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Quality of Medical Products & Public Health

Short Course: 4-9 July 2016

Improving health worldwide

The London School of Hygiene & Tropical Medicine is a world-leading centre for research and postgraduate education in public and global health, with 4,000 students and more than 1,000 staff working in over 100 countries. The School was named the world's leading research-focused graduate school (Thomson Reuters / Times Higher Education) and has been cited as one of the world's top universities for collaborative research.

Our mission is to improve health and health equity in the UK and worldwide; working in partnership to achieve excellence in public and global health research, education and translation of knowledge into policy and practice.

Entrance requirements

Applicants will normally have a medical, science, public health or legal degree and post-experience qualifications. Previous experience, documented interest, and current positions will be taken into account in all cases. Applicants should have a good standard of written and spoken English and of English comprehension. If applicants are in doubt about their English qualifications they should enquire at the address given below. A curriculum vitae should be submitted with the application.

How to Apply

Applicants should complete the online application form available on the course webpage:
www.lshtm.ac.uk/study/cpd/medicalproducts.html

Registry

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Email: shortcourses@lshtm.ac.uk
Website: www.lshtm.ac.uk/study/cpd/medicalproducts.html

Course Facts

- The course will be limited to a maximum of 25 participants
- The course will be held at the London School of Hygiene & Tropical Medicine in central London, UK
- The course will cost £800 for students, £1,000 for academic staff, £1,500 for the private sector. The cost includes refreshment breaks, lunches, reception and course dinner.

Further Information:

www.lshtm.ac.uk/study/cpd/medicalproducts.html

Who Should Attend?

The course is aimed at personnel who are involved and/or interested in medical product quality (medicines, diagnostics, vaccines). The course will focus on public health issues found in low to high-income countries.

The course is relevant to those working in regulatory bodies; health decision and funding agencies; international health organisations; academia and the pharmaceutical industries.

International Teaching Faculty

Professor Amir Attaran, University of Ottawa, Canada
Dr Céline Caillet, WWARN, University of Oxford, UK
Dr Martin Cinnamond, The Global Fund, Switzerland
Mr Mick Deats, WHO, Switzerland
Professor Facundo Fernández, Georgia Institute of Technology, USA
Mr Paul Fleming, British Generic Manufacturers Association, UK
Professor Philippe Guerin, WWARN, University of Oxford, UK
Dr Harparkash Kaur, LSHTM, UK
Professor Marya Lieberman, University of Notre Dame, USA
Dr Souly Phanouvong, United States Pharmacopeia, USA
Dr Elisabeth Pisani, London
Ms Aline Plançon, INTERPOL, France
Dr Raffaella Ravinotto, Institute of Tropical Medicine, Belgium
Dr David Sumo, Liberia Medicines and Health Products Regulatory Authority, Liberia
Professor Veronika Wirtz, University of Boston, USA
Professor Susan Whyte, University of Copenhagen, Denmark
Mr Stephen Young, Medicines & Healthcare Products Regulatory Agency, UK
Professor Muhammad Zaman, University of Boston, USA



Photo provided by: Teun Bousema

Course Organiser

Course Director: Professor Paul Newton, University of Oxford
Local Co-ordinator: Professor Simon Croft, London School of Hygiene & Tropical Medicine.

Course Outline

There is increasing interest in poor quality medical products, their epidemiology, detection and impact and how to intervene to reduce their frequency. Poor quality medicines especially affect vulnerable populations in financially poor countries and although access to medicines has rightly been highlighted, access to good quality medicines has not. The number of research groups and international organisations working in this field has increased modestly over the past decade. There has also been increasing engagement of medicines regulatory agencies and the pharmaceutical industry.

There are enormous difficulties in the field, revolving around definitional and legal issues but also with a paucity of funded chemical analysis laboratories and minimal research on evaluation of novel diagnostic tools and research that will inform appropriate public engagement. Most academic papers come from a few groups and there is a need to foster greater interest in a diversity of university departments to help build evidence for informing policy and build research capacity for the future.

This one week course will address the need to build capacity and consensus in quality of medical products, and stimulate more research and action in this neglected field.

Attendance

The course will be full time for 5.5 days and will include 37 hours of formal teaching and 9 hours of practical sessions and group work. Participants will be assigned a personal advisor to support their work and stay in London.



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Aims of the Course

- To bring together a diversity of faculty and attendees, including undergraduate/postgraduate students, interested in the subject to learn and discuss together. As the field is a young one, both faculty and attendees will benefit from this networking
- To review and analyse a wide range of relevant topics - including definitions, law, epidemiology, public health impact, ethics, patient and health worker knowledge, chemical analysis, packaging, regulation and potential interventions
- To close with participant presentations, a media engagement programme with panel discussion and demonstration of poor quality medicines and their diagnosis.

By the end of the course participants should be able to understand and discuss the issues surrounding:

- medicine quality definitions
- the epidemiology of poor quality medicines and the data gaps that need to be filled
- the basics of medicine regulation, GMP and laws as they relate to medicines
- the basics of chemical & packaging analysis and rapid tests
- the steps needed to improve the global medicine supply and how to justify this.

Course Content

This is an introductory course that will cover:

1. Introduction to medical product quality problems & public health impact of different types of poor quality medical products with case-studies
2. Structure and function of the pharmaceutical industry, innovative and generic
3. The definitions debate
4. The law – medicine quality, public health and intellectual property
5. Access to good quality medicines
6. Medicine regulatory authorities – standards, enforcement and regulation
7. Quality standards, good pharmaceutical manufacturing and good pharmacy practice

Teaching Methods

Teaching will include formal lectures, with appropriate reading lists provided in advance of the course.

Accreditation

A certificate of course attendance and completion will be issued by the London School of Hygiene & Tropical Medicine.

Methods of Assessment

Participants will be invited to give feedback on presentations through a form distributed at the start of the course.

Scholarships

A limited number of scholarships, funded by the Wellcome Trust and the ACT Consortium, London School of Hygiene & Tropical Medicine, are available to fund travel, accommodation and course fees for those from low- and middle-income countries. Please state on the web application form if you would like to be considered and provide a 300 word statement as to why you would like to attend the course.

8. Supply chain complexity in resource-poor countries and regulatory oversight problems
9. Prequalification programmes for manufacturers and laboratories
10. Poor quality medicines, medical devices & diagnostic tests, their quality assurance and epidemiology
11. When, why and how to conduct medicine quality sampling? The ethics of sampling
12. Monitoring and surveillance initiatives to counter poor quality medicines
13. Chemical analysis techniques – HPLC, Mass Spec, Minilab, colour tests etc. Practical examples.
14. Investigation techniques and applied forensic science
15. Public awareness, perceptions and end user awareness
16. Potential interventions and the future