

Regulatory Affairs

In the College of Sciences

OFFICE: Geology/Mathematics/Computer Science 619

TELEPHONE: 619-594-6030 / FAX: 619-594-6381

E-MAIL: regsci@mail.sdsu.edu

<http://regsci.sdsu.edu>

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 with enrollment 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) Curriculum vitae or resume 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 Life Science Professionals (3)
 - R A 750 Leadership for Change and Continuous Improvement (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 Life Science Professionals (3)
 - R A 783 Effective Communication for Life Science 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 778 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 Regulatory Affairs 798, capstone project.

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> 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:

Graduate Admissions
Enrollment Services
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) Curriculum vitae or resume, demonstrating a minimum of two years of professional experience in the biotechnology, medical technology, or related life science industries;
- (3) 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 602 Food and Drug Law (3)
- R A 781 Ethics for Healthcare Professionals (3)
- LWIP 535 (USD) Survey of Pharmaceutical Law & Policy (2)
- LWIP 570 (USD) Patent Law (3)

Elective(s) from approved list of courses offered at SDSU or USD School of Law (two units required).

The certificate candidate must earn a cumulative grade point average of B (3.0) or higher and earn a passing grade in all courses. Certificate candidate must also meet all credit, course, grade point average, and other academic requirements to be eligible for conferral of the certificate.

A maximum of nine units may be transferred to a master's degree program with consent of the graduate adviser and Dean of Graduate Affairs, when applicable.

Advanced Certificate in Regulatory Affairs

(Offered through the College of Extended Studies)

(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 life science 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 600. Seminar (1-3)

Prerequisite: Consent of graduate adviser.

An intensive study in specific areas of regulatory affairs. May be repeated with new content. See *Class Schedule* for specific content. Maximum credit six units applicable to a master's degree.

R A 601. Pharmaceutical, Biotechnology, and Medical Device Industries (3)

Introduction and foundational knowledge of biotechnology, medical device, and pharmaceutical industries. Commercialization-associated activities to include chemical synthesis, control, drug discovery, manufacturing, marketing, post-marketing surveillance, quality assurance, and regulatory affairs. Company organization and product development.

R A 602. Food and Drug Law (3)

Prerequisite: Regulatory Affairs 601.

Laws and regulations enforced by the FDA for biotechnology, medical device, pharmaceutical, and related industries. Federal Food, Drug, and Cosmetic Act, Freedom of Information Act, related laws, and the U.S. legal system. Laws and regulations affecting biologics, cosmetics, devices and diagnostics, drugs, foods, tobacco products, and veterinary products. Combination products, import/export requirements, international regulations, orphan products, and product liability.

R A 605. Medical/Scientific Writing for Life Science Professionals (3)

Prerequisite: Regulatory Affairs 601.

Writing conducted during the development of a new biologic or drug. Effective writing of regulatory documents to include analyses of scientific literature for critical appraisal of drugs, informed consents, and reports of laboratory results.

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

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: Graduate standing.

Introduction to strategies for effective management, planning, and scheduling of regulatory affairs activities and related tasks associated with project development in biomedical industries.

R A 750. Leadership for Change and Continuous Improvement (3)

Prerequisite: Graduate standing.

Control and facilitation of change at a variety of levels within the biotechnology industry. Strategic improvements to increase competitive advantages. Process improvement concepts and methods, quality and statistical tools, and their applications to leadership, manufacturing, and production challenges.

R A 770. Current Good Manufacturing Practices - General Concepts (3)

Prerequisite: Regulatory Affairs 602.

Interpretation and application of current Good Manufacturing Practices (GMPs) to drug substance and drug product manufacture. Differentiation between full and appropriate GMPs required for clinical supplies production and commercial manufacturing. Variances between FDA and European Union requirements for the control and manufacture of pharmaceuticals. Aseptic regulatory inspections processing and preparation.

R A 771. Current Good Manufacturing Practices - Advanced Topics (3)

Prerequisite: Regulatory Affairs 770.

Expanded analysis of current Good Manufacturing Practice regulations to assure quality of marketed drug and biological products. Discussions of FDA methods of enforcement by inspections of manufacturing establishments.

R A 772. Post-Approval Activities (3)

Prerequisite: Regulatory Affairs 602.

FDA and FTC rules and regulations governing advertising, labeling, and promotion for biologics, generic, over-the-counter, and prescription drugs; and medical devices. Annual reporting requirements, changes to approved marketing applications, Good Manufacturing Practice inspections, post-marketing adverse reaction reporting, product recalls, and risk management.

R A 773. Medical Device Regulations (3)

Prerequisite: Regulatory Affairs 602.

Introduction to regulatory affairs requirements for the medical device industry through stages of product development. FDA medical device regulations, terminology, timelines, and actual steps followed by regulatory affairs professionals. Commercial, operational, and strategic aspects of the regulatory approval process for in vitro diagnostics (IVD) and medical devices. Marketing, regulatory intelligence, risk management, and strategic considerations. 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.

Content, planning, requirements, and strategy for developing and preparing Food and Drug Administration regulatory submissions to include biologics license applications (BLA), device premarket applications (PMA), device premarket notifications (510[k]), investigational device exemptions (IDE), investigational new drug applications (IND), new drug applications (NDA). Combination product submissions, future submission trends, and risk management. 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.

Issues in conduct, design, and evaluation of clinical trials by biotechnology, medical device, and pharmaceutical companies for marketing approval of products being studied in human subjects. Macro view of clinical trials within corporate, legal, and regulatory environments. Key steps required to develop and execute a successful clinical development program.

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.

Validation in biotechnology, medical device, and pharmaceutical industries. Validation of computerized systems, equipment, facilities and critical utilities, laboratory instrumentation, and manufacturing processes. Regulatory requirements for validation, maintenance of validation programs, validation master plan, and writing effective validation protocols.

R A 778. Quality Control and Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3)

Prerequisite: Regulatory Affairs 602.

Quality and compliance functions in biotechnology and pharmaceutical companies to include out-of-specification results, developing product specifications, and writing compliant process deviations. Good Laboratory Practices (GLPs). Graded approach for Active Pharmaceutical Ingredients (APIs) manufacturing. Biologics, drugs, and medical device regulations. Quality control (QC) role vs. quality assurance (QA) role. Current trends in industry.

R A 779. International Regulatory Affairs (3)

Prerequisite: Regulatory Affairs 602.

International medical device regulations to include those in the European Union and other key areas of the world that pertain to the development and commercialization of biologics, medical devices, and pharmaceuticals.

R A 781. Ethics for Life Science Professionals (3)

Prerequisite: Regulatory Affairs 602.

Ethical issues confronting regulatory affairs professionals. Development of capacities to apply, generalize, and translate principles and ideas to modern biomedical practice. Responsible conduct surrounding clinical trials, human subjects, informed consent, institutional animal care and use, institutional review boards, trial design, and whistle blowing.

R A 783. Effective Communication for Life Science Professionals (3)

Prerequisite: Regulatory Affairs 602.

Advanced interpersonal, oral, and written communication strategies for the regulatory affairs business environment. Audience analysis, barriers to communication, and cultural considerations. Communication types to include email communications, executive summaries, informational documentation, persuasive arguments, research-based proposals, and visuals for presentations.

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

Prerequisite: Consent of graduate adviser.

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 graduate adviser.

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

R A 799A. Thesis or Project (3) Cr/NC/RP

Prerequisites: 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.
