Want to discuss your ideas with the FDA? Join the "America's Got Regulatory Science Talent" Competition

University of Rochester Office of Government and Academic Research Alliances and the Clinical and Translational Science Institute (CTSI), in collaboration with the Rochester Center of Excellence in Data Science, University of Rochester Center for Medical Technology and Innovation (CMTI) and the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

Competition Announcement

Students at the University of Rochester are invited to participate in the 2nd annual competition! The competition aims to promote student interest in *Regulatory Science* – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.

The competition involves each team developing and presenting a proposed solution to a current opportunity in the area of Regulatory Science. There are numerous needs in Regulatory Science and students should consult the FDA scientific priority areas identified in the August 2011 FDA Strategic Plan for Regulatory Science:

http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm

A team can be either an individual or up to four students, although each team member has to contribute to the proposed solution or the presentation. The presentation must be five minutes in duration or less. It may be as simple as a verbal description or may utilize AV materials. Creativity is strongly encouraged. Presentations should also aim to have high regulatory impact. Each presentation will be followed by two minutes of Q&A. Breakfast will be served to competing teams and prizes will be awarded for the top teams. **The local competition will be held at the University of Rochester campus on Tuesday, Feb 10, 2015. The winning team(s) will travel to the DC/MD region to meet with the FDA and M-CERSI winners and present their proposal(s).** Completed Information Sheets are due to the Office of Government and Academic Research Alliances by Friday, January 30, 2015 at 5pm.

Questions? Email: Scott.Steele@rochester.edu

UNIVERSITY of MARYLAND

UNIVERSITY of ROCHESTER

Examples of Proposed Solutions

Developing drugs, devices, and biologics is fraught with challenges. Likewise, there is continued need for new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. Example proposed solutions include: an idea for a new toxicology test; a better biomarker; an approach to improve manufacturing; a way to detect counterfeit biologics; a test that evaluates a new medical technology; a new data signal that detects adverse reactions from a new drug; a way for FDA to better communicate risks of medications (e.g. friendlier product labels, use of social media or YouTube); use of crowdsourcing; a test for food contaminants; a way to respond to a nuclear agent; and how to get patients to use a device safely.

> **Regulatory Science Competition Winners for 2014 presented their ideas to the FDA.** University of Rochester student David Brodell and University of Maryland graduate student Chelsea Virgile (a former graduate of UR) traveled to the Food and Drug Administration campus in Silver Spring, Maryland to present their winning "America's Got Regulatory Science Talent" competition proposals.
> *Read more here.*

Criteria

Eligibility. All full-time and part-time students (e.g. undergraduate, professional, graduate) at the University of Rochester are eligible.

Presentation evaluation. Each presentation (~5 minutes in length) will be evaluated by a panel of judges from the University of Rochester and local industry for the proposed solution and presentation quality. Elements of proposed solution include novelty and potential significance. Short-term feasibility is a plus, but not a requirement. Elements of presentation quality include verbal communication, visual communication, impact of any AV materials or demonstrations, as well as Q&A responses.

Faculty Advisor. While it is not required to have a faculty advisor for this project, it is strongly suggested that you at least consult with faculty familiar with the regulatory issues in the field of your proposal. If you would like assistance in being paired with a faculty advisor, contact us at the email below. Keep in mind that material presented should be non-confidential.

Dates and Deadlines

- Friday, January 30, 2015 – Completed Information Sheet is due by 5pm
- Tuesday, February 10, 2015 – "America's Got Regulatory Science Talent" Competition takes place at the University of Rochester, Saunders Research Building (Room 1.412) from 9:00am to 10:30am
- March or April 2015 – Winning Team travels to the DC/MD region to meet with the FDA

"America's Got Regulatory Science Talent" Competition

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Team name: _____

50 words or less description of proposed solution (no confidential information):

FDA Priority Area addressed:

Name of team lead/contact: _____

Email of team lead/contact: _____

Faculty advisor (optional): _____

Anticipated AV needs (e.g. microphones, sound system, PPT):

_____

Names of team members and their school/program affiliation:

_____

_____

_____

Questions? Email: Scott.Steele@rochester.edu
This form is due to Scott.Steele@rochester.edu by Friday, January 30, 2015 at 5pm. Electronic copies are available here: Office of Government and Academic Research Alliances website.