

# Advancing a Vision for Regulatory Science Training

Joan E. Adamo, Ph.D.<sup>1</sup>, Erin E. Wilhelm, M.P.H.<sup>2</sup>, and Scott J. Steele, Ph.D.<sup>3</sup>

## Abstract

Regulatory science, a complex field which draws on science, law, and policy, is a growing discipline in medical-related applications. Competencies help define both a discipline and the criteria to measure high-quality learning experiences. This paper identifies competencies for regulatory science, how they were developed, and broader recommendations to enhance education and training in this burgeoning field, including a multifaceted training approach. Clin Trans Sci 2015; Volume #: 1–4

**Keywords:** regulatory science, translational science, training, competencies

## Introduction

Regulatory science and translational science have shared goals to ensure that the significant investments and advances in basic science research are transformed into products that improve public health. The U.S. Food and Drug Administration (FDA) has defined regulatory science as “the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.” New tools and approaches to keep pace with or anticipate emerging technologies may reduce costs or increase the availability of safe and effective medical products. Because the goals of regulatory science align with those of translational science, the U.S. National Institutes of Health (NIH) and FDA have partnered on regulatory science initiatives, including a series of regulatory science research and education programs, and establishing the NIH-FDA Joint Leadership Council to coordinate collaborative activities.<sup>1–3</sup>

The FDA has described the agency’s vision and priority areas for regulatory science through its 2011 strategic plan.<sup>4</sup> This effort was furthered by the awarding of four Centers of Excellence in Regulatory Science and Innovation (CERSIs) at academic institutions,<sup>5</sup> which aim to promote regulatory science research, education, training, and professional development.

Regulatory science has received sustained attention from nongovernmental organizations as well. In 2011, the Institute of Medicine (IOM) hosted a workshop, *Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development*,<sup>6</sup> to explore whether regulatory science represents a new discipline requiring unique educational needs and careers paths. The workshop included discussion about the need for “core competencies” as a means to define regulatory science as an academic discipline, although those specific competencies remained unidentified.

The focus of this paper is the subsequent development of competencies for regulatory science, initially by the Clinical and Translational Science Awards (CTSA) Regulatory Science Workgroup, and further refined through a 2014 workshop: *Regulatory Science Core Competencies and Curricular Guidelines*.

## Development of Regulatory Science Competencies

Educational programs utilize competencies to define the knowledge, skills, and abilities that trainees should develop through a program. Competencies help shape curricula, aid in planning learning opportunities, and guide the application of metrics to assess the program and its components.<sup>7,8</sup> While

the ongoing debate about the definition and scope of regulatory science along with its multidisciplinary nature make the development of competencies a challenge, it is a significant gap that must be addressed.

In 2013, the CTSA-initiated Regulatory Science Workgroup began this process, utilizing the existing CTSA Competencies for Clinical and Translational Research as a framework.<sup>9,10</sup> With leadership from the University of Rochester, the Workgroup included representatives from NIH-sponsored CTSA institutions, CERSI institutions, the FDA, and NIH. Through an iterative process, the Workgroup identified “Core Thematic Areas” (*Figure 1*) as a means to group related competencies. The Core Thematic Areas and associated competencies were shared with academic, industry, and government partners for additional refinement, and provided the basis for the 2014 workshop.

## Workshop: Regulatory Science Core Competencies and Curricular Guidelines

An interdisciplinary group of experts convened in Washington, DC, on September 23, 2014, for a moderated discussion on the core competencies and curricular guidelines for regulatory science. The workshop included 36 leaders from academia ( $n = 14$ ), government ( $n = 10$ ), industry ( $n = 5$ ), and related associations and foundations ( $n = 7$ ). Represented disciplines included medicine, public health, pharmacy, pharmacology, bioengineering, clinical and translational research, regulatory science, and regulatory affairs.<sup>11,12</sup> The workshop focused on regulatory science as applied to medical products, including drugs, biologics, and devices. While the field of regulatory science is broad and encompasses areas such as food, cosmetics, veterinary products, and tobacco products, the focus of the working group was on biomedical products, and so these other areas were beyond the scope of discussion.

PhRMA Foundation hosted the workshop, building on its demonstrated interest in regulatory science education and training and its prior experience hosting a similar workshop for Comparative Effectiveness Research.<sup>13</sup> The authors of this paper served on the workshop planning committee, developing the workshop concept and objectives. The workshop agenda included a panel discussion on workforce training needs among academia, industry, and government, as well as breakout group activities focused in these areas: (A) Teaching Methods and Case Studies, (B) Process Map for Curriculum Development, and (C) Career

<sup>1</sup>Clinical & Translational Science Institute, University of Rochester Medical Center, Rochester, New York, USA; <sup>2</sup>Program for Regulatory Science & Medicine, Georgetown University, Washington, DC, USA; <sup>3</sup>Department of Public Health Sciences, University of Rochester Medical Center, Rochester, New York, USA.

Correspondence: Scott J. Steele (Scott.Steele@rochester.edu)

DOI: 10.1111/cts.12298

- ① Regulatory Science Research Questions and Priorities
- ② Regulatory Policies and Process
- ③ Research Ethics
- ④ Drug Discovery and Development
- ⑤ Medical Device Innovation
- ⑥ Preclinical
- ⑦ Clinical Trials
- ⑧ Post-Marketing and Compliance
- ⑨ Analytical Approaches and Tools
- ⑩ Communication
- ⑪ Technology and Innovation

**Figure 1.** Core Thematic Areas. These 11 areas will help shape the training experiences of biomedical researchers pursuing regulatory science. The core thematic areas are based on a subset of the FDA's regulatory science priority areas and define the areas where focused skills, knowledge and abilities can be addressed by specific competencies.

Development Pathways. In preparation for the workshop, a literature review was conducted and a landscape analysis was compiled, the latter comprising named “regulatory science” or related graduate education programs at US universities (Appendix 1).

### Survey Methods and Results

Prior to the workshop, a survey was developed to query experts about the CTSA Regulatory Science Workgroup-proposed Core Thematic Areas and related competencies. The survey asked respondents to apply a five-point scale to rate their level of agreement with the inclusion of each competency as part of a required curriculum. Choosing “Disagree” or “Strongly Disagree” responses for any competency prompted the respondent to indicate whether the competency should be an elective component, rather than required. The overall response rate was 69% and survey data were collected and managed using the Research Electronic Data Capture tool.<sup>14</sup>

Survey respondents were from academia (55%), industry (21%), government (14%), nonprofit organizations (7%), and associations and foundations (3%). Respondents indicated engagement in regulatory science through participation in active or past research, education and training initiatives, or related mentorship. More than 70% of the respondents affirmed a need for regulatory science-specific education and training.

The final list of 11 proposed Core Thematic Areas and the 68 related competencies are listed in Appendix 2 and were based on survey results and workshop discussion.

### Panel Discussion: Training and Workforce Needs in Academia, Industry, and Government

As previously mentioned, a panel of experts from industry, government, and academia gathered during the workshop to discuss: “Clarifying Education and Workforce Training Needs in Regulatory Science.” Panelists universally agreed that experiential opportunities are a critical and central component of education and training in regulatory science. Chris Austin (National Center for Advancing Translational Science, NIH) and Michael Rosenblatt (Merck & Co., Inc.) echoed the need for hands-on learning experiences and suggested that rotations in academia, industry, and at the FDA would be an ideal method of training

to ensure a “regulatory science practitioner” fully understands the breadth of the discipline and the differences between it and regulatory affairs.

The FDA provides lengthy training curriculum for reviewers and other regulatory science staff. The typical reviewer training spans three years or more where formal courses are supplemented with guided experience, similar to an apprenticeship. This extensive training of new hires exacerbates a current and growing shortage of personnel, which significantly impacts the agency, as well as the sponsors who rely upon FDA regulatory decisions. Leslie Wheelock (FDA) suggested that regulatory science-competent professionals who receive training prior to joining the FDA could help address the critical shortage in trained FDA personnel. Collaborative regulatory science programs linked to academic medical centers can help address these needs.<sup>15</sup>

UCSF and Stanford offer a master's degree program in bioengineering and a certificate program in regulatory affairs as a foundation for further regulatory science training.<sup>12</sup> In describing these programs, Kathy Giacomini (UCSF) reinforced the need for the workshop, its discussion, and recommendations, as important resources for those developing new or transforming existing programs to include more robust regulatory science components.

While the panelists and other workshop participants agreed that experiential learning opportunities are critical, what is less certain (due to confidentiality issues) is the feasibility of a rotation-based training program that includes time at the FDA. An in-depth examination of the requirements and regulations around who may work for the agency was recommended to explore the practicality of such a program.

### Key Takeaways and Recommendations

#### Application of the proposed regulatory science competencies

The workshop served as a means to achieve a level of agreement on the competencies, however it should not be taken as final. The nature of regulatory science and therefore regulatory science education will shift as science and scientific understanding continues to evolve. While the Core Thematic Areas do not cover all regulated products, the proposed competencies may serve as a basis for the development of competencies in other regulatory science areas. In addition, the level of training (i.e., Master of Science degree program versus certificate, etc.) will depend upon the milieu at each university.

Institutions should design and develop a program that meets the needs of its faculty and students, utilizing a process guided by these Core Thematic Areas and aligned with the institution's strategic mission and strengths. Based on workshop discussion and feedback from the survey, the following guidelines address practical issues that may arise as a regulatory science program is developed:

- (1) Adopt and adapt the competencies to align with institutional and program strengths. No one institution will cover the breadth of regulatory science concepts. However, several Core Thematic Areas are relevant across disciplines and should be included in every program, including regulatory science research questions, priorities and leadership, regulatory policies and process, research ethics, and communication (see Appendix 2).
- (2) Recruit faculty from diverse disciplines in pharmacology, pharmacy, bioinformatics, toxicology, law, and others. In addition to teaching and mentorship, faculty should be

provided with opportunities to engage in regulatory science research and these efforts should be recognized in promotion and tenure decisions.

- (3) Apply the competencies in consideration of the global nature of regulatory science, including the roles of authorities such as FDA, international regulatory agencies, or global health agencies with regulatory authority. Recognize that the authority and requirements of any regulatory agency can be addressed in these competencies.
- (4) Design education and training programs with evaluation and assessment features to ensure the learning experiences effectively prepare trainees for regulatory science careers.
- (5) Include perspectives of all relevant stakeholders as education and training programs are developed. Relevant stakeholders include industry, regulatory agencies, clinicians, and patients.

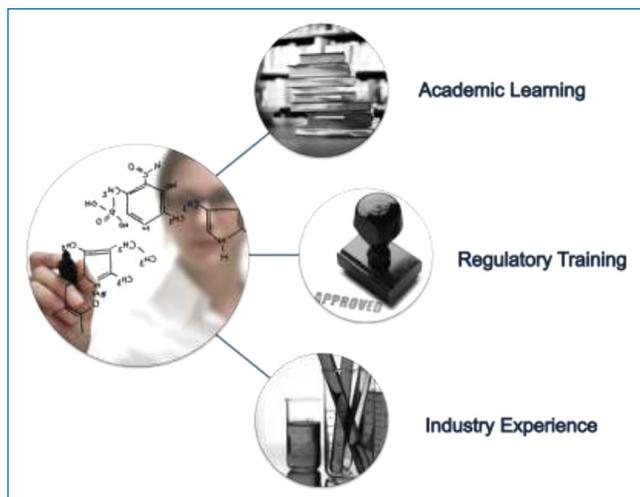
The workshop discussion offered other ways to promote regulatory science research and education. The following themes and recommendations emerged from that discussion.

### Experiential learning opportunities and team science

One of the key messages from the workshop participants was the need to provide regulatory science training with critical thinking skills necessary for team science settings, a shared priority adopted in translational science. Imparting knowledge in this way should rely on case study-based learning strategies and experience-based learning that can only occur outside of the classroom. Experiential learning opportunities should supplement didactic education methods, and these opportunities should be found among all key stakeholders, at all stages of the career lifecycle. The availability of internships or fellowships in academia, industry, and government are a critical component of a successful regulatory science program. *Figure 2* depicts the multilateral training approach that was endorsed by workshop participants.

### Consortium model

Several ideas were proposed and general agreement centered on a consortium-based model leading to a comprehensive electronic collection of education and training resources. Since regulatory science is a multidisciplinary field, and relies on far-ranging areas



**Figure 2.** Multipart Training. These represent several components to the education and training lifecycle which would benefit the Regulatory Science Practitioner.

of expertise, a consortium model would allow for all regulatory science concepts to be addressed, without relying solely on any one institution. Creating alliances among potential competitors—whether in academia, industry, or government—would allow for wide distribution of curricula and opportunities as well as sharing of faculty to cover all areas of expertise. Furthermore, such a model would facilitate the portability of a curriculum. The CTSA Consortium was proposed as an academic home for regulatory science initiatives because of its established infrastructure that can readily support regulatory science education and training, although barriers within the academic centers would need to be addressed. Several nonprofit and nongovernmental organizations are also well suited to host this type of program, such as the Reagan-Udall Foundation or PhRMA Foundation.

### Funding for regulatory science research, education, and training

Another important topic of discussion focused on the practical means of financially developing and sustaining regulatory science education and training programs. Existing training grant mechanisms (e.g., TL1, KL2, R25) could be targeted to regulatory science to drive collaborative development of new regulatory science curriculum and training opportunities. NIH has taken this approach for data science training, and this could serve as a model for regulatory science as well. More broadly, the group agreed that all key stakeholders should address the question of funding, and who should sponsor and support regulatory science education and training, including through diverse business models. A formal economic analysis to measure and determine the value proposition of regulatory science education and training would demonstrate the value of a graduate degree or certificate in regulatory science to both the institution and to prospective students.

### Communications

Related to the issues outlined above, workshop participants agreed that there is a missing link between the promise of regulatory science and what is understood about the discipline within the medical product development community and the public. Tied to the proposal for an economic analysis, a cohesive and deliberate communications strategy should promote the value proposition of regulatory science education and training.

### Conclusion

The proposed regulatory science competencies can provide a useful guide to building or improving high-quality education and training offerings for regulatory science. The Regulatory Science Workgroup is committed to continued engagement and implementation of the recommendations identified above. As discussed, several nonprofit organizations have aligned missions to promote regulatory science education and training and could serve as a critical mechanism to seed these efforts. Most importantly, the work achieved to date and described herein affirms the need for a coordinated and multiprong education and training initiative in regulatory science among all key stakeholders, including government, industry, academia, foundations, and other partners.

### Acknowledgments

This work was supported by the PhRMA Foundation; the authors thank Eileen Cannon for her participation on the

planning committee as well as her assistance with the workshop. The Regulatory Science workgroup was instrumental in the creation of these competencies and we would also like to thank the participants of the 2014 Regulatory Science Workshop. The authors thank Alicia Augustine, PhD, for assistance with the landscape research and survey design, Katie Libby for graphics assistance, as well as Robert Meyer, MD, and Carol Merchant, MD, MPH, for their review of the manuscript. Additional support came from the University of Rochester CTSA award number UL1 TR000042 from the National Center for Advancing Translational Sciences of the National Institutes of Health, and the Georgetown University Center of Excellence in Regulatory Science and Innovation award number U01 FD004319 from the U.S. Food and Drug Administration. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health or Food and Drug Administration.

### Supporting Information

Additional supporting information may be found in the online version of this paper.

**Appendix S1:** Programs at a Glance: Regulatory Science Education Programs at US Academic Institutions. This summary of Regulatory Science programs was taken from coursework and curriculum details that are available online at institutions across the US. As new programs are developed, this landscape will be updated.

**Appendix S2:** Regulatory Science Competencies in 11 Core Thematic Areas. The 68 specific Regulatory Science Competencies are aligned with 11 broad Core Thematic Areas.

### References

1. Hamburg MA, Collins FS. The path to personalized medicine. *N Engl J Med*. Jul 22 2010; 363(4): 301–304.
2. NIH and FDA Announce Collaborative Initiative to Fast-Track Innovations to the Public. 2010; February 24, 2010; <http://www.nih.gov/news/health/feb2010/od-24.htm>. Accessed May 29, 2015.
3. The Common Fund Regulatory Science 2012; <http://commonfund.nih.gov/regulatoryscience>. Accessed May 29, 2015.
4. Advancing Regulatory Science at FDA: A Strategic Plan. 2011; <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm>. Accessed May 29, 2015.
5. Regulatory Science Special Topics. 2011; <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm301667.htm>. Accessed May 29, 2015.
6. Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development. 2011; <http://www.iom.edu/Reports/2011/Strengthening-a-Workforce-for-Innovative-Regulatory-Science-in-Therapeutics-Development.aspx>. Accessed May 29, 2015.
7. Diamond RM. *Designing and Assessing Courses and Curricula: A Practical Guide*. 3rd ed. San Francisco: John Wiley & Sons, Inc; 2008.
8. Accreditation Council for Graduate Medical Education (ACGME), Outcome Project. 2003; <https://www.acgme.org>. Accessed May 29, 2015.
9. CTSA Core Competencies. 2011; <https://ctsacentral.org/consortium/best-practices/335-2/>. Accessed May 29, 2015.
10. Meyers FJ, Begg MD, Fleming M, Merchant C. Strengthening the career development of clinical translational scientist trainees: a consensus statement of the Clinical Translational Science Award (CTSA) Research Education and Career Development Committees. *Clin Transl Sci*. Apr 2012; 5(2): 132–137.
11. Regulatory Science Workshop Agenda. 2014; <http://www.phrmafoundation.org/regulatory-science-documents/>. Accessed May 29, 2015.
12. Regulatory Science Workshop Participants. 2014; <http://www.phrmafoundation.org/regulatory-science-documents/>. Accessed May 29, 2015.
13. Murray MD. Curricular considerations for pharmaceutical comparative effectiveness research. *Pharmacoepidemiol Drug Saf*. Aug 2011; 20(8): 797–804.
14. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Informat*. Apr 2009; 42(2): 377–381.
15. Meyer RJ. The role of academic medical centers in advancing regulatory science. *Clin Pharmacol Therapeut*. May 2014; 95(5): 471–473.

## Introduction and Background

The study and application of regulatory science as a scientific discipline has increased in recent years, led in part by efforts of the U.S. Food and Drug Administration (FDA) to advance the development, evaluation, and manufacture of medical products. The establishment of formal regulatory science education and training programs has increased due to the FDA-supported Centers of Excellence in Regulatory Science and Innovation (CERSIs), which aim to promote regulatory science research, scientific exchange, education, and training.

The FDA has defined 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.” FDA-regulated products include medical products (i.e., drugs, devices, biologics), food, and tobacco products. In some cases, regulatory *science* is confused with regulatory *affairs*, a complementary field focused on a deep understanding and utilization of the current laws, regulations, and statutes that govern regulatory activities. The goal of this document is to identify named regulatory science education programs, and distinguish programs focused on regulatory affairs from regulatory science.

## Methods

An Internet query was conducted using the key words: “regulatory science” in combination with one or more of the following key words: education, degree, coursework, graduate, program, master’s program, certificate program, or doctoral program. The search did not include the following terms: regulatory affairs, or clinical and translational research. The final list of programs was narrowed to include only U.S. universities offering current or pending graduate certificate or degree-granting programs in “Regulatory Science,” or those offering regulatory science coursework within another degree-granting program (e.g., Harvard’s Certificate Program in Therapeutics). The final list includes institutions that have either a) a program or track identified as “regulatory science,” whose curriculum reflects the FDA’s definition of Regulatory Science, or b) a program identified as “regulatory science,” but whose curriculum is more aligned with the definition of regulatory affairs. Therefore, the list does not include an exhaustive compilation of all regulatory affairs programs, nor does it include other non-degree programs such as internships, fellowships, and others.

## How to Use This Document

The table below describes 15 academic institutions that promote a regulatory science graduate education program in the United States. This list is intended as a reference guide for stakeholders. For each program, the table identifies the university (its CERSI affiliation as applicable) and website, a brief description of the program, the degree(s) granted and credits required, the primary program focus (e.g., medical products, food science, etc.), the mode of instruction (i.e., onsite, online, or blended), and requirements of candidates. In addition, based upon a review of programs’ curricula, the table indicates if the program is focused on *regulatory science* or *regulatory affairs*.

Incorrect or incomplete information may be amended by contacting Erin Wilhelm, MPH, Georgetown University ([ew6@georgetown.edu](mailto:ew6@georgetown.edu)).

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<b>Arizona State University</b> <a href="https://nursingandhealth.asu.edu/crm/master-science-clinical-research-management-concentration-regulatory-science?destination=node/5245">https://nursingandhealth.asu.edu/crm/master-science-clinical-research-management-concentration-regulatory-science?destination=node/5245</a>	<p>The Regulatory Science concentration can be earned within the framework of the Master of Science in Clinical Research Management degree program and is designed to develop understanding in meeting regulatory oversight requirements as they relate to the conduct of clinical studies. This Regulatory Science concentration will also offer students the option of taking elective courses during the CRM degree program.</p>	<p>Master of Science, Clinical Research Management, Concentration in Regulatory Science: 33 credits</p>	<p>Medical Products: Drugs Devices</p>	<p>Regulatory Affairs</p>	<p>Onsite – 100%</p>	<p>Bachelor's degree in clinical research, health science, nursing, allied health, or life sciences (or other bachelor's degree with required medical/anatomy prerequisite coursework)</p>
<b>Fairleigh Dickinson University</b> <a href="http://view.fdu.edu/default.aspx?id=10476">http://view.fdu.edu/default.aspx?id=10476</a> <a href="http://view.fdu.edu/default.aspx?id=8015">http://view.fdu.edu/default.aspx?id=8015</a>	<p>The primary goal of this degree track is to prepare students for significant roles in government agencies, pharmaceutical and biotechnological industries, health care provider organizations, and other sectors of the health care industry where compliance and regulation are crucial. The track will allow students to develop a comprehensive understanding of the protocols, procedures, statistical analysis, assessment of risk/benefit, documentation, and legal and ethical concerns that play a critical role in the day-to-day responsibilities of the field.</p>	<p>Doctor of Pharmacy, or Master of Health Science, Concentration in Regulatory Science: 31 credits</p>	<p>Medical Products: Drugs</p>	<p>Regulatory Science</p>	<p>Blended – online and onsite</p>	<p>Bachelor's degree (disciplines not specified); admission granted based on pre-pharmacy academic performance, Pharmacy College Admissions Test (PCAT) or Graduate School Record Exam (GRE), personal interviews, written applications, and letters of recommendation.</p>
<b>Georgetown University</b> <i>CERSI institution</i> <a href="http://regulatoryscience.georgetown.edu/MS-RS">http://regulatoryscience.georgetown.edu/MS-RS</a>	<p>The program provides a foundation in key skills such as applications of bioethics to research, systematic clinical trial design and administration, data collection and analysis, and the methods of behavioral and social sciences. The Regulatory Science concentration includes elective courses in regulatory science, an applied form of clinical and translational science (CTR).</p>	<p>Master of Science in Clinical and Translational Research, Regulatory Science: 33 credits  Certificate: 19 credits</p>	<p>Medical Products: Drugs Biologics</p>	<p>Regulatory Science</p>	<p>Online – 100%</p>	<p>Candidates who have or currently pursue a master's degree or higher in a related discipline, with demonstrated interest in CTR or regulatory science</p>

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<p><b>Harvard University</b></p> <p><a href="http://hits.harvard.edu/th-e-program/program-in-regulatory-science/about">http://hits.harvard.edu/th-e-program/program-in-regulatory-science/about</a></p>	<p>The Therapeutics Graduate Program is a certificate program that provides a rigorous curriculum and builds a community of PhD students and faculty with common interests in Therapeutic Sciences, to offer a rigorous multidisciplinary training in the sciences relevant to identifying and developing novel diagnostics and therapeutics, and in understanding and elucidating mechanisms of drug action, understanding clinical failures, developing compounds and applying them in preclinical and clinical studies, and understanding the societal implications and impact of these activities. Importantly, the training the students receive will also include intensive, hands-on internship experiences. The ultimate purpose of the program is to prepare Ph.D. students for careers in academic, industrial and clinical settings.</p>	<p>Graduate Certificate in Therapeutics: 6 courses, internship</p>	<p>Medical Products: Drugs Diagnostics</p>	<p>Regulatory Science</p>	<p>Onsite – 100%</p>	<p>Year 1 PhD students enrolled in Harvard Integrated Life Science programs</p>
<p><b>Johns Hopkins University</b></p> <p><i>CERSI institution</i></p> <p><a href="http://advanced.jhu.edu/academics/graduate-degree-programs/regulatory-science">http://advanced.jhu.edu/academics/graduate-degree-programs/regulatory-science</a></p>	<p>Curriculum offers practical hands-on, real life regulatory science experience through case-study assignments and a unique Practicum course at the end of the program. Students are expected to research, evaluate and present scientifically and legally justifiable positions on case studies from different perspectives of advanced regulatory topics.</p>	<p>Master of Science in Regulatory Science: 10 courses</p>	<p>Medical Products: Drugs Biologics</p>	<p>Regulatory Affairs</p>	<p>Online – 100% Onsite – 100%</p>	<p>Candidates who hold a Bachelor of Science in related discipline</p>

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<p><b>Regis College</b>  <a href="http://www.regiscollege.edu/graduate_programs/departments/Health_Product_Reg">http://www.regiscollege.edu/graduate_programs/departments/Health_Product_Reg</a></p>	<p>The Master of Science in Regulatory and Clinical Research Management is designed to help students navigate the increasingly complex areas of drug, device and biologics regulatory affairs, health economics and reimbursement, health policy and development, and clinical trial management. This program allows the student to focus on one of two specialty tracks including Product Regulation and Clinical Research Management. Electives allow the student to take the courses for both tracks or to pursue other areas of interest. Our students acquire skills, knowledge, and field experience that provide the necessary credentials to enhance or enter careers in regulatory affairs, clinical affairs, and health policy.</p>	<p>Master of Science Degree in Regulatory and Clinical Research Management: 9 courses                       Certificate: 4 courses</p>	<p>Medical Products: Drugs Devices Biologics</p>	<p>Regulatory Affairs</p>	<p>Online – 100%                      Onsite – 100%</p>	<p>Bachelor’s degree from an accredited university</p>
<p><b>San Diego State University</b>  <a href="http://regsci.sdsu.edu">http://regsci.sdsu.edu</a></p>	<p>Students build a foundation of knowledge focused on current laws, regulations, and good manufacturing processes mandated by major governmental regulatory agencies, specifically the Food and Drug Administration (FDA) and European Medicines Agency (EMA). Topics related to the discovery, development, testing, manufacture, commercialization, and post-marketing surveillance of pharmaceutical, biologic, and medical device products are at the core of these programs.</p>	<p>Master of Science in Regulatory Affairs: 12 courses                       Advanced Certificate in Regulatory Affairs: 4 courses</p>	<p>Medical Products: Drugs Devices Biologics</p>	<p>Regulatory Affairs</p>	<p>Online – 100%</p>	<p>A baccalaureate degree from an institution accredited by a regional accrediting association; Previous related graduate-level coursework, when available; professional experience</p>

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<p><b>Stanford University</b> <i>CERSI Institution</i> <a href="http://biodesign.stanford.edu">http://biodesign.stanford.edu</a></p>	<p>Our mission is to train students, fellows and faculty in the Biodesign Process: a systematic approach to needs finding and the invention and implementation of new technologies.</p>	<p>Courses offered in biodesign; Not a degree program</p>	<p>Medical Products: Devices</p>	<p>Regulatory Science</p>	<p>Onsite; Online</p>	<p>Graduate or postdoctoral students from the Schools of Business, Engineering, Humanities &amp; Science, Law and Medicine</p>
<p><b>Texas A&amp;M University</b> <a href="http://regsci.tamu.edu">http://regsci.tamu.edu</a></p>	<p>The Regulatory Science in Food Systems prepares graduates with the knowledge and skills to interpret U.S. and international regulatory guidelines and standards, assess the impact of existing and emerging regulations on business operations, establish practical strategies for compliance and reporting, lead regulatory reviews, and navigate an increasingly complex regulatory environment.</p>	<p>Graduate Certificate in Regulatory Science Food Systems: 12 credits</p>	<p>Food Science</p>	<p>Regulatory Affairs</p>	<p>Online – 100%</p>	<p>Candidates hold a four-year baccalaureate degree or higher from a college or university of recognized standing</p>
<p><b>University of Arkansas</b> <a href="http://publichealth.uams.edu/academics/certificates/certificate-in-regulatory-science">http://publichealth.uams.edu/academics/certificates/certificate-in-regulatory-science</a></p>	<p>The program includes courses in current regulatory statutes, safety assessment, clinical trials design and management, and data quality requirements for regulatory decision-making. The Certificate in Regulatory Science provides an extension to the PhD student's existing toxicology/pharmacology training. A primary goal of the program is to provide students with insight into the complexities of the laws, regulations, policies, risk assessments, risk-benefit analyses and risk management processes. This training provides graduates with a working knowledge of regulatory science and provides leaders in regulatory science for industry, government, and academia.</p>	<p>Graduate Certificate in Regulatory Science: 12 credits</p>	<p>Medical Products: Drugs Devices Biologics</p>	<p>Regulatory Science</p>	<p>Onsite – 100%</p>	<p>Students for the Certificate in Regulatory Science are recruited from existing pools of potential students. The first is comprised of post-doctoral ORISE fellows training in the research laboratories at NCTR. The second is made up of regular FDA employees at the FDA's Jefferson Laboratories. A third group includes entering and current students enrolled in the Ph.D. programs at UAMS, particularly students pursuing the Ph.D. in toxicology or pharmacology.</p>

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<p><b>University of California, San Francisco</b></p> <p><i>CERSI institution</i></p> <p><a href="http://bts.ucsf.edu/acdrs">http://bts.ucsf.edu/acdrs</a></p>	<p>The American Course on Drug Development and Regulatory Sciences (ACDRS) a graduate course aimed to promote modernization of the development and regulation processes for new medical products. This modernization will be accomplished through comprehensive instruction for integrating the cutting-edge concepts and best practices of medical product development and regulatory sciences. The program is offered onsite in San Francisco and Washington, DC.</p>	<p>Course only; graduate degree program forthcoming</p>	<p>Medical Products: Drugs Diagnostics Biologics</p>	<p>Regulatory Science</p>	<p>Onsite</p>	<p>Applicants must have a higher university degree, such as MD, PharmD, PhD, Master's, or JD and a primary interest in medical product discovery, development, regulation or related activity.</p>
<p><b>University of Maryland</b></p> <p><i>CERSI institution</i></p> <p><a href="http://www.pharmacy.umaryland.edu/academics/regulatoryscience">http://www.pharmacy.umaryland.edu/academics/regulatoryscience</a></p>	<p>The MS in Regulatory Science program at the University of Maryland School of Pharmacy primarily focuses on drugs, although aspects of biologics, diagnostics, devices, and nutritional products are also addressed. The program covers all major areas of drug product regulatory science, including:</p> <ul style="list-style-type: none"> <li>• Chemistry, Manufacturing, and Controls (CMC)</li> <li>• Clinical Research</li> <li>• Pharmacovigilance</li> <li>• Pharmacoepidemiology</li> <li>• Drug Discovery</li> </ul> <p>The strength of the program is its science-driven understanding of drug product development and regulation.</p> <p>The program covers regulatory affairs in a global manner, including the application of regulatory principles worldwide.</p>	<p>Master of Science in Regulatory Science: 30 credits</p>	<p>Medical Products: Drugs Devices Biologics</p>	<p>Regulatory Science</p>	<p>Online – 100%</p>	<p>Candidates who have earned a BA or BS in an area of science, health or policy, engineering, or business</p>

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<p><b>University of Michigan</b></p> <p><a href="http://isd.engin.umich.edu/degree-programs/pharmaceutical-engineering/regulatory-science.htm">http://isd.engin.umich.edu/degree-programs/pharmaceutical-engineering/regulatory-science.htm</a></p>	<p>Master of Engineering in Pharmaceutical Engineering, with a Regulatory Science Concentration; Accelerating discoveries in molecular biology and genetics are energizing the development of new and improved pharmaceutical processes, products, and therapeutic agents. As companies work to turn the process of developing new medicines from an art to a well-understood science, there is also a growing opportunity for individuals with regulatory science expertise.</p>	<p>Master of Engineering in Pharmaceutical Engineering, Regulatory Science Concentration: 30 credits</p>	<p>Medical Products: Devices</p>	<p>Regulatory Science</p>	<p>Onsite – 100%</p>	<p>Bachelor's degree in engineering or related discipline. The equivalent of two years of full time industrial experience in pharmaceutical and related industries. Exceptions granted on a case-by-case basis.</p>
<p><b>University of Pennsylvania</b></p> <p><a href="http://www.itmat.upenn.edu/mtr.shtml">http://www.itmat.upenn.edu/mtr.shtml</a></p>	<p>The objective of the Master of Science in Translational Research (MTR) program is to provide students with in-depth instruction in the fundamental skills, methodology and principles necessary to become a well-trained translational investigator. The Regulatory Science track in the MTR program is intended to broaden the spectrum and enhance the quality of training by providing an educational curriculum to teach the skill set needed to perform Regulatory Science.</p>	<p>Master of Science in Translational Research, Regulatory Science track:</p>	<p>Medical Products: Drugs, Biologics, Devices</p>	<p>Regulatory Science</p>	<p>Onsite – 100%</p>	<p>Bachelor's degree from an accredited university</p>
<p><b>University of Southern California</b></p> <p><a href="http://regulatory.usc.edu">http://regulatory.usc.edu</a></p>	<p>The Regulatory Science program serves both full and part-time students interested in expanding their knowledge of regulatory affairs, clinical research and quality systems. Our goal is to develop leaders in regulatory science in industry, government and academia.</p>	<p>PhD in Regulatory Science: 64 units Master of Science: 36 units Certificate: 12 units</p>	<p>Medical Products: Drugs, Biologics, Devices</p>	<p>Regulatory Affairs</p>	<p>Online – 100% Onsite – 100%</p>	<p>Candidates who hold a baccalaureate or graduate degree in an appropriate discipline</p>

Programs at a Glance: Regulatory Science Education Programs at U.S. Academic Institutions

University	Brief Description	Degrees Offered	Primary Focus	Regulatory Science or Regulatory Affairs	Online/ Onsite	Candidate Requirements
<p><b>University of St. Thomas</b></p> <p><a href="https://www.stthomas.edu/engineering/graduate/masters/msrs">https://www.stthomas.edu/engineering/graduate/masters/msrs</a></p>	<p>The Regulatory Science Master's Program was developed in consultation with industry leaders. It embodies the flexibility, quality instruction and career enhancement opportunities that University of St. Thomas graduates have realized over the years. Through selection of electives, graduates acquire information and skills allowing them to pursue regulatory careers.</p>	<p>Master of Science in Regulatory Science: 13 courses</p>	<p>Medical Products: Devices</p>	<p>Regulatory Affairs</p>	<p>Onsite – 100%</p>	<p>Candidates include those interested in transitioning into the field of Regulatory Science. It is also intended for new regulatory professionals who recognize the need to acquire a broader understanding of regulatory requirements and how to achieve them.</p>

## Appendix: Regulatory Science Competencies in 11 Core Thematic Areas

### **Regulatory Science Research Questions and Priorities**

- ① Summarize current and emerging Regulatory Science priorities, including FDA Priority Areas and others
- ② Identify additional Regulatory Science questions via gap analysis of translational research pathway, considering current evaluation and approval process of medical products
- ③ Critique Regulatory Science research questions and priorities
- ④ Identify approaches and techniques to address areas of Regulatory Science; outline a vision for a research program
- ⑤ Describe principles of decision science and evidence based decision making, considering the role of patients, patient advocates, clinicians, payors, and regulators
- ⑥ Describe principles of Team Science, including the specific roles within a multidisciplinary network of individuals in and across organizations

### **Regulatory Policies and Process**

- ① Understand current regulatory system and structure appropriate to the relevant field of study
- ② Evaluate and analyze laws, regulations, and guidance documents relevant to the field of study
- ③ Apply proposed regulatory strategies for the design and development of a medical product from bench to bedside, analyzing opportunities and challenges within current regulatory framework

### **Research Ethics**

- ① Explain the ethical principles and requirements related to the development of new regulations and guidance documents
- ② Identify current and emerging research ethics issues in Regulatory Science, including clinical trials
- ③ Discuss issues of risk-benefit disclosure during the process of consent
- ④ Define COI and discuss financial and non-financial examples of conflict with nascent approaches including mediating and monitoring techniques
- ⑤ Develop an understanding of current risk-benefit assessment initiatives and requirements; while identifying opportunities and challenges of implementing new approaches to risk-benefit assessment, including for emerging innovative technologies
- ⑥ Define, identify and apply ethical issues and implications for dual-use research

### **Drug Discovery and Development**

- ① Describe the traditional process of drug discovery and development, including target identification, validation, lead molecule identification and optimization
- ② Discuss incorporation of new technology to further target identification (High-Throughput Screening, in vitro models, lead optimization and qualification, systems biology, network analysis, human organs on chips)
- ③ Describe importance of correlating in vitro models for applicability to toxicology, target mechanism, metabolism
- ④ Identify and understand the relative utility of biomarkers and surrogate endpoints for addressing questions of efficacy and toxicity
- ⑤ Outline parameters for clinical proof of mechanism and proof of concept

## Appendix: Regulatory Science Competencies in 11 Core Thematic Areas

### **Medical Device Innovation**

- ① Outline the process to translate a preclinical or clinical observation into a clear statement of Regulatory Science need
- ② Discuss how to filter and prioritize needs based on safety, quality and regulatory impact and other considerations
- ③ Identify needs in applying quality systems regulations to product development
- ④ Describe preclinical and clinical tests necessary to show effectiveness
- ⑤ Understand how to apply Regulatory Science approaches to respond to necessary post market changes

### **Preclinical**

- ① Evaluate the stages of preclinical testing in the context of drug and device development
- ② Describe how to define preclinical testing requirements and design appropriate pre-clinical study
- ③ Describe the basic principles for GLP research and when such methods are needed
- ④ Explain how the preclinical results fit with formulation and clinical aspects of drug development
- ⑤ Describe selection, qualification and innovation of animal models and animal model alternatives to promote novel clinical trial design
- ⑥ Explain the need to develop better preclinical models of human adverse response (e.g. cell/tissue based assays) that more accurately represent human susceptibility to adverse reactions
- ⑦ Explain the need to evaluate data at multiple levels (e.g., genes, proteins, pathways, cell/organ function) to better understand toxicity mechanisms
- ⑧ Describe the need for identification and evaluation of biomarkers and how related endpoints can be used in pre-clinical evaluations

### **Clinical Trials**

- ① Describe the stages of individual clinical trials
- ② Outline the design/elements of an appropriate clinical trial for a medical product
- ③ Understand options for alternative/novel clinical trial designs (including adaptive trial design) that may be more informative, impactful and/or efficient for special needs (e.g., small trials for orphan indications, designs and endpoints for pediatric and neonatal trials)
- ④ Describe adverse event management strategies within individual trials and development programs, both pre and post-marketing
- ⑤ Outline potential for pharmacogenomic approaches to refine target populations and opportunities for parallel co-development of drugs and diagnostics
- ⑥ Describe the role for pharmacometrics in clinical studies and the drug approval process
- ⑦ Discuss parameters for testing in specialized populations (e.g., pediatrics, geriatrics, altered organ function, cardiac toxicity)
- ⑧ Understand how outcomes of trials might vary if the study population differs significantly from the targeted population for use.
- ⑨ Explain the need to identify improved clinical endpoints and related biomarkers
- ⑩ Describe the use of modeling and simulation to enhance clinical trial design and effectiveness

### **Post-Marketing and Compliance**

- ① Outline the role of the FDA in post-marketing processes
- ② Describe the range of enforcement options available to the FDA when dealing with compliance issues
- ③ Understand the role of new technology as it applies to sampling and product testing for contaminated or counterfeit product

## Appendix: Regulatory Science Competencies in 11 Core Thematic Areas

### **Analytical Approaches and Tools**

- ① Explain potential applications of computational methods and in silico modeling to predict human efficacy, toxicity and risk-benefit and to inform regulatory decisions
- ② Evaluate applications of statistical approaches, biomedical informatics and models (e.g., missing data, multiple endpoints, patient enrichment, adaptive designs) to promote novel clinical trial design
- ③ Describe basic statistical concepts (e.g., identify a research question, conceptualize hypotheses, identify sources of data, utilize appropriate study designs, determine appropriate analytical methods, draw valid and meaningful conclusions)
- ④ Describe the process to identify, evaluate, and synthesize information from RCTs, observational studies, and other study designs
- ⑤ Identify appropriate applications for various scientific methods to gather and validate information (e.g., systematic reviews, meta-analysis, etc.)
- ⑥ Describe principles and applications of various analytic tools and techniques (e.g., bioinformatics, patient-reported outcomes, clinical effectiveness research, translational research, etc.)
- ⑦ Discuss results from data mining techniques to explore existing clinical trial data (e.g., analysis of electronic health records from accessible large healthcare databases to identify sources of variation among studies, differentiate subsets of diseases, improve understanding of relationships between clinical parameters and outcomes, evaluate clinical utility of potential biomarkers and evaluate post-marketing data)
- ⑧ Describe use of informatics to inform both clinical trials and pharmacometrics
- ⑨ Outline current legal and policy requirements related to data storage, maintenance, access, privacy and security
- ⑩ Discuss approaches to address data storage, access, sharing, privacy and confidentiality (including patient, industry, government and other data sources)
- ⑪ Describe requirements and permissions associated with Biobanking tissue and others collections
- ⑫ Describe use of novel strategies and existing data sets for repurposing

### **Communication**

- ① Compare and contrast communication, evidence-based communication, and risk communication
- ② Explain approaches to risk communication and the underlying social and behavior sciences that inform these approaches
- ③ Describe various research approaches that inform regulatory decisions (e.g., focus groups, surveys, experiments, etc.)
- ④ Discuss results-oriented approaches, and corresponding evaluation criteria, to achieve short- and long-term goals of communication strategies
- ⑤ Effectively communicate the value of Regulatory Science, including priorities and gaps to stakeholders, including colleagues, policy makers, the media, and the public
- ⑥ Discuss the need to provide guidance to sponsors and manufacturers about how to effectively and transparently communicate the risks, benefits and uncertainties of regulated products to the public
- ⑦ Recognize international and cultural aspects in developing communication plans, including the roles for international organizations

### **Technology and Innovation**

- ① Describe emerging key technology areas and how they may impact Regulatory Science processes and policies (e.g., manufacturing, toxicology, etc.)
- ② Explain the global nature of medical product innovation and technology development
- ③ Outline aspects impacting economic viability of novel medical products, including the role for payors in coverage and reimbursement decisions