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# 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

\*A. Stephen Dahms, Ph.D., Professor of Chemistry and Biochemistry,  
Director, Center for Biopharmaceutical and Biodevice  
Development

\*Larry E. Gundersen, Ph.D., Senior Staff Scientist (equivalent rank of  
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Gretchen N. Vik, Ph.D., Professor of Information and Decision  
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\*Robert Wang, Ph.D., Senior Staff Scientist (equivalent rank of  
Professor), Director, Corporate Affairs, Associate Director, Center  
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tions 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 Bulletin of the Graduate Division. 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:

1. Submit scores on the GRE General Test (verbal and quantitative portions only).
2. Have three letters of recommendation sent from persons who are knowledgeable about the candidate's potential for success in graduate study.
3. Submit an Applicant Essay that describes the applicant's purpose in pursuing graduate studies in regulatory affairs and relationship to personal and career objectives.
4. 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:

- 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)
- Complete 15 units of electives, at least 12 units of which must be chosen 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 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)

## 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 one course selected from Regulatory Affairs 696 entitled "International Regulatory Affairs," 705, 772, 774 for a total of 12 units. 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. 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 Graduate Division 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)

Prerequisite: 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)

Prerequisite: 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)

Prerequisite: Regulatory Affairs 602.

Selected topics in 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 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 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.

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)**

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(R)).

### **R A 774. Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices (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.

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

Prerequisite: 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)**

Prerequisite: 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)**

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 780. Good Clinical Practices (2)**

Prerequisite: 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 797. Research (1-3) Cr/NC/RP**

Prerequisite: 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**

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.

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