



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. In 2022, FDA’s Office of the Chief Data Officer is engaging with the University of Maryland regulatory science talent competition and is interested in applications with proposed solutions to opportunities or challenges in regulatory science which use data science techniques. FDA staff are available to mentor student teams whose proposed solutions use data science techniques and may be available for other student teams focusing on other topics as well.

The competition involves each team developing and presenting a proposed solution to a current opportunity or challenge in regulatory science. There are numerous needs in regulatory science. Students should consult either the FDA Center/Office Regulatory Science Research Priority Areas for the CERSI Program (<https://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm609908.htm>) or the 2021: Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science (FARS) report (<https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science>). See the below examples of proposed solutions to opportunities or challenges in regulatory science .

The competition will be held in-person at the University of Maryland Baltimore campus on **Fri Feb 4 2022 from 9-11AM in Pharmacy Hall Room N103**. 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. By **January 14**, please email a completed Information Sheet (below) to RegSciTalent@rx.umaryland.edu.

Questions? Email: RegSciTalent@rx.umaryland.edu

Examples of Proposed Solutions for Regulatory Science

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.umd.edu by **Dec 1**. If possible, please indicate your preferred topic for the talent event (e.g., drug safety, device design, topic that uses data science techniques) and FDA will try to identify an FDA scientist who is willing to mentor your team; 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 14**, please email RegSciTalent@rx.umd.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. The competition will be held in-person on **Fri Feb 4 2022 from 9-11AM**.

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). 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

Due to RegSciTalent@rx.umaryland.edu by **Jan 14, 2022**. This form is available at www.cersi.umd.edu.