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
Last Taught: Fall 2025
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
Last Taught: Spring 2026
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

BIOMDSCI 800 – INTELLECTUAL PROPERTY, PATENTS AND LICENSING
2 credits.

Explore core concepts of how intellectual property, patent law, trademarks, copyrights, trade secrets, licensing and patent litigation specifically relate to the field of biotechnology. Evaluate how types of intellectual property work to protect a product or service. Explain the importance of patents in terms of licensing and technology transfer. Assess the unique aspects of early-stage intellectual property, including how it pertains to market dynamics, pricing and valuation.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Fall 2025
Learning Outcomes: 1. Distinguish the principal types of intellectual property and how to protect a service or product.
Audience: Graduate

2. Assess technology transfer opportunities and its importance to the field of biotechnology.
Audience: Graduate

3. Evaluate market dynamics, pricing, and valuation of early-stage intellectual property.
Audience: Graduate

4. Deliver a technology assessment plan based on legal issues.
Audience: Graduate

BIOMDSCI 801 – BIOTECHNOLOGY REGULATION AND ETHICS
2 credits.

Explore political, legal, and ethical issues and paradigms that drive product development within the biotechnology industry with special emphasis given to how new drugs, devices, and biologics are regulated by local, national, and global agencies. Describe the regulations and ethics of human subjects' research. Develop skills to support how regulation and politics interact with business and finance to influence the formation and growth of biotechnology companies. Discuss how ethics and regulatory policy influence how biotechnology products come to market.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Fall 2025
Learning Outcomes: 1. Examine the structure of the US legal and regulatory system.
Audience: Graduate

2. Explore ethical concerns regarding research on biotechnology and applications of biotechnology.
Audience: Graduate

3. Investigate content of key laws and regulations governing biotechnology research and its medical applications.
Audience: Graduate

4. Deliver an ethical argument that justifies a regulatory position.
Audience: Graduate

BIOMDSCI 802 – BUSINESS OF BIOTECHNOLOGY: BUSINESS FUNDAMENTALS
2 credits.

Discover the business challenges inherent in translating scientific discoveries into a successful business. Apply fundamental business principles that guide the operations of biotechnology companies.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Fall 2025
Learning Outcomes: 1. Compare scientific and commercial success strategies.
Audience: Graduate

2. Evaluate how new product selection and development delivers a positive return on investment.
Audience: Graduate

3. Practice using financial tools to evaluate investments and monitor the financial progress of a company.
Audience: Graduate

4. Deliver a technology assessment plan utilizing business strategies.
Audience: Graduate

BIOMDSCI 803 – MOLECULAR TECHNOLOGIES I: DIAGNOSTIC TESTING
2 credits.

Assess various biotechnology techniques to determine effective and efficient methods used in biotechnology product development. Utilize analytical and communication skills when critiquing biotechnology applications that simulate both corporate and academic biotechnology settings.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Fall 2025
Learning Outcomes: 1. Build effective communication skills and science theory and practice by developing a laboratory notebook and scientific presentations.
Audience: Graduate

2. Perform and evaluate molecular based technologies for genetic mutation detection.
Audience: Graduate

3. Identify the vocabulary of biotechnology and the science that underlies it through hands-on laboratory experience.
Audience: Graduate

4. Critically assess research studies and laboratory results for technology recommendations.
Audience: Graduate

BIOMDSCI 810 – BIOTECHNOLOGY OPERATIONS
4 credits.

Explore the six operational specialties of product development: Regulatory; Quality Assurance; Biomanufacturing; Quality Control; Nonclinical Development; and Clinical Development. Expand upon leadership skills by implementing biotechnology operation plans that successfully bring new products to market.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Spring 2026
Learning Outcomes: 1. Examine key disciplines and principles required to successfully develop a variety of biotechnology products for targeted markets.
Audience: Graduate

2. Select the regulatory environments required for biotechnology product development.
Audience: Graduate

3. Design a biotechnology product development strategy, to clearly communicate objectives, and to provide leadership throughout implementation.
Audience: Graduate

4. Appraise the interplay between quality and efficacy in biotechnology product development relative to patient, regulatory, and business risk.
Audience: Graduate

5. Collaborate effectively to develop concise and accurate presentations and papers on key regulatory topics critical for biotechnology product development.
Audience: Graduate

BIOMDSCI 812 – PROJECT MANAGEMENT AND LEADERSHIP
2 credits.

Practice developing, modifying, and maintaining project management plans within the biotechnology and medical device industries. Hone leadership skills and experience by working among diverse teams and addressing situations faced by Project Managers.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Spring 2026
Learning Outcomes: 1. Distinguish the components of technical project management, and the social and leadership skills that are needed to lead a team in the global biopharmaceutical or medical device industries.
Audience: Graduate

2. Apply effective leadership skills to work within diverse groups of professionals and communities as they address and solve problems, make critical decisions, and measure and mitigate risk.
Audience: Graduate

3. Design, use, and defend a project management plan using common project management methods.
Audience: Graduate

4. Discuss social forces that impact a team.
Audience: Graduate

BIOMDSCI 813 – MOLECULAR TECHNOLOGIES II: BIOMANUFACTURING
2 credits.

Develop, create, and present scientific poster presentation. Utilize and assess multiple technology platforms used in biomanufacturing. Develop and critique batch records used in biomanufacturing and bio-engineering environments.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Last Taught: Spring 2026
Learning Outcomes: 1. Determine the importance of nucleic acid and protein analysis applications in biotechnology research and manufacturing.

Audience: Graduate

2. Perform and compare biomanufacturing strategies required to purify target biomolecules critical in biotechnology.
Audience: Graduate

3. Evaluate current technologies in agricultural biotechnology and protein engineering.
Audience: Graduate

4. Compose effective scientific poster presentations, biomanufacturing batch records, and genetic identity analysis reports.
Audience: Graduate

BIOMDSCI 820 – EARLY DRUG DISCOVERY
4 credits.

Examine the early drug discovery process, including target identification and validation, generation of diverse chemical libraries, assay development and high throughput screening, lead optimization by compound profiling, and drug targeting and delivery.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Assess the early drug discovery process and key steps, from target identification to nonclinical trials.
Audience: Graduate

2. Determine the scientific mechanism of one or more disease processes and assess how modulation of that target could treat or prevent a disease.
Audience: Graduate

3. Compare current and emerging methods for generating compound diversity in chemical libraries, natural products, and antibodies, including molecular modeling and structure-based drug design.
Audience: Graduate

4. Evaluate a technology used in drug discovery, understand the unmet need it addresses, and summarize the key information in a clear and concise way, both verbally and in a written format.
Audience: Graduate

BIOMDSCI 822 – BUSINESS OF BIOTECHNOLOGY: COMMERCIALIZATION PATHWAYS
2 credits.

Explore contemporary issues in the business of biotechnology and apply concepts critical to the success of modern biotechnology firms. Focus on modern problem-solving topics, including issues relating to corporate leadership, fundings sources for product development, customer identification, financial accounting management, and negotiation.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Justify risks and challenges associated with commercialization of early-stage research and innovation.
Audience: Graduate

2. Analyze the elements that make up a viable business opportunity.
Audience: Graduate

3. Evaluate strengths and limitations of various business models.
Audience: Graduate

4. Develop an argument to influence product buy in and support.
Audience: Graduate

BIOMDSCI 823 – MOLECULAR TECHNOLOGIES III: ASSAY DEVELOPMENT
2 credits.

Evaluate laboratory assays and methods used in primary, secondary, and in vitro ADMETox (Absorption, Distribution, Metabolism, Excretion, Toxicity) drug screening. Build scientific communication and critical thinking skills while working on team projects and analyzing scientific results.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Employ effective scientific communication methods demonstrating knowledge and skills when: writing scientific papers, preparing detailed scientific protocols, critiquing scientific journal articles in drug discovery, and developing and presenting detailed scientific presentations.
Audience: Graduate

2. Determine how protein kinase and cytochrome P450 enzyme assay technologies are used in the drug discovery process.
Audience: Graduate

3. Perform and evaluate multiple assay formats (luminescent, fluorescent, colorimetric) including, but not limited to: Cytochrome P450 enzymes, kinase assay technologies, cell culture techniques, and genome editing and CRISPR/Cas-9.
Audience: Graduate

4. Compare and contrast the roles that fluorescent microscopy, high content screening, and in vivo imaging play in the drug discovery process and biotechnology.
Audience: Graduate

5. Analyze and interpret scientific data and quality control measures as they relate to biotechnology and drug discovery, facilitating critical thinking.
Audience: Graduate

BIOMDSCI 830 – PROFESSIONAL DEVELOPMENT AND EFFECTIVE MANAGEMENT
1 credit.

Focus on effective management and career development techniques that lead to career success. Practice and apply skills needed to effectively lead synergistic team success within a biotechnology company. Explore different communication styles used to engage and assess employees. Expand career pathways through networking and by generating professional resumes and interviewing skills.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Evaluate team culture in terms of what really matters to set goals, enable results, and provide psychological safety.
Audience: Graduate

2. Create situational, behavioral, and impact driven feedback strategies so that both the employee and manager are successful.
Audience: Graduate

3. Prepare a career development plan that includes effective resumes, cover letters, networking, and employment research skills.
Audience: Graduate

4. Analyze skills required to influence, prioritize, and set goals in a biotechnology company.
Audience: Graduate

BIOMDSCI 831 – ADVANCED BIOTECHNOLOGY: GLOBAL PERSPECTIVES
3 credits.

Investigate state-of-the-art topics of global importance to biotechnology. Integrated skills and knowledge to achieve synergistic levels of understanding the importance of biotechnology today. Formulate the scientific, ethical, and regulatory standards used in the development of novel technologies around the globe. Increase awareness for intellectual collaboration and entrepreneurship opportunities.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Identify, research, and create a final research project with both faculty and peer input, from numerous perspectives (science, business, law, regulatory, ethical, and political).
Audience: Graduate

2. Evaluate an assigned special topic in global biotechnology, including stem cell applications, healthcare innovations, biomanufacturing issues, metagenomic and microbiome analysis, or agricultural biotechnology.
Audience: Graduate

3. Develop effective written and oral communication through a variety of formats to a variety of audiences.
Audience: Graduate

4. Build effective strategies for researching and critically assessing different biotechnologies.
Audience: Graduate

BIOMDSCI 832 – BUSINESS OF BIOTECHNOLOGY: CORPORATE STRATEGY
3 credits.

Examine how companies gain and sustain competitive advantages by utilizing business tools, methods, and strategies. Critique how company leaders make decisions under uncertainty. Integrate the knowledge and skills gained from prior studies (e.g., marketing, management, finance, accounting) to apply synergistic responses and insights when developing company-wide strategy.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Analyze industry forces and environmental trends to distinguish industry potential and competitive advantage.
Audience: Graduate

2. Relate how companies add value across diverse lines of business through knowledge of Research and Development strategic management.
Audience: Graduate

3. Evaluate how negotiation and management skills guide strategic change efforts.
Audience: Graduate

4. Deliver business strategies to support company growth.
Audience: Graduate

BIOMDSCI 834 – BIOTECHNOLOGY CAPSTONE
1 credit.

Identify a global biotechnology problem, find a novel technical solution, analyze all aspects from a business, regulatory, and intellectual property perspective, and deliver a final written capstone thesis.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: No
Learning Outcomes: 1. Identify an important global biotechnology-based problem and formulate a novel biotechnology-based solution to address it.

Audience: Graduate

2. Analyze the economic logic of the global biotechnology problem and solution. Consider customers, market, pricing, and competitors.
Audience: Graduate

3. Compose insightful business and technical questions to research including identifying effective resources and subject matter experts.
Audience: Graduate

4. Identify a company to implement your proposed solution to augment the company's current portfolio.
Audience: Graduate

5. Justify key regulatory, intellectual property, manufacturing, social, and/or political issues that could impact the success of the solution.
Audience: Graduate

6. Critique both technical and business considerations in a clear, concise, and logical manner to make credible technical and business solutions and recommendations.
Audience: Graduate

BIOMDSCI 890 – BIOTECHNOLOGY INDEPENDENT STUDY
1-3 credits.

Learning experience to further develop skills and apply them in an independent and/or research project with a faculty advisor.
Requisites: Declared in Biotechnology MS
Course Designation: Grad 50% - Counts toward 50% graduate coursework requirement
Repeatable for Credit: Yes, for 2 number of completions
Learning Outcomes: 1. Apply concepts learned in coursework to real life professional experiences (academic or industry).
Audience: Graduate

2. Develop critical, analytical, and independent thinking skills using scientific, business, legal, and/or regulatory knowledge.
Audience: Graduate

3. Evaluate scientific, business, legal, and/or regulatory practices as an active team member.
Audience: Graduate