

Comments from Recent Students

THE COURSE

- *"All lecturers are very enthusiastic, interesting and knowledgeable. Makes the content fun and enjoyable."*
- *"Very informative with good workshops and high quality teaching"*
- *"Lecturers with extensive practical experience, will definitely recommend the course."*
- *"Really enjoyed the workshops with examples to work through - made it easier to learn."*
- *"Lecturers and workshops are of very high quality"*
- *"Overall atmosphere - a fun way to learn, with stimulating interactive sessions."*
- *"Some tough subjects dealt with in a very entertaining way which made them easier to understand."*
- *"Teaching quality - leaders in the industry!"*
- *"Thank you, I enjoyed it very much and learned a lot."*

SPECIFIC LECTURES

- The EMA and the EU risk management guideline
"Thoroughly enjoyed this talk and could have listened to more. Especially liked the RMP proposals"
- Multivariable analysis and propensity scores
"Particularly enjoyed these lectures. I didn't think it was possible to put something so difficult in such simple terms. Content, pitch, speed and delivery were wonderful"
- Meta analysis of Randomized Trials
"Just like the Clinical Trials lecture, this was brilliant. Both these lectures have given me something that I'll have to practice during my work to try to become proficient"
- Critical appraisal of meta analysis
"First time I've got to grips with concept of meta analysis."
- Structured examination of a response to an ADR alert
"The workshop was brilliant! Great way to demonstrate the applications and explain the difficulties in this field of work"
- Case only design and analysis
"Excellent lecturer - topic not the easiest, but lecture kept lively with good examples. Good summary of the key message at the end"

The London School of Hygiene & Tropical Medicine (LSHTM) is part of the University of London and is the University's major resource for postgraduate teaching and research in public health and tropical medicine. The School is a leading postgraduate medical institution in Europe. It is a major national and international focus of collaboration in teaching and research, where clinical, population, laboratory and social sciences are integrated to address the broad issues of health. Associated with the School as a teaching hospital is the Hospital for Tropical Diseases, which is located 10 minutes walk from the School.

The School has particular skills in clinical and population sciences, making it ideally placed to provide a course addressing drug safety at a population level, drawing on core sciences such as epidemiology and statistics.

The LSHTM is situated at the centre of the Bloomsbury colleges, a consortium of six University of London colleges, which provide opportunities to participate in a wide range of university activities. The University of London Union provides social, sporting and recreational facilities; clubs and societies of all kinds; and discounts on goods and travel. The School is also close to many of the cultural and social facilities in central London.

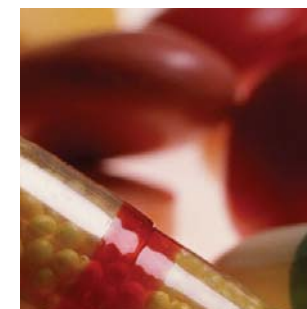
Application forms, and further details of other courses offered by the School are available on:
www.lshtm.ac.uk/courses or can be obtained from:

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LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE



CERTIFICATE IN PHARMACOEPIDEMIOLOGY & PHARMACOVIGILANCE

SHORT COURSE

7 November 2011 - 31 May 2012

The Mission of the London School of Hygiene & Tropical Medicine is to contribute to the improvement of health world-wide through the pursuit of excellence in research, postgraduate teaching and advanced training in national and international public health and tropical medicine, and through informing policy and practice in these areas.

Certificate in Pharmacoepidemiology & Pharmacovigilance

Further Information <http://www.lshtm.ac.uk/prospectus/short>

Certificate in Pharmacoepidemiology & Pharmacovigilance

The 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. 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.

This 20-week examined course in pharmacoepidemiology 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.

Course Dates

The course dates for 2011/2012 are: 7 November 2011 – 31st May 2012. The course is part-time and comprises 200 hours (approximately one day per week on average) which are spent as follows: 80 hours formal teaching and contact time, 70 hours self-directed study and 50 hours project work. Formal (face-to-face) teaching will take place in three blocks in 2011/2012: 7-11 November 2011, 13-17 February 2012, and 16-20 April 2012. Participants will be allocated a personal academic advisor, who will give them guidance in writing their project. The course is followed by examinations taking place on 31 May 2012.

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. Students will gain an understanding of how pharmacoepidemiological principles and methods are applied to practical drug issues.

Approach to Teaching and Examination

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, 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 course.

Who Should Apply?

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

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

Entry Qualifications

Applicants will normally have a science, biomedical or biostatistical background, hold a second class honours degree of a United Kingdom university (or equivalent) in a science, medical, statistical or related subject and will usually have some experience in the area. However, previous experience will be taken into account in all cases. A Curriculum Vitae should be submitted with the application.

Applicants must have a good standard of written and spoken English, and of English comprehension. In certain cases the School may ask the applicant to provide evidence of a satisfactory standard of English.

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. Examinations will be held on 31 May 2012.

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. The course is accredited for continuing medical and pharmacy education purposes.

Course Fees

The course fee is £4,095. This fee includes tuition, supervision and examination fees, but excludes accommodation and meals. Course fees must be paid in full by 10 October 2011. We regret that tuition fees cannot be paid in instalments.

Aims of the Course

The course will help participants acquire a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance. Specifically, it will:

- enable participants to understand issues surrounding the risks and benefits of drug use in humans including the cause, manifestations and consequences of adverse drug effects (ADEs), the manner in which these are detected and monitored, and the related historic and legal frameworks
- introduce participants to fundamental statistical, economic and epidemiological concepts and methods
- introduce participants to important pharmacoepidemiological concepts and methods and to enable them to apply these methods to drug issues
- equip participants with skills to facilitate further learning in these areas.

Course Organisers

Course Organiser: Ian Douglas

Email: Ian.Douglas@lshtm.ac.uk

Course Co-organiser: Ann Arscott

Email: Ann.Arscott@lshtm.ac.uk

Enquiries should be made to Ann Arscott in the first instance.