UNIVERSITY of MARYLAND
SCHOOL OF PHARMACY

Thanks for attending the Virtual Open House on our

MS in Regulatory Science program.

We will join the session at 4:25pm ET (Baltimore/Washington).

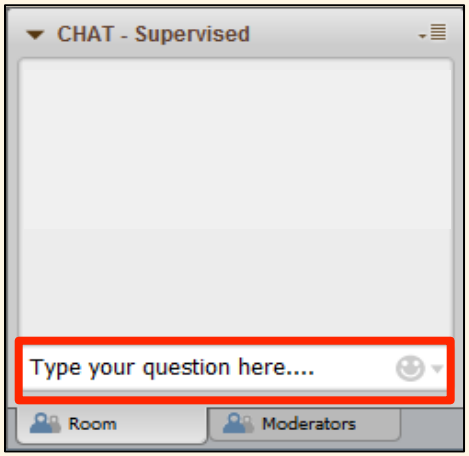
www.pharmacy.umaryland.edu/regulatoryscience

Prepare for the session

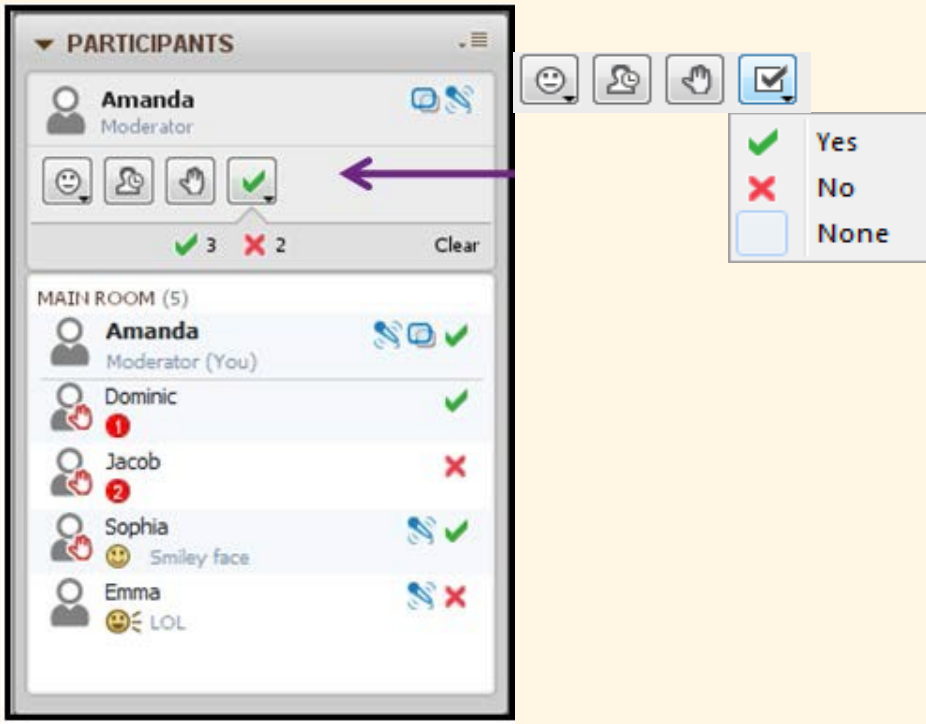
Note: This virtual Open House does not require participant to have a microphone.

1. Configure your audio using the **Audio Setup Wizard**.
   - The Audio Setup Wizard is located in the upper right hand corner of the Audio & Video panel in the top left corner of your screen.

2. Enter any questions into the Chat room.



3. Give us a **green checkmark** if you can hear us.
   - The checkmark is located on the Participants panel above the box that lists the session attendees.



MS in Regulatory Science at the University of Maryland School of Pharmacy

Note: This session will be recorded and posted to the web. Participant names will not be viewable from the recorded/posted version.

www.pharmacy.umaryland.edu/regulatoryscience

Who's Who?

- James E. Polli, PhD, Graduate Program Director
  - Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics
  - Interests are in drug absorption, formulation, and pharmacokinetics/metabolism
  - jpolli@rx.umaryland.edu
- Sharese Essien, Program Manager
  - sessien@rx.umaryland.edu
  - regsci@rx.umaryland.edu

- www.pharmacy.umaryland.edu/regulatoryscience

Poll: Question 1

- Which type of FDA regulated product most interests you?
  - A. Drugs
  - B. Biologics
  - C. Devices
  - D. Other

NOTE: The poll response options are located in the same place where the green checkmark was found during the intro.

Poll: Question 2

- Which of the following best describes your interest in regulatory science?
  - A. Chemistry/manufacturing/controls (CMC)
  - B. Clinical research
  - C. Pharmacovigilance and Phase IV research (e.g. pharmacoepidemiology)
  - D. Other

NOTE: The poll response options are located in the same place where the green checkmark was found during the intro.

Background: Regulatory Science

- Regulatory Science
  - "…the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products."
  - Advancing Regulatory Science at FDA, A Strategic Plan. August, 2011
- Motivation for program
  - Stakeholders (e.g. industry, FDA)
  - 2010 report from RAPS
  - 2012 report from Institute of Medicine "Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary"

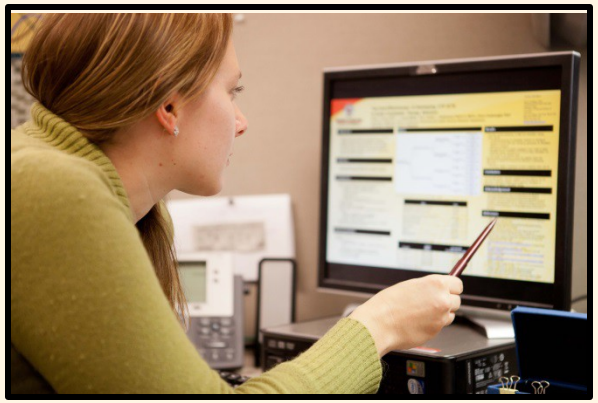
Background: Regulatory Science

- University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)
  - Cooperative agreement with FDA

- Several recent 1-day conferences, such as:
  - www.pharmacy.umaryland.edu/pedexposure (at FDA)
  - www.pharmacy.umaryland.edu/patient_focused_drug_development (in Bethesda, MD)
  - www.pharmacy.umaryland.edu/BiasInBigData (at FDA)
  - Evidentiary Consideration for Integration of Biomarkers in Drug Development (in Baltimore)

Elements of program

- Non-thesis, PT program; 30 credits; exclusively online
- Drug and Biologics focus
- Five courses (each 6 credits)
  - Drug, Biologic, and Device Regulation
  - Drug and Biologics Discovery
  - Drug and Biologics Development
  - Clinical Research
  - Regulated Products in the Marketplace



Program objectives

- A graduate will be able to:
  - 1. Devise and implement global strategies for drug, biologic, and device development and evaluation
  - 2. Differentiate FDA and other region requirements for drug and biologics product development and registration
  - 3. Apply principles of basic and applied pharmaceutical sciences in drug and biologics discovery and development

Program objectives

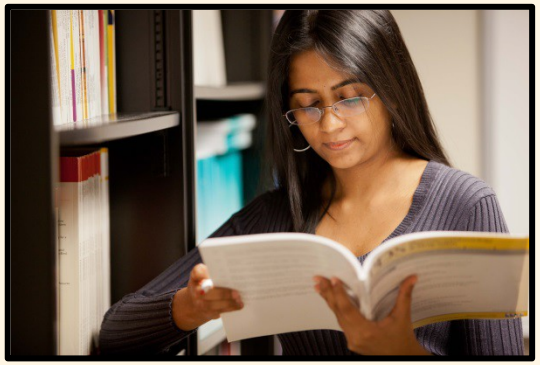
- A graduate will be able to:
  - 4. Formulate critical elements of chemistry, manufacturing, & controls (CMC) to drug and biologics development
  - 5. Relate principles of clinical research design to practices in clinical trial management
  - 6. Apply critical methods of risk assessment and drug utilization from pharmacoepidemiology and post-marketing surveillance, and evaluate economic and sociodemographic factors that influence drug/biologics use

Faculty

- University of Maryland
  - www.pharmacy.umaryland.edu
- FDA
- NIH
- Pharmaceutical companies
  - Large and small
- Significant FDA and industry input into the program

Students

- Working professionals
  - chemistry/manufacturing/controls (CMC)
  - clinical research
  - pharmacovigilance and Phase IV research (e.g. pharmacoepidemiology)
- Part-time graduate program
- Expanded career opportunities
  - Program graduates will possess knowledge and skills to contribute to drug regulation and pharmaceutical product lifecycles.



Admission requirements

- Three letters of recommendation
- A “Statement of Goals in Regulatory Science” that discusses career objectives pertaining to regulatory science, including relevant work experience
- Preferred minimum 3.0 Grade Point Average (GPA) and overall quality of academic transcripts
- Graduate Record Examination (GRE) if less than 5 years work experience.
  - GRE is exempt if applicant has more than 5 years work experience related to regulatory science, as reflected in "Statement of Goals in Regulatory Science.”
  - Preferred GRE results should meet the minimum scores of 152 verbal (i.e. 500 on previous scale), 152 quantitative (i.e. 500 on previous scale), and 4.0 for analytical writing.
  - A subject GRE test is not required.
- International applicants must also take TOEFL or IELTS
  - minimum 600 for the paper-based test and 100 for the internet-based test; or, minimum score of 8 on the IELTS
- No residency requirements

Courses and timeline

- Five 6-credit courses
  - Drug, Biologic, and Device Regulation (Fall in Y1)
  - Drug and Biologics Discovery (Spring in Y1)
  - Drug and Biologics Development (Summer in Y1)
  - Clinical Research (Fall in Y2)
  - Regulated Products in the Marketplace (Spring in Y2)
- Target is to complete in less than two years
- Follows U of Maryland (Baltimore) calendar
  - Fall from about mid-Aug until mid-Dec (16 weeks)
  - Spring from about mid-Jan until mid-May (16 weeks)
  - Summer from about start of June to early Aug (10 weeks)

Next class starts Aug 21, 2017

Online class

- Pre-recorded lectures (i.e. asynchronous lectures)
- Web conferencing with two-way voice
- Online active-learning instruction
- Chat and message boards
- Online learning groups
- Non-thesis, but project work for each course
  - e.g. Briefing Package
- Office hours

Technology

- Blackboard
  - Notes and readings
  - Web conferencing
- Prerecorded lectures on the internet
- Student computer and internet connection
  - Students must have access to computer that meets the minimum system requirements for the program, and Microsoft Office software
  - Broadband internet access and a headset microphone (for participation in web conferences)

Advising and Career Progress

- Reg Sci Advisor
- Portfolio of Accomplishments
  - Health Science and Human Services Library
  - http://guides.hshsl.umaryland.edu/distancestudents

Tuition and fees

- 2015-16 Academic year Tuition and Fees are:
  - In-State Tuition - per credit hour: $653 ($3,918/six cedits)
  - Out-of-State Tuition - per credit hour: $1,168 ($7,008/six credits)
  - Technology Fee - per credit hour $10 ($60/six credits)
  - Student fees $35.50 (per semester)

- www.umaryland.edu/institutionalresearch/tuition
- www.pharmacy.umaryland.edu/regulatoryscience

Virtual Open Houses

- Additional Dates
  - Thurs., March 16th – 12:30 – 1pm
  - Wed., May 10th – 4:30 – 5 pm
  - Thurs., June 8th – 4:30 – 5 pm

- Hear about the program and ask questions.

Contact information

- Sharese Essien
- Email: regsci@rx.umaryland.edu
- www.pharmacy.umaryland.edu/regulatoryscience

- For any questions, please enter them into the Chat Room.

- Deadline is June 30, 2017