

# Biotechnology (BIOT)

## Courses

### BIOT 5120. Foundations in Biotechnology. (3 Hours)

Provides an interdisciplinary, state-of-the-art introduction to biotechnology. Covers the molecular foundations of biotechnology, molecular microbiology, receptor pharmacology, drug development processes, biotech process development and scale-up, drug approval and regulatory affairs, genomics, microarray analysis, proteomics, computational biology, molecular modeling, analytical biotechnology, and bioterrorism and biotechnology.

### BIOT 5145. Basic Biotechnology Lab Skills. (1 Hour)

Introduces selected key skills and techniques central to life sciences research. Combines hands-on training in basic laboratory skills with lecture and live demonstration. Laboratory exercises highlight the importance of precision/accuracy in dispensation of liquids and in the preparation of solutions and standards, documentation and record keeping, and maintaining a safe and sterile work environment while performing scientific research.

### BIOT 5219. The Biotechnology Enterprise. (2 Hours)

Exposes students to the business of biotech from scientific discovery startup through its product launch and subsequent organizational and scientific pipeline growth. Topics include scientific discovery, biotech-related funding and organizational structures, regulatory and clinical trial considerations, biotech alliances, patient access, ethics and compliance, and commercialization and growth while meeting unmet patient or consumer needs in this highly regulated industry. Although the focus is on the highest regulated standards in biopharma, the course also touches upon various aspects of other biotechnology domains.

### BIOT 5220. The Role of Patents in the Biotechnology Industry, Past and Future. (1 Hour)

Covers the basics of patenting and the application of patents to the biotechnology industry, including the controversial area of gene patents.

### BIOT 5225. Managing and Leading a Biotechnology Company. (3 Hours)

Covers managing projects and personnel in a technology-based organization. Such activities are best carried out by those who combine the technical knowledge of their industry with the insight into the best practices for working with groups of highly educated, and often very experienced people. The biotechnology industry is strongly dependent on the concept that knowledge is always shared and ownership is collective. As the fundamental organizational mantra is teamwork, the principles of managing in this environment are key to achieving important goals. How to accomplish this and make decisions that drive innovation and success have common threads with other technology based industries, but with the added complexity of the scientific challenges facing the biotechnology industry. Restricted to students in the Bouvé College of Health Sciences and in the College of Science or by permission of the program office.

**Prerequisite(s):** BIOT 5219 with a minimum grade of C-

### BIOT 5226. Biotechnology Entrepreneurship. (3 Hours)

Biotechnology by its very nature is an innovative multidisciplinary industry. This is especially true for the biopharmaceutical industry in which the process of discovering new drugs and new drug targets requires novel approaches to solving difficult questions about disease processes and human health. This course focuses on the essential nature of innovation in the biotech industry, exposes students to the basics of creating startup organizations, explains the key role of business planning in enterprise creation, describes means for assessing risks, making choices from available options and how to measure success. Various business models, outsourcing work and establishing strategic partnerships are examined. Restricted to students in the Bouvé College of Health Sciences and in the College of Science or by permission of the program office.

**Prerequisite(s):** BIOT 5219 with a minimum grade of C-

### BIOT 5227. Launching Your Science: Biotechnology Entrepreneurship. (3 Hours)

Focuses on the essential startup elements that lead to pitching your science to investors and funding your biopharmaceutical enterprise. Exposes students to the basics of establishing an unmet patient need and matching that to a scientific discovery or biotechnology platform, analyzing the marketplace from a scientific perspective, determining a draft regulatory pathway and product development plan through a target product profile (TPP), appropriately sizing and hiring your early stage management team, and assessing the financial needs and risks for appropriate exit strategies. Students produce a baseline pitch deck as the culminating project for the course.

**Prerequisite(s):** BIOT 5219 with a minimum grade of C-

### BIOT 5330. Drug Safety and Immunogenicity. (3 Hours)

Introduces the fundamental molecular interactions involved in immunological responses as well as in measuring and testing in a research and regulated environment. Other drug-safety-related topics include adventitious agents (viruses, microorganisms, mycoplasma) and risk factors such as product-related substances (aggregates and post-translationally modified variants), endotoxins, DNA, host-cell proteins, process contaminants such as antibiotics, and the means of testing and removing these through validated processes.

**BIOT 5340. Introduction to Biotherapeutic Approvals. (3 Hours)**

Introduces students to biologics. The class of drugs referred to as biologics or biotherapeutics, proteins drugs, makes up a large portion of the drugs in development and on the market today. Focuses on considerations for approval for such drugs. Offers students an opportunity to learn how to be able to describe and explain both biologics and biosimilars.

**BIOT 5400. Scientific Information Management for Biotechnology Managers. (3 Hours)**

Introduces biotechnology students to scientific information management specifically related to the biotechnology field. Covers an introduction to data sciences, its history, and how it is relevant to biotech today. Offers students an opportunity to obtain the background needed to assess and use modern data management capabilities such as "the cloud," big data, etc. Covers recent developments in origination of data, metadata, data models, data management, and organization and storage of data in biotechnology.

**BIOT 5500. Concepts in Regulatory Science. (3 Hours)**

Introduces the science that supports regulatory affairs in the biopharmaceutical industry. Focuses on the methods and instruments used to characterize the processes and products of biotechnology including the production, separation, purification, characterization, and formulation of biologics; the pharmacokinetics of proteins; chemical and biological equivalencies of biologics; stability testing; high throughput assays; cell system expression; variants; method validation; and quality control.

**BIOT 5560. Bioprocess Fundamentals. (3 Hours)**

Focuses on the fundamental principles and elements in the process of manufacturing biopharmaceuticals. Covers kinetics of enzymatic reactions; selected microbial and cell metabolism and relevant control mechanisms; kinetics of cell growth, cell death, substrate consumption, and product formation; mathematical modeling and representation of bioprocesses; examples of industrial bioprocesses to illustrate types and operations of upstream and downstream unit operations and mass transfers in fermentation systems—the affecting factors and the impact on process development and scale-up. Also includes an overview of economic considerations. Emphasizes bioprocesses for recombinant protein production.

**BIOT 5621. Protein Principles in Biotechnology. (3 Hours)**

Discusses the fundamentals in structural biology and biochemistry in drug design and applied biotechnology with special focus on protein chemistry. Explores the nature, structure, and function of proteins in the context of analytical analysis, molecular medicine, and drug discovery. Emphasizes bioinformatics and computational systems biology. Specifically investigates the analysis of ongoing research projects, case studies, and practical concepts of biotechnology.

**BIOT 5631. Cell Culture Processes for Biopharmaceutical Production. (3 Hours)**

Covers the principles and concepts involved in the development of mammalian and other types of cell culture processes for the manufacturing of biopharmaceutical products such as monoclonal antibodies and recombinant proteins. Topics include protein expression and clone generation, batch and perfusion processes and media development, bioreactor operations and scale-up, and innovations in cell culture processes. Regulatory concepts include quality assurance in a cGMP environment.

**BIOT 5635. Downstream Processes for Biopharmaceutical Production. (3 Hours)**

Addresses the development of recombinant protein purification processes in biotechnology. Provides an overview of the scientific principles, engineering strategies, and unit operations facilities involved in scalable protein purification processes. Also discusses viral clearance and inactivation strategies; cGMP considerations; and technological advances to improve effectiveness and efficiency, such as membrane-based disposable systems.

**BIOT 5640. Drug Product Processes for Biopharmaceuticals. (3 Hours)**

Covers the development and implementation of the drug product manufacturing process for biopharmaceuticals. Focuses on biologic products, specifically proteins. Covers the workflow required for the development and implementation of the production process with the scientific and engineering principles highlighted. Topics include the preformulation process for early stage product development, the selection of formulation compatible with the targeted product presentation, optimization of formulations to meet stability and usage objectives, the design of a scalable process for production, large-scale process equipment and operations, process scale-up considerations, and regulatory compliance issues for drug product manufacturing facilities and operations. Students who do not meet course prerequisites may seek permission of instructor.

**Prerequisite(s):** CHEM 5620 with a minimum grade of C- or CHEM 5620 with a minimum grade of D-

**BIOT 5700. Molecular Interactions of Proteins in Biopharmaceutical Formulations. (3 Hours)**

Offers an up-to-date survey and review of the research and understanding of the molecular interactions of proteins in biopharmaceutical formulations, including both liquid and solid formats, during the process of drug product manufacturing. Focuses on protein-protein interactions, protein-excipients (e.g., stabilizers, surfactants) interactions, and protein at interface surfaces interactions that are critical and impactful on the stability and integrity of therapeutic proteins of interest. Emphasizes understanding the mechanistic aspect of the interactions; the approaches, methods, and techniques employed to study these phenomena; and measures considered to modulate such interactions to enhance the performance of the biopharmaceutical formulations. Students who do not meet course prerequisites may seek permission of instructor.

**Prerequisite(s):** CHEM 5620 with a minimum grade of C- or CHEM 5620 with a minimum grade of D-

**BIOT 5800. Gene Therapies. (2 Hours)**

Provides an overview of specific gene therapy applications and diseases that are, or may be, a target of gene therapies. Includes case study analysis of gene therapies with publicly available information, as well as tools for proper identification of gene targets in disease states.

**BIOT 5810. Cutting-Edge Applications in Molecular Biotechnology. (3 Hours)**

Introduces the uses of molecular biology in a biotechnology setting. Includes a brief review of the basics and then dives into state-of-the-art molecular biology applications used in biotechnology today. These applications include stability and expression of cloned gene products, gene cloning strategies, transgenic species, mutation creation and analysis, DNA fingerprinting, PCR technology, microarray technology, gene probes, gene targeting, gene therapy, stem cell technology, antisense RNA, CAR T-cell therapy, RNA interference, and CRISPR/Cas9.

**BIOT 5820. Cellular Therapies. (2 Hours)**

The ever-changing landscape of the biotechnology field requires constant training. This course is designed to familiarize participants with some of the most cutting-edge topics available in molecular biology today: stem cells, RNA interference, CRISPR/CAS9, CAR T-cells, gene therapy, and more. Offers participants an opportunity to learn the theory behind these new technologies, how they are done, and their power in scientific discovery and treatment.

**BIOT 5830. Regulatory Landscape of Cell and Gene Therapies. (2 Hours)**

Introduces the current state of regulatory approvals for cell and gene therapies. Focuses on the scientific and technical considerations for approval for such drugs in the United States, in Europe, and in other key global markets. Explores the scientific challenges in the context of regulatory approval of these products, as well as how the process differs from traditional biotherapeutic product approvals. Examines how these regulatory pathways are evolving with a specific focus on quality, efficacy, and safety throughout the product life cycle (manufacturing through commercialization).

**BIOT 5840. Cell and Gene Therapy Lab. (3 Hours)**

Introduces selected key skills and techniques central to cell and gene therapy research. Combines hands-on training in cell and gene therapy skills with lecture and demonstration. Laboratory exercises highlight the current technical skills needed in the cell and gene therapy field, such as cell culture, siRNA, CRISPR/Cas9, stem cells, gene therapy, and editing, etc.

**BIOT 5850. Higher-Order Structure Analytics. (3 Hours)**

Offers a comprehensive look at various aspects of higher-order protein structures in biotherapeutics and their implications on biological drug design. Focuses heavily on protein aggregation, a type of HOS, and analysis of those aggregates including functional implications. Topics include a review of protein structure, protein aggregation, functional aspects, and techniques to reduce HOS using protein expression and purification strategies, protein folding in disease, macromolecular crystallography, nuclear magnetic resonance, analytical ultracentrifugation, circular dichroism, light scattering, electron spin labelling, cryo-EM, WAXS, and HDX-MS. Highlights experimental design and application to the biotechnology industry in identifying and reducing HOS.

**BIOT 5910. Vaccines and Immunization. (3 Hours)**

Emphasizes the importance of using vaccines in order to prevent the spread of infectious diseases and viruses. Discusses the evolution of vaccines throughout medical history (e.g., smallpox, polio), emphasizing lessons learned so they can be adapted to development of new and novel vaccines. Explains the molecular mechanism of how vaccines, such as vaccines that use attenuated virus to more novel vaccines that use mRNA, elicit an immune response. Examines the importance of immunization in the context of the immune system.

**BIOT 5920. Foundations in Vaccine Regulatory Science. (3 Hours)**

Explores the science behind how regulatory pathways were developed and how vaccines were approved for human use. The pathway for vaccine approvals by national regulatory authorities has been well established for decades. The SARS-CoV-2 pandemic created an immediate need to create new vaccines, which also created a new need for the regulatory approval of these vaccines. Examines how SARS-CoV-2 vaccines caused an increased interest in the regulatory science behind vaccine regulatory approval, specifically exploring the use of emergency use authorization (EUA) in getting SARS-CoV-2 vaccines to market. Discusses how the use of EUAs changed the regulatory science landscape of vaccines.

**BIOT 5930. Molecular Tools for Vaccine Design. (3 Hours)**

Discusses the molecular tools used for vaccine design and development, including the experimental tools used for attenuated whole-organism vaccines, purified macromolecule vaccines, and DNA or mRNA vaccines. Emphasizes vector design and development and specifically the challenges associated with vaccine design and development. Also studies computational tools that aid vaccine development.

**BIOT 5964. Projects for Professionals. (0 Hours)**

Offers students an applied project setting in which to apply their curricular learning. Working with a sponsor, students refine an applied research topic, perform research, develop recommendations that are shared with a partner sponsor, and create a plan for implementing their recommendations. Seeks to benefit students with a curriculum that supports the development of key business communication skills, project and client management skills, and frameworks for business analysis. Offers students an opportunity to learn from sponsor feedback, review 'lessons learned,' and incorporate suggestions from this review to improve and further develop their career development and professional plan. May be repeated twice.

**BIOT 5976. Directed Study. (1-4 Hours)**

Offers independent work under the direction of members of the department on chosen topics. May be repeated without limit.

**BIOT 6100. Agricultural Biotechnology. (3 Hours)**

Explores the key agricultural biotechnology (agritech) principles and methods that are used in industry today; serves as a foundational course exposing students, briefly, to all aspects of agritech. Topics covered include gene transfer and genetic modification; cloning; plant biotechnology, animal science, food and ecological biotechnology; consumer concerns; safety testing; and other issues related to agritech.

**BIOT 6110. Cannabis Biotechnology: Science, Society, and Regulation. (3 Hours)**

Explores key cannabis biotechnology principles, methods, tools, societal/business perspectives, and regulations that are vital to industry today. Offers students an opportunity to discover essential connections between scientific principles, societal impacts, and legal developments underlying the cannabis biotech industry. Topics include the fundamental scientific principles of cannabis biotechnology, including important tools such as cloning, tissue culture, genetic modification, analytical biotechnology, as well as traditional breeding techniques. Explores practical issues including consumer and safety concerns, regulation, ethical issues, and careers in the cannabis industry.

**BIOT 6214. Experimental Design and Biostatistics. (2 Hours)**

Explores the principles of experimental design and statistical analysis. Emphasizes research in the molecular and biological sciences and biotechnology. Topics include probability theory, sampling hypothesis formulation and testing, and parametric and nonparametric statistical methods.

**BIOT 6290. Foundation in Quality for Biotechnology. (3 Hours)**

Presents concepts, tools, and techniques for real-world, on-the-job application of quality that is practical for a wide range of organizations. Offers an insight into the mindset of quality, along with an overview of the concepts, principles, processes, and activities involved in quality assurance, quality control, and regulatory compliance within the life sciences industry. Emphasizes understanding the business of biotech; the remit of global regulatory agencies; principles and processes for establishing and enforcing regulation and guidance; quality management systems, operations, and compliance; quality leadership; quality planning; and careers in the quality profession. Includes presentations from a variety of industry experts.

**BIOT 6300. Pharmaceutical Microbiology. (3 Hours)**

Studies those microorganisms associated with the manufacture of pharmaceuticals, including biopharmaceuticals. Focuses on how to exclude microorganisms, such as exotoxins and endotoxins, from pharmaceutical processes to produce a sterile product. Considers how products react to microorganism contamination and methods of disinfection. Discusses pharmaceutical microbiology as related to clean rooms and controlled environments and methods and specifications related to microorganisms based on the United States Pharmacopeia guidelines. Lastly, discusses facility monitoring, specifically EM/critical utility testing, process monitoring, and maintenance throughout with an emphasis on what regulators expect to see in terms of data.

**BIOT 6310. CGMP Statutes and Regulation. (3 Hours)**

Focuses on the laws and regulations related to pharmaceuticals manufacture and administration. Discusses an overview of laws and regulations and provides guidance in the context of why they exist, their evolution, and implementation. Specifically focuses on the laws and regulations around good manufacturing practices (GMP), postapproval safety concerns, regulation of manufacture, violations and enforcement, and what to expect during an inspection from a regulatory body. Surveys the laws and regulations on a global level focusing on specific examples related to the United States, Europe, Asia, and other regulatory agencies.

**BIOT 6320. Quality Management Systems and Validation. (3 Hours)**

Emphasizes quality management systems (QMS) and validation as it relates to the production and processes related to pharmaceuticals, including biopharmaceuticals. Discusses the implementation of a QMS plan, to include document processes, procedures, metrics, reporting, and responsibilities, aligned with pharmaceutical and biotechnology companies' business objectives. Emphasizes implementation, signaling problems (continual improvement), transparency, validation, and team cooperation/dynamics. Specifically discusses the International Council on Harmonisation (ICH) Q10 guidelines. Topics related to QMS may include objectives, manual, organization structural responsibilities, data management, processes, product quality, continuous improvement plans, quality instruments, and document control.

**BIOT 6340. Sterile Manufacturing Operations. (3 Hours)**

Discusses the importance of sterile operations in producing drug products, as part of good manufacturing practice (GMP). Emphasizes sterile manufacturing operations for all drugs.

**BIOT 6400. Pre-co-op Experience. (0 Hours)**

Offers students an opportunity to gain necessary skills and practical experience in order to prepare for graduate co-op.

**BIOT 6500. Professional Development for Co-op. (0 Hours)**

Introduces the cooperative education program. Offers students an opportunity to develop job-search and career-management skills; to assess their workplace skills, interests, and values and to discuss how they impact personal career choices; to prepare a professional resumé; and to learn proper interviewing techniques. Explores career paths, choices, professional behaviors, work culture, and career decision making.

**BIOT 6600. Agents of Bioterrorism. (3 Hours)**

Examines the probable weapons of biowarfare—including biological, chemical, and nuclear weapons— from several perspectives. Offers fundamental information on the biology and mechanism of action of the most important potential agents of terror and an introduction to the role of government. Topics include biological impact, detection and recognition, epidemiology, and treatment. Evaluates potential dangers and effectiveness and investigates strategies for defense against attacks by such weapons. Discusses the bioethical challenges of anti-bioterror research. Also offers students an opportunity to develop skills in scientific literacy and writing.

**BIOT 6610. Biosecurity and Bioterrorism. (3 Hours)**

Examines the national and international political, legal, and policy dimensions of response to threats of bioterrorism and resurging epidemics. Explores how the interagency community works at local, tribal, state, national, and international levels to meet these growing challenges. Resurging epidemics are now gaining national attention in a way not seen for generations. These threats join the long-standing challenges of potential domestic and foreign state-sponsored biowarfare attacks and the growing awareness of the threat of bioterrorism.

**BIOT 6954. Co-op Work Experience - Half-Time. (0 Hours)**

Provides eligible students with an opportunity for work experience. May be repeated without limit.

**BIOT 6955. Co-op Work Experience Abroad - Half-Time. (0 Hours)**

Provides eligible students with an opportunity for work experience. May be repeated without limit.

**BIOT 6962. Elective. (1-4 Hours)**

Offers elective credit for courses taken at other academic institutions. May be repeated without limit.

**BIOT 6964. Co-op Work Experience. (0 Hours)**

Provides eligible students with an opportunity for work experience. May be repeated without limit.

**BIOT 6965. Co-op Work Experience Abroad. (0 Hours)**

Provides eligible students with an opportunity for work experience abroad. May be repeated without limit.

**BIOT 6980. Biotechnology Capstone. (2 Hours)**

Offers students an opportunity to integrate and apply the skills learned in earlier courses to an independent project supervised by a faculty mentor. The goals of the capstone are to develop skills in communicating the results of independent projects; increase student awareness of research in biotechnology outside of their own work; demonstrate a familiarity with the literature background to their work, including a working knowledge of literature searching; and provide an opportunity to reflect on individual progress toward a career in biotechnology.

**BIOT 7245. Biotechnology Applications Laboratory. (3 Hours)**

Presents a laboratory course in biotechnology with a focus on cutting-edge instrumentation that is currently used in the field. Directs special attention at the practical aspects of laboratory work in this field, for example, techniques in sample preparation, procedures for protein analysis, and new bioinformatic approaches. Focuses on the emerging field of chemoproteomics, which is the study of the interaction of small molecules with the proteome, that is, the full complement of proteins expressed in an individual cell or organism. Exposes the student to hands-on experience with modern instrumentation, such as mass spectrometry and high performance liquid chromatography.

**BIOT 7250. Advanced Biotechnology Applications Laboratory. (3 Hours)**

Focuses on advanced biological and bioprocess engineering concepts. Uses industrial-scale systems and technology platforms. Offers students an opportunity to learn lab techniques used in manufacturing and production of biotherapeutic products (protein-based drugs such as monoclonal antibodies) and cell and gene therapies. Offers hands-on experience with industrial-scale bioreactors, protein purification systems, and mass spectrometry. Emphasizes understanding critical process parameters (CPPs) and critical quality attributes (CQAs) in drug production.