



University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

“America’s Got Regulatory Science Talent” Competition

### **Competition Announcement**

Students at the Baltimore and College Park campuses of the University of Maryland are invited to participate in a 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 regulatory science. There are numerous needs in regulatory science. Students should consult the FDA Center/Office Regulatory Science Research Priority Areas for the CERSI Program (<https://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm609908.htm>).

The competition will be held at the University of Maryland Baltimore campus on **Wed, Feb 6, 2019 from 1-2PM**. A team can include either an individual or any number of students, although each team member has to contribute to the proposed solution or the presentation. The presentation must be 5 minutes in duration or less. It may be as simple as a verbal description or may utilize AV materials. Creativity is encouraged. Proposed solutions should also aim to have high regulatory impact. Each presentation will be followed by 2 minutes of Q&A. Most importantly, lunch will be served to competing teams! Prizes will be awarded to the top teams. By **January 30**, please email a completed Information Sheet (below) to [RegSciTalent@rx.umaryland.edu](mailto:RegSciTalent@rx.umaryland.edu).

Questions? Email: [RegSciTalent@rx.umaryland.edu](mailto:RegSciTalent@rx.umaryland.edu)

### **Example Proposed Solutions**

Developing drugs, devices, and biologics is fraught with challenges. Likewise, there is a continuing need for new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products. Examples of proposed solutions include: toxicological assays (in vivo and in vitro) to compare toxicity across different types of tobacco products within the same class, including electronic nicotine delivery systems (ENDS); reducing healthcare-associated infection; methods to improve quality and safety of FDA-regulated products (e.g. methodologies for complex generic drugs, biosimilars,

biological products, and medical devices; discovery and validation of minimally invasive biomarkers); and methods and tools to improve and streamline clinical and postmarket evaluation of FDA-regulated products (e.g. approaches to incorporating patient input into regulatory decision-making; approaches to leveraging large data to inform regulatory decision-making, including use of “real world” data sources and mobile technologies; product safety and efficacy in special populations). Some previous winning ideas involved improving how to report an adverse medication event to FDA, counterfeit drug detection, and a mobile application to communicate drug/device risks.

Teams that wish to have a mentor from FDA must request a mentor by emailing [RegSciTalent@rx.umaryland.edu](mailto:RegSciTalent@rx.umaryland.edu) by **Dec 15**. If possible, please indicate your preferred topic for the talent event (e.g., drug safety, device design) and FDA will try to identify an FDA scientist who is willing to mentor; if a mentor is found, you will be contacted via email.

### **Criteria**

Eligibility. All full-time and part-time students (e.g., undergraduate, professional, graduate) at the Baltimore or College Park campus of the University of Maryland are eligible.

Presentation evaluation. Each presentation will be evaluated by a panel of judges from Maryland and FDA in terms of proposed solution and presentation quality. Elements of the 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, and Q&A responses.

### **Dates, Deadlines, and Parking**

By **January 30**, please email [RegSciTalent@rx.umaryland.edu](mailto:RegSciTalent@rx.umaryland.edu) with a completed Information Sheet for M-CERSI “America’s Got Regulatory Science Talent” Competition. The form is available at [www.cersi.umd.edu](http://www.cersi.umd.edu). The competition will be held at Pharmacy Hall at the University of Maryland Baltimore campus on **Wed, Feb 6, 2019 from 1-2PM**: University of Maryland School of Pharmacy, Pharmacy Hall, 20 Pine Street, Baltimore, MD 21201.

Parking information is available at: <http://www.umaryland.edu/parking/garages/> . We suggest the Saratoga garage and Penn garage.

## About M-CERSI

M-CERSI is an FDA-sponsored center at the Baltimore and College Park campuses of the University of Maryland ( [www.cersi.umd.edu](http://www.cersi.umd.edu) ). The mission of the Center is to foster the development of regulatory science – the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.



Information Sheet for

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Team name:

Less-than-12-word description of proposed solution:

Name of team captain:

Email of team captain:

Faculty or FDA advisor (optional):

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

Names of team members (and their college/school/program affiliation):

Questions? Email: [RegSciTalent@rx.umaryland.edu](mailto:RegSciTalent@rx.umaryland.edu)

Due to [RegSciTalent@rx.umaryland.edu](mailto:RegSciTalent@rx.umaryland.edu) by Jan 30, 2019. This form is available at [www.cersi.umd.edu](http://www.cersi.umd.edu).