

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).

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>Arizona State University</p> <p>https://nursingandhealth.asu.edu/crm/master-science-clinical-research-management-concentration-regulatory-science?destination=node/5245</p>	<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>
<p>Fairleigh Dickinson University</p> <p>http://view.fdu.edu/default.aspx?id=10476</p> <p>http://view.fdu.edu/default.aspx?id=8015</p>	<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>
<p>Georgetown University</p> <p><i>CERSI institution</i></p> <p>http://regulatoryscience.georgetown.edu/MS-RS</p>	<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</p> <p>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>

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<p>Harvard University</p> <p>http://hits.harvard.edu/th-e-program/program-in-regulatory-science/about</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>Johns Hopkins University</p> <p><i>CERSI institution</i></p> <p>http://advanced.jhu.edu/academics/graduate-degree-programs/regulatory-science</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>

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<p>Regis College http://www.regiscollege.edu/graduate_programs/departments/cfm?id=Health_Product_Reg</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>San Diego State University http://regsci.sdsu.edu</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>

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Stanford University <i>CERSI Institution</i> http://biodesign.stanford.edu	<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 & Science, Law and Medicine</p>
Texas A&M University http://regsci.tamu.edu	<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>
University of Arkansas http://publichealth.uams.edu/academics/certificates/certificate-in-regulatory-science	<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>

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<p>University of California, San Francisco</p> <p><i>CERSI institution</i></p> <p>http://bts.ucsf.edu/acdrs</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>University of Maryland</p> <p><i>CERSI institution</i></p> <p>http://www.pharmacy.umaryland.edu/academics/regulatoryscience</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"> • Chemistry, Manufacturing, and Controls (CMC) • Clinical Research • Pharmacovigilance • Pharmacoepidemiology • Drug Discovery <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>

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<p>University of Michigan</p> <p>http://isd.engin.umich.edu/degree-programs/pharmaceutical-engineering/regulatory-science.htm</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>University of Pennsylvania</p> <p>http://www.itmat.upenn.edu/mtr.shtml</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>University of Southern California</p> <p>http://regulatory.usc.edu</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>

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<p>University of St. Thomas</p> <p>https://www.stthomas.edu/engineering/graduate/masters/msrs</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>