COMMENTARY

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New Postgraduate Qualifications in Pharmacovigilance from the Drug Safety Research Unit in the UK

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Abstract

The Drug Safety Research Unit in the UK has recently launched new postgraduate certificate, diploma and masters courses in pharmacovigilance, in association with the University of Portsmouth. These courses have been developed to address the continuing demand for quality accredited education in pharmacovigilance and are aimed particularly at drug safety staff working in the pharmaceutical industry, regulatory bodies or academia. Flexibility is ensured by the availability of a wide choice of units, the use of online facilities for learning and assessment, and the possibility that previous relevant training or experience may be counted towards the awards.

The Drug Safety Research Unit (DSRU) in Southampton, UK, is established as one of the leading providers of high quality, good-value training in the field of drug safety, with over a decade of experience. The unit has built up a loyal following amongst pharmaceutical companies and regulatory bodies in the UK, Europe and beyond. Many delegates attend two or more DSRU courses, and it was recognized that there is an unmet need for quality *accredited* training in pharmacovigilance. For this reason, flexible postgraduate programmes have been constructed, accredited by the University of Portsmouth, based on attendance at DSRU courses, as well as completion of course work. The DSRU will, of course, continue to provide a portfolio of around 15 short courses, which are available to all delegates, whether or not they are registered for the postgraduate programmes.

1. Aim of The Courses

The aim of the courses is to equip students with the skills and competencies required to fulfil their pharmacovigilance roles in advanced and complex settings. In addition, the courses also aim to provide:

- a deep awareness of adverse drug reactions; their nature, epidemiology, detection, and clinical and economic impact;
- a systematic understanding of knowledge and skills required in the application of the practice of pharmacovigilance;
- a critical awareness of current problems and/or new insights in pharmacovigilance;
- a comprehensive understanding of pharmaco-epidemiological techniques, their advantages, limitations and future development;
- originality in the application of knowledge, including a practical understanding of how established techniques of research and enquiry are used to create and interpret knowledge in pharmacovigilance;
- a conceptual understanding that enables you to critically evaluate current research and advanced scholarship in pharmacovigilance, and to select current and future methodologies to test new hypotheses.

2. Course Structure

The postgraduate certificate (PgC) comprises three compulsory units, plus one further unit from a choice of nine, as shown in table I, to be completed within 2 years. The postgraduate diploma (PgD) comprises three compulsory units, plus five further units from a choice of nine, to be completed within 4 years. The Master of Science (MSc) will be available from September 2011 and will comprise three compulsory units, plus five further units from a choice of nine, as well as a research project, to be completed within 7 years.

The units comprise DSRU 2-day training courses that take place throughout the year in either Southampton or London. Pre- and post-course work must be completed for each unit. Assessments may include essays, multiple choice questions or written exams. Students may register to start the courses in January, June and September each year.

3. Flexible Training

The PgC, PgD and MSc in pharmacovigilance are adaptable, part-time courses designed to suit those working full-time in pharmacovigilance, requiring a few days' attendance each year and many hours of private study. In many cases, previous equivalent training or experience may be taken into account, reducing the number of units that the student is required to complete.

Most of the course materials, including assessments, will be available through Victory, the University of Portsmouth's virtual learning environment.

For all units there is no formal sequence of attendance. With the exception of the mandatory units, there is no fixed programme of units for this collaborative programme. Instead students may choose which of the optional units are relevant to them, with guidance from the course staff and work-based tutors, ensuring that key competencies are met.

4. Who Should Apply?

These courses are aimed at staff already working in pharmacovigilance or related areas, in the pharmaceutical industry, regulatory authorities, academia or independent research units who

Table I. Units required for each postgraduate award[a]

Unit title	Equivalent study hours	Credit points	Assessment contributions to total	Stage
Compulsory Units				
Back to Basics in Pharmacovigilance	150	15	100% CW	PgC/PgD
Introduction to Pharmacoepidemiology	150	15	100% CW	PgC/PgD
Medical Aspects of Adverse Drug Reactions	150	15	60% CW, 40% exam	PgC/PgD
Optional Units				
Case Narrative Writing for Reporting Adverse Events	150	15	60% CW, 40% exam	PgC/PgD
Monitoring Safety in Clinical Trials and Drug Development	150	15	100% CW	PgC/PgD
Critical Appraisal of Medical and Scientific Papers: How to Read Between the Lines	150	15	60% CW, 40% exam	PgC/PgD
Risk Benefit Assessment in Pharmacovigilance	150	15	100% CW	PgC/PgD
Staying Current and in Control in the Constantly Changing Global Regulatory Pharmacovigilance Environment	150	15	100% CW	PgC/PgD
Periodic Safety Update Reports	150	15	100% CW	PgC/PgD
Regulations and Guidelines for Pharmacovigilance	150	15	100% CW	PgC/PgD
Pharmacovigilance in Products Subject to Licensing Agreements	150	15	100% CW	PgC/PgD
Pharmacovigilance Planning and Risk Management	150	15	100% CW	PgC/PgD
MSc Research Project	600	60	100% CW	MSc

a PgC requires 60 credits, PgD requires 120 credits and MSc requires 180 credits.

CW = course work; **MSc** = Master of Science; **PgC** = postgraduate certificate; **PgD** = postgraduate diploma.

wish to study part-time for a recognized academic qualification. They may also be suitable for independent medical writers and staff working in clinical research, medical affairs, medical information or regulatory affairs.

Applicants must possess either a first- or second-class honours degree in the biosciences, veterinary science, dentistry, pharmacy or medicine, or an equivalent professional qualification. Candidates without any of these qualifications may be admitted following submission of a portfolio demonstrating suitability for the course. All candidates may be required to demonstrate proficiency in English, where English is not the first language, by attaining a certain level in an approved test. Students will be asked to nominate an educational supervisor to support them in their studies.

5. Further Information

Further information may be obtained online at www.dsru.org, or from Lisa Harvey, Manager of Education and Training, at lisa.harvey@dsru.org, or telephone +44 (0)23 8040 8624.

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