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# Center of Excellence in Regulatory Science and Innovation & Masters of Science in Regulatory Science and Food Safety Regulation – 2023 Writing Competition Guidelines

## The Competition

The Johns Hopkins Center of Excellence in Regulatory Science and Innovation (JH-CERSI), in partnership with the Masters of Science in Regulatory Science and Masters of Science in Food Safety Regulation programs, is pleased to announce a writing competition to encourage students interested in the field of regulatory science. Winning papers will receive a cash prize, be publicized on the JH-CERSI website and in other regulatory science forums, and be shared with relevant leadership within the Food and Drug Administration (FDA).

Competitors should submit a manuscript focused on a topic of their choice. Submissions should either identify a new and heretofore unexplored challenge for regulatory science or food safety regulation, or provide scholarly discourse regarding an already identified regulatory science or food safety regulation need and how such challenge can best be addressed.

## Prizes

1st place - $3,000 | 2nd place - $2,000 | 3rd place - $1,000

## Who is Eligible

Entrants must be enrolled in the Masters of Science in Regulatory Science or Masters of Science in Food Safety Regulation at Johns Hopkins University during the 2022-23 academic year.

## Judges and Considerations

Members of the Office of Regulatory Science and Innovation at FDA, the CERSI executive committee and faculty in the Regulatory Science and Food Safety Regulation programs will judge submitted manuscripts. Submissions will be evaluated based on a variety of factors including:

- Importance of topic and public impact
- Thoughtfulness and depth of discussion
- Quality of research
- Writing ability
- Form and quality of citations

## Manuscript Requirements

- Submissions should be between 2000 and 3000 words in length, excluding references
- Submission must include a cover page with title, author and word count
- Submissions should be a Word document using Arial 11 pt font, 1 inch margins and include endnotes

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Submissions

Please submit manuscripts to jcoker5@jhu.edu by **Thursday, June 1st** at Midnight EDT.

Selection of Topics

Topics may be selected based on participants' professional experience or coursework in regulatory science or food safety regulation and should be of high value and current relevance to the FDA. Ideas for suitable topics may also be derived through review of documentation issued by FDA and different FDA Centers, such as the following:

- FDA, Strategic Plan for Regulatory Science and Nine Priority Areas
- CERSI, Center/Office Regulatory Science Research Priority Areas for CERSI Program
- FDA, Focus Areas of Regulatory Science 2022
- Center for Devices and Radiological Health, Regulatory Science Priorities 2019
- Center for Drug Evaluation and Research/Center for Biologics Evaluation and Research Data Standards Strategy 2018-2022
- Center for Biologics Evaluation and Research, Strategic Plan 2021-2025
- Center for Tobacco Products Research Priorities

For example, review of these materials will highlight some of the following questions as suitable for examination:

- What existing registries may contribute to a National Medical Device Post-market Surveillance System and/or how may ongoing registry efforts best meet the needs of stakeholders outside of the FDA such as the medical device industry, health care providers, patients, academia, third-party payers, hospitals, healthcare data holders and other government agencies?
- How can FDA's current statutory, regulatory and policy framework best be modernized to facilitate medical countermeasure development?
- How can FDA leverage existing data on tobacco product flavoring to assess impact on initiation, progression, complete/partial switching, transition to non-flavored products, and cessation behaviors?
- How can elements of REMS, such as ETASUs, communication plans or medication guides, be designed for better integration into the existing and evolving healthcare system without undue burden of patients, healthcare professionals or the healthcare system?
- How can a global regulatory curriculum in low and middle income countries be developed and implemented to insure high-quality and consistent training for food and drug regulatory personnel across the globe?
- Where are there greater opportunities for a more rapid and comprehensive response to food-borne illness? Where might opportunities lie prior to outbreaks for prevention and identification of food-borne illnesses?

These materials are to serve as examples but are by no means exhaustive of potential areas of importance.

Past examples of Competition winners are available on the JH-CERSI website