

# Applied Biotechnology (ABT)

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## Courses

### **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. Fall and Spring.

### **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. Fall and Spring.

### **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. Fall and Spring.

### **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. Spring.

### **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. Spring.

### **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. Spring.

### **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/cGMP practices necessary to meet quality standards.

### **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.

### **ABT 745. Industrial Applications in Regulatory Affairs. 3 Credits.**

Examines the global regulatory environments in risk-based assessment of biotechnological developments across diverse sectors, 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.

### **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.

### **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.

### **ABT 760. Quality and Project Management. 3 Credits.**

Quality and project management issues and roles during different phases from R&D to market in the biotechnology industry. Introduction to Installation qualification, operation qualification and process qualification (IQ/OQ/PQ). Project management phases: conceptualizing, planning, executing and closing. Project schedule and time management tools and techniques. Project requirements including quality assurance.

**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.

**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.

**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). Students will also evaluate and adapt existing computational approaches for specific use in solving a problem in biotechnology.

**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.

**ABT 790. Capstone. 3 Credits.**

Student will 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.