Biomedical Quality Systems

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

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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, 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)

No new students are being admitted to the Master of Science program. For further information, contact Dr. Catherine J. Atkins, Graduate Adviser and Associate Dean in the College of Sciences. Applications are being accepted for the Advanced Certificate in Biomedical Quality Systems.

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 Graduate Bulletin.

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 Biomedical Quality Systems.

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) English language 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 Biomedical Quality Systems
Director of Biomedical Quality Systems Programs, CBBD
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 quality assurance and quality control and relationship to personal and career objectives.

(3) List of any employment or volunteer experience relevant to the degree program.

(4) 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 Four of this bulletin.
Specific Requirements for the Master of Science Degree
(Major Code: 09994) (SIMS Code: 771491)

In addition to meeting the requirements for classified graduate standing and the basic requirements for the master's degree as described in Part Four of this bulletin, the student must complete a graduate program consisting of a minimum of 39 units as follows:

1. Complete 24 units of required courses.
   - BQS 601 Biomedical Quality Systems (3)
   - BQS 621 Quality Audits: Internal, Vendors, and Contract Services (3)
   - BQS 730 Good Manufacturing, Laboratory, and Clinical Practices (3)
   - BQS 745 Document Control Quality System (3)
   - R A 778 Quality Control and Quality Assurance: Pharmaceuticals, Biologics, and Medical Devices (3)
   - B A 651 Organizational Behavior (3)
   - B A 662 Operations and Supply Chain Management (3)
   - MIS 705 Communication Strategies (3)

2. Complete 15 units of electives from list of elective courses and Biomedical Quality Systems 799A for students in Plan A. Students in Plan B must complete a comprehensive examination.

   Elective Courses
   - BQS 696 Advanced Topics in Biomedical Quality Systems (1-4)
   - BQS 740 Statistical Process Control (3)
   - BQS 797 Research (1-3) Cr/NC/RP
   - BQS 798 Special Study (1-3) Cr/NC/RP
   - R A 601 Pharmaceutical, Biotechnology, and Medical Device Industries (3)
   - R A 770 Current Good Manufacturing Practices – General Concepts (3)
   - R A 771 Current Good Manufacturing Practices – Advanced Topics (3)
   - R A 773 Medical Device Regulations (3)
   - R A 774 Investigational and Marketing Applications for Drugs and Biologics (3)
   - R A 775 Clinical Trials: Issues in Design, Conduct, and Evaluation (3)
   - R A 776 Validation Aspects of Drugs, Biologics, and Device Product Development and Manufacturing, Including Computer Related Systems and Software (3)

Advanced Certificate in Biomedical Quality Systems
(Offered through the College of Extended Studies)

The Advanced Certificate in Biomedical Quality Systems includes the completion of Biomedical Quality Systems 601, 603, 730, and 745. Biomedical Quality Systems 601 covers the philosophies, organization, and active role of the international regulatory agencies. Biomedical Quality Systems 603 is designed to present the major elements and principles of the international quality systems used in the development and commercialization of biomedical products. Biomedical Quality Systems 730, students learn the major elements and principles of the international regulations governing the development and commercialization of biomedical products. Biomedical Quality Systems 745 will ensure that 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. Courses in the Advanced Certificate in Biomedical Quality Systems may be applied to the Master of Science degree in Regulatory Affairs as electives.

The program adviser is Dr. Catherine J. Atkins, Graduate Adviser and Associate Dean in the College of Sciences. For more information see http://www.cbbd.sdsu.edu/. To enroll in this certificate program, call 619-594-6030.

Courses Acceptable on Master's Degree Program in Biomedical Quality Systems (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)
   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 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. 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 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 745. Document Control Quality System (3)
   Prerequisite: Biomedical Quality Systems 601. Regulatory requirements for developing and manufacturing documentation, supporting the quality assurance function.

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
   Prerequisites: 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/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.