

# APPLIED BIOTECHNOLOGY (ABT)

## ABT 700 – PRINCIPLES OF BIOTECHNOLOGY

3 credits.

Principles and techniques pertaining to biotechnology and its applications to our society. Survey of classical and emerging techniques.

**Requisites:** Declared in Applied Biotechnology program

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Appraise the applications of biotechnology to various industrial settings. Audience: Graduate

2. Demonstrate general understanding on the key concepts and assess the technologies that impact current biotechnology developments. Audience: Graduate

3. Demonstrate understanding pertaining to genes, genomes and their organizations, gene expression, genetic variation and genetic engineering. Audience: Graduate

4. Compare various biotechnologies approaches and recommend appropriate strategies for problem solving. Audience: Graduate

5. Critique biotechnology-related journal articles and appraise the broader impacts of such studies. Audience: Graduate

6. Demonstrate the ability to synthesize ideas to solve given problems and write scientific reports in the area of biotechnology. Audience: Graduate

## ABT 705 – ETHICS, SAFETY, AND REGULATORY ENVIRONMENTS IN BIOTECHNOLOGY

3 credits.

Ethical and safety concerns in development, production, funding, and application of biotechnology. Analysis of socioeconomic impacts. Understanding the importance of data integrity. Overview of risk assessment and management in a regulatory environment designed to ensure safety of workers, study subjects, and patients, and protect intellectual property, data, and the environment.

**Requisites:** Declared in Applied Biotechnology program

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Critically assess workplace and research situations that may lead to ethical conflicts of interest and demonstrate appropriate responses. Audience: Graduate

2. Identify regulatory agencies and recommendation bodies that inform and/or enforce areas of ethical oversight in both the US and abroad. Audience: Graduate

3. Obtain and interpret primary documentation from regulatory bodies. Audience: Graduate

4. Analyze and assess the costs and benefits of different regulatory frameworks. Audience: Graduate

5. Communicate regulatory information to others in a professional capacity. Audience: Graduate

**ABT 710 – PROFESSIONAL AND TECHNICAL COMMUNICATION IN BIOTECHNOLOGY**

3 credits.

Application and analysis of professional scientific communication, both written and oral. Focuses on designing documents that convey complex, data-rich technical and scientific content to audiences with diverse information needs using a variety of professional genres, including reports, proposals, presentations, and documentation.

**Requisites:** Declared in Applied Biotechnology program

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Communicate technical and scientific information in biotechnology contexts Audience: Graduate

2. Evaluate and select the most appropriate communication strategies (modalities, methods, tools, and practices) to convey complex ideas effectively to diverse audiences Audience: Graduate

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

4. Design and deliver effective professional presentations Audience: Graduate

5. Analyze and integrate scientific literature into a variety of professional genres Audience: Graduate

**ABT 715 – TECHNIQUES IN BIOTECHNOLOGY**

3 credits.

Application of biological and chemical methods to modern biotechnological product development. Overview of analysis techniques used to characterize products and evaluate quality and safety. Exploration of technological pipeline from conception to market, including proof-of-concept assessment, pre-clinical trials, clinical trials, and post-production testing.

**Requisites:** ABT 700

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Outline proper experimental design, experimental controls, and quality controls for proper quantitative experimental design Audience: Graduate

2. Identify and interpret basic statistical methods and their outcomes in experimental data Audience: Graduate

3. Summarize the phases of product development, testing, and commercialization Audience: Graduate

4. Compare classical and emerging technologies for the identification and characterization of biotechnological products Audience: Graduate

5. Analyze product safety and efficacy Audience: Graduate

6. Employ knowledge of biotechnological safety and efficacy requirements to assess the commercialization potential of a product Audience: Graduate

7. Critique existing product development processes using technological information on the safety and efficacy of the product Audience: Graduate

8. Interpret data from product testing to assess viability of product for commercialization Audience: Graduate

9. Apply appropriate technologies to analyze biotechnological products Audience: Graduate

**ABT 720 – EXPERIMENTAL DESIGN AND ANALYSIS IN BIOTECHNOLOGY**

3 credits.

Principles of descriptive and inferential statistics with applications in biotechnology including experimental design, quantitative data analysis, and bioinformatic evaluation of complex molecular and biological data sets.

**Requisites:** Declared in MS Applied Biotechnology or Capstone Certificate in Applied Bioinformatics

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Apply statistical methods that are commonly used in experimental design in biotechnology research Audience: Graduate

2. Explain the rationale behind statistical procedures as it relates to experimental design Audience: Graduate

3. Select an appropriate statistical method and design experiments for a given experimental question Audience: Graduate

4. Implement statistical procedures using software, especially R and RStudio Audience: Graduate

5. Implement bioinformatic methods using a set of software tools Audience: Graduate

6. Communicate statistical findings in biotech research to stakeholders Audience: Graduate

**ABT 725 – LEADERSHIP IN ORGANIZATIONS**

3 credits.

Focuses on strategies and tools that managers use to maximize employee contribution and create organizational excellence. Basic business and leadership principles. Best practices to overcome biases that inhibit organizations and teams from communicating effectively. Examples will come from diverse biotechnology fields, including pharmaceuticals, agriculture, and biotechnology services.

**Requisites:** Declared in Applied Biotechnology program

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Evaluate technical, human and cultural factors contributing to an organization's readiness for significant change, and for success or failure of previous or current change processes. Audience: Graduate

2. Create organizational change vision, mission, and objectives by creating dialogue among stakeholders and incorporating diverse perspectives and objectives Audience: Graduate

3. Develop change process and strategy to achieve biotechnology organizational objectives and communicate the need for organizational change and a vision for change. Audience: Graduate

4. Develop a systems perspective and identify the ways in which organizational behavior, structure and culture contribute to successful organizational change. Audience: Graduate

5. Clarify why leaders lose their way and develop the self-awareness needed to avoid derailment. Audience: Graduate

6. Gain clarity about their leadership principles, values, and ethical boundaries, and how they will respond under pressure when challenged. Audience: Graduate

7. Implement their leadership and empower other leaders, while they are optimizing their leadership effectiveness. Audience: Graduate

8. Create a Personal Leadership Development Plan. Audience: Graduate

**ABT 730 – PYTHON FOR BIOINFORMATICS**

3 credits.

Introduce diverse strategies for computational analysis of macromolecular data using Python including sequence alignment, genome annotation, data retrieval from databases, phylogenetic analysis, and molecular evolution. Experiential learning is emphasized; confidence in practical skills is developed through persistent application of course content to projects focused on current problems in bioinformatic research.

**Requisites:** Declared in MS Applied Biotechnology or Capstone Certificate in Applied Bioinformatics

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Select appropriate computational strategies for the analysis of genomic, transcriptomic, proteomic, and metabolomic data. Audience: Graduate

2. Implement analyses of large datasets and model relationships among elements of very complex systems. Audience: Graduate

3. Use python programming strategies to solve problems in bioinformatics. Audience: Graduate

4. Demonstrate the ability to integrate python programming strategies with complementary resources, especially UNIX, GitHub, and libraries. Audience: Graduate

**ABT 735 – QUALITY CONTROL AND VALIDATION**

3 credits.

Focuses on the importance of quality control and validation in biotechnology product design, development, and manufacturing. Explores quality systems and documentation, global quality standards, and methods for assessing validation including installation, operational, and performance qualifications. Overviews biomanufacturing processes, automation, and cGMP practices necessary to meet quality standards.

**Requisites:** ABT 700, 705, and 710

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Describe and contrast various quality systems and how Quality by Design is implemented in biotechnology Audience: Graduate

2. Appraise the current quality standards that are used in the US and abroad Audience: Graduate

3. Compare the Current Good Practices that are required in biotechnology product development (cGMPs) and assess how they are implemented Audience: Graduate

4. Describe the key aspects of CMC (Chemistry, Manufacturing, and Controls) and how they impact biotechnology product development Audience: Graduate

5. Design a biomanufacturing process including upstream and downstream processes Audience: Graduate

6. Justify the importance of validation (IQ/OQ/PQ) and risk assessment and reduction in biotechnology Audience: Graduate

7. Explain the importance of facilities, equipment, and utilities in biotechnology Audience: Graduate

**ABT 740 – REGULATORY PRACTICE AND COMPLIANCE**

3 credits.

Identifies and examines the key regulatory agencies and practices that govern the highly regulated and diverse biotechnology industry, both domestically and internationally. Highlights current and emerging FDA and ICH regulations and guidance documents to successfully navigate meeting with the agencies and to submit required documentation for successful product development.

**Requisites:** ABT 700, 705, and 710

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Describe and contrast the FDA, ICH, EMA, and Japanese PMDA Audience: Graduate

2. Justify the importance of regulatory affairs in biotechnology Audience: Graduate

3. Develop a meeting and communication strategy for interacting with the FDA and submitting appropriate documentation Audience: Graduate

4. Analyze the regulations that impact drug and biologics development, medical devices and diagnostics, agricultural biotechnology, and industrial biotechnology Audience: Graduate

5. Analyze and compare nonclinical and clinical testing and the regulations that govern the use of animals and humans in research Audience: Graduate

6. Describe genome editing and regulatory considerations that impact its applications in agriculture and humans Audience: Graduate

**ABT 745 – INDUSTRIAL APPLICATIONS IN REGULATORY AFFAIRS**

3 credits.

Examines regulatory environments in risk-based assessment of biotechnological developments in industry, agriculture, and probiotics ensuring consumer and environmental protection. Addresses how validation is essential to the incorporation of emerging technologies into viable, accessible, and successful products. Highlights the stakeholders' role in regulatory oversight and policy through relevant industry case studies.

**Requisites:** ABT 700, 705, and 710

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Describe global regulatory environments for biotechnology Audience: Graduate

2. Compare and contrast the regulatory roles of the US Food and Drug Administration, the US Department of Agriculture, and the US Environmental Protection Agency in development of biotechnology products Audience: Graduate

3. Explain stakeholder's role in regulatory oversight and policy Audience: Graduate

### **ABT 750 – BIOTECHNOLOGY MARKETING AND ENTREPRENEURSHIP**

3 credits.

Examines marketing case studies in diverse areas of biotechnology. Addresses marketing fundamentals and strategies, communicating value proposition strategy, ethical and regulatory concerns, startup strategies, pharmaceutical marketing, b2b marketing, salesforce development, branding, and promotion. Culminates with the creation of a marketing plan/analysis.

**Requisites:** Declared in Applied Biotechnology program

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Categorize fundamental concepts of marketing management Audience: Graduate

2. Compare and Contrast marketing segmentation, innovation, and positioning in the bio-technology industry and related marketing channels Audience: Graduate

3. Understand channel systems of marketing and simulate personal selling and customer satisfaction service Audience: Graduate

4. Integrate advertising elements, publicity marketing, and sales promotion in a Business to Business (B2B) model Audience: Graduate

5. Evaluate decisions leading to successful and unsuccessful biotechnology products Audience: Graduate

6. Synthesize marketing plan for biotechnology products Audience: Graduate

7. Demonstrate team work aspects and leadership attributes in marketing elements Audience: Graduate

8. Integrate Data into the Marketing decision making model Audience: Graduate

### **ABT 755 – GLOBAL OPERATIONS AND SUPPLY CHAIN MANAGEMENT**

3 credits.

Focuses on the strategic importance of operations and supply chain to overall performance relevant to a variety of business processes specific to biotechnology. Topics include production, transportation, distribution systems, sourcing, and purchasing.

**Requisites:** Declared in Applied Biotechnology program

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Recognize and use terminology commonly used in the management of general supply chains Audience: Graduate

2. Apply concepts to manage suppliers, production and distribution in biotech firms/industry Audience: Graduate

3. Select and use appropriate quantitative and/or qualitative techniques to manage suppliers, production and distribution in biotech firms/industry Audience: Graduate

4. Demonstrate ability to use technology, communication skills, and teamwork Audience: Graduate

**ABT 760 – QUALITY AND PROJECT MANAGEMENT**

3 credits.

Quality and project management issues and roles during different phases from RD to market. Introduction to Installation qualification, operation qualification and process qualification (PQ). Project management phases: conceptualizing, planning, executing and closing. Project schedule and time management tools and techniques. Project requirements including quality assurance.

**Requisites:** ABT 720 and 725

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Justify the importance of quality management in biotechnology. Audience: Graduate

2. Understand the IQ/OQ/PQ validation process. Audience: Graduate

3. Demonstrate the role of quality assurance in product development Audience: Graduate

4. Demonstrate the design for manufacturing, design for reliability, design for safety and design for sustainability concept Audience: Graduate

5. Practice the key components to project management Audience: Graduate

6. Understand the relationship of leadership to effective management to maximize outcomes Audience: Graduate

7. Explain the implementation of ISO and HACCP system in biotechnology organizations as well as how to conduct auditing activates to evaluate the system compliance Audience: Graduate

8. Use project management tools to support project management practices Audience: Graduate

**ABT 765 – ASSESSING INNOVATION IN BIOTECHNOLOGY**

3 credits.

A survey of biotechnology assessments in areas such as regenerative medicine, agricultural biotechnology, and bioremediation. Course links disciplines with the critical evaluative role played by scientific discovery, market valuation, intellectual property, freedom-to-operate (FTO), and licensing strategy by assessing the role each played in the commercialization of a specific technology.

**Requisites:** ABT 700

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Demonstrate effective listening, written, verbal, and nonverbal communication skills Audience: Graduate

2. Evaluate and describe systems of product research, development, and production Audience: Graduate

3. Analyze the potential for commercialization of innovations within the biotechnology industry Audience: Graduate

4. Identify and provide evidence-based solutions to problems in compliance, product development, personnel, and finance Audience: Graduate

5. Demonstrate understanding of relevant domestic and global regulatory agencies, laws, policies, and guidance Audience: Graduate

6. Assess intellectual property considerations in biotechnology Audience: Graduate

## ABT 770 – PRODUCT DEVELOPMENT

3 credits.

Explores strategies in evaluating and implementing new technologies or products in the context of different bioindustries. Identifies considerations in product valuation, feasibility of production, scalability, and supply chain management. Models the process of business growth and innovation through integration of emerging technologies.

**Requisites:** ABT 700 and 715

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Outline the factors that inform valuation of a new technology and potential for product development  
Audience: Graduate

2. Discuss biotic and abiotic considerations in the process design of different bioindustry production platforms Audience: Graduate

3. Describe the purpose of Good Practice (GMP, GCP, GLP, etc.) standards in production and different modes through which these standards can be achieved Audience: Graduate

4. Evaluate the pertinent regulatory standard and appropriate product quality assessments in bioindustry production pipelines Audience: Graduate

5. Propose and defend a process design for production of a new technology in an existing or startup bioindustry model Audience: Graduate

## ABT 775 – TOOLS FOR DATA ANALYSIS

3 credits.

Using a variety of existing and emerging bioinformatics tools and computational methods, emphasizes hands-on experiences analyzing and interpreting large data sets (e.g. genomic, proteomic, microbiomics, interactome, target discovery). Evaluate and adapt existing computational approaches for specific use in solving a problem in biotechnology.

**Requisites:** ABT 700 and 715

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Describe the revolution in big data related to advances in science and the bottlenecks the corresponding data analytics  
Audience: Graduate

2. Explain how several disciplines and specialties within biotechnology analyze and interpret various datasets to address a biological question Audience: Graduate

3. Develop practical bioinformatics skills applicable to various data types and biological studies Audience: Graduate

4. Utilize and discriminate between various bioinformatics and data visualization tools to answer research question Audience: Graduate

5. Construct and deliver effective professional written and oral presentations incorporating scientifically relevant outcomes from various data analytics Audience: Graduate



**ABT 780 – BIOINFORMATIC INQUIRY**

3 credits.

Advances the development of competencies promoting efficient analysis of biological data. Emphasizes matching a research problem with the most effective tools for its completion, balancing use of existing software and de novo software development. Advanced aspects of Python and R, algorithmics, machine learning, simulations, and effective communication of results are emphasized.

**Requisites:** ABT 720 and 730

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Implement successful solutions to tasks in bioinformatics using existing software and newly developed code.

Audience: Graduate

2. Write R scripts and packages, including formulation of new R classes.

Audience: Graduate

3. Create helpful, user-defined classes in Python. Audience: Graduate

4. Implement knowledge of algorithmics to write elegant solutions to bioinformatics tasks. Audience: Graduate

5. Interface with a MySQL database in Python. Audience: Graduate

6. Simulate biological data to use as a null distribution for novel test statistics. Audience: Graduate

7. Decide when machine learning methods are appropriate to a task in bioinformatics. Audience: Graduate

8. Use GitHub to effectively share new software and manage version control. Audience: Graduate

9. Communicate complicated methodology and results to a variety of stakeholders. Audience: Graduate

**ABT 785 – APPLICATION OF BIOINFORMATICS**

3 credits.

Exploration and application of existing bioinformatic tools. Implementation of pre-coded solutions to data acquisition, wrangling, analysis, visualization, and structural modeling problems. Complete a project that generates a multi-system workflow to solve bioinformatic problems.

**Requisites:** ABT 720 and 730

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Fall 2023

**Learning Outcomes:** 1. Identify and demonstrate use of existing databases for genomic, transcriptomic, proteomic, and metabolomics analysis Audience: Graduate

2. Describe construction and limitations for existing databases Audience: Graduate

3. Identify and demonstrate existing tools for sequence analysis Audience: Graduate

4. Identify and critique methods and tools for annotation of genomes and phylogentic analysis Audience: Graduate

5. Identify and critique methods for assigning protein structure and function and metabolite profiles Audience: Graduate

6. Describe and select best practices in adapting and editing existing tools Audience: Graduate

7. Identify methods for developing multi-tool workflows; build, analyze, and critique functional workflows Audience: Graduate

### **ABT 789 – PRE-CAPSTONE**

1 credit.

Prepares the student for applied self-directed capstone experience. Addressing problem identification, research, and project formulation. Culminates in an oral and written proposal with project schedule.

**Requisites:** Consent of instructor

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Identify a problem the individual capstone project will address Audience: Graduate

2. Integrate scientific knowledge and professional skill development accrued through research, didactic learning, and professional networking Audience: Graduate

3. Develop a well-articulated, focused project Audience: Graduate

4. Present a project proposal in a professional manner to one's peers Audience: Graduate

### **ABT 790 – CAPSTONE**

3 credits.

Complete a project (report, business plan, program, etc.) in an area of quality assurance and compliance, business and management, and/or research and development. Culminating in a substantive body of work, executive summary, and reflection. Networking and communication in a professional capacity is expected.

**Requisites:** ABT 789

**Course Designation:** Grad 50% - Counts toward 50% graduate coursework requirement

**Repeatable for Credit:** No

**Last Taught:** Spring 2024

**Learning Outcomes:** 1. Integrate scientific knowledge and professional skill development accrued through research, didactic learning, and professional networking, to achieve fruition of a project Audience: Graduate

2. Develop a well-articulated written paper and summation of the capstone Audience: Graduate

3. Reflect upon the capstone experience Audience: Graduate