

# Quality of Medical Products and Public Health

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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”*

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### 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](mailto:rpieciak@bu.edu).

## Emergency Contact Information

<b>Veronika Wirtz</b> Course Instructor <a href="mailto:vwirtz@bu.edu">vwirtz@bu.edu</a> P: +1-617-414-1440 C: +1-617-230-4197	<b>Rachel Pieciak</b> Course Manager <a href="mailto:rpieciak@bu.edu">rpieciak@bu.edu</a> P: +1-617-414-1223 C: +1-586-255-8856	<b>Boston University Police</b> In Case of Emergency ONLY P: +1-617-353-2121
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## 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

## Scholarship Student Housing Accommodations

Many of the course participants have been booked for the duration of their stay at

**Boston University Student Village Complex**

**10 Buick Street**

**Boston, MA 02215**

*For more information about scholarship student housing and pictures of the floorplan and accommodations please see **Appendix C**.*

For any questions or concerns please contact Rachel Pieciak at [rpieciak@bu.edu](mailto:rpieciak@bu.edu).

## Navigating Boston

All participants will arrive at Boston Logan International Airport.

### *Taxi*

If you chose to hail a taxi from the airport, please give the taxi driver the address to the Student Village Complex (listed above).

Typical Minimum Charge (Taxi)	\$35.00 USD
Travel Time	~20 minutes

### *Public Transportation: From Airport to BU Student Housing*

- 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 **Green Line towards Boston College**. Take the green line 10 stops to **St. Paul Street**.
- Get off at the **St. Paul St.** stop and walk to 10 Buick St. (0.2 mi, ~3 minute walk).

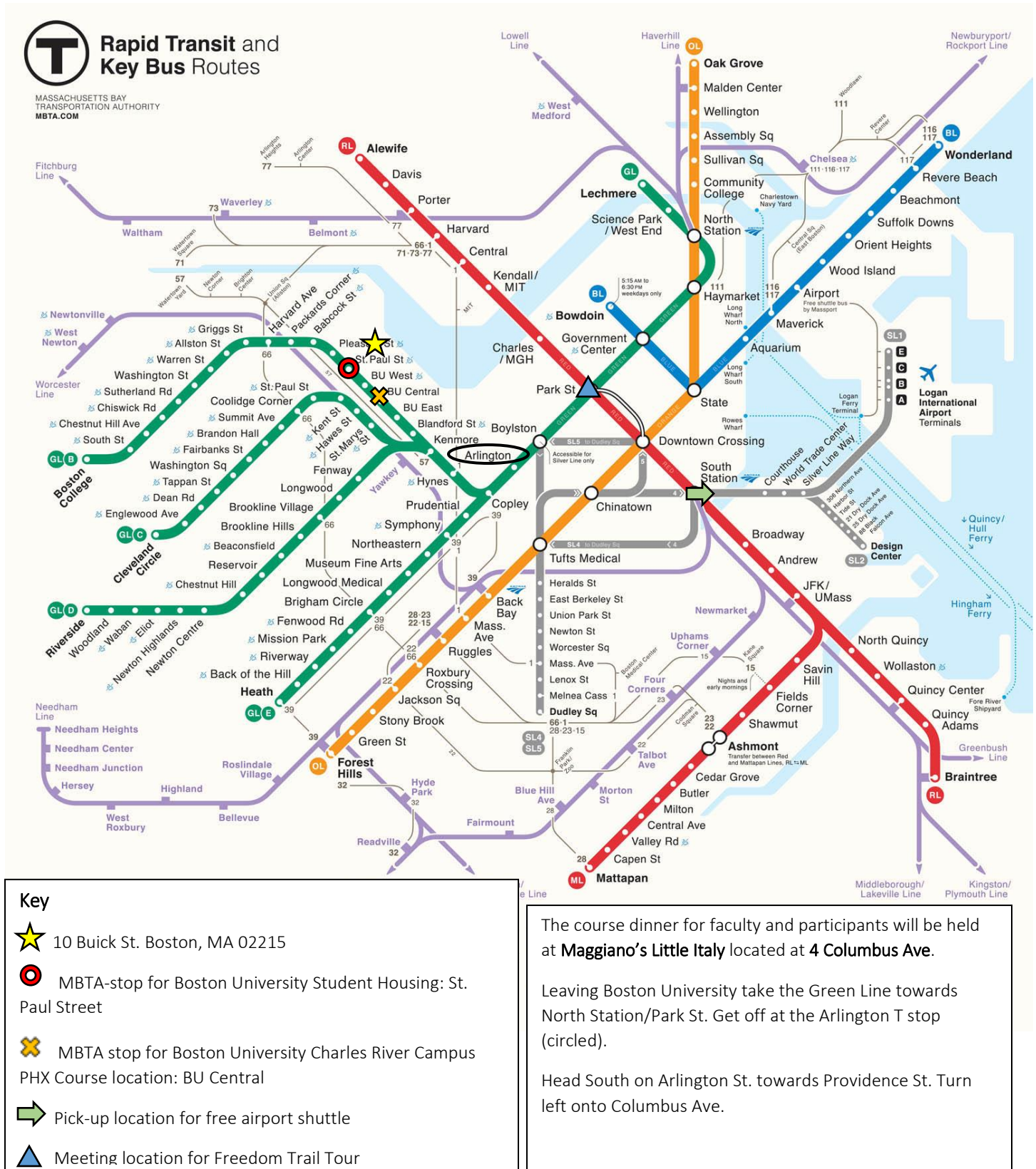
*For a detailed map of public transportation (MBTA) services, please see **Appendix A**.*

Typical Charge	\$2.75 USD/ride with 1 free transfer
Travel Time	~55 minutes

### *Public Transportation: From Student Housing to PHX Course Location*

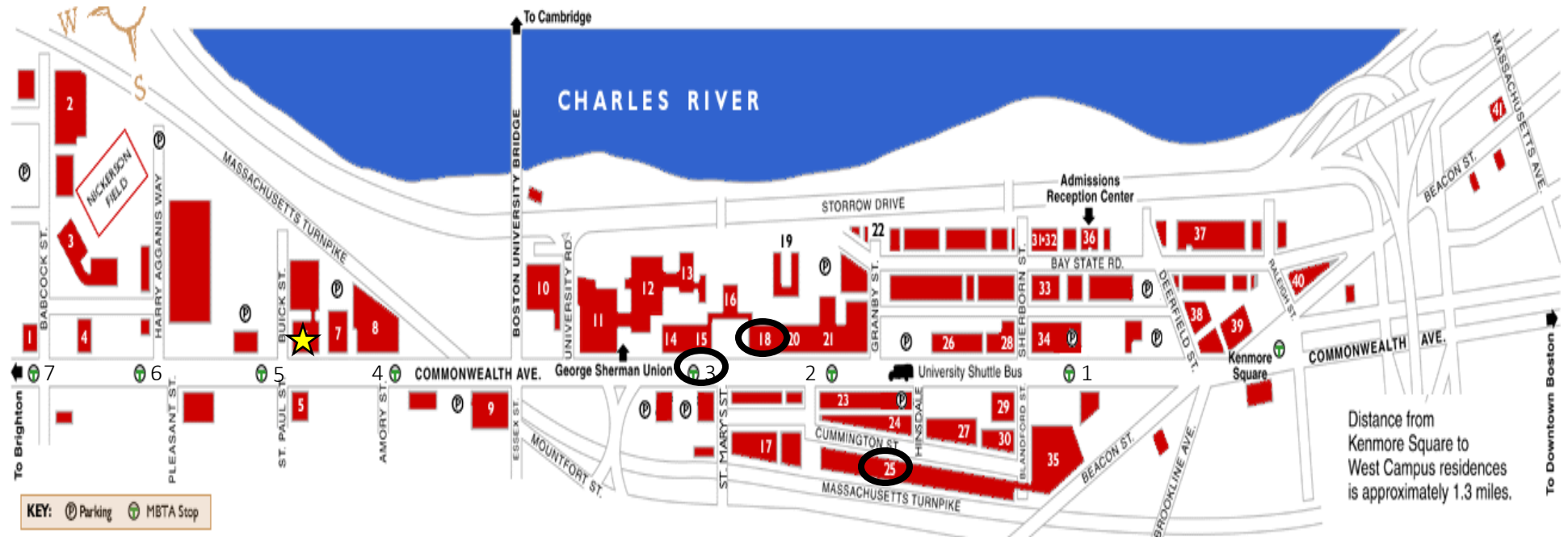
- Leave your apartment at 10 Buick St. to the St. Paul St. MBTA Stop
- At the St. Paul Street stop, get on the **Green Line Towards Park/North Station**
- Get off at **BU Central** (2 stops). Courses are in CAS Building 18 (as shown in Appendix B).

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- closet stop to Student Housing
- 6- Pleasant St.
- 7- Babcock St.

**Key**

- ★ **Scholarship Student Housing:** 10 Buick St. Boston, MA 02215
- 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.



## Appendix C: BU Scholarship Student Housing Information

### 10 Buick Street

In the fall of 2000, Boston University opened 10 Buick Street, an air-conditioned, apartment-style residence located on the west end of campus in the Student Village complex. Each unit has four single-occupancy bedrooms, two bathrooms, a small kitchen and a living area. Bedrooms are furnished with a twin bed, desk and chair, dresser, and include a closet. Kitchens are equipped with a refrigerator, sink, stove, and microwave oven, but kitchen supplies or utensils are not provided. Living areas are set comfortably with a sofa and chairs along with a dinette set. There is also a television in the living area, and iron with ironing board in the living area closet. Please refer to the floor plan below for a typical apartment at 10 Buick Street.

Guests are supplied with bed and bath linens and basic amenities including soap shampoo and conditioner. Beds are made prior to arrival. Daily maid service is **not** provided. For long-term programs, linens will be changed and trash will be removed once a week. Linens can also be exchanged at the Front Desk at any time, and trash rooms are available on each floor with extra bags available upon request at the front desk.

The Buick Street Market & Café, located on the ground floor, stocks convenience food items including whole meal solutions, organic and natural options, and a grab 'n' go section, and features a Dunkin' Donuts, Charles River Bread Company for gourmet sandwiches, and Loose Leafs for tossed-to-order salads. This residence also has several common areas that can be reserved by guests staying in the building, including a rooftop lounge and several small meeting rooms on the lower level. Laundry facilities and vending machines are available on the ground floor of the building.

The Events & Conferences Front Desk Staff is available to assist guests with checking in to the residence on their designated arrival date beginning at 3:00pm. Guests must check out prior to 11:00am on their designated departure date. The Front Desk Staff is also available on a daily basis from 6am until Midnight to assist guests with both campus and general information. A complimentary coffee station is available on the lobby level, along with a 24 hour business center for your printing and copying needs.





*(Left) Photo of the exterior of 10 Buick Street.*



*(Above) photo of common living space in 10 Buick Street apartment.*



*(Right) photo of bedroom space in 10 Buick Street apartment*

### Contact Information

<p><b>10 Buick St. Front Desk</b> P: +1-617-358-0657 <i>The front desk is staffed from 6:00am EST-12:00am EST. If you arrive outside of these times, please call this number to alert an on-call person to check you in.</i></p>	<p><b>Catherine Wood</b> Conferences and Events Coordinator P: +1-617-353-2238 C: +1-970-310-4972</p>
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**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 \_\_\_\_\_