
Regulatory Affairs

In the Center for Biopharmaceutical and Biodevice Development
and the College of Sciences

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Faculty Members of the Center for Biopharmaceutical and Biodevice Development

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*Serves on the Faculty Governing Board which makes recommendations on admissions and curriculum.

General Information

The Center for Biopharmaceutical and Biodevice Development offers advanced degree programs that focus on training students in areas related to development, manufacturing, and marketing of biopharmaceutical, pharmaceutical, and medical device products. The center integrates faculty and programs from various departments. The center addresses 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 only through special sessions. Students in the program enroll in courses 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://www.cbbd.sdsu.edu/regaffairs>.

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.

Upon successful completion of the degree program, students will have detailed knowledge and understanding of current regulations with an understanding for their practical application to the development and commercialization of drug, biologic, and medical device products. Included in the core of required courses for the degree are graduate level business administration courses that address communications and management skills that are essential for the successful regulatory affairs professional in an industry work environment.

Master of Science Degree in Regulatory Affairs

(Offered through the College of Extended Studies)

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 director of the center or call the College of Extended Studies.

This degree program provides a comprehensive background in regulatory science with the additional training and experience required of regulatory affairs professionals to address federal and state regulatory statutes and laws with emphasis on the Food and Drug Administration. The degree is offered through the College of Sciences.

The degree offering focuses on laws and regulations imposed by the Federal government, especially the Food and Drug Administration, 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. Also incorporated into the degree program are business administration courses that will provide students with communication and management skills essential for the successful regulatory affairs professional in an industry work environment.

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 center.

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

Center for Bio/Pharmaceutical and Biodevice Development

The following materials should be mailed or delivered to:

Master of Science in Regulatory Affairs
Director of Regulatory Affairs Programs, CBBDD
San Diego State University
5500 Campanile Drive
San Diego, CA 92182-4610

- (1) Three 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) List any employment or volunteer experience relevant to the proposed new degree major program.

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 completed the undergraduate 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 nature of their deficiency and the time allowed to achieve full classified graduate standing. If the student's undergraduate preparation is insufficient, the student will be required to take courses for removal of the deficiency. Courses taken to make up such deficiencies are in addition to the minimum units for the master's degree and may not be included on the student's program of study.

Advancement to Candidacy

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

Specific Requirements for the Master of Science Degree

(Major Code: 49045)

In addition to meeting the requirements for classified graduate standing and the basic requirements for the master's degree as described in Part Two of this bulletin, the student must complete a graduate program consisting of a minimum of 39 units as follows:

1. Complete 24 units of required courses.
 - RA 601 Pharmaceutical, Biotechnology, and Medical Device Industries (3)
 - RA 602 Food and Drug Law (3)
 - RA 705 Project Planning for the Biomedical Industries (3)
 - RA 770 Current Good Manufacturing Practices – General Concepts (3)
 - RA 774 Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices (3)
 - BA 651 Organizational Behavior (3)
 - BA 662 Operations Management (3)
 - IDS 705 Communication Strategies (3)
2. Complete 12 units of electives, at least 9 units of which must be selected from Category A.

CATEGORY A

- RA 696 Advanced Topics in Regulatory Affairs (1-4)
- RA 771 Current Good Manufacturing Practices – Advanced Topics (3)
- RA 772 Post-Approval Activities, Including FDA Advertising, Promotion, and Labeling (3)
- RA 773 Medical Device Regulations (3)
- RA 775 Clinical Trials: Issues in Design, Conduct, and Evaluation (3)
- RA 776 Validation Aspects of Drugs, Biologics, and Device Product Development and Manufacturing, Including Computer Related Systems and Software (3)
- RA 778 Quality Control and Quality Assurance: Pharmaceutical, Biologics, and Medical Devices (3)
- RA 779 International Regulatory Affairs (3)
- RA 780 Good Clinical Practices (2)
- RA 781 Ethics for Healthcare Professionals (3)
- RA 797 Research (1-3) Cr/NC/RP
- RA 798 Special Study (1-3) Cr/NC/RP

CATEGORY B

- MGT 721 Seminar in Group Processes and Leadership (3)
- IDS 744 Seminar in Lean Six Sigma Quality and Productivity Management (3)
- IDS 754 Seminar in Operations Strategy (3)

3. Complete three units. Students must select Plan A or Plan B in consultation with the adviser. Students electing Plan A must complete Regulatory Affairs 799A (3) Cr/NC/RP. Students electing Plan B must select one additional course for three units in lieu of Regulatory Affairs 799A from the list of elective courses and pass a comprehensive examination.

SDSU and California State University, East Bay Track

In addition to meeting the requirements for classified graduate standing and the basic requirements for the master's degree as described in Part Two of this bulletin, the student must complete 37 semester units including the Advanced Certificate in Regulatory Affairs at California State University, East Bay (16 quarter units equivalent to 10 semester units). In addition, the student must also complete a minimum of 27 units as follows:

1. Complete 15 units of required courses.
 - RA 705 Project Planning for the Biomedical Industries (3)
 - RA 774 Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices (3)
 - BA 651 Organizational Behavior (3)
 - BA 662 Operations Management (3)
 - IDS 705 Communication Strategies (3)
2. Complete 12 to 15 units of electives selected from:
 - RA 696 Advanced Topics in Regulatory Affairs (1-4)
 - RA 771 Current Good Manufacturing Practices – Advanced Topics (3)
 - RA 772 Post-Approval Activities, Including FDA Advertising, Promotion, and Labeling (3)
 - RA 773 Medical Device Regulations (3)
 - RA 775 Clinical Trials: Issues in Design, Conduct, and Evaluation (3)
 - RA 776 Validation Aspects of Drugs, Biologics, and Device Product Development and Manufacturing, Including Computer Related Systems and Software (3)
 - RA 778 Quality Control and Quality Assurance: Pharmaceutical, Biologics, and Medical Devices (3)
 - RA 779 International Regulatory Affairs (3)
 - RA 780 Good Clinical Practices (2)
 - RA 781 Ethics for Healthcare Professionals (3)
 - RA 797 Research (1-3) Cr/NC/RP
 - RA 798 Special Study (1-3) Cr/NC/RP
3. Complete three units. Students must select Plan A or Plan B in consultation with the adviser. Students electing Plan A must complete Regulatory Affairs 799A (3) Cr/NC/RP. Students electing Plan B must select one additional course for three units in lieu of Regulatory Affairs 799A from the list of elective courses and pass a comprehensive examination.

Advanced Certificate in Regulatory Affairs

(Offered through the College of Extended Studies)

The Advanced Certificate in Regulatory Affairs involves 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 will examine some of the most significant ethical issues confronting healthcare professionals. To enroll in this certificate program, call 619-594-5152.

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) (Offered only as a distance education course)

Prerequisites: Chemistry 365.

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.

R A 602. Food and Drug Law (3) (Offered only as a distance education course)

Prerequisites: Regulatory Affairs 601.

Laws governing drug, biological, and medical device products. Discussion of Federal Food, Drug, and Cosmetic Act, U.S. Public Health Service Act, Title 21 Code of Federal Regulations, and various amendments.

R A 696. Advanced Topics in Regulatory Affairs (1-4) (Offered only as a distance education course)

Prerequisites: Regulatory Affairs 602.

Selected topics in regulatory affairs. May be repeated with new content. See *Class Schedule* for specific content. Credit for 596 and 696 applicable to a master's degree with approval of the graduate adviser.

R A 705. Project Planning for the Biomedical Industries (3) (Offered only as a distance education course)

Prerequisites: 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 770. Current Good Manufacturing Practices - General Concepts (3) (Offered only as a distance education course)

Prerequisites: 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) (Offered only as a distance education course)

Prerequisites: 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, Including FDA Advertising, Promotion, and Labeling (3) (Offered only as a distance education course)

Prerequisites: 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) (Offered only as a distance education course)

Prerequisites: 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(R)).

R A 774. Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices (3) (Offered only as a distance education course)

Prerequisites: 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.

R A 775. Clinical Trials: Issues in Design, Conduct, and Evaluation (3) (Offered only as a distance education course)

Prerequisites: Regulatory Affairs 602.

Issues and requirements in design, conduct, and evaluation of clinical trials for new drugs, biologics, and medical devices. Introduction to biostatistics.

R A 776. Validation Aspects of Drugs, Biologics, and Device Product Development and Manufacturing, Including Computer Related Systems and Software (3) (Offered only as a distance education course)

Prerequisites: Regulatory Affairs 602.

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

R A 778. Quality Control and Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3) (Offered only as a distance education course)

Prerequisites: 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) (Offered only as a distance education course)

Prerequisites: 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 780. Good Clinical Practices (2) (Offered only as a distance education course)

Prerequisites: Regulatory Affairs 602.

International regulatory requirements for pharmaceutical development regarding clinical research practices. Current issues in GCP; standards for design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. Regulatory standards also evaluated in light of geo-cultural and implications for practice of medicine.

R A 781. Ethics for Healthcare Professionals (3) (Offered only as a distance education course)

Prerequisites: 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) (Offered only as a distance education course)

Prerequisites: Regulatory Affairs 601.

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

Regulatory Affairs

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

Prerequisites: Advancement to candidacy.

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

Prerequisites: 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

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

Prerequisites: 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.