
Biomedical Quality Systems

In the Center for Bio/Pharmaceutical 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/>

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

*A. Stephen Dahms, Ph.D., Professor of Chemistry and Biochemistry, Director, Center for Bio/Pharmaceutical and Biodevice Development

*Larry E. Gundersen, Ph.D., Senior Staff Scientist (equivalent rank of Professor), Director, Regulatory Affairs Program, Center for Bio/Pharmaceutical and Biodevice Development

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

Faculty Members of the California State University Program for Education and Research in Biotechnology

*E. Dale Sevier, Ph.D., Senior Staff Scientist (equivalent rank of Professor), Director, Workforce Development and Operations, California State University Program for Education and Research in Biotechnology

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

General Information

The Center for Biopharmaceutical and Biodevice Development offers an interdisciplinary advanced degree program that focuses on training students in areas related to development, manufacturing, production, processing, and marketing of biotechnological, biopharmaceutical, pharmaceutical, in vitro diagnostic, 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.

Master of Science Degree in Biomedical Quality Systems

(Offered through the College of Extended Studies)

The coursework in this curriculum is offered only in special sessions. Students enroll through the College of Extended Studies and are subject to a fee structure that is different from that for regularly matriculated students. For more information, contact the director of the program or call the College of Extended Studies.

This degree program provides a comprehensive background in quality systems principles and practices for the development, testing, and manufacture of pharmaceutical, biopharmaceutical, and medical device products with the additional training necessary for compliance with regulatory requirements. The degree is offered through the College of Sciences.

The degree offering focuses on principles of quality control and quality assurance that support compliance with the 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. The degree program will provide students with detailed knowledge and understanding of current practices and 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 courses that provide students with communication and management skills essential for the successful quality assurance and quality control 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 quality assurance and quality control and relationship to personal and career objectives.
4. List any employment or volunteer experience relevant to the degree program.
5. Candidates for admission will typically come from one of the disciplines offered in the life and physical sciences and engineering.

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: 09994)

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.

BQS 601	Quality Systems and Management (2)
BQS 602	Quality Systems Impact on Biomedical Industry (1)
BQS 621	Quality Audits: Internal, Vendors, and Contract Services (3)
BQS 730	Good Manufacturing, Laboratory, and Clinical Practices (3)
BQS 745	Quality Assurance Documentation (3)
BQS 799A	Thesis or Project (3) Cr/NC/RP
BQS 799B	Thesis or Project Extension (0) Cr/NC
RA 778	Quality Control and Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3)

BA 651	Organizational Behavior (2)
BA 662	Operations Management (2)
IDS 705	Communication Strategies (3)

2. Complete 15 units of electives.

Category A Elective Courses

BQS 620	Quality Control Methods Development (3)
BQS 696	Advanced Topics in Biomedical Quality Systems (1-4)
BQS 740	Statistical Process Control (3)
BQS 741	Statistical Experiment Design (3)
BQS 746	Quality Control Laboratory Validation (3)
BQS 797	Research (1-3) Cr/NC/RP
BQS 798	Special Study (1-3) Cr/NC/RP
RA 601	Pharmaceutical, Biotechnology, and Medical Device Industries (3)
RA 780	Good Clinical Practices (2)

No more than nine elective units from Category B may be applied towards the proposed degree.

Category B Elective Courses

RA 770	Current Good Manufacturing Practices – General Concepts (3)
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 774	Investigational and Marketing Applications for Drugs, Biologics, and Medical Devices (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)

Courses Acceptable on Master's Degree Program in Biomedical Quality Systems (BQS)

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

BQS 601. Quality Systems and Management (2)

Origins, history of quality, major concepts, theories, principles, founders. Quality planning, assurance, improvement. Roles and responsibilities of quality assurance and quality control.

BQS 602. Quality Systems Impact on Biomedical Industry (1)

Global view of biomedical and safe medical devices act. Quality assurance and quality control integration into research and development. Role of quality in good manufacturing practices (GMP), good clinical practices (GCP), and good laboratory practices (GLP), and good documentation practices (GDP).

BQS 620. Quality Control Methods Development (3)

Prerequisite: Biomedical Quality Systems 601.

Strategies and approaches for development of quality control methods for characterizing drugs and biologics. Development of high pressure liquid chromatography (HPLC) methods.

BQS 621. Quality Audits: Internal, Vendors, and Contract Services (3)

Prerequisite: Biomedical Quality Systems 601.

Audit topics explored from viewpoint of industry professional, current industry, and regulatory information.

BQS 696. Advanced Topics in Biomedical Quality Systems (1-4)

Prerequisite: Consent of instructor.

Current issues and topics in quality systems evaluated and discussed. Recent developments and changes in selected areas of quality systems presented by faculty and industry professionals. May be repeated with new content. See *Class Schedule* for specific content. Maximum credit six units applicable to a master's degree.

BQS 730. Good Manufacturing, Laboratory, and Clinical Practices (3)

Prerequisite: Biomedical Quality Systems 601.

Roles and responsibilities of a Quality Assurance (QA) function in the biopharmaceutical, medical device, and pharmaceutical industries. Equip middle and upper level biomedical professionals with "real world" skills, approaches, and solutions to multifaceted quality issues.

BQS 740. Statistical Process Control (3)

Prerequisites: Biomedical Quality Systems 601 and basic statistics.

Statistical methods for quality control and improvement, focusing on control charts, measurement systems analysis, process improvement, and process capability assessment.

BQS 741. Statistical Experiment Design (3)

Prerequisite: Biomedical Quality Systems 601.

Effective experimental strategy, factorial and fractional factorial designs, experiments with random factors, nested effects, categorical factors, and split plots. Use of computer software for design construction and analysis.

BQS 745. Quality Assurance Documentation (3)

Prerequisite: Biomedical Quality Systems 601.

Regulatory requirements for developing and manufacturing documentation, supporting the quality assurance function.

BQS 746. Quality Control Laboratory Validation (3)

Prerequisite: Biomedical Quality Systems 601.

Roles and responsibilities of a typical validation department function in the biopharmaceutical, medical device, and pharmaceutical industries. Equip the middle and upper level biomedical professionals with "real world" skills, approaches, and solutions to multifaceted validation issues.

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

Prerequisite: Advancement to candidacy.

Research in the area of quality systems. Maximum credit six units applicable to a master's degree.

BQS 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.

BQS 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.

BQS 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.