



## Medical Device Recycling & Reprocessing Certificate Program

### Course Descriptions

#### BIOE 8110 – STERILIZATION AND CLEANING ENGINEERING

Summer minimester A

**DESCRIPTION:** This course provides a detailed overview of sterilization, cleaning, and packaging requirements for reprocessing medical devices. Emphasis will be on the application of testing and evaluation methods for materials analysis, biocompatibility, and sterilization/cleaning methods in the manufacturing and healthcare sectors. Specification generation in compliance with industry standards and government regulations will be addressed, including packaging development processes, materials and container types, and equipment design and process development for sterilization and cleaning.

##### COURSE LEARNING OBJECTIVES:

- To recognize the role of various cleaning and sterilization methods used in medical device reprocessing
- To apply fundamental concepts of biology & biochemistry to problems related to medical device sterilization & cleaning
- To analyze packaging requirements for medical devices as related to sterilization and cleaning demands
- To design a process of cleaning, sterilization, packaging, and reprocessing for a representative medical device

#### BIOE 8130 – INDUSTRIAL ENGINEERING

Spring

**DESCRIPTION:** Industrial Bioengineering exposes students to additional aspects of the field necessary for success in a biomedical career “beyond the bench.” This will move students towards a broad-based understanding of industry-related functions beyond typical academic and research related positions. The goal of this course is to begin building a knowledge base to allow a graduate to quickly adapt to an industrial career in medical device research and development and understand the additional roles and interplay between quality, sales, and “design for a purpose” methodology.

##### COURSE LEARNING OBJECTIVES:

- To acquire and practice skills associated with various aspects of industrial bioengineering
- To understand best practices for quality systems related to the biomedical device industry including regulatory activities, and the impact of marketing and sales
- To develop a product cycle for biomedical applications

#### BIOE 8140 – MEDICAL DEVICE COMMERCIALIZATION

Fall

**DESCRIPTION:** This course provides an overview of design control and regulations for medical device reprocessing and their practical application in the scope of project management and commercialization. Introduction to a cross disciplinary approach for launching and marketing a new device, including device lifecycle management and intellectual property laws relative to the medical device reprocessing industry.

##### COURSE LEARNING OBJECTIVES:

- To recognize the role of design controls and regulations in medical device reprocessing
- To apply fundamental commercialization principles to problems in medical device reprocessing & sustainability
- To analyze lifecycle management as related to medical device manufacturing and reprocessing
- To design a commercialization plan for a reusable medical device

**BIOE 8150 – DESIGN, MANUFACTURING AND VALIDATION METHODS  
FOR REUSABLE MEDICAL DEVICES**

**Spring**

**DESCRIPTION:** This course provides a detailed overview of design theories, regulations, methods and best practices governing the medical device reprocessing industry. Covered topics include materials, fabrication processes and manufacturing techniques with an emphasis on remanufacturing, reprocessing and sustainability. Knowledge and skills needed to comply with the process verification and validation requirements for Quality System Regulations are discussed, as well as information on how to implement an effective validation program with emphasis on a reprocessing approach.

**COURSE LEARNING OBJECTIVES:**

- To recognize the impact of materials selection on manufacturing and medical device reprocessing
- To apply fundamental engineering design principles to problems related to medical device design for reprocessing
- To analyze manufacturing processes used in medical device reprocessing as related to testing, verification and validation processes
- To design an example manufacturing process for a reusable medical device

**BIOE 8900 – INDUSTRY PRACTICUM**

**By Arrangement**

**DESCRIPTION:** Observation and assignment in a medical college, dental college, hospital, veterinary clinic, dental clinic, health service, or industrial department.

**OBJECTIVES:** The major goal of this course is to offer a unique didactic experience where students will learn on-site the clinical and/or industrial requirements for effective medical device development and to appreciate medical device technology from concept to market. It aims to encourage engineering students to participate in hands-on experiences that will substantially enhance their training and education related to optimizing medical device designs for recycling, reprocessing and reuse and promoting sustainability in healthcare.

**PRACTICUM SITE:** Clinical, research, and industrial sites are eligible for the program. Applicants are responsible for contacting the preceptor(s) at the practicum site. Expenses incurred for internship are the responsibility of the enrolled student. A total of 135 hours of contact are required.