

Request for Applications Fellowship in Regulatory Science

Georgetown University-PhRMA Fellowship in Regulatory Science

Georgetown University and the Pharmaceutical Research and Manufacturers of America (PhRMA) established a fellowship program in Regulatory Science. This Request for Applications (RFA) seeks qualified candidates with doctoral degrees who wish to receive specialized research training in pediatric regulatory science, including access to expert faculty and scientists from Georgetown University, PhRMA, the U.S. Food and Drug Administration (FDA), and innovators in industry.

Background and Goals

Regulatory science is an applied scientific discipline that generates and makes use of evidence-based knowledge to inform decision-making about the safety and benefits of medical products, and comprises an emerging, specialized, and interdisciplinary field of biomedical research and education. Early in its evolution, the field holds great promise for scholarship, innovation, and application to improve the safety and effectiveness of medical products to improve public health. The Georgetown University-PhRMA Fellowship in Regulatory Science aims to develop researchers and scholars in this field to reach their fullest potential in advancing innovative research and public health. The Fellowship will provide a research opportunity that includes co-mentors from academia, industry, and the FDA. Co-mentors will collaborate to supervise and guide the fellow's research projects to successful conclusion, including peer-reviewed publication, presentation at national and international research meetings, and the like. In addition, the fellow will have the unique opportunity to engage in real-world training experiences in regulatory science, such as rotations with industry, interactions with the FDA via the Georgetown University CERSI, or other experiential learning opportunities.

Fellowship Activities

The fellow will work with dedicated mentors to advance regulatory science research and knowledge. Activities will include the following:

- Receive multidisciplinary training in regulatory science, clinical trial design and conduct, and statistical approaches for regulatory science
- Develop a comprehensive understanding of regulatory science and its applications to research
- Learn about current challenges facing drug, biologic, and device development
- Collaborate with faculty and scientists from Georgetown University, PhRMA, industry, and FDA on regulatory science research and education initiatives
- Attend graduate education courses in regulatory science, scientific rounds, and other relevant seminars at Georgetown University, MedStar Health-affiliated hospitals, FDA, National Institutes of Health, Institute of Medicine, and other organizations
- Attend scientific meetings and summarize the process and outcomes of any meetings attended
- Present on selected regulatory science topics at meetings or in a written format
- Hands-on opportunities or "real-world" experiences with industry, such as rotations in the industry setting and co-mentorship by industry experts, to develop a better understanding of the dynamics of the drug development process throughout the product lifecycle
- Exposure to or experiential learning opportunities with the FDA (e.g., direct interactions with Agency staff, giving or attending presentations, attendance at public meetings)



Mentorship

The fellowship will provide co-mentorship training from experts at Georgetown and collaborating academic and healthcare institutions, from PhRMA and its associated industry innovators, and from government scientists and educators (i.e., U.S. Food and Drug Administration) who share a great stake in evidence-based decision making.

Within the first three months of award and working under the direction of co-mentors, fellows will develop research proposals, including plans for institutional review board (IRB) and other regulatory reviews. Throughout the yearlong fellowship, fellows and their co-mentors will meet together monthly to review progress and provide direction. All fellows and co-mentors in the program will convene together quarterly to review the individual and collective progress of the program. The co-mentored regulatory science research conducted during the annual fellowship is expected to result in one or more peer-reviewed publications of the research.

Fellows interested in blending fellowship and mentoring in a succeeding second year of support are expected to have made application for sponsored support of their research by the conclusion of their initial fellowship year, or an innovative instructional approach to promote regulatory science.

Candidate Qualifications

Ideal candidates will demonstrate a strong interest in regulatory science through their professional and educational backgrounds. Candidates should be enthusiastic, self-motivated individuals who are able to articulate a strong interest in regulatory science, and have a deep desire to develop their careers at the intersection of academia, industry and government. Specifically, candidates should possess the following qualifications:

- Advanced degree in a related scientific field (e.g., MD, PhD, PharmD, MPH)
- Clinical research experience
- Basic understanding of the design, conduct, and analysis of clinical trials
- Ability to write and communicate clearly and thoughtfully
- Comfort working in an academic research setting
- Demonstrated capacity to work independently and collaboratively

Application Requirements and Deadlines

1. Applicants must submit an email indicating their intent to apply to regulatoryscience@georgetown.edu (by February 12, 2016).
2. Submit the following materials to regulatoryscience@georgetown.edu (by February 29, 2016):
 - Curriculum vitae
 - Personal statement (not exceeding 500 words) describing professional background, interest in regulatory science, and how the fellowship will benefit long-term career goals
 - Example(s) of scientific publications
 - Two or more professional letters of reference

Due Date	Application Component
February 12, 2016	Email of Intent Due
February 29, 2016	Full Application Due



Location and Duration

The fellow will work full time at the Georgetown University Medical Center in Washington, D.C. Training opportunities may be arranged for special mentoring with FDA and industry scientists.

The fellow will be awarded an initial one-year term, with renewal options, for up to two years of support. The anticipated start date of the first year will be on or before July 1, 2016, with the possibility of a one-year extension after successful completion of the first year.

Benefits

- Competitive salary
- Comprehensive [benefits](#) including medical, dental, vision, and others
- Funds for travel to professional conferences, at the discretion of fellowship mentors
- Support for research and publications costs

Conditions

This fellowship is supported by PhRMA and administered by the Georgetown University Program for Regulatory Science & Medicine. The awardee will be appointed to the Department of Pharmacology & Physiology as an academic fellow. Upon appointment, Georgetown University will require the fellow to complete annual disclosure forms listing financial and other interests that they, their spouses or minor children, or organizations in which they are involved (as a partner, employee, board member, etc.), have a financial interest that may give rise to real or apparent conflicts with the work of the fellowship.

Partner Organizations

- Georgetown University's [Program for Regulatory Science & Medicine \(PRSM\)](#) seeks to advance regulatory science and medicine through research and education, drawing on the expertise of a diverse group of scholars and knowledgeable faculty from academia, industry, and government. The Georgetown University Center of Excellence in Regulatory Science and Innovation (CERSI) engages scientists from across the university and FDA to work collaboratively on projects that promote regulatory science. PRSM and CERSI include an array of innovative research and education opportunities, engaging faculty, students, and researchers at the university in the rapidly developing field of regulatory science. With proximity to regulators and scientific innovators in government, academia, and industry, Georgetown University offers a unique milieu for regulatory science training and research.
- [PhRMA](#) represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$550 billion in the search for new treatments and cures, including an estimated \$51.1 billion in 2013 alone.

Both PRSM and PhRMA value the human, educational, and research resources that encompass evidence-based regulatory science and are committed to supporting the advancement of this field.

Questions

Please contact regulatoryscience@georgetown.edu with any questions.

