Further Information: www.lshtm.ac.uk/study/cpd/medicalproducts.html

Who Should Attend?
The course is aimed at people who are involved and/or interested in medical product quality (medicines, diagnostics, vaccines). The course will focus on public health issues found in low-income and 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 and pharmaceutical industries.

International Teaching Faculty
Ms Aline Plançon, INTERPOL, Lyon, France
Dr Michael Green, US CDC, USA
Mr James Gannon, Novartis
Professor Amor Attaran, University of Ottawa, Canada
Professor Facundo Fernández, Georgia Institute of Technology, USA
Dr Harparkash Kaur, LSHTM, UK
Dr Martin Cinnamon, The Global Fund, Switzerland
Professor Marya Lieberman, University of Notre Dame, USA
Mr Michael Deats, WHO, Switzerland
Ms Patricia Taberner, University of Oxford, UK
Professor Paul Newton, University of Oxford and LSHTM, UK
Professor Philippe Guerin, University of Oxford, UK
Dr Raffaella Ravinetto, Institute of Tropical Medicine, Belgium
Mr Stephen Young, MHRA, UK
Dr Souly Phanouvong, United States Pharmacopoeia, USA
Mr Paul Fleming, British Generic Manufacturers Association

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 recently 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
London School of Hygiene & Tropical Medicine
Keppel Street
London WC1E 7HT
UNITED KINGDOM

Telephone: +44 (0)20 7299 4646
Fax: +44 (0)20 7299 4656
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 £550 for students, £750 for academic or NGO staff, £1,050 for the private sector. The cost includes refreshment breaks, lunches, reception and course dinner.
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.

**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 public and 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
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
15. Investigation techniques and applied forensic science
16. Public awareness, perceptions and end user awareness
17. Potential interventions and the future

**Course Outline**

- **Introduction**
  - Poor quality medicines, their impact in low-income countries
  - Why do we care about them?
  - The need for research

- **Definitional and legal issues**
  - Definitions
  - Laws, regulations

- **Public health impact**
  - Epidemiology
  - Outcomes

- **Ethics**
  - Patient and health worker knowledge

- **Chemical analysis**
  - Techniques
  - Practical examples

- **Packaging**
  - Analysis

- **Regulation**
  - GMP
  - Standards

- **Interventions**
  - Policy

- **Future**

**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.