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](http://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.umd.edu

• Sharese Essien, Program Manager
  – sessien@rx.umd.edu
  – regsci@rx.umd.edu

• www.pharmacy.umd.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](http://www.pharmacy.umaryland.edu/pedexposure) (at FDA)
  - [www.pharmacy.umaryland.edu/patientFocusedDrugDevelopment](http://www.pharmacy.umaryland.edu/patientFocusedDrugDevelopment) (in Bethesda, MD)
  - [www.pharmacy.umaryland.edu/BiasInBigData](http://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)
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.umd.edu/distancestudents
Tuition and fees

- 2015-16 Academic year Tuition and Fees are:
  - In-State Tuition - per credit hour: $653 ($3,918/six credits)
  - 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 16\(^{th}\) – 12:30 – 1pm
  - Wed., May 10\(^{th}\) – 4:30 – 5 pm
  - Thurs., June 8\(^{th}\) – 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