

# 2021 Global Conference on Regulatory Science

## Digital Health and Medical Devices

**OCTOBER 12-13 | VIRTUAL**

Hosted by  Harvard-MIT Center  
for Regulatory Science

### **Working Group: Education in Regulatory Science**

Oct 13, 10am – 12pm Eastern Time (*Virtual*)

*Moderator: Scott Steele, Associate Professor, Director of Regulatory Science Programs,  
Clinical and Translational Science Institute, University of Rochester Medical Center*

#### **Background:**

The U.S. Food and Drug Administration (FDA) defines Regulatory Science as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.” The FDA has also identified a series of Focus Areas of Regulatory Science (FARS) for further research, to accelerate the development of innovative products and support the generation of data and methods to inform regulatory decision-making. Both regulatory science and translational science have a shared goal to enhance the continuum of medical product development, ensuring that safe and effective medical products are ultimately available to the public. Achieving this goal requires diverse and adaptive regulatory science education that aligns with these evolving scientific areas and supports “trainees” across different career stages and paths. This working group session is designed to discuss and launch the development of specific educational resources to advance regulatory science, including sharing information on training programs and best practices.

#### **Working Group Objectives:**

The working group session will particularly focus on:

- Developing a guide/best practices for establishing and integrating Regulatory Science internships and fellowships into training
- Reviewing the role and alignment of current Regulatory Science training competencies
- Exploring considerations for developing educational case studies

#### **Questions to Consider in Advance:**

##### Regulatory Science Internships and Fellowships

- Where are they occurring (industry, government, internal, other university)?
- What is the funding source?



To learn more go to [regsciglobal.org](http://regsciglobal.org) or email us at [hits\\_regsci@hms.harvard.edu](mailto:hits_regsci@hms.harvard.edu)

- What is the length?
- Where are interns/fellows in their career stage?
- Are these part of a formal program or standalone?
  - o Expectations?
  - o Structure?
  - o Are these aligned with training competencies?
- Where do you draw trainees from and what is the uptake/utilization?
- Challenges/issues to consider?

#### Regulatory Science Competencies

- Do you utilize? (for program development, scholar assessment, program evaluation?)
- Which competencies (source)?
- Have you mapped to educational resources?
- Have you performed a needs assessment (trainees vs. professionals in the field- industry, government, academia, NGOs)
- Review competencies and consider recommendations of areas to update

#### **Selected References/Resources:**

- 2021: Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science, available at: <https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science>
- Joan E. Adamo, Erin E. Wilhelm, and Scott J. Steele. [Advancing a Vision for Regulatory Science Training](#). Clinical and Translational Science. 2015; 8(5):615-618
- [Examples of Regulatory Science fellowship/internship programs](#) (not exhaustive and will be updated based on discussion)
- Alexandra J. Greenberg-Worisek, Katherine E. Cornelius, Luz Cumba Garcia, Felicity T. Enders, Nilay D. Shah and Anthony J. Windebank. [Translating innovation in biomedical research: Design and delivery of a competency-based regulatory science course](#). J Clin Transl Sci. 2020 Feb; 4(1): 8–15.



To learn more go to [regsci.global.org](http://regsci.global.org) or email us at [hits\\_regsci@hms.harvard.edu](mailto:hits_regsci@hms.harvard.edu)