

Quality of Medical Products and Public Health

ORGANIZED BY: VERONIKA WIRTZ, PHD, MSC, ASSOCIATE PROFESSOR,
GLOBAL HEALTH, BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH &
PAUL NEWTON, D.PHIL, MRCP, DTM&H, PROFESSOR OF TROPICAL
MEDICINE, OXFORD UNIVERSITY

MONDAY JULY 10-FRIDAY JULY 14, 2017

BOSTON UNIVERSITY

BOSTON, MA



Boston University School of Public Health

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



PHX
Population Health Exchange

“Promoting access to quality assured medicines is a core public health function that requires concerted efforts by all stakeholders in the pharmaceutical sector”

Table of Contents

Emergency Contact Information	1
General Course Information.....	2
Course Schedule.....	4
Faculty Housing Accommodations	5
Travel to Hotel.....	5
Appendix A: MBTA Routes.....	6
Appendix B: Boston University Charles River Campus Map.....	7
STANDARD PHOTO/VIDEO RELEASE	8

ACTION REQUIRED

Prior to the start of the course, please complete and return the Photo/Video Release Form.

Once completed, please return the form to Rachel Pieciak at rpieciak@bu.edu.

Emergency Contact Information

Veronika Wirtz Course Instructor vwirtz@bu.edu P: +1-617-414-1440 C: +1-617-230-4197	Rachel Pieciak Course Manager rpieciak@bu.edu P: +1-617-414-1223 C: +1-586-255-8856	Boston University Police In Case of Emergency ONLY P: +1-617-353-2121
--	---	--

General Course Information

Meeting Dates: Monday July 10-Friday July 14, 2017 9am-5pm EST

Location: Boston University Charles River Campus: College of Arts and Sciences (CAS) Rooms 222 and 225
685-725 Commonwealth Ave, Boston, MA, United States

Monday 7/10-Wednesday 7/12 classes will be held in Room 225

Thursday 7/13-Friday 7/14 classes will be held in Room 222

Breakfast will be served from 8:00-9:00 each morning and lunch will be provided during the 12:45-13:30 break period.

Course Resources: [Website](#)

Course Description

Poor quality of medicines affects all countries but in particular vulnerable populations in low- and middle-income countries. There is increasing interest in poor quality medical products, their epidemiology, detection, and impact and how to intervene to reduce their frequency. The number of research groups and international organizations working in this field has seen a modest increase over the past decade, accompanied by the growing engagement of medicines regulatory agencies and the pharmaceutical industry.

In spite of some progress there are many remaining challenges, from legal issues to the lack of funding, and more evidence is needed to help inform policy and build research capacity. This course will address the need to build capacity in quality assurance of medical products, and stimulate more research and action in this neglected field. Hosted at the London School of Hygiene & Tropical Medicine in 2015 and 2016, this short course on Quality of Medical Products and Public Health will be hosted by Boston University School of Public Health in July 2017.

Competencies

Participants will learn to understand and discuss issues related to:

- 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 quality;
- The basics of chemical & packaging analysis and rapid tests;
- The steps needed to improve the global supply of quality assured medicines and how advocate for them.

Acknowledgements

We thank the PQM, a program funded by the United States Agency for International Development (USAID) and implemented by USP, for supporting four country participants from Nigeria, Pakistan and Bangladesh as well as two faculty members using USAID funds. We also thank Medicines for Malaria Venture (MMV) for providing scholarship funding for three country participants from Sub-Saharan African countries. Finally, we would like to acknowledge all the faculty for their generous contributions of time and funding to support this course.

Faculty

- **Brian Donnelly**, Pfizer
- **Celine Caillet**, Infectious Diseases Data Observatory (IDDO), University of Oxford, UK
- **Darash Desai**, Boston University
- **David Gaul**, Georgia Institute of Technology
- **Jude Nwokike**, United State Pharmacopeial Convention
- **Marya Lieberman**, University of Notre Dame
- **Michael Deats**, WHO, Switzerland
- **Muhammad Zaman**, Boston University
- **Paul Newton**, Oxford University
- **Raffaella Ravinetto**, Institute of Tropical Medicine, Belgium
- **Richard Laing**, Boston University School of Public Health
- **Sangeeta Vaswani Chatterjee**, Food and Drug Administration
- **Souly Phanouvong**, USP
- **Stephen Zambrzycki**, Georgia Institute of Technology
- **Tim Muntinga**, Oxford University, UK
- **Veronika Wirtz**, Boston University School of Public Health

Course Schedule

Day	Monday July 10	Tuesday July 11	Wednesday July 12	Thursday July 13	Friday July 14
	Chair – P. Newton	Chair – M. Deats	Chair- R. Ravinetto	Chair – M. Lieberman	Chair – V. Wirtz
09:00-10:00	Welcome and introductions P. Newton & V. Wirtz	Medicine regulation in LMICs (Part I) S. Phanouvong	Group work – Supplier MQAS Audit R. Ravinetto	Group Exercise: Epidemiology & Sampling C. Caillet	Robust Technology Development for Drug Quality Testing (until 10:30am) M. Zaman, D. Desai
10:00-11:00	Medicine Quality—Definitions and Public Health Impact (Part I) P. Newton	Medicine regulation in LMICs (Part II) S. Phanouvong	Group Presentations – An Exercise R. Ravinetto	Review of the Different Technologies and Devices S. Zambrzycki & C. Caillet	Q&A session (30 min) Faculty and participants
11:00-11:15	Tea/coffee	Tea/coffee	Tea/coffee	Tea/coffee	Tea/coffee
11:15-12:45	Medicine Quality—Definitions and Public Health Impact (Part II) P. Newton	Protecting the U.S. Drug Supply Chain S. Vaswani Chatterjee	Promoting the Quality of Medicines J. Nwokike	Chemical analysis –Mass Spectrometry & Forensic Techniques D. Gaul	Counterfeit Medicines: A North American Perspective B. Donnelly
12:45-13:30	Lunch	Lunch	Lunch	Lunch	Lunch
13:30-14:30	Supply Chains in Low and Middle-Income Countries R. Ravinetto	Quality of Medicines: An Ethical Issue? R. Ravinetto	Medical Devices & Vaccines R. Ravinetto	Internet Pharmacies & Medicine Quality T. Muntinga	Medicines for NCDs R. Laing and V. Wirtz
14:30-15:30	GMP, MQAS for Procurement Agencies & Prequalification R. Ravinetto	Group exercise R. Ravinetto	Field Screening of Medicines M. Lieberman	Hands on session M. Lieberman, M. Zaman/D. Desai, T Muntinga, D. Gaul	Medicines for NCDs R. Laing and V. Wirtz
15:30-16:00	Tea/coffee	Tea/coffee	Tea/coffee	Travel between workstations	Tea/coffee
16:00 – 17:30	Epidemiology & Sampling with group exercise C. Caillet	Substandard and Falsified Medical Products M. Deats	High performance liquid chromatography (HPLC) M. Lieberman	Hands on session M. Lieberman, Zaman/ Desai, T Muntinga, D. Gaul	Discussion panel and course feedback Faculty and participants
Evening 18:00	Course Reception and Open Mic	18:15 Optional walk - Freedom Trail	Film Screening The Third Man	19:00 Course Dinner –Maggiano’s Little Italy	Free

Faculty Housing Accommodations

DoubleTree by Hilton Hotel Boston-Downtown

821 Washington Street

Boston, MA 02111 USA

Phone: +1-617-956-7900

Hotel bookings have been made for all faculty who have requested housing accommodations during their stay in Boston. Reservations have been made under your name and have been pre-paid.

For any questions or concerns please contact Rachel Pieciak at rpieciak@bu.edu.

Travel to Hotel

If you arrive at Boston Logan International Airport you can take a taxi or public transportation to your accommodation.

Taxi

If you chose to hail a taxi from the airport, please give the taxi driver the address to the hotel (listed above). Please save all travel receipts so that you can be reimbursed for your travel costs.

Typical Minimum Charge (Taxi)	\$35.00 USD
Travel Time	~15 minutes

Public Transportation from Airport to Hotel

- At the airport, follow the signs for “Public Transportation”.
- Once outside, wait for the **Silver Line 1** (The bus display will read “SL1: South Station”).
- Take the SL1 to the South Station stop. From there transfer to the **Red Line towards Alewife**.
- Take the red line for one stop and get off at **Downtown Crossing**.
- At **Downtown Crossing** transfer to the **Orange Line towards Forest Hills**.
- Take the Orange line for two stops, exiting at the “**Tufts Medical Center**” stop. Exit the stop and walk about 1 min (266 ft.) to the hotel. The hotel is located at 821 Washington St.

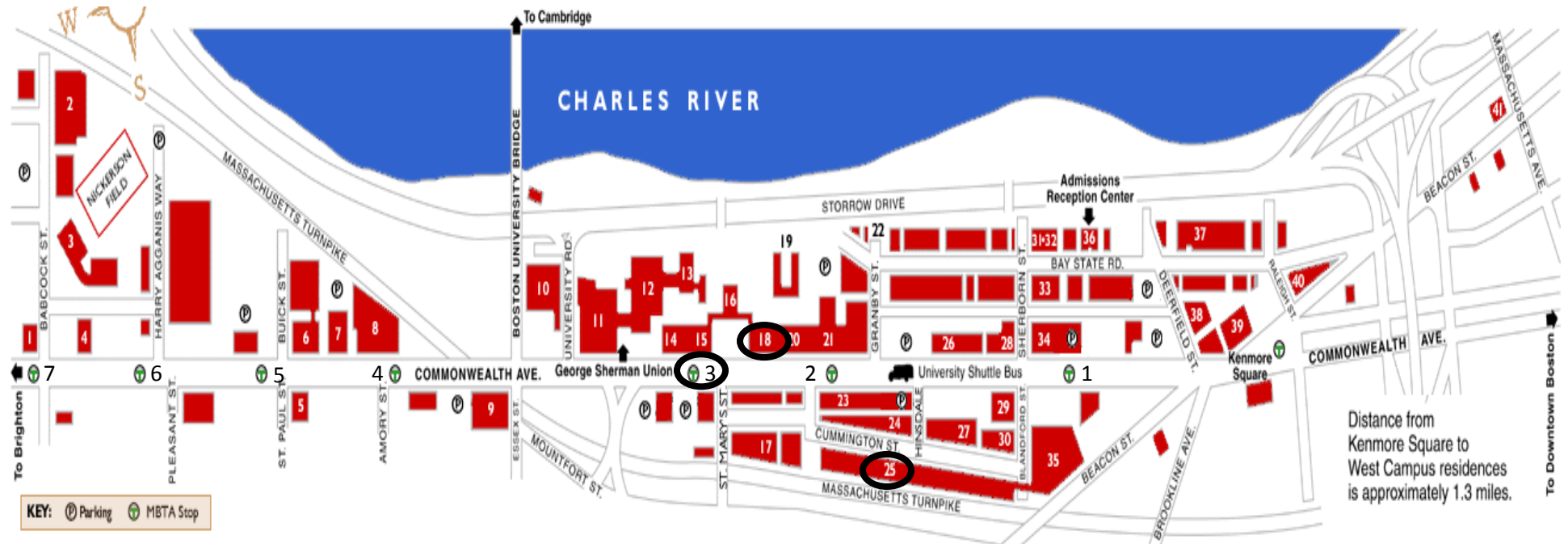
*For a detailed map of public transportation (MBTA) services, please see **Appendix A**.*

Typical Charge	\$2.75 USD/ride with 1 free transfer
Travel Time	~40 minutes

Appendix A: MBTA Routes



Appendix B: Boston University Charles River Campus Map



Key	
MBTA Stops	
1-	Blanford St.
2-	BU East
3-	BU Central- closet stop to CAS (circled)
4-	BU West
5-	St. Paul
6-	Pleasant St.
7-	Babcock St.

Key	
Instructional Buildings: CAS Building 18 (circled)	
Classes will be held in the College of Arts and Sciences Rooms	
Monday 7/10-Wednesday 7/12 will be in Room 225	
Thursday 7/13-Friday 7/14 will be in Room 222	
All lunch breaks and coffee/tea breaks will be held in the Board Room	
Hands on Sessions will be held at M. Zaman’s lab at 36 Cummington Mall, Room 306.	



Boston University School of Public Health

STANDARD PHOTO/VIDEO RELEASE

I, _____, give permission to Boston University School of Public Health to use my name and photographs or video images of me in ANY university educational and promotional materials in any medium.

I understand that I will not receive any compensation for, or retain any rights in, these photographs or videos, and I release Boston University from any liability for their use.

Name (print full name) _____

Signature _____

Date _____

Project _____