
Regulatory Affairs

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

OFFICE: Physical Sciences 101
TELEPHONE: 619-594-6030 / **FAX:** 619-594-6132
E-MAIL: cbbd@sciences.sdsu.edu
<http://www.cbbd.sdsu.edu/regaffairs>

Faculty Members of the Center for Biopharmaceutical and Biodevice Development

*Larry E. Gundersen, Ph.D., Senior Staff Scientist (equivalent rank of Professor), Director, Regulatory Affairs Program

E. Dale Sevier, Ph.D., Director Workforce Development and Operations, CSUPERB

*Robert Wang, Ph.D., Senior Staff Scientist (equivalent rank of Professor), Director, Corporate Affairs, Associate Director, Center for Biopharmaceutical and Biodevice Development

*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, CBBB
 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 40 units as follows:

1. Complete 25 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)
RA 799A	Thesis or Project (3) Cr/NC/RP
BA 651	Organizational Behavior (2)
BA 662	Operations Management (2)
IDS 705	Communication Strategies (3)
2. Complete 15 units of electives, at least 12 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 Quality and Productivity Management (3) |
| IDS 754 | Seminar in Operations Planning and Strategy (3) |

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 38 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 28 units as follows:

1. Complete 16 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)
RA 799A	Thesis or Project (3) Cr/NC/RP
BA 651	Organizational Behavior (2)
BA 662	Operations Management (2)
IDS 705	Communication Strategies (3)
2. Complete 12 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

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.