
Regulatory Affairs

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In the Center for Bio/Pharmaceutical and Biodevice Development
and the College of Sciences

Faculty Members of the Center for Bio/Pharmaceutical and Biodevice Development

- *A. Stephen Dahms, Ph.D., Professor of Chemistry, Director, Center for Bio/Pharmaceutical and Biodevice Development
- *Larry E. Gundersen, Ph.D., Senior Staff Scientist (equivalent rank of Professor), Director, Regulatory Affairs Program
- *Robert Wang, Ph.D., Senior Staff Scientist (equivalent rank of Professor), Director, Corporate Affairs, Associate Director, Center for Bio/Pharmaceutical and Biodevice Development

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

General Information

The Center for Bio/Pharmaceutical and Biodevice Development offers an interdisciplinary advanced degree program that focuses on training students in areas related to development, manufacturing, and marketing of biotechnological, biopharmaceutical, pharmaceutical, in vitro diagnostic and medical device products. As an administrative, instructional, and research entity, 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.

Master of Science Degree in Regulatory Affairs

(Offered only through the College of Extended Studies)

The coursework in this curriculum is offered only in special sessions that generally are during the semester calendar. 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 will provide 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:

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 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 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 797 Research (1-3) Cr/NC/RP
- RA 798 Special Study (1-3) Cr/NC/RP

CATEGORY B

- MGT 701 Organizational Theory and Design (3)
- MGT 721 Seminar in Group Processes and Leadership (3)
- MGT 741 Seminar in Organization Power and Politics (3)
- IDS 744 Seminar in Quality and Productivity Management (3)
- IDS 754 Seminar in Operations Planning and Strategy (3)

CATEGORY C

Selected courses at California Western School of Law.

Courses Acceptable on Master's Degree Program in Regulatory Affairs (R A)

GRADUATE COURSES

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

Prerequisite: Chemistry 361A or 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. (Formerly numbered Regulatory Affairs 573.)

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. (Formerly numbered Regulatory Affairs 575.)

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.

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.

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.

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.

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.

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)).

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.

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.

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.

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.

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

Prerequisite: Advancement to candidacy.

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

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.

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.

799B. Thesis or Project Extension (0) Cr/NC/RP

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.
