to join the live online course at the stated time. Courses will be delivered through a combination of online lectures and interactive workshops in smaller groups, with regular screen breaks. You can still network with other delegates and speakers via scheduled online discussion sessions. Enjoy full access to the presentations afterward and rest assured that you can use this course as part of your Continuing Professional Development (CPD) because points are equivalent to a face-to-face course.

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 408621

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 2021.
Overview

Courses

**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.

27 - 28 Jan 2021

**Back to Basics in Pharmacovigilance**

This course is designed to provide solid practical foundations for those working in all areas of drug safety. Expert speakers will cover principles of pharmacovigilance, regulations and proactive strategies for risk management.

24 - 25 Feb 2021 & 8 - 9 Sept 2021

**EU Regulations and Guidelines in Pharmacovigilance**

This course will cover the requirements of Good Pharmacovigilance Practices (GVP) as well as other aspects of the current legislation. Consideration will be given to the effects on pharmacovigilance requirements of the UK leaving the EU.

10 - 11 Mar 2021

**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.

31 March – 1 April 2021

**Periodic Safety Reports: PSURs/PBRERs and Introduction to DSURs**

This course will cover the rationale and theory behind the evolution of the PSUR/PBRER and DSUR. It offers practical advice designed to give you a working knowledge of planning and writing them.

5 - 6 May 2021

**How to Manage an Audit and Inspection**

Providing an overview of the key features of audits and inspections as well as what makes a successfully run audit/inspection regardless of the findings.

TBC

**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.

9 - 11 Jun 2021
### Pharmacovigilance Planning and Risk Management

This course will critically explore existing and developing strategies to plan and optimise risk management activities for known and potential risks of a newly approved product.

### Risk Benefit Assessment in Pharmacovigilance

This course enables delegates to explore the relationship between risk and benefit from various stakeholder perspectives (regulator, marketing authorisation holder, academic, patient, and prescriber). The integration of appropriate strategies within risk management plans will also be reviewed.

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

This course covers the current and future requirements for the production of individual case safety reports, at an individual level and also within regulatory submissions such as periodic benefit risk evaluation reports.

### Pharmacovigilance in Products Subject to Licensing Agreements

Partnerships between pharmaceutical companies to develop and market products are becoming increasingly common. This course provides delegates with an overview of the nature and types of relationships and agreements between such partners.
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 2019/20 courses included:

• Kristina Strutt, Sanofi
• Glyn Belcher, PV Consultancy
• Shelley Gandhi, NDA Regulatory Science Ltd.
• Vicki Edwards, AbbVie
• Zeshan Iqbal, Kinapse
• Carrie Scott, AbbVie
• Joanne Webbe, Gilead Sciences Intl.
• Martin Menke, CSL Behring
• Jane Knight, MedDRA
• Barry Mulchrone, IQVIA
• Seema Jaitly, Essjay Solutions Ltd
• Elspeth McIntosh, Castle Pharmacovigilance Ltd.
• Anne-Ruth van Troostenburg de Bruyn, Gilead Sciences Intl.
• Tony Fox, Kings College London
• Nicholas Rees, AbbVie
• Peter de Veene, Alexion Pharmaceuticals, Inc
• Adele Sylvester, Gilead Sciences International Ltd
• Hermone Berhane, Roche
• Pedro Lima, Sanofi
• Speakers 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 over 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

Advances in Pharmacovigilance for Herbal Medicines

5-8 October 2021

Aimed at:
• Individuals working in medicines regulatory authorities and pharmacovigilance centres, pharmaceutical industry settings, particularly in pharmacovigilance, medical information, regulatory affairs, and clinical development
• Herbal/phytomedicines industry settings
• Academia, particularly in pharmacovigilance/pharmacoepidemiology, pharmacognosy, phytotherapy/herbal medicines
• Pharmacists and other health professionals
• Herbal/traditional medicine practitioners and organisations

This conference aims to provide a comprehensive and critical update on advances in pharmacovigilance activities for herbal medicines at the national and global levels. It will explore challenges in pharmacovigilance for herbal medicines, developments and new approaches in safety monitoring for herbal medicines, stakeholder perspectives, and future directions.

Keep up-to-date with conference developments by visiting www.dsrtr.org

Background:
The use of herbal medicines, including traditional herbal preparations, for health and well-being, as well as for prevention and treatment of disease remains a popular choice globally. While herbal medicines may bring health benefits, as with other medicinal products, there is also a risk of harm, including from poor-quality products. Developments in regulation for herbal medicines have strengthened pharmacovigilance (safety monitoring) for these products but unique challenges in identifying and responding to herbal safety concerns remain.
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 from DCSI to CCSI and the SPC
• Developmental Risk Management Plans – The challenges
• Monitoring safety in clinical trials
• Data Safety Monitoring Boards
• Clinical Trials Directive – current requirements, challenges and future changes
• Background and implementation of Developmental Safety Update Reports
• Pharmacovigilance in GCP inspections
• Future drug safety regulatory challenges on the horizon for clinical trials and drug development

Fee:
The registration fee includes 20% discount due to being held online
£952.00 + VAT – Standard registration fee
£620.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities

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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.
Fee: The registration fee includes 20% discount due to being held online (February)
£952.00 + VAT** (online) £1190.00 + VAT – Standard registration fee
£620.00 + VAT** (online) £775.00 + – 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.
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:
The EU pharmacovigilance regulations and guidelines became effective in Europe in 2012. They describe the structures, requirements, procedures, roles and activities of the various stakeholders. These are detailed for the collection, verification, presentation and interpretation of adverse reports to exchange information within the EU, to monitor safety products on the market in the EU, to proactively manage safety concerns and to guarantee continuous surveillance of the benefit risk profile of such drugs. Our EU Regulations and Guidelines in Pharmacovigilance course will cover the development and current requirements of Good Pharmacovigilance Practices (GVP). The course will also cover other aspects of the current legislation and will provide delegates with a professional working knowledge of EU Pharmacovigilance 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:
• Timetable for implementation and requirements of Good Pharmacovigilance Practices (GVP)
• Pharmacovigilance System Master Files
• Reporting of adverse drug reactions; reporting requirements, procedures and roles of stakeholders
• Use of pharmacovigilistry in the detection and investigation of signals
• Inspections; demonstration of compliance

Fee:
The registration fee includes 20% discount due to being held online
£952.00 + VAT – Standard registration fee
£620.00 + VAT – Reduced registration fee for delegates from academic units, public sector organisations or registered charities.

**Introduction to Pharmacoepidemiology**

Aimed at:
• Pharmaceutical industry personnel from areas including pharmacoepidemiology, clinical research, medical affairs, medical writing, regulatory 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.
Fee: The registration fee includes 20% discount due to being held online
£952.00 + VAT** (online) £1190.00 + VAT – Standard registration fee
£620.00 + VAT **(online) £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.

*At the time of going to press, we plan to run all courses online until the end of March 2021. We will restart to face-to-face training (in London or Southampton) once it is safe to do so, according to UK government advice.
Courses

Periodic Safety Reports – PSURs/PBRERs & Introduction to DSURs
5 - 6 May 2021
Southampton*

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:
The Periodic Safety Reports – PSURs/PBRERs and Introduction to DSURs course covers the rationale and theory behind the evolution of these reports. It offers an understanding of the respective International Conference on Harmonisation (ICH) guidelines (E2C and E2F), and practical advice designed to give you a working knowledge of planning and writing them. Group sessions and workshops will discuss the practical application of the guidelines to emerging data on drug products. Issues such as the 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. This course has been developed for those who have no previous training in writing PSURs/PBRERs and/or DSURs, as well as those who have a basic knowledge which they wish to improve.

Outline:
• Periodic Safety Reports – what are they for?
• Format and content of PSURs/PBRERs and DSURs
• Planning, writing and reviewing of PSURs and PBRERs
• Reviewing and evaluating a PBRER: the regulator's perspective

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

How to Manage an Audit and Inspection
20 May 2020
London*

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

Background:
The number of audits and inspections is continuing to increase as all companies implement partner audit programmes and more regulatory authorities initiate inspection programmes. As these activities become increasingly time consuming and complex, it is vital that those involved in the management of the audit or inspection have an understanding of what is required and why.

The course will provide you with an overview of the key feature of audits and inspections and discuss what makes a successfully run audit/inspection regardless of the findings. You will obtain practical information and advice on provider audit, the keys to preparing for and effectively managing inspection, as well as gaining insight into the roles and expectations of key personnel. We will also consider differences between inspections in key global markets.

Outline:
• Internal audits, partner audit and inspection – the key features, differences and scope of activities
• Audit/Inspection for service providers
• The role of the QPPV
• Managing audit and inspection – planning and logistics
• Audit/Inspection interviews
• The Inspector’s view
• Industry perspective on differences between inspections from various authorities (FDA, Europe, Japan)
• After the Inspection: Initial feedback, CAPA management and tracking

Fee:
The registration fee includes course materials, refreshments, lunch.
£595.00 + VAT – Standard registration fee
£387.00 + 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?

**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, Australia, New Zealand, the Middle East, Africa 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

*At the time of going to press, we plan to run all courses online until the end of March 2021. We will restart to face-to-face training (in London or Southampton) once it is safe to do so, according to UK government advice.
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

Medication Errors: Collecting, Assessing and Reporting
TBC

Pharmacovigilance Planning and Risk Management
22 - 23 September 2021
Southampton*

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:
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

Pharmacovigilance Planning and Risk Management
22 - 23 September 2021
Southampton*

*At the time of going to press, we plan to run all courses online until the end of March 2021. We will restart to face-to-face training (in London or Southampton) once it is safe to do so, according to UK government advice.
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 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
• 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 and informal risk benefit assessment

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 DISRU 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

*At the time of going to press, we plan to run all courses online until the end of March 2021. We will restart to face-to-face training (in London or Southampton) once it is safe to do so, according to UK government advice.
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

Accommodation
Details of accommodation will be provided when delegates register.

Registration
Registration
To register please visit our website www.dsu.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.

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Postgraduate Certificate, Diploma and Masters in Pharmacovigilance

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 2020-2021: 7 September 2020, 4 January 2021, 7 June 2021
- Intake dates for 2021-2022: 6 September 2021, 3 January 2022, 6 June 2022

### 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 - Optional</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 Pharmacovigililence</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 and Introduction to DSURs</td>
<td>15</td>
<td>PgC/PgD – Optional</td>
</tr>
<tr>
<td>EU Regulations &amp; Guidelines in Pharmacovigililence</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>