The Master of Science in Chemistry is a part-time program designed to allow practicing chemical professionals in the greater Boston area who have an earned bachelor’s degree in chemistry to pursue a master’s part-time in chemistry by completing a course work program during the evening weekday hours. The department offers a diverse range of part-time in chemistry by completing a course work program during the evening weekday hours. The department offers a diverse range of interdisciplinary training in biotechnology, biology, chemistry, and pharmaceutical sciences with the development of high-value business skills critical to success in today's dynamic workplace. Students are offered the opportunity to gain hands-on experience during the program through Northeastern’s established co-op program.

The biotechnology program also offers several graduate certificates in the areas of biopharmaceutical analytical sciences, biotechnology, biotechnology enterprise, experimental biotechnology, molecular biotechnology, pharmaceutical technologies, process science, and regulatory science.

Programs

Doctor of Philosophy (PhD)

- Chemistry (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/chemistry-phd/)
- Chemistry—Advanced Entry (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/chemistry-phd-advanced/)

Master of Science (MS)

- Biotechnology (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/biotechnology-graduate-certificate/)
- Chemistry (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/chemistry-ms/)

Graduate Certificate

- Biopharmaceutical Analytical Sciences (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/biopharmaceutical-analytical-science-graduate-certificate/)
- Biotechnology (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/biotechnology-graduate-certificate/)
- Biotechnology Enterprise (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/biotechnology-enterprise-graduate-certificate/)
- Experimental Biotechnology (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/experimental-biotechnology-graduate-certificate/)
- Manufacturing and Quality Operations in Biotechnology (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/manufacturing-quality-operations-biotechnology-graduate-certificate/)
- Molecular Biotechnology (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/molecular-biotechnology-graduate-certificate/)
- Pharmaceutical Technologies (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/pharmaceutical-technologies-graduate-certificate/)
- Process Science (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/process-science-graduate-certificate/)
- Regulatory Science (http://catalog.northeastern.edu/graduate/science/chemistry-chemical-biology/regulatory-science-graduate-certificate/)
Courses

Chemistry and Chemical Biology Courses

Search CHEM Courses using FocusSearch (http://catalog.northeastern.edu/class-search/?subject=CHEM/)

CHEM 5460. Enzymes: Chemistry and Chemical Biology. 3 Hours.
Focuses on enzymes: their chemistry, mechanisms, and applications. Examines the underlying chemical and mechanistic principles. Introduces the techniques and approaches in enzymology. Bridges the gap between classroom learning and real-world practice in the related fields, e.g., medicinal chemistry, chemical biology, engineering, and pharmaceutical research.

CHEM 5501. Chemical Safety in the Research Laboratory. 1 Hour.
Covers the material needed to complete successfully all the online safety training that is required for our graduate students, best practices for the safe execution of common chemical laboratory procedures, advanced procedures, as well as incidents from the recent literature. Includes discussions of case studies on topics relevant for the safe and effective use of chemicals and other materials in a research laboratory environment. Undergraduates may enroll with permission of the instructor.

CHEM 5550. Introduction to Glycobiology and Glycoprotein Analysis. 3 Hours.
Covers the background and methods used for glycoprotein characterization. Offers students an opportunity to obtain the background needed to assess the analytical steps necessary for development of glycoprotein drugs. Analyzes regulatory issues behind glycoprotein drug development. Covers recent developments in analytical and regulatory sciences.

CHEM 5599. Introduction to Research Skills and Ethics in Chemistry. 0 Hours.
Seeks to prepare students for success in CHEM 5600 and in CHEM 7730. May be repeated once. Must be taken in consecutive semesters before registration into CHEM 5600 and CHEM 7730.

CHEM 5600. Research Skills and Ethics in Chemistry. 3 Hours.
Discusses ethics in science. Topics include documentation of work in your laboratory notebook, safety in a chemistry research laboratory, principles of experimental design, online computer searching to access chemical literature, reading and writing technical journal articles, preparation and delivery of an effective oral presentation, and preparation of a competitive research proposal.

CHEM 5610. Polymer Chemistry. 3 Hours.
Discusses the synthesis and analysis of polymer materials. Covers mechanisms and kinetics of condensation/chain-growth polymerization reactions and strategies leading to well-defined polymer architectures and compositions, including living polymerizations (free radical, cationic, anionic), catalytic approaches, and postpolymerization functionalization. Discusses correlation of chemical composition and structure to physical properties and applications.

CHEM 5611. Analytical Separations. 3 Hours.
Describes the theory and practice of separating the components of complex mixtures in the gas and liquid phase. Also includes methods to enhance separation efficiency and detection sensitivity. Covers thin-layer, gas, and high-performance liquid chromatography (HPLC) and recently developed techniques based on HPLC including capillary and membrane-based separation, and capillary electrophoresis.

CHEM 5612. Principles of Mass Spectrometry. 3 Hours.
Describes the theory and practice of ion separation in electrostatic and magnetic fields and their subsequent detection. Topics include basic principles of ion trajectories in electrostatic and magnetic fields, design and operation of inlet systems and electron impact ionization, and mass spectra of organic compounds.

CHEM 5613. Optical Methods of Analysis. 3 Hours.
Describes the application of optical spectroscopy to qualitative and quantitative analysis. Includes the principles and application of emission, absorption, scattering and fluorescence spectroscopies, spectrometer design, elementary optics, and modern detection technologies.

CHEM 5614. Electroanalytical Chemistry. 3 Hours.
Describes the theory of electrode processes and modern electroanalytical experiments. Topics include the nature of the electrode-solution interface (double layer models), mass transfer (diffusion, migration, and convection), types of electrodes, reference electrodes, junction potentials, kinetics of electrode reactions, controlled potential methods (cyclic voltammetry, chronoamperometry), chronocoulometry and square wave voltammetry, and controlled current methods (chronopotentiometry).

CHEM 5616. Protein Mass Spectrometry. 3 Hours.
Offers students an opportunity to obtain a fundamental understanding of modern mass spectrometers, the ability to operate these instruments, and the ability to prepare biological samples. Undoubtedly the most popular analytical method in science, mass spectrometry is utilized in fields ranging from subatomic physics to biology. Focuses on the analysis of proteins, with applications including biomarker discovery, tissue characterization, detection of blood doping, drug discovery, and the characterization of protein-based therapeutics. By the end of the course, the student is expected to be able to solve a particular chemistry- or biology-related problem by choosing the appropriate sample preparation methods and mass spectrometer.

CHEM 5617. Protein Mass Spectrometry Laboratory. 3 Hours.
Offers students an opportunity to develop an appreciation of the appropriate choice of mass spectrometer for a particular application.

CHEM 5620. Protein Chemistry. 3 Hours.
Describes proteins (what they are, where they come from, and how they work) in the context of analytical analysis and molecular medicine. Discusses the chemical properties of proteins, protein synthesis, and the genetic origins of globular proteins in solution, membrane proteins, and fibrous proteins. Covers the physical intra- and intermolecular interactions that proteins undergo along with descriptions of protein conformation and methods of structural determination. Explores protein folding as well as protein degradation and enzymatic activity. Highlights protein purification and biophysical characterization in relation to protein analysis, drug design, and optimization.

CHEM 5621. Principles of Chemical Biology for Chemists. 3 Hours.
Explores the use of natural and unnatural small-molecule chemical tools to probe macromolecules, including affinity labeling and click chemistry. Covers nucleic acid sequencing technologies and solid-phase synthesis of nucleic acids and peptides. Discusses in-vitro selection techniques, aptamers, and quantitative issues in library construction. Uses molecular visualization software tools to investigate structures of macromolecules. Intended for graduate and advanced undergraduate students.

CHEM 5622. Lab for CHEM 5621. 1 Hour.
Accompanies CHEM 5621. Complements and reinforces the concepts from CHEM 5621 with emphasis on fundamental techniques. Offers an opportunity to complete independent projects in modern chemical biology research.
CHEM 5625. Chemistry and Design of Protein Pharmaceuticals. 3 Hours.
Covers the chemical transformations and protein engineering approaches to protein pharmaceuticals. Describes protein posttranslational modifications, such as oxidation, glycosylation, formation of isospecific acid, and disulfide. Then discusses bioconjugate chemistry, including those involved in antibody-drug conjugate and PEGylation. Finally, explores various protein engineering approaches, such as quality by design (QbD), to optimize the stability, immunogenicity, activity, and production of protein pharmaceuticals. Discusses the underlying chemical principles and enzymatic mechanisms as well.

CHEM 5626. Organic Synthesis 1. 3 Hours.
Surveys types of organic reactions including stereoisomerism, influence of structure and medium, mechanistic aspects, and synthetic applications.

CHEM 5627. Mechanistic and Physical Organic Chemistry. 3 Hours.
Surveys tools used for elucidating mechanisms including thermodynamics, kinetics, solvent and isotope effects, and structure/reactivity relationships. Topics include molecular orbital theory, aromaticity, and orbital symmetry. Studies reactive intermediates including carbenes, carbonium ions, radicals, biradicals and carbanions, acidity, and photochemistry.

CHEM 5628. Principles of Spectroscopy of Organic Compounds. 3 Hours.
Studies how to determine organic structure based on proton and carbon nuclear magnetic resonance spectra, with additional information from mass and infrared spectra and elemental analysis. Presents descriptive theory of nuclear magnetic resonance experiments and applications of advanced techniques to structure determination. Includes relaxation, nuclear Overhauser effect, polarization transfer, and correlation in various one- and two-dimensional experiments. Requires graduate students to have one year of organic chemistry or equivalent.

CHEM 5636. Statistical Thermodynamics. 3 Hours.
Briefly reviews classical thermodynamics before undertaking detailed coverage of statistical thermodynamics, including probability theory, the Boltzmann distribution, partition functions, ensembles, and statistically derived thermodynamic functions. Reconsiders the basic concepts of statistical thermodynamics from the modern viewpoint of information theory. Presents practical applications of the theory to problems of contemporary interest, including polymers and biopolymers, nanoscale systems, molecular modeling, and bioinformatics.

CHEM 5638. Molecular Modeling. 3 Hours.
Introduces molecular modeling methods that are basic tools in the study of macromolecules. Is structured partly as a practical laboratory using a popular molecular modeling suite, and also aims to elucidate the underlying physical principles upon which molecular mechanics is based. These principles are presented in supplemental lectures or in laboratory workshops.

CHEM 5651. Materials Chemistry of Renewable Energy. 3 Hours.
Studies renewable energy in terms of photovoltaics, photoelectrochemistry, fuel cells, batteries, and capacitors. Focuses on the aspects of each component and their relationships to one another.

CHEM 5660. Analytical Biochemistry. 3 Hours.
Focuses on the analysis of biological molecules, which include nucleic acids, proteins, carbohydrates, lipids, and metabolites. Methods used for isolation, purification, and characterization of these molecules are discussed.

CHEM 5672. Organic Synthesis 2. 3 Hours.
Continues CHEM 5626. Surveys types of organic reactions including stereoisomerism, influence of structure and medium, mechanistic aspects, and synthetic applications.

CHEM 5676. Bioorganic Chemistry. 3 Hours.
Covers host guest complexation by crown ethers, cryptands, podands, spherands, and so forth; molecular recognition including self-replication; peptide and protein structure; coenzymes and metals in bioorganic chemistry; nucleic acid structure; interaction of DNA with proteins and small molecules including DNA-targeted drug design; catalytic RNA; and catalytic antibodies.

CHEM 5700. Topics in Organic Chemistry. 3 Hours.
Offers various topics within the breadth of organic chemistry. Intended to meet the needs and interests of students. Topics could range from the physical and material aspects of organic chemistry to the biochemical and biomedical aspects of organic chemistry. Undergraduate students who have completed a second semester of organic chemistry with a grade of at least C− may be admitted with permission of instructor. May be repeated once.

CHEM 5904. Seminar. 1 Hour.
Focuses on oral reports by master of science and PlusOne participants on current research topics in chemistry and chemical biology. May be repeated up to two times.

CHEM 5976. Directed Study. 1-4 Hours.
Offers independent work under the direction of members of the department on a chosen topic. Course content depends on instructor. May be repeated without limit.

CHEM 5984. Research. 1-6 Hours.
Offers an opportunity to conduct research under faculty supervision. May be repeated up to three times for up to 6 total credits.

CHEM 6500. Cheminformatics. 3 Hours.
Introduces the subject of cheminformatics. Focuses on informatic, or computer, methods to solve chemical problems. Focuses on the approaches to mine data, looking at structural similarities, and evaluating compound designs and libraries for diversity and other characteristics. In addition, briefly discusses molecular modeling of proteins.

CHEM 6962. Elective. 1-4 Hours.
Offers elective credit for courses taken at other academic institutions. May be repeated without limit.

CHEM 7247. Advances in Nanomaterials. 3 Hours.
Designed to provide an entry-level perspective of solid-state chemistry both from a fundamental and applied perspective. Discusses the basic aspects of materials science encompassing broad areas of structure, physical properties, and classification in the context of both bulk and surface (thin films, interfaces) properties.

CHEM 7305. Special Topics in Inorganic and Materials Chemistry. 3 Hours.
Presents selected topics of current importance in inorganic and materials chemistry. May be repeated without limit.

CHEM 7317. Analytical Biotechnology. 3 Hours.
Focuses on the analytical methods used for the characterization of recombinant DNA-derived proteins for human therapeutic use. Combines the description of advanced analytical methods, in particular HPLC and mass spectrometry, with protein chemistry. An important aspect is the development of a method that can identify protein modifications that are present in a product as a result of biosynthetic modifications, contaminants, or degradative reactions. Provides an integrative overview of the role of analytical methods at the different stages of development and production of protein therapeutics including upstream (cell line development, cell culture), downstream (recovery and purifications), formulation development, stability studies, and clinical assay.
CHEM 7710. Laboratory Rotations in Chemistry and Chemical Biology. 0 Hours.
Offers an opportunity for students to gain exposure to research laboratories in the department to help them choose a thesis advisor and project.

CHEM 7730. Advanced Laboratory Methods. 4 Hours.
Seeks to provide intensive practical laboratory training in a chosen thematic area. Students select from organic and medicinal chemistry, physical and materials chemistry, or analytical and biological chemistry. The course involves a common practical training module followed by specialized modules in the chosen concentration area. The practical training features a combination of formal laboratory instruction coupled with rotation through selected research laboratories. Full-time PhD students only.

CHEM 7750. Advanced Problem Solving. 3 Hours.
Designed to provide skills necessary to lead advanced problem-solving case studies. Faculty mentors in one of three thematic areas chosen from organic and medicinal chemistry, physical and materials chemistry, or analytical and biological chemistry assign casework to students for presentation and analysis in group sessions. Students are required to provide rational solutions to complex problems derived from the contemporary literature and engage in dialogue with faculty mentors to justify their analysis. The faculty mentors assign grades to reflect intellectual maturity and ability of the students to display creative, independent thinking. Full-time PhD students who have successfully completed qualifying examinations only.

CHEM 7962. Elective. 1-4 Hours.
Offers elective credit for courses taken at other academic institutions. May be repeated without limit.

CHEM 7990. Thesis. 1-4 Hours.
Offers thesis supervision by members of the department. May be repeated without limit.

CHEM 7996. Thesis Continuation. 0 Hours.
Offers continuing thesis supervision by members of the department.

CHEM 8504. Graduate Seminar. 1 Hour.
Focuses on oral reports by the participants on current research topics in chemistry and chemical biology. May be repeated without limit.

CHEM 8960. Exam Preparation—Doctoral. 0 Hours.
Offers the student the opportunity to prepare for and take the PhD qualifying exams (cumulative exams).

CHEM 8984. Research. 1-6 Hours.
Offers the chance to conduct original research, written thesis thereon, or to the establishment of doctoral candidacy. May be repeated without limit.

CHEM 8986. Research. 0 Hours.
Offers the student the opportunity to conduct full-time research for the master's degree. May be repeated without limit.

CHEM 9000. PhD Candidacy Achieved. 0 Hours.
Indicates successful completion of the doctoral comprehensive exam.

CHEM 9984. Research. 1-4 Hours.
Offers an opportunity to conduct research under faculty supervision. May be repeated without limit.

CHEM 9986. Research. 0 Hours.
Offers the student the opportunity to conduct full-time research for the PhD. May be repeated without limit.

CHEM 9990. Dissertation. 0 Hours.
Offers the student the opportunity to conduct theoretical and experimental research for the PhD degree. Open to chemical biology students. May be repeated once.

CHEM 9996. Dissertation Continuation. 0 Hours.
Offers dissertation supervision by members of the department. Open to chemical biology students. May be repeated without limit.

Biotechnology Courses
Search BIOT Courses using FocusSearch (http://catalog.northeastern.edu/class-search/?subject=BIOT/)

BIOT 5040. Fundamentals of Biochemistry for Biotechnology. 4 Hours.
Covers the fundamentals of biochemistry for biotechnology applications, including protein structure and function, DNA technologies, bioenergetics, and biosynthesis. Requires permission of instructor for those students not majoring in biotechnology.

BIOT 5050. Organic Chemistry for Biotechnology. 4 Hours.
Offers an introduction to organic chemistry that seeks to prepare students for the MS in biotechnology program. Explores the nature of and the biological aspects of organic compounds. Covers the fundamentals of the structure, nomenclature, properties, and reactions of carbon compounds. Also introduces the chemistry of biological molecules, including amino acids, proteins, carbohydrates, and lipids, as well as spectroscopic structure determination known as nuclear magnetic resonance (NMR). Requires prior completion of chemical principles 2/ general chemistry 2 with lab; restricted to biotechnology students or by permission of instructor.

BIOT 5120. Introduction to Biotechnology. 3 Hours.
Provides an interdisciplinary, state-of-the-art introduction to biotechnology to students of the Master of Science in Biotechnology program. 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 5130. Team Skills in Biotechnology. 2 Hours.
Focuses on project management and leadership skills in the biotechnology industry. Emphasizes professional etiquette, teamwork, and team leadership in a diverse, multidisciplinary workplace. Also offers students an opportunity to develop their technical communication skills (scientific writing, public speaking, and technical presentations).

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 a broad spectrum of concepts and issues that are common to biotechnology companies. Provides an overview of innovation, intellectual property, planning, government regulation, and strategic alliances. Introduces biotechnology entrepreneurship; management; and the legal aspects of science, technology, and research in the biotechnology context.
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.

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.

BIOT 5227. Economics and Marketing for Biotechnology Managers. 3 Hours.
Provides a foundation for making financial decisions in the biotechnology industry. Examines accounting methods, forecasting, corporate valuation, exit strategies and drug pipeline economics. Introduces concepts for marketing pharmaceutical products. Restricted to students in the Bouvé College of Health Sciences and in the College of Science or by permission of the program office.

BIOT 5230. 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 5360. Drug Stability. 2 Hours.
Focuses on stability testing of both small molecule and protein drugs. Studies the difference between small molecule and protein drug stability testing. Offers students an opportunity to learn how to explain the International Council on Harmonisation (ICH)-Quality (Q1) guidelines and how they are applied to drug development and approvals.

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. Introduction to 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 biogenerics; 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 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.

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-exipients (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.

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 5821. Introduction to Biopharmaceutical Technologies. 1 Hour.
Covers the basic techniques used to develop a modern-day biopharmaceutical product. Topics include DNA fingerprinting, PCR technology, microarrays, gene probes and targeting, expression of cloned gene products, gene cloning strategies, transgenic species, and mutation creation and analysis. Offers students an opportunity to learn the theory and practical application behind these technologies—how they are done and their power in scientific discovery and treatment. Emphasizes the latest advances in these classic technologies.

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 5964. Experiential Project. 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 (agri tech) 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 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 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 (QSM) 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 QSM may include objectives, manual, organization structural responsibilities, data management, processes, product quality, continuous improvement plans, quality instruments, and document control.

BIOT 6330. Plant Design and Facilities. 3 Hours.
Studies plant design and facilities for the manufacture of both biopharmaceuticals and traditional pharmaceuticals. Covers design-relevant topics related to manufacturing plant design (safety, operations, environmental, and other key considerations), including good manufacturing practice (GMP). Focuses on understanding the links that need to be considered when designing a manufacturing plant to ensure quality of the products produced.

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 resume; and to learn proper interviewing techniques. Explores career paths, choices, professional behaviors, work culture, and career decision making.

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.