Improving Health Worldwide

Professional Certificate in Pharmacoepidemiology & Pharmacovigilance

Background

The global health challenge of maximising drug safety yet maintaining public confidence has become increasingly complex. Pharmaceutical companies are required to employ named members of staff responsible for pharmacovigilance. NGOs need to ensure that the medicines and products they provide to communities are both effective and safe. Medical research charities need to ensure they can interpret and communicate up to date information on drug effects. Health authorities grapple with the need to provide quality care whilst containing a burgeoning drug budget. Regulatory authorities must balance the potential benefits of new drugs with varying levels of suspicion of their potential harm.

The course

This 30-week examined training in pharmacoepidemiology, drug safety and and pharmacovigilance addresses the increasing need for well informed professionals to work in all areas related to the assessment of drug safety and risk-benefit of drug use.

It is an introductory course and should meet the needs of a wide variety of practitioners. The range of backgrounds and the knowledge possessed by lecturers ensures that the course offers sound mixture of the theoretical and the practical issues surrounding drug safety.

Upon completion of the course, students have the necessary knowledge progress onto the LSHTM short course “Practical Pharmacoepidemiology”.

Starting from the 2019/2020 intake, the course will include a number of additional dedicated “Focus on Europe” sessions. These will be led by renowned experts in EU pharmacovigilance and pharmacoepidemiology, and will ensure that the course content remains of utmost relevance to those working in the EU.

Aims & objectives

The aim of this well-established training programme is to equip students with a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance. By the end of the course, students should be able to:

- demonstrate an understanding of, and critically evaluate, issues surrounding the risks and benefits of drug use in humans including the cause, manifestations and consequences of adverse drug effects (ADEs), the manner of which these are detected and monitored, and the related historic and legal frameworks
- be familiar with and compare fundamental statistical, economic and epidemiological concepts and methods
- gain an understanding of, and reflect upon, important pharmacoepidemiological concepts and methods and how these methods can be applied to specific drug issues and pharmaceutical risk management
- assess and critically analyse the results of pharmacoepidemiological studies (other investigators’), including critical appraisal of the study question, study design, methods and conduct, statistical analyses and interpretation

Course dates

The course is part-time and comprises 300 hours (approximately one day per week on average) which are spent as follows: 80 hours formal teaching and contact time, 120 hours self-directed study and 100 hours project work. The dates for the formal teaching are:

- Block 1: 4 - 7 November 2019
- Block 2: 17 - 21 February 2020
- Block 3: 6 - 9 April 2020
- Exam: 2 June 2020

For students wanting to complete the course but unable to attend in person, there is a **distance learning option** available. This includes the option of following a blended learning approach, where students register for the distance learning course but attend Block 1 of the London-based course. For more information about this option visit: lshtm.ac.uk/study/short-courses/pharmacoepi-pharmacovigilance-online

Course content

The curriculum will provide an introduction to epidemiology, statistics, pharmacoepidemiology and health economics. It will also cover the historical and legal background to pharmacovigilance and pharmacoepidemiology, and pharmacological basis of ADEs, addressing ADE issues at individual and population levels, and the application of pharmacoepidemiological principles and methods to practical drug issues.

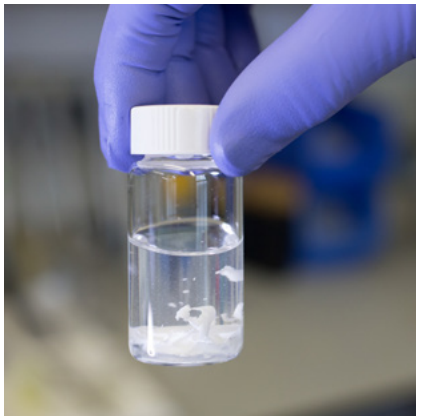
Who should apply?

The course is aimed at personnel concerned with the safe use of medicines, including those working (or intending to work) in:

- the pharmaceutical industry who are involved in drug development, licensing, and surveillance
- NGOs and medical research charities
- regulatory bodies who are involved in licensing and surveillance
- the health service who are involved in drug policy, and
- health policy decision-making agencies

Assessment

The course is examined through unseen written examinations and submission of a written project, the subject of which is determined by the course organiser. All materials for the project will be provided, and each student will be supported by an academic adviser. Additionally two lectures on the chosen topic will be included in the syllabus.



Teaching methods

Teaching will include traditional lectures and seminar/workshops during formal teaching, self-directed learning in between formal teaching and self-directed (but supervised) project work. Workshops will address topics such as designing a pharmacoepidemiological study, critical appraisal of published papers, developing risk management plans and responding to a drug safety alert. The self-directed component will be facilitated by the provision of detailed course material. Students will be provided with a reading list pertinent to the training.

The variety of backgrounds and the knowledge possessed by lecturers ensures that the course has a sound mixture of the theoretical and the practical issues surrounding drug safety. The teachers range from academic staff at the School, with expertise in areas such as pharmacology, epidemiology and statistics, to senior practitioners in the international pharmaceutical industry, regulatory authorities, and public health who have practical expertise in pharmacovigilance and pharmacoepidemiology.

Accreditation

The face-to-face course has been approved by the Federation of the Royal Colleges of Physicians of the UK for 30 Category 1 (external) Continuing Professional Development (CPD) credits.

Key information

Course organisers:
Dr Rohini Mathur & Dr Kevin Wing

Fees for 2019-20:
£5,260 (face-to-face)
£4,848 (distance learning)

Contact email:
shortcourses@lshtm.ac.uk

Find out more and apply:
www.lshtm.ac.uk/study/short-courses/pharmacoepi-pharmacovigilance-london