Regulatory Affairs
In the College of Sciences

Graduate Adviser: Lorah W. Bodie, Ed.D.

General Information
Regulatory science programs focus on training students in areas related to development, manufacturing, and marketing of biopharmaceutical, pharmaceutical, and medical device products. Programs address research and workforce needs of companies as they make the transition from research and development to manufacturing and production, including the legal, ethical, and regulatory elements that both guide and restrict the industry.

The courses for the degree program are offered fully online through special sessions. Students in special session courses enroll through the College of Extended Studies. Since the degree program is self-supporting, the fee structure for courses is different than for courses in programs that are supported with state funding. For more information on degree program admissions, courses, requirements, and fees visit http://regsci.sdsu.edu.

The degree program provides a comprehensive background in regulatory science necessary for regulatory affairs professionals to competently address regulatory requirements associated with pharmaceutical, biopharmaceutical, and medical device products. Regulatory affairs courses focus on practical applications and approaches for compliance with development, testing, manufacturing and post-marketing surveillance laws and requirements enforced by the Food and Drug Administration (FDA) and international counterparts. Upon successful completion of the degree program, students will have detailed knowledge and understanding of current regulations and their practical application to the development and commercialization of drug, biologic, and medical device products.

Master of Science Degree in Regulatory Affairs
(Offered through the College of Extended Studies)
The Master of Science degree in regulatory affairs is offered through the College of Sciences. The coursework in this curriculum is offered only in special sessions. Students in special session courses enroll through the College of Extended Studies and follow a fee structure that is different from that for regularly matriculated students. For more information, contact the regulatory affairs program adviser.

This degree program provides a comprehensive background in regulatory science with the additional training and experience required of regulatory affairs professionals to address federal, state, and international regulatory statutes and laws. The degree offering focuses on laws and regulations imposed by regulatory agencies related to drug discovery, development, testing, and manufacture of products for commercial distribution. Also included are requirements for ongoing post-marketing surveillance. The degree program will provide students with detailed knowledge and understanding of current regulations and their practical application to the development and commercialization of drug, biologics, and medical device products.

Admission to Graduate Study
All students must satisfy the general admission and examination requirements for admission to the university with classified graduate standing, as described in Part Two of the Graduate Bulletin. In addition, the applicant must satisfy the following requirements before being considered for admission to classified graduate standing by the admissions review committee of the department.

Students applying for admission should electronically submit the university application available at http://www.csumentor.edu along with the $55 application fee.

All applicants must submit admissions materials separately to SDSU Graduate Admissions and to the Regulatory Affairs office.

Graduate Admissions
The following materials should be submitted as a complete package directly to:

Graduate Admissions
Enrollment Services
San Diego State University
San Diego, CA 92182-7416

(1) Official transcripts (in sealed envelopes) from all postsecondary institutions attended;

Note:
• Students who attended SDSU need only submit transcripts for work completed since last attendance.
• Students with international coursework must submit both the official transcript and proof of degree. If documents are in a language other than English, they must be accompanied by a certified English translation.

(2) GRE scores (http://www.ets.org. SDSU institution code 4682);

(3) English language score, if medium of instruction was in a language other than English (http://www.ets.org. SDSU institution code 4682).

Regulatory Affairs
The following materials should be mailed or delivered to:

Master of Science in Regulatory Affairs
Director of Regulatory Affairs Programs
San Diego State University
5500 Campanile Drive
San Diego, CA 92182-1010

(1) Two letters of recommendation sent from persons who are knowledgeable about the candidate's potential for success in graduate study;

(2) Applicant essay that describes the applicant’s purpose in pursuing graduate studies in regulatory affairs and relationship to personal and career objectives;

(3) Resume or curriculum vita listing employment or volunteer experience relevant to the proposed new degree major program;

(4) One set of official transcripts (in addition to those sent to Graduate Admissions).

Candidates for admission will typically come from one of the disciplines offered in the life and physical sciences and engineering. In some cases, candidates who have not fully met admissions requirements may be admitted with conditionally classified standing, subject to space availability, after consideration of those who meet the requirements for classified graduate standing. Students so admitted will be advised as to the conditions of their admittance and the time allowed to achieve full classified graduate standing.

Advancement to Candidacy
All students must satisfy the general requirements for advancement to candidacy, as described in Part Four of this bulletin.

Specific Requirements for the Master of Science Degree
(Major Code: 49045) (SIMS Code: 779901)
In addition to meeting the requirements for classified graduate standing and the basic requirements for the master’s degree as described in Part Four of this bulletin, the student must complete a graduate program consisting of a minimum of 39 units as follows:

1. Complete 30 units of required courses:
   R A 601 Pharmaceutical, Biotechnology, and Medical Device Industries (3)
   R A 602 Food and Drug Law (3)
   R A 605 Medical/Scientific Writing for Healthcare Professionals (3)

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Affairs is a joint certificate program designed for life science professionals who have no formal legal training and whose research or work responsibilities or ambition would benefit from knowledge of regulatory affairs and intellectual property law. Ideal candidates include working professionals with a minimum of two years of experience in the biotechnology, medical technology, or related life sciences industries, who will benefit from learning the fundamentals of intellectual property and regulatory law.

The Advanced Certificate in Intellectual Property and Regulatory Affairs requires the completion of Regulatory Affairs 601, 602, 770, and 781. The Advanced Certificate in Regulatory Affairs extends the curriculum to include the following courses: (Offered through the College of Extended Studies)

**Advanced Certificate in Intellectual Property and Regulatory Affairs**

*(SIMS Code: 779903)*

The Advanced Certificate in Intellectual Property and Regulatory Affairs is a joint certificate program designed for life science professionals who have no formal legal training and whose research or work responsibilities or ambition would benefit from knowledge of regulatory affairs and intellectual property law. Ideal candidates include working professionals with a minimum of two years of experience in the biotechnology, medical technology, or related life sciences industries, who will benefit from learning the fundamentals of intellectual property and regulatory law but who do not wish to become attorneys. The certificate program provides flexibility to design an individualized plan of study from designated course offerings from SDSU's College of Sciences and the University of San Diego (USD) School of Law to best enhance each candidate's professional development. Candidates will take courses at SDSU and the law school, designing individual plans from a broad list of existing courses. Regulatory Affairs courses in the advanced certificate may be applied to the Master of Science degree in regulatory affairs.

**Admission Requirements**

Applicants must have completed a bachelor's degree from an accredited institution in the United States or its equivalent from a foreign institution.

Students applying for admission should electronically submit the university application available at [http://www.csumentor.edu](http://www.csumentor.edu) along with the $55 application fee.

All applicants must submit admissions materials separately to SDSU Graduate Admissions and to the Regulatory Affairs office.

**Graduate Admissions**

The following materials should be submitted directly to:

- San Diego State University
- San Diego, CA 92182-7416

Official transcripts (in sealed envelopes) from all postsecondary institutions attended;

Note:

- Students who attended SDSU need only submit transcripts for work completed since last attendance.
- Students with international coursework must submit both the official transcript and proof of degree. If documents are in a language other than English, they must be accompanied by a certified English translation.

**Regulatory Affairs**

The following materials should be mailed or delivered to:

- Master of Science in Regulatory Affairs
- Director of Regulatory Science Programs
- San Diego State University
- 5500 Campanile Drive
- San Diego, CA 92182-1010

1. Official transcripts for all university and colleges attended (undergraduate and graduate);
2. A resume, demonstrating a minimum of two years of professional experience in the biotechnology, medical technology, or related life science industries;
3. A personal statement detailing the applicant's interest in and qualification for the program;
4. One or more letters of recommendation.

**Specific Requirements**

To receive the certificate, candidates must successfully complete the following courses (minimum of 13 credits/units) and earn a minimum grade point average of 3.0 or higher.

**R A 750** Quality Improvement Management (3)

**R A 770** Current Good Manufacturing Practices – General Concepts (3)

**R A 773** Medical Device Regulations (3)

**OR**

**R A 774** Investigational and Marketing Applications for Drugs and Biologics (3)

**R A 775** Clinical Trials: Issues in Design, Conduct, and Evaluation (3)

**R A 779** International Regulatory Affairs (3)

**R A 781** Ethics for Healthcare Professionals (3)

**R A 783** Effective Communication for Healthcare Professionals (3)

2. Complete six units of electives from the following courses.

**R A 696** Advanced Topics in Regulatory Affairs (1-4)

**R A 705** Project Planning for the Biomedical Industries (3)

**R A 771** Current Good Manufacturing Practices – Advanced Topics (3)

**R A 772** Post-Approval Activities (3)

**R A 773** Medical Device Regulations (3)

**OR**

**R A 774** Investigational and Marketing Applications for Drugs and Biologics (3)

**R A 776** Validation Aspects of Drugs, Biologics, and Device Product Development and Manufacturing, Including Computer Related Systems and Software (3)

**R A 777** Quality Control and Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3)

**R A 797** Research (1-3) Cr/NC/RP

**R A 798** Special Study (1-3) Cr/NC/RP

3. Complete three units of 798 or 799A. Students must select Plan A or Plan B in consultation with the adviser. Students electing Plan A must complete three units of Regulatory Affairs 799A. Students electing Plan B must complete three units of Regulatory Affairs 798.

**Advanced Certificate in Regulatory Affairs**

*(SIMS Code: 779902)*

The Advanced Certificate in Regulatory Affairs requires the completion of Regulatory Affairs 601, 602, 770, and 781. Regulatory Affairs 601 covers the various steps in the development process for pharmaceuticals, biologics, and medical devices, with an understanding of the regulatory impact on this process. Regulatory Affairs 602 provides a basic knowledge of the laws and regulations governing these industries. In Regulatory Affairs 770, students learn the basic concepts of good manufacturing practices. Regulatory Affairs 781 examines some of the most significant ethical issues confronting healthcare professionals. Courses in the Advanced Certificate in Regulatory Affairs may be applied to the Master of Science degree in regulatory affairs. To enroll in this certificate program, call 619-594-6030.
Courses Acceptable on Master's Degree Program in Regulatory Affairs (R A)

Refer to Courses and Curricula and Regulations of the Division of Graduate Affairs sections of this bulletin for explanation of the course numbering system, unit or credit hour, prerequisites, and related information.

GRADUATE COURSES

R A 601. Pharmaceutical, Biotechnology, and Medical Device Industries (3)
Pharmaceutical, biotechnology, and medical device industries. Company organization and product development and commercialization associated activities, e.g., drug discovery, chemical synthesis, quality assurance, regulatory affairs, manufacturing, control and marketing.

Prerequisite: Regulatory Affairs 601.


R A 605. Medical/Scientific Writing for Healthcare Professionals (3)
Prerequisite: Regulatory Affairs 601.

Writing for development of a new drug or biologic. Emphasis on effective writing of project reviews, research, reports, protocols, and CTDs.

Prerequisite: Consent of graduate adviser.

Selected topics in regulatory affairs. May be repeated with new content. See Class Schedule for specific content. Credit for 696 applicable to a master's degree with approval of the graduate adviser.

R A 705. Project Planning for the Biomedical Industries (3)
Prerequisite: Regulatory Affairs 601.

Complexity of biomedical product development. Projects and strategies for effectively planning and managing them. Understanding and utilization of management and planning strategies as applied to these biomedical product development projects. Strategies for planning, scheduling, and effective management of regulatory affairs activities and related tasks associated with development of a biomedical product.

R A 750. Quality Improvement Management (3)
Prerequisite: Regulatory Affairs 602.

Change management as it relates to strategic planning and quality improvement to increase competitive advantage. Controlling and facilitating change utilizing quality and statistical tools and concepts, and process improvement methods, as applied to management and leadership challenges and production and manufacturing issues.

R A 770. Current Good Manufacturing Practices - General Concepts (3)
Prerequisite: Regulatory Affairs 602.

Current Good Manufacturing Practice regulations to assure quality of marketed products. Application to manufacturer’s organization, personnel, facilities, equipment, control systems, production, process controls, laboratory procedures and records.

R A 771. Current Good Manufacturing Practices - Advanced Topics (3)
Prerequisite: Regulatory Affairs 770.


R A 772. Post-Approval Activities (3)
Prerequisite: Regulatory Affairs 602.

FDA and FTC rules and regulations governing advertising, promotion, and labeling for prescription drugs, biologics, medical devices, and over-the-counter drugs.

R A 773. Medical Device Regulations (3)
Prerequisite: Regulatory Affairs 602.

Laws and FDA regulations for medical devices, in vitro diagnostics, radiological devices, FDA jurisdiction, registration, listing, labeling requirements, classification, Investigational Device Exemptions (IDE), premarket approval (PMA) and premarket notification (510(k)). Not a repeatable course. Maximum combined credit six units of Regulatory Affairs 773 and 774 applicable to a master's degree.

R A 774. Investigational and Marketing Applications for Drugs and Biologics (3)
Prerequisite: Regulatory Affairs 602.

Development and informational content for investigational new drug applications (IND), investigational device exemptions (IDE), new drug applications (NDA), product license applications (PLA), and biologics license applications (BLA) for FDA review. Not a repeatable course. Maximum combined credit six units of Regulatory Affairs 773 and 774 applicable to a master's degree.

R A 775. Clinical Trials: Issues in Design, Conduct, and Evaluation (3)
Prerequisite: Regulatory Affairs 602.

Review requirements, procedures, controls, and documentation for quality control and assurance in manufacture and commercial distribution of drugs, biologics, and medical devices.

R A 776. Validation Aspects of Drugs, Biologics, and Device Product Development and Manufacturing, Including Computer Related Systems and Software (3)
Prerequisite: Regulatory Affairs 602.

Verification and validation of computer hardware, software, and peripherals for applications in pharmaceutical, biologic, and medical device industries.

R A 777. Quality Control and Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3)
Prerequisite: Regulatory Affairs 602.

Review requirements, procedures, controls, and documentation for quality control and assurance in manufacture and commercial distribution of drugs, biologics, and medical devices.

R A 779. International Regulatory Affairs (3)
Prerequisite: Regulatory Affairs 602.

International medical device regulations pertaining to pharmaceuticals, biologics, and devices. Emphasis on European Union and other appropriate areas of the world.

R A 781. Ethics for Healthcare Professionals (3)
Prerequisite: Regulatory Affairs 602.

Ethical issues confronting healthcare professionals. Moral positions concerning impact on laboratory animals, human subjects, patients, and consumers, both on a case-specific level and as applied to field in general. Develop capacities to generalize, translate, and apply principles and ideas to modern biomedical practice.

R A 783. Effective Communication for Healthcare Professionals (3)
Prerequisite: Regulatory Affairs 602.

Written, oral, and interpersonal communication strategies for the business environment with emphasis on regulatory affairs.

R A 797. Research (1-3) Cr/NC/RP
Prerequisite: Consent of staff; to be arranged with program director/graduate adviser and instructor.

Research in the area of regulatory sciences. Maximum credit six units applicable to a master's degree.

R A 798. Special Study (1-3) Cr/NC/RP
Prerequisite: Consent of staff; to be arranged with department chair and instructor.

Individual study. Maximum credit six units applicable to a master's degree.

R A 799A. Thesis or Project (3) Cr/NC/RP
Prerequisite: An officially appointed thesis committee and advancement to candidacy.

Preparation of thesis or project for the master's degree.

R A 799B. Thesis or Project Extension (0) Cr/NC
Prerequisite: Prior registration in Thesis 799A with an assigned grade of RP. Registration required in any semester or term following assignment of RP in Course 799A in which the student expects to use the facilities and resources of the university; also students must be registered in the course when the completed thesis or project is granted final approval.