

Biomedical Quality Systems

ADMINISTERED BY REGULATORY AFFAIRS
IN THE COLLEGE OF SCIENCES

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General Information

The Advanced Certificate in Biomedical Quality Systems provides foundational knowledge covering quality systems principles and practices for the development, testing, and manufacture of pharmaceutical, biopharmaceutical, and medical device products with additional training necessary for compliance with regulatory requirements. This certificate 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, and international counterparts related to drug discovery, development, testing, and manufacture of products for commercial distribution. The certificate is offered in partnership with the College of Sciences and the College of Extended Studies.

Advanced Certificate in Biomedical Quality Systems

(Offered through the College of Extended Studies)

(SIMS Code: 771492)

Students in the Advanced Certificate in Biomedical Quality Systems are presented with an international view of the biomedical industry and Safe Medical Devices Act from a quality perspective. Roles and responsibilities of a typical quality assurance (QA) department are reviewed for biopharmaceutical, medical device, and pharmaceutical industries. Also covered are practical skills, approaches, and solutions related to auditing, change control, compliance, documentation, laboratory, material, and production control issues. Students build a foundational and practical knowledge in quality systems and biomedical regulations related to major elements and principles of international regulations governing control of data, documents, information, and records associated with biomedical products.

The certificate requires 12 units to include Biomedical Quality Systems 601, 603, 730, and 745. Certificate courses may be applied to the Master of Science degree in regulatory affairs as elective courses.

For more information, go to <http://regsci.sdsu.edu> or call 619-594-6030.

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 department. Students applying for admission should electronically submit the university application available at <http://www.calstate.edu/apply> 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
5500 Campanile Drive
San Diego, CA 92182-7416

1. Official transcripts (in sealed envelopes) from all postsecondary institutions attended;
2. Students who attended SDSU need only submit transcripts for work completed since last attendance;
3. 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.

Regulatory Affairs

The following materials should be mailed or delivered to:

Biomedical Quality Systems Certificate

Director of Regulatory Affairs Programs
San Diego State University
5500 Campanile Drive
San Diego, CA 92182-1010

1. Resume or curriculum vita listing employment or volunteer experience relevant to the proposed new degree major program;
2. One set of official transcripts (in addition to those sent to Graduate Admissions).

Courses Required for the Biomedical Quality Systems Certificate (BQS)

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

BQS 601. Biomedical Quality Systems (3)

Global view of biomedical industry and Safe Medical Devices Act from quality perspective to provide foundation in field of biomedical quality systems.

BQS 603. Foundational Quality Systems (3)

Prerequisite: Biomedical Quality Systems 601.

Roles and responsibilities of a typical quality assurance (QA) department in biopharmaceutical, medical device, and pharmaceutical industries. Practical skills, approaches, and solutions to multifaceted auditing, change control, compliance, documentation, laboratory, material, and production control issues.

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. Credit for 596 and 696 applicable to a master's degree with approval of the graduate adviser.

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 745. Document Control Quality System (3)

Prerequisite: Biomedical Quality Systems 601.

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