BIOMEDICAL SCIENCES AND TECHNOLOGIES (BIOMDSCI)

BIOMDSCI 720 – SURVEY OF QUALITY ASSURANCE AND REGULATORY AFFAIRS IN BIOTECHNOLOGY
3 credits.

Success in the biotechnology industry is based on learning the language and understanding the development process utilized in bringing products to market. Focus on techniques used in the biotechnology industry to comply with the quality and regulatory requirements set forth by professional and governmental agencies in the effort to develop, manufacture, and commercialize products safely for the public.
Requisites: Declared in the Capstone Certificate in Quality Assurance and Regulatory Affairs in Biotechnology
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Recognize, foster, and apply principles of ethical and professional conduct.
Audience: Graduate

2. Describe local, national, and international agencies involved in ensuring quality and safety.
Audience: Graduate

3. Integrate how testing and manufacturing relies upon regulatory requirements.
Audience: Graduate

4. Demonstrate effective listening, written, verbal, and nonverbal communication skills.
Audience: Graduate

5. Analyze product development and project management innovations in terms of quality assurance and regulatory compliance requirements.
Audience: Graduate

BIOMDSCI 721 – TOPICS IN QUALITY ASSURANCE AND REGULATORY AFFAIRS IN BIOTECHNOLOGY
3 credits.

Quality Assurance and Regulatory Affairs departments influence and facilitate successful product development within the biotechnology industry. Use a case study approach to explore and apply how quality assurance and regulatory compliance systems are used to bring medical devices to market. Practice how cross functional teams work together to meet regulatory standards of safety.
Requisites: Declared in the Capstone Certificate in Quality Assurance and Regulatory Affairs in Biotechnology
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Evaluate quality systems used in product development and commercialization of medical devices.
Audience: Graduate

2. Influence medical device development and project vision from quality assurance and regulatory affairs standpoints.
Audience: Graduate

3. Produce quality and regulatory strategies to achieve organizational objectives of medical devices.
Audience: Graduate

4. Compose effective communication with colleagues, customers, and regulatory agencies.
Audience: Graduate

5. Troubleshoot design and manufacturing issues of medical device development to meet regulatory standards.
Audience: Graduate

6. Monitor how diverse teams fit into organizational culture and successfully contribute towards product development.
Audience: Graduate

BIOMDSCI 722 – LEADERSHIP IN QUALITY ASSURANCE AND REGULATORY AFFAIRS IN BIOTECHNOLOGY
3 credits.

Leaders in the Quality Assurance and Regulatory Affairs departments influence and facilitate bringing products to market within the biotechnology industry. Focus on building communication among cross functional teams; exercising writing to specific audiences; and meeting internal and external customer needs and expectations. Explore and apply how quality and regulatory affairs skills are managed within diverse product and project teams.
Requisites: Declared in the Capstone Certificate in Quality Assurance and Regulatory Affairs in Biotechnology
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Influence product and project vision from quality assurance and regulatory affairs standpoints.
Audience: Graduate

2. Develop strategies to achieve organizational objectives.
Audience: Graduate

3. Communicate effectively with colleagues, customers, and regulatory bodies.
Audience: Graduate

4. Illustrate leadership principles and use ethical behavior in challenging and ambiguous situations.
Audience: Graduate

5. Practice how diverse teams fit into organizational culture and successfully contribute from product development through submission, product launch, and post-market surveillance.
Audience: Graduate