AS.410 (BIOTECHNOLOGY)

Courses

AS.410.601. Biochemistry. 4 Credits.
This course explores the essential roles of key biological molecules: proteins, lipids, and carbohydrates. It provides a systematic and methodical application of general and organic chemistry principles, particularly as applied to protein biochemistry. Students examine the structure, function, and regulation of a wide variety of proteins, and also the techniques and laboratory methods used to purify and characterize proteins. Enzyme mechanisms, kinetics and inhibition are covered in detail. Major pathways for carbohydrate metabolism are examined from thermodynamic and regulatory perspectives. This course illuminates the links between the disciplines of chemistry and biology.

AS.410.602. Molecular Biology. 4 Credits.
This course provides a comprehensive overview of the key concepts in molecular biology. Topics to be covered include nucleic acid structure and function, DNA replication, transcription, translation, chromosome structure, and the remodeling and regulation of gene expression in prokaryotes and eukaryotes. Extended topics to be covered include methods in recombinant DNA technology, microarrays, and microRNA.

AS.410.603. Advanced Cell Biology. 4 Credits.
This course covers cell organization and subcellular structure. Students examine the evolution of the cell, chromosome, and plasma membrane structures and behaviors, as well as the mechanics of cell division, sites of macromolecular synthesis and processing, transport across cell membranes, cell dynamics, organelle biogenesis, and cell specialization. Students are also introduced to the experimental techniques used in cell biology to study cell growth, manipulation, and evaluation.

AS.410.604. Cellular Signal Transduction. 4 Credits.
Students examine cell-to-cell signaling that involves hormones and receptors, signal transduction pathways, second messenger molecules, cell adhesion, extracellular matrix, cell cycle, programmed cell death, methylation of DNA, modification of chromatin structure, and mechanisms of the cell. The roles that defects in signal transduction pathways play in the development of cancer and other disease states will be stressed. Prerequisites: 410.603 Advanced Cell Biology or equivalent.

AS.410.606. Emerging Applications in Biotechnology. 4 Credits.
This foundational hybrid graduate laboratory course offers an interdisciplinary and state-of-the-art introduction to investigative approaches and experimental methods in biotechnology. It combines demonstrations of basic laboratory skills with virtual immersive technical training to introduce the application of standard laboratory methods and the use of equipment and techniques central to biotechnology research. Laboratory exercises highlight cutting-edge instrumentation currently used in the field. This course provides broad coverage of topics including cell and molecular biology, genetics, multi-omics, and more, providing students with the essential tools and knowledge to understand various applications in biotechnology research and development.

AS.410.607. The Biotechnology Enterprise. 4 Credits.
This foundational biotechnology course provides the biotechnology student an introduction to the business of biotechnology, from scientific This foundational biotechnology course provides the biotechnology student an introduction to the business of biotechnology, from scientific discovery through product launch and subsequent organizational and scientific pipeline growth. The course introduces the biotechnology student to various disciplines and activities (such as funding, research and development, biomanufacturing, commercialization) for biotechnology enterprise formation, development, and operation. A course-long project involving several assignments that include aspects of a biotechnology organizational simulation is reflected in a student learning organization (SLO) construct. Course Prerequisites: AS.410.603 Advanced Cell Biology or equivalent, or approval of program committee.

AS.410.608. Neurological Disease. 4 Credits.
Knowledge about neuronal structure, function, and circuitry will be applied in order to understand the genetic and molecular bases of a wide variety of diseases that affect the central and/or peripheral nervous systems. This course will incorporate explorations of the recent primary literature, as it relates to specific disease pathologies and treatments, and innovative research tools used in their study. The particular pathologies covered will vary by semester, but will include some of the following: brain/spinal cord injury, epilepsy, stroke, multiple sclerosis, Parkinson's disease, Alzheimer's disease, schizophrenia, depression/bipolar disorder, amyotrophic lateral sclerosis, Huntington's disease, infectious disease, prion-based disease, addiction, autism spectrum disorder, and disorders of neural development. This course is a natural continuation of, and builds upon the foundations provided in, the Neurobiology course. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I, 410.604 Advanced Cell Biology II, 410.628 Neurobiology. SCI

AS.410.609. Developmental Biology. 4 Credits.
This course will explore the cellular and molecular mechanisms involved in the growth and development of complex organisms. In particular, students will be introduced to the mechanisms of fertilization, formation of the early body plan, cell type determination, organogenesis, morphogenesis, and stem cell niches. The course will examine the cellular and morphological changes during development, as well as the molecular signals responsible for development of organisms.

AS.410.610. Epigenetics, Gene Organization & Expression. 4 Credits.
Students use genetic analysis and molecular biology techniques to investigate chromosome organization, chromatin structure, functional genomics, and mechanisms of differential gene expression. Other topics include DNA methylation, silencers, enhancers, genomic imprinting, and microarray analysis. Prerequisites: 410.602 Molecular Biology or equivalent.
Distribution Area: A, A, P

AS.410.611. Vaccinology. 4 Credits.
This course explores the interdisciplinary process of vaccine development, with a dual focus on computational design and biomanufacturing. Students will examine the immunological foundations of vaccination, including the roles of innate and adaptive immunity, and the mechanisms by which vaccines confer protection. The course emphasizes modern experimental and computational strategies in vaccine design that accelerate the identification and optimization of vaccine candidates. Innovative formulation technologies will be discussed alongside advances in delivery platforms such as lipid nanoparticles, needle-free systems, and plant-based or genetically modified food vectors. The course also provides an overview of the biomanufacturing pipeline—from preclinical development and scale-up to formulation, quality control, and regulatory approval. Emphasis is placed on both legacy production platforms and emerging technologies that enable rapid vaccine deployment in response to global health threats. Prerequisites: 410.603 Advanced Cell Biology or Equivalent, previous immunology course.

AS.410.612. Human Molecular Genetics. 4 Credits.
In this course, students learn to use the tools of modern genomics to elucidate phenotypic variation within populations. The course uses human disease (from simple Mendelian disorders to common, complex disorders) to exemplify the types of studies and tools that can be used to characterize cellular pathophysiology as well as to provide genetic diagnostics and therapies. Students become facile with linkage analysis, cancer genetics, microarray analysis (oligo and DNA arrays), gene therapy, SNP studies, imprinting, disequilibrium mapping, and ethical dilemmas associated with the Human Genome Project.

AS.410.613. Principles of Immunology. 4 Credits.
This course covers molecular and cellular immunology. Topics include innate immunity, adaptive immunity, the development and function of B cell and T cell antigen receptors, the major histocompatibility complexes, innate effector mechanisms, humoral and cellular immune responses, and regulation of immune responses. Special topics include immunomodulation, immunodeficiency diseases, autoimmunity, evasion and subversion of the immune system by pathogens, immunotherapies, and vaccines. Students are also introduced to the applied aspects of immunology, which include protein and cellular-based immunoassays. Prerequisites: 410.603 Advanced Cell Biology or equivalent

AS.410.614. Clinicopathologic Foundations of Cancer. 4 Credits.
This course presents an overview of major and minor cancers by body systems. Topics include incidence, signs, symptoms, diagnosis, prognosis, gross and microscopic pathology, molecular biology, surgical techniques, bioengineering applications, and treatment modalities. Clinical cases from history or clinical experience are included. Prerequisites: 410.601 Biochemistry or equivalent, 410.602 Molecular Biology or equivalent, 410.603 Advanced Cell Biology or equivalent. SCI

AS.410.615. Applied Microbiology. 4 Credits.
This course examines the principles of applied microbiology and microbial technology important to clinical diseases and biotechnology. Students are introduced to the general This course examines the principles of applied microbiology and microbial technology important to clinical diseases and biotechnology. Students are introduced to the general concepts concerning the morphology, genetics, and reproduction of these microbial agents. Lectures focus on individual organisms, with emphasis on infectious diseases, biotechnology applications, molecular and biochemical characteristics, and molecular and serological identification methods. Students will also discuss the impact that biotechnology, particularly genomics, will have on the development of antibiotics and vaccines as treatments and preventive measures. Prerequisite: 410.603 Advanced Cell Biology or equivalent

AS.410.616. Virology. 4 Credits.
This course covers the advanced study of viruses with regard to the basic, biochemical, molecular, epidemiological, clinical, and biotechnological aspects of animal viruses primarily, and bacteriophage, plant viruses, viroid's, prions, and unconventional agents secondarily. Specific areas of virology, including viral structure and assembly, viral replication, viral recombination and evolution, virus-host interactions, viral transformation, gene therapy, antiviral drugs, and vaccines, are presented. The major animal virus families are discussed individually with respect to classification, genomic structure, viroid structure, virus cycle, pathogenesis, clinical features, epidemiology, immunity, and control. The viral vectors and their application in biotechnology are discussed. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I. SCI

AS.410.621. Agricultural Biotechnology. 4 Credits.
This course is designed to provide an introduction to the application of recombinant DNA technology in agriculture. We will study methods for the introduction of foreign DNA into plant and animal cells and the generation of stably transformed plants and animals. We will discuss specific examples of the use of transgenic plants and animals in biotechnology, which can provide protection against insects, diseases, and tolerance to specific herbicides. We will also investigate how recombinant growth hormones can result in leaner meat, greater milk yield, and better feed utilization, as well as how transgenic plants and animals can serve as bioreactors for the production of medicinals or protein pharmaceuticals. Because recombinant agricultural products are released into the environment or consumed as foods, we will also discuss environmental safety issues. Prerequisites: 410.601 Biochemistry 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

AS.410.622. Molecular Basis of Pharmacology. 4 Credits.
This course begins by reviewing receptor binding and enzyme kinetics. Various cellular receptors and their physiology are discussed, as are the pharmacological agents used to define and affect the receptor's function. Students study the pharmacology of cell surface receptors and intracellular receptors. Also considered are the drugs that affect enzymes. Prerequisites: 410.603 Advanced Cell Biology or equivalent, 410.604 Cellular Signal Transduction or equivalent.

AS.410.625. Industrial Microbiology. 4 Credits.
This laboratory course covers the principles of various processes associated with the production and recovery of different bioproducts derived from prokaryotes. Topics include the classification of microorganisms, media development, instrumentation, fermentation principles, microbial cell propagation, product recovery, protein purification, and the principles of Current Good Manufacturing Practices. Emphasis is on large-scale production methods and the production of recombinant proteins for diagnostic and clinical applications. Prerequisites: 410.606 Emerging Applications in Biotechnology.

AS.410.627. Translational Biotechnology: From Intellectual Property to Licensing. 4 Credits.
This course provides an extensive overview of a process for the development of a pharmaceutical by a biotechnology company or pharmaceutical company. The course emphasizes the importance of intellectual property, the basic sciences underpinning the development of a product, and the importance of the interaction between a company and the Food and Drug Administration. Students learn to appreciate the importance of quality control and assurance, good manufacturing practices, preclinical and clinical testing, and the lengthy regulatory processes that govern the development, manufacturing, and eventual sale of biotechnological products. Hands-on solving of practical problems and guest lecturers who are experts in the field familiarize students with the intricacies of the process. Prerequisites: 410.607 The Biotechnology Enterprise, or admission to one of the business/regulatory programs

AS.410.628. Neurobiology. 4 Credits.
This course provides a framework for understanding the molecular physiology of neuronal structure, signaling, and circuitry, and how this cellular design is ultimately integrated to achieve higher cognitive functions, such as perception, control of movement, learning, and memory. The course introduces the students to various current neuroscience topics, including but not limited to membrane physiology and electrical excitability of neurons, neurotransmitters and synaptic transmission, signaling at the neuromuscular junction, cellular and higher-order aspects of perception and motor control, molecular mechanisms of neural development, and the molecular basis of learning and memory. This course places particular emphasis on the genetic and molecular bases of a wide variety of neurological and neurodegenerative diseases, such as multiple sclerosis, amyotrophic lateral sclerosis, Parkinson's, and Alzheimer's. Prerequisites: 410.603 Advanced Cell Biology or equivalent, 410.604 Cellular Signal Transduction or equivalent.

AS.410.629. Genes & Disease. 4 Credits.
Because of recent advances, powerful diagnostic tests now detect genetic diseases, and there is promise of gene replacement therapy. In this course, students cover general genetic principles, DNA tools for genetic analysis, cytogenetics, gene mapping, the molecular basis of genetic diseases, animal models, immunogenetics, genetics of development, genetics of cancer, and treatment of genetic diseases. Molecular methods of analysis are emphasized. Prerequisites: 410.603 Advanced Cell Biology or equivalent.

AS.410.630. Gene Therapy. 4 Credits.
In this course, students learn about how gene therapy can be used to treat or prevent genetic disease in the human population. This course is centered around how disease-causing variations in the human genome, including inherited diseases, mutations, epigenetic modifications, and viral infections, can be targeted using molecular technologies. Students will learn about the benefits and limitations of gene therapy and the bioethical concerns involved with this field of research and medicine. Prerequisites: 410.603 Advanced Cell Biology or equivalent.

AS.410.631. Infectious Diseases. 4 Credits.
This course focuses on infectious diseases of mankind and is presented in a system-by-system format. Basic principles of host defense and microbial virulence will be discussed. Practical, up-to-date information on the clinical presentation, symptoms, physical findings, laboratory diagnosis, treatment, and prevention of the general array of diseases caused by bacteria and viruses will be presented. The use of antibiotics, prophylactic agents, and vaccines, along with selected aspects of pathogenesis and epidemiology, will be covered. More cursory coverage will be given to the fungal and parasitic agents of human disease. The student will develop a broad understanding of the many different kinds of infectious processes to which our bodies are subjected on an ongoing basis. Prerequisites: 410.603 Advanced Cell Biology or equivalent.

AS.410.632. Emerging Infectious Diseases. 4 Credits.
This course focuses on emerging infectious diseases from many different perspectives. The maladies addressed range from diseases that have reappeared in altered genetic forms, such as the influenza virus and West Nile virus, to the lethal hemorrhagic fever caused by the Ebola virus. Also discussed is the threat of recombinant and ancient infectious agents, such as Bacillus anthracis, the causative agent of anthrax, which can be used in biological warfare weapons. Opinions from noted scientists and leaders concerning emerging diseases and the prospects for battling them successfully provide scientific and social perspectives. Prerequisites: 410.603 Advanced Cell Biology or equivalent.

AS.410.633. Introduction to Bioinformatics. 4 Credits.
This course explores the theory and practice of biological database searching and analysis. In particular, students are introduced to integrated systems where a variety of data sources are connected through internet access. Information retrieval and interpretation are discussed, and many practical examples in a computer laboratory setting enable students to improve their data mining skills. Methods included in the course are searching the biomedical literature, sequence homology searching and multiple alignment, phylogeny, gene prediction, protein sequence motif analysis and secondary structure prediction, and several genome browsing methods. Introductory analysis using the R programming language is introduced. Computer access is required. Corequisite: 410.602 Molecular Biology or equivalent.

AS.410.634. Practical Computer Concepts for Bioinformatics. 4 Credits.
This course introduces students with a background in the life sciences to the basic computing concepts of the UNIX operating system, relational databases, structured programming, object-oriented programming, and the Internet. Included is an introduction to SQL and the Python scripting language. The course emphasizes relevance to molecular biology and bioinformatics. It is intended for students with no computer programming background but with a solid knowledge of molecular biology. Prerequisites: 410.602 Molecular Biology or equivalent.

AS.410.635. Bioinformatics: Tools for Genome Analysis. 4 Credits.
Large-scale DNA sequencing efforts have resulted in increasingly large numbers of DNA sequences being deposited in public databases. Assigning annotations, such as exon boundaries, repeat regions, and other biologically relevant information accurately in the feature tables of these sequences requires a significant amount of human intervention. This course instructs students on computer analytical methods for gene identification, promoter analysis, and introductory gene expression analysis using software methods. Additionally, students are introduced to comparative genomics and proteomic analysis methods. Students will become proficient in annotating large genomic DNA sequences. This course covers customizing genome browsers with novel data. Next-generation sequence analysis is covered through sequence quality control and assembly and analysis of ChIP-seq and RNA-seq data. Students complete two large sequence analysis projects during the course. Prerequisites: 410.602 Molecular Biology or equivalent; 410.633 Introduction to Bioinformatics.

AS.410.637. Bioethics. 4 Credits.
Students in this course analyze and discuss traditional philosophical theories regarding the nature of the moral good. They then apply these theories to critical issues and selected cases involving experiments with human subjects, organ transplantation, in vitro fertilization, the use of animals in research, the collection and publication of research data, peer review, conflicts of interest, and other topics of current concern.

AS.410.638. Cancer Biology. 4 Credits.
This course provides students with knowledge of the fundamental principles of the molecular and cellular biology of cancer cells. The course explores the role of growth factors and signal transduction mechanisms, oncogenes, tumor suppressor genes, tumor viruses, and angiogenesis in tumorigenesis and metastasis. Special topics include cancer prevention and the array of cancer therapies, which include surgery, chemotherapy, radiation therapy, hormonal therapy, stem cell transplant, and immunotherapies. 410.603 Advanced Cell Biology or equivalent, 410.604 Cellular Signal Transduction or equivalent.

AS.410.639. Protein Bioinformatics. 4 Credits.
Many protein-related bioinformatics databases, query tools, and data analysis software tools have been developed to organize and provide biological annotations for proteins to support sequence, structural, functional, and evolutionary analyses in the context of pathway, network, and systems biology. This course provides a working knowledge of various computer-based tools for protein science research. Topics include protein database searching, protein physicochemical properties, secondary structure prediction, statistical verification, post-translational modification (PTM) and networks analysis, protein-protein interaction (PPI) prediction, and bioinformatics approaches in proteomics. Also covered are graphic visualization of the different types of three-dimensional folds and predicting three-dimensional structures by homology methods, machine learning, and neural network analysis. Computer laboratories complement the material presented in lectures. Prerequisites: AS.410.602 Molecular Biology or equivalent, 410.633 Introduction to Bioinformatics; 410.634 Practical Computer Concepts for Bioinformatics.

AS.410.640. Molecular Phylogenetic Techniques. 4 Credits.
This course will provide a practical, hands-on introduction to the study of phylogenetics and comparative genomics. Theoretical background on molecular evolution will be provided only as needed to inform the comparative analysis of genomic data. The emphasis of the course will be placed squarely on the understanding and use of a variety of computational tools designed to extract meaningful biological information from molecular sequences. Lectures will provide information on the conceptual essence of the algorithms that underlie various sequence analysis tools and the rationale behind their use. Only programs that are freely available as either downloadable executables or as Web servers will be used in this course. Students will be encouraged to use the programs and approaches introduced in the course to address questions relevant to their own work. Prerequisites: 410.602 Molecular Biology or equivalent, 410.633 Introduction to Bioinformatics.

AS.410.641. Clinical & Molecular Diagnostics. 4 Credits.
This course covers basic concepts and practical applications of modern laboratory diagnostic techniques. Topics include the principles of testing methodology, quality assurance, and the application of molecular methods to the clinical and research laboratory. The test methods to be covered include nucleic acid-based methods, such as hybridization, amplification, and sequencing, non-nucleic acid methods, such as HPLC, GLC, and protein analysis, and technologies such as PFGE, ribotyping, RFLP, and serological testing methodologies. In addition to the test procedures, students are exposed to aspects of statistics, quality control, and regulatory issues, as well as applications of these methods to the diagnosis and prognosis of human disease.

AS.410.643. Managing and Leading Biotechnology Professionals. 4 Credits.
The roles of managers and leaders within biotechnology companies undergo constant change. Biotechnology managers and leaders must engage in new and innovative problem-solving strategies, lead a diverse and global workforce, develop partnerships with other businesses, customers, and competitors, manage horizontally and across teams, and utilize technology to a competitive advantage. The student is able to address and cure challenges in his/her own organization and learn methods of implementing change, such as negotiation techniques and motivation. The course includes in-depth discussions of leadership skills, communication, conflict resolution, and goal integration. Students research a biotechnology organization, analyze what is working and not working within its management systems, and suggest alternatives.

AS.410.644. Marketing Aspects of Biotechnology. 4 Credits.
This course introduces students to the strategic and tactical approaches used in the marketing of biotechnological produce and services. Students gain a thorough understanding of the research and planning necessary to develop a marketing plan, the relationship between the marketing and sales functions, the difference between marketing a scientific product and a scientific service, pricing strategies, distribution alternatives, communications, promotion, and the importance of perception. Knowledge of marketing terminology and techniques proves helpful to anyone in the industry.

AS.410.645. Biostatistics. 4 Credits.
This course introduces statistical concepts and analytical methods as applied to data encountered in biotechnology and biomedical sciences. It emphasizes the basic concepts of experimental design, quantitative analysis of data, and statistical inferences. Topics include probability theory and distributions; population parameters and their sample estimates; descriptive statistics for central tendency and dispersion; hypothesis testing and confidence intervals for means, variances, and proportions; categorical data analysis; linear correlation and regression model; logistic regression; analysis of variance; and nonparametric methods. The course provides students a foundation with which to evaluate information critically to support research objectives and product claims and a better understanding of statistical design of experimental trials for biological products/devices.

AS.410.646. Creating a Biotechnology Enterprise. 4 Credits.
This course provides a foundation to start or help guide a young biotechnology company from inception through early growth. Topics include market assessment of innovative technology, patents and licensing, corporate law, preparing a business plan, raising money from angels and venture capitalists, government grants, strategic alliances, sales and marketing, real estate, human resources, and regulatory affairs. The course provides a survey and overview of the key tasks and challenges typically faced by biotech entrepreneurs, their management team, and directors. Students will prepare a business plan for a biotech startup and present the plan to a panel of industry experts and financiers. Leaders from our local bioscience community will be guest lecturers for many of the classes.

AS.410.648. Clinical Trial Design and Conduct. 4 Credits.
Through a case study approach, this course will cover the basic design issues of clinical trials, specifically targeting protocol, case report forms, analysis plans, and informed consent. The design of a specific trial will be studied to illustrate the major issues in the design of a study, such as endpoint definition, control group selection, and eligibility criteria. The course will also cover the analysis plan for a study, including approaches that are central to clinical trials, such as stratified analysis, adjustment factors, and "intention-to-treat" analysis. The planned analytical techniques will include the analysis of correlated data (i.e., clustered data and longitudinal data), survival analysis using the proportional hazards (Cox) Regression model, and linear models. A semester-long project will include the creation of a protocol, case report forms, and informed consent.

AS.410.649. Introduction to Regulatory Affairs - Medical Products. 4 Credits.
Regulatory affairs are comprised of the rules and regulations that govern product development and post-approval marketing. In the U.S., the FDA establishes and oversees the applicable regulations under several statutes, many regulations, and partnerships with legislators, patients, and customers. Biotechnology products may be classified as drugs, biologics, or medical devices. Each type is regulated by a different center within the FDA. This course provides an overview of RA and its effect on product development. Topics include RA history, regulatory agencies, how to access regulatory information, drug submissions, biologics submissions, medical device submissions, GLP, GCP, GMP, and FDA inspections.

AS.410.651. Clinical Development of Drugs and Biologics. 4 Credits.
This course introduces students to the planning and work required to develop potential new drugs and biologics efficiently. Students gain a thorough appreciation of FDA and International Council for Harmonisation regulations and guidelines. Because the course emphasizes the importance of planning before the execution of any of the necessary steps, lectures use a "backward" approach, discussing the final analysis and report before developing protocols. Topics also include an overview of preclinical investigations, NDA/BLA format and content, clinical development plans, product and assay development, the IND, and trial design, implementation, and management. Prerequisites: 410.607 The Biotechnology Enterprise, or admission to one of the business/regulatory programs

AS.410.652. Mammalian Cell Culture Techniques. 4 Credits.
This laboratory course illustrates the use of basic mammalian cell culture techniques for bioscience research and commercial applications. Students are introduced to mammalian cell cultivation methods, including proper use of a biological safety cabinet, sterile technique, cell enumeration and media preparation, cultivation of mammalian cell lines, detection of contamination, cryopreservation, transfection, mammalian cell culture scale-up, and bioassays. This course is designed for students with no prior knowledge or with limited knowledge of mammalian cell culture methods. Prerequisites: 410.603 Advanced Cell Biology or equivalent

AS.410.653. Regenerative Medicine: from Bench to Bedside. 4 Credits.
Regenerative Medicine is a multidisciplinary field developing next-generation therapies that aim to augment, repair, replace or regenerate tissues and organs. This field can be broadly defined by three overlapping technology domains: cell therapy, gene therapy, and tissue engineering. In this course, we will explore these regenerative medicines from bench to bedside. We will discuss relevant biological, engineering, clinical, legal, regulatory, and ethical principles and perspectives to understand the emerging field of regenerative medicine. Specific topics will include induced pluripotent stem cells, bioartificial organs, cell-based immunotherapy, and gene editing techniques such as a CRISPR/Cas-9. In addition to gaining a scientific foundation, students will become familiar with the current state of the industry and the process of bringing these regenerative medicine products to market, including market trends and opportunities, process development and manufacturing, and commercialization challenges and successes. Readings will be drawn primarily from scientific journals. Prerequisite: 410.603 Advanced Cell Biology or equivalent.

AS.410.655. Ethical & Legal Issues in Data Science. 4 Credits.

AS.410.656. Recombinant DNA Laboratory. 4 Credits.
This laboratory course introduces students to methods for manipulating and analyzing nucleic acids. Students gain extensive hands-on experience with plasmid purification, restriction mapping, ligations, bacterial transformations, gel electrophoresis, and applications of the polymerase chain reaction. This course is not recommended for students with substantial experience in these methodologies.

AS.410.658. Biodefense & Infectious Disease Laboratory Methods. 4 Credits.
This laboratory course introduces students to the methods and techniques used for biothreat detection, surveillance, and identification. Using bio simulants and demonstrations, various bio detection platforms will be discussed and presented, such as point-of-detection devices and methods, laboratory-based screening and identification technologies (culture, quantitative PCR, immunoassays, biosensors), and high-throughput environmental surveillance methods. Statistical methods for determining diagnostic sensitivity and specificity and assay validity will be discussed. Laboratory practices and procedures for working in simulated Biosafety Level 2 and 3 environments will be practiced. Students will be introduced to the current bioinformatics genomic and proteomic databases used for select agent (category A, B, and C) identification and characterization. Prerequisites: 410.603 Advanced Cell Biology, 410.615 Microbiology, or approval of academic advisor.

AS.410.660. Immunological Techniques in Biotechnology. 4 Credits.
This laboratory course introduces students to methods for analyzing the immune system. Participants gain experience with various immunologic techniques used in research and biotechnology laboratories, such as immunoassays, immunofluorescence, western blot analysis, SDS-PAGE, antibody purification (protein A), and cytokine assays. Additional topics for discussion include hybridism technology phage antibody libraries, therapeutic monoclonal antibodies, and flow cytometry. Prerequisites: 410.603 Advanced Cell Biology or equivalent, 410.613 Principles of Immunology, or approval of academic advisor.

AS.410.664. Ethics in Emerging Bioscience Technologies. 4 Credits.
This course covers basic ethical notions in the conduct of research into regenerative medicine. Specific case studies involving informed consent, gene editing, organ transplantation, animal research, sources of stem cell lines, the use of placebos, and eugenics will be covered. Students will examine navigating the institutional research boards of different universities, hospitals, and institutions. Authorship, peer review, conflict of interest, and copyright law will be discussed. Students will explore international differences and approaches to the ethics of regenerative medicine and how that affects practice and how patients are treated.

AS.410.671. Gene Expression Data Analysis and Visualization. 4 Credits.
This course will introduce students to various methods for analyzing and interpreting transcriptomics data generated from technologies such as oligonucleotides or two-channel microarrays, qRT-PCR, and RNA sequencing. Topics will include scaling/normalization, outlier analysis, and missing value imputation. Students will learn how to identify differentially expressed genes and correlate their expression with clinical outcomes such as disease activity or survival with relevant statistical tests; methods to control for multiple testing will also be presented. An introduction to linear and nonlinear dimensionality reduction methods and both supervised and unsupervised clustering and classification approaches will be provided. Open source tools and databases for biological interpretation of results will be introduced. Assignments and concepts will make use of publicly available datasets, and students will compute and visualize results using the statistical software R. Prerequisites: 410.602 Molecular Biology, 410.645 Biostatistics, 410.634 Practical Computer Concepts for Bioinformatics

AS.410.673. Biological Processes in Regulatory Affairs. 4 Credits.
This course provides an overview of the biological processes and laboratory techniques utilized for the discovery, development, and evaluation of therapeutic drugs. Students investigate drug development processes, such as gene cloning, culture scale-up, downstream processing, and product purification. Emphasis is placed on the theory and application of laboratory methods used in drug development, such as recombinant DNA techniques, antibody technology, protein purification, immunoassays, high-throughput drug screening, chromatography, electrophoresis cell receptor characterization, pharmacokinetics, drug toxicity testing and evaluation of therapeutic drugs, diagnostics, and vaccines. Prerequisites: 410.607 The Biotechnology Enterprise, or admission to one of the business/regulatory programs

AS.410.674. Food Microbiology. 4 Credits.
Food microbiology encompasses the study of microorganisms that have both beneficial and deleterious effects on the quality and safety of raw and processed meat, poultry, and egg products. Food microbiology focuses on the general biology of the microorganisms that are found in foods, including their growth characteristics, identification, and pathogenesis. Specifically, areas of interest that concern food microbiology are food poisoning, food spoilage, food preservation, and food legislation. Pathogens in products, or harmful microorganisms, result in major public health problems in the United States and worldwide, and are the leading causes of illnesses and death.

AS.410.675. International Regulatory Affairs. 4 Credits.
Pharmaceutical/biotechnology product approval and marketing requires a good understanding of international regulatory affairs in order to successfully compete in today's global marketplace. It is important for tomorrow's leaders to understand and follow the regulatory differences to ensure optimum product development strategies, regulatory approvals, and designs for exports conforming to the foreign regulatory bodies. There are various product development strategies that industry is using to shorten the product development time by conducting preclinical programs outside the U.S., but the strategies require careful planning and interaction with the U.S. and foreign regulatory agencies. With the increased globalization of economy and exports, international regulations will have a bigger impact on the biotechnology business in the future. The course provides a review and analysis of the pharmaceutical/biotechnology product approval processes within the world's major markets. The key strategies required in phases from preclinical product development to marketing approval of the products in Europe, Japan, and the U.S. will be compared and discussed. Students will explore the European Union regulations and their overall importance to international markets. The course will cover the salient features of common technical and regulatory documents required for submission and approval to the leading regulatory bodies in the world, general guidance documents, international harmonization, and the General Agreement on Tariffs and Trade.

AS.410.676. Food And Drug Law. 4 Credits.
The Food, Drug, and Cosmetic Act governs the regulatory approval process for bringing a drug, biologic, medical device, food, or cosmetic to market. The class will discuss administrative procedures followed by the FDA. The course includes an overview of the drug, biologic, and medical device approval processes and the regulation of food and dietary supplements. Students then will be exposed to the enforcement activities of the FDA, including searches, seizure actions, injunctions, criminal prosecutions, and civil penalties authorized under the FD&C Act as well as other statutes, like the Public Health Service Act, which regulates the development and approval of biologics.

AS.410.679. Practicum in Regulatory Science. 4 Credits.
This integrative, case-based course will focus on applying knowledge gained from previous courses in the Master of Science in Regulatory Science program to actual cases from the FDA. For each case, students will assume the role of a regulatory specialist, an FDA reviewer or senior-level policy-maker, or other involved stakeholders, such as a consumer group or an advocacy group. Students will be expected to research, evaluate, and present scientifically and legally justifiable positions on case studies from the perspective of their assigned roles. Students will present their perspectives to the class and be asked to debate the issues with the other students from the perspective of their assigned roles. The major responsibility of the students in this course will be to make scientifically and legally defensible recommendations and to justify them through oral and written communication.

AS.410.680. Finance for Biotechnology. 4 Credits.
Students will build an understanding of the basics of contemporary global monetary systems and the essentials of financial management. This course will include the means to develop a working knowledge of the critical financial factors for decision-makers from the perspectives of key stakeholders. The syllabus is designed to provide students with limited or no background in finance an opportunity to establish an understanding of financial basics and communicate clearly in financial terms when conducting business. This course is uniquely designed to meet the current needs of those leading the global life science industry. Prerequisites: 410.607 The Biotechnology Enterprise, or admission to one of the business/regulatory programs

AS.410.683. Introduction to cGMP Compliance. 4 Credits.
Current Good Manufacturing Practice regulations are the minimum standards for the design, production, and distribution of drugs, biologics, and medical devices in the U.S. and internationally. In the U.S., they are codified at the federal level in the FD&C Act and the Code of Federal Regulations and are actively enforced by the FDA. These regulations, however, only begin to describe the practices used in the pharmaceutic and biotech industries. Additional sources of insight and guidance include the FDA's guidance documents and training manuals, industry trade publications, international compendia, and standards-setting organizations. Students will learn the scope and history of the regulations, industry-standard implementation strategies and "best-practices" approaches, and the FDA's current expectations. Students will also learn to apply practical solutions to the regulatory issues faced in the pharmaceutical and biotech industries today.

AS.410.684. Technology Transfer & Commercialization. 4 Credits.
This course is an introduction to the multidisciplinary aspect involved in the process of translating innovations in technology into commercial use, particularly research discoveries emanating from universities and other nonprofit organizations.

AS.410.686. Regulation of Good Food Production Practices. 4 Credits.
Good Food Production Practices are production and farm level approaches to ensure the safety of food for human consumption. Good food production and post-harvest guidelines are designed to reduce the risk of foodborne disease contamination. These good food production procedures can be tailored to any production system and are directed toward the primary sources of contamination: soil, water, hands, and surfaces. Good food production protocols were developed in response to the increase in the number of outbreaks of foodborne diseases resulting from contaminated food. Students will learn to develop good food production regulatory protocols using case studies.

AS.410.687. Ethical,Legal & Regulatory Aspects of the Biotechnology Enterprise. 4 Credits.
This course provides an overview of the important ethical, legal, and regulatory issues that are critical to the biotechnology industry. The course shares current trends and essential elements of ethics, legal issues, and regulations in a way that allows for an appreciation of how each influences the others. Students will examine core ethical values that guide the practice of science in the biotechnology industry. The course will provide an overview of legal issues, such as protecting inventions, intellectual property, licensing, and the range of regulatory oversight mechanisms with which the biotech industry must comply. This course will review the implications of strategic ethical, legal, and regulatory choices that add value to the biotechnology firm, customers, and society.

AS.410.688. Project Management in Biotechnology. 4 Credits.
Today, many organizations use the approach called project management to handle activities that have a limited life span as opposed to routine, ongoing operations. This course will answer the question, "What do I do to be successful?" The units will provide guidance for project management success by considering each phase in the life of a typical project, from concept to closeout. We will discuss the nature of project management, the structure of projects, working with teams of technical experts, and all the other activities that make project management different from any other discipline. The course will rely heavily on group discussions. Topics will include deciding making decisions, developing a project plan, risk management, team leadership, monitoring and controlling during the project, scope change control, and traditional and modern approaches to project closeout. Concepts presented will be consistent with the Project Management Institute's "Guide to the Project Management Body of Knowledge," the U.S. standard for project management.

AS.410.689. Leading Change in Biotechnology. 4 Credits.
As bioscience companies grow and mature, leadership needs to evolve. Students will learn how to identify their company's position in the "Leadership Life Cycle" and learn how to select the right leadership capabilities based on their current organizational needs. Research shows that the right leaders at the right time dramatically improve organizational success. Bioscience leaders need to lead change to include knowledge paradigm shifts, role of Artificial Intelligence, external environmental research climate. Leaders need skills of resilience, adaptability, and growth mindset. Transformative leadership skills to manage mergers, downsizing, disruptions, remote work, and succession planning will be covered. Use of measurements KPI (Key Performance Indicators) and SMART goals for long-term decision making will be explored.

AS.410.692. Biological & Chemical Threat Response & Forensics. 4 Credits.
This course will explore the world of chemical and biological threats ranging from the foundational scientific principles to the history of chemical and biological warfare. The chemical and biological threat methodologies for detection, identification, medical intervention, and forensic attribution will be discussed from a foreign and domestic defense standpoint. The course material covers a spectrum of topics pertaining to the use of biological and chemical agents, including the historical background of biological and chemical agents in classic and discretionary warfare, the introduction of scientific evidence in criminal proceedings and chain of custody for evidentiary materials in crimes and terrorism, quality assurance in laboratory operations, threat containment, threat characterization, toxicological assessments, decontamination and remediation, health and safety of responders and analysts, risk assessments, protection, and emerging threats. The scientific principles behind the instrumentation used to characterize, assess, and detect threats for forensic analysis of both biological (bacterial, viral, biological toxins, agricultural threats) and chemical (traditional chemical agents, toxic industrial chemicals, incapacitants) agents will be discussed. In depth molecular and chemical mechanisms of action for each chemical and biological agent will be described linking the biochemical and cellular processes responsible for the whole body symptoms observed following exposure to these threats. Medical countermeasures and/or therapeutics used to defend against chemical and biological threats will also be discussed in detail. Prerequisites: 410.603 Advanced Cell Biology, 410.615 Applied Microbiology, or approval of academic advisor.

AS.410.693. Science, Medicine & Policy in Biodefense. 4 Credits.
This course provides a comprehensive introduction to Biodefense. It covers the properties of the Biological Select Agents and Toxins (BSAT); their historical and potential use as biological warfare or bioterrorism weapons, their medical consequences, diagnosis, detection, identification, treatment and prevention. Relevant international and domestic policy issues are explored, along with defense strategies and the nature of existing threats to national security. Prerequisites: 410.603 Advanced Cell Biology, 410.615 Applied Microbiology, or approval of academic advisor.

AS.410.694. FDA Premarket Applications. 4 Credits.
This course provides a comprehensive overview of the U.S. Food and Drug Administration's (FDA's) regulation of the research and development, and marketing of new drugs, biologics, and medical devices. The regulatory requirements for investigational (Investigational New Drug (IND) and Investigational Device Exemption (IDE)) and premarket approval (New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), premarket notification (510(k)), Premarket Approval (PMA)) applications will be addressed. The content and format requirements for the preparation, submission, and maintenance of these applications will be covered.

AS.410.696. Bioassay Development. 4 Credits.
This course will cover methodological approaches to bioassay development for high-throughput screening. Both cell-based (cytotoxicity, cytoprotection, high content imaging, and reporter systems) and cell-free assay systems (enzyme, FRET, time-resolved fluorescence, quenching assays, and immunological assays) will be included with discussion of the potential promise and pitfalls associated with each assay system. Various assay formats, visualization techniques, and current developments in assay technology will be discussed. Project management techniques will be utilized to aid in the process of assay development. Prerequisites: 410.603 Advanced Cell Biology.

AS.410.699. Nanobiotechnology. 4 Credits.
The emerging field of nanobiotechnology utilizes developments in nanotechnology and molecular biology for applications to biomedical science and clinical practice, fundamental cell biology research, and industrial biotechnology. Nanobiotechnology is an interdisciplinary field that exploits the unique functional properties of natural and synthetic biomolecular-sized (nanometer-scale) constructs, such as quantum dots, carbon nanotubes, nanostructured surfaces, liposomes, artificial membranes, and molecular machines for biotechnology and medicine. This course will survey the research, development, and applications of nanotechnology to medical diagnostics, imaging, and therapeutics (including drug delivery and anti-cancer treatments), cell biology and single-cell analysis, nanofluidics, bioassays, biosensors, and bio-inspired engineering. Prerequisites: 410.603 Advanced Cell Biology.

AS.410.700. Food Labeling and Packaging Regulations. 4 Credits.
Regulatory requirements for labeling food and beverage products in the United States are established in the United States Code of Federal Regulation for many elements included on retail packages. These requirements, and their enforcement, are primarily the responsibility of the Food & Drug Administration and/or the United States Department of Agriculture. Food labeling is required for packaged foods sold directly to consumers and includes mandatory features such as a statement of identity, net quantity of contents, nutrition labeling, ingredient statements, allergen labeling, and contact information. Additional features on many food labels, including claims, ad-copy, cooking instructions, bioengineered disclosures statements, and more, can also be subject to specific regulations. This course addresses the regulations for each mandatory feature commonly required on food labels, reviews requirements for claims and marketing statements, and discusses future trends and expectations in food policy and regulation.

AS.410.701. Introduction to Regulatory Affairs-Food, Cosmetics, Alcohol and Tobacco. 4 Credits.
This introductory course is designed to provide students with a high-level understanding of the complex legal and regulatory requirements for foods. The United States will be the primary focus, but other country regulations will be discussed as contrasts. The history of food regulations will be presented along with the progression to current regulations. Discussions regarding the multitude of agencies overseeing regulations and how they interact will be covered. Regulatory impact on product development, supply chains and food safety culture with be among several topics to introduce foundations for effective communication and collaboration with stakeholders to ensure brand and consumer trust.

AS.410.702. AI and Software Regulation in Biomedical Science. 4 Credits.
As artificial intelligence (AI) and software play an increasingly critical role in biomedical science and healthcare, understanding their regulatory landscape is essential. This course explores how the U.S. government, particularly the FDA and other regulatory agencies, oversees AI/ML-based technologies, digital health solutions, and software used in biomedical applications. Topics include the regulation of software as a medical device (SaMD), model-informed drug discovery (MIDD), AI-driven diagnostics and imaging, telehealth platforms, electronic health records, clinical trial technologies, and laboratory information management systems. Additionally, the course examines HIPAA privacy rules, cybersecurity considerations, real-world evidence applications, and evolving policies for AI in regulatory decision-making.

AS.410.703. Strategic Planning for the Biotechnology Enterprise. 4 Credits.
This course is an overview of the strategic planning process of a biotechnology enterprise. It focuses on creating value through strategy formulation and implementation. Topics covered include leadership and technology competencies, performance indicators, intellectual property, corporate governance, regulatory strategy, and appropriating value. The thesis of the course is that effective strategic planning and implementation is critical to success and provides a valuable, structured process for creating enterprise value and managing business risks. Best practices in strategic planning and managing the planning process are also discussed.

AS.410.705. Problem Solving and Innovation. 4 Credits.
Whether tackling small business challenges in a community or creating global initiatives, innovators are problem solvers. This course focuses on equipping students with problem-solving strategies and innovation models necessary to be the solution. Students will develop an understanding of design thinking principles, apply an innovation framework to develop user-driven solutions, practice communicating complex ideas with clarity, and collaborate on cross-functional teams utilizing tools to create positive change in any context. While evaluating real-world problems, students will consider how these techniques can be utilized to turn an innovative idea into an effective solution. Student assessments include driving results for real-world projects, turning their ideas into practical action, and demonstrating their ability to leverage social innovation through community-based and global initiatives.

AS.410.706. Building and Leading Teams in Health Care. 4 Credits.
In order to provide the best care possible, health care professionals are working together more now than ever before. As a result, strong leadership and teamwork skills are becoming necessities in joining the health care field. This course will provide hands-on activities to help students develop problem-solving skills, learn basic negotiation and mediation strategies, and understand their own tendencies as leaders and team members. Using real-world examples, students will explore how strong leadership and teamwork can drive innovative solutions to public health issues.

AS.410.707. The Psychosocial Determinants of Health, Implications on Diagnostics. 4 Credits.
In this capstone course, students will learn basic diagnostic techniques and use case studies to explore the relationship between physiological illnesses and diagnostic output. Through discussions and guided interviews, students will explore the role of psychology and sociology in patient care choices as well as physician recommendations to patients. Students will practice cultural sensitivity through group activities and discussion of pressing public health issues. Students will undertake final group projects that identify needs in the local community and attempt to create solutions that could feasibly be completed with limited resources.

AS.410.709. Cancer Genomics. 4 Credits.
Alterations to the genome are the basis of cancer development, but not all mutations cause cancer. Cancer genomics is the study of cancer cell genomes to elucidate how changes from the normal host genome drive cancer development and how these changes can be targeted for better prevention, diagnosis, and treatment of cancer. In this course, students learn about the multi-step process of tumorigenesis and the confounding development of passenger mutations that challenge the use of genomics to inform therapies. Students will use bioinformatics tools to analyze human cancer genomic data sets to understand the genetic basis of cancer and how to identify genetic signatures in tumors to guide treatment. Topics also include the development of drug resistance, biological sample acquisition, the technologies used to identify and distinguish pathogenic alleles, and how data is stored, referenced, and shared. Discussions about clinical trials and standards of care based on cancer genomics, and about the ethical challenges raised by the use of genomic information to make personal care decisions, are included in the course. Prerequisites: 410.602 Molecular Biology or equivalent; 410.603 Advanced Cell Biology or equivalent; 410.638 Cancer Biology; 410.633 Introduction to Bioinformatics.

AS.410.712. Advanced Practical Computer Concepts for Bioinformatics. 4 Credits.
This intermediate-to-advanced-level course, intended as a follow-on to 410.634 Practical Computer Concepts for Bioinformatics (a prerequisite for this new class), will integrate and expand on the concepts from that introductory class to allow students to create working, Web-based bioinformatics applications in a project-based course format. After a review of the concepts covered in 410.634, students will learn how to create functional Web applications on a UNIX system, using Python and CGI to create forms that can be acted upon, and using the Perl DBI module to interface with MySQL relational databases that they will create and populate to retrieve and present information. This will be demonstrated by building an in-class, instructor-led project. More advanced SQL concepts and database modeling will also be covered, as well as introductions to HTML5, CSS3, and Javascript/JQuery. Class time in the latter weeks of the class will be devoted to individual assistance on student projects and to short lectures on advanced topics. Once again, whenever possible, this course will emphasize relevance to solving problems in molecular biology and bioinformatics. Prerequisites: 410.602 Molecular Biology or equivalent; 410.634 Practical Computer Concepts.

AS.410.715. Medical Device Regulation. 4 Credits.
This course provides a comprehensive introduction to medical devices and how they are regulated by the FDA. Topics that will be covered include an overview of the laws and regulations that govern medical devices, the FDA's organizational structure and responsibilities for medical device regulation, and administrative and legal requirements for medical devices throughout the full product life cycle. Particular focus will be placed on the premarket review, post-market programs enforcement (e.g., Quality Systems Regulation, and FDA inspectional programs). Included will be discussions on the responsible offices and major program requirements and resources. Students will be given various case studies to examine the application of regulations and participate in a 510(k)/PMA workshop, mock inspectional audit, and mock enforcement action. Upon completion of this course, the student will have a working knowledge of the requirements and policies of FDA regulation of medical devices.

AS.410.716. Food Toxicology. 4 Credits.
Food toxicology is the study of the nature, properties, effects, and detection of toxic substances in food, and their disease manifestation in humans. This course will provide a general understanding of toxicology related to food and the human food chain. Fundamental concepts will be covered, including dose-response relationships, absorption of toxicants, distribution and storage of toxicants, biotransformation and elimination of toxicants, target organ toxicity, teratogenesis, mutagenesis carcinogenesis, food allergy, and risk assessment. The course will examine chemicals of food interest, such as food additive mycotoxins and pesticides, and how they are tested and regulated.

AS.410.717. Risk Assessment and Management. 4 Credits.
Risk analysis is composed of three separate but integrated elements, namely, risk assessment, risk management, and risk communication. Risk communication is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties. Risk management is the process of weighing policy alternatives in light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. Students will learn how to integrate risk assessment, risk management, and risk communication using case studies.

AS.410.718. Food Safety Audits and Surveillance. 4 Credits.
Food safety audits provide a credible verification system to the entire food processing industry, including retail environments, meat, fish, and poultry, vegetable, and produce suppliers. Having a HACCP plan in place is often the first step to a successful food safety program, but is not entirely enough to ensure that food safety standards are being adhered to on a consistent basis. In this course, students will learn how to adequately plan for a food crisis situation.

AS.410.719. Regulation of Dietary Supplements. 4 Credits.
This course addresses regulations that govern the manufacturing practices of dietary supplements, labeling compliance, ingredient safety, permitted claims and enforcement/litigation trends, adverse event reporting, the implications of FTC and FDA regulations, emerging issues and solutions, and relevant regulatory practices around the world. This course will enhance students' abilities to manage the regulation of dietary supplements in human food and animal food/feed manufacturing sectors.

AS.410.721. Cannabis Food Safety Regulations. 4 Credits.
The Food Safety Regulation course is designed to provide students with in-depth knowledge and practical skills in ensuring the safety and quality of cannabis-infused food products. The course will cover regulatory compliance, food safety protocols, and the unique challenges associated with the cannabis industry, preparing students for leadership roles in this emerging field.

AS.410.727. Regulatory Strategies in Biopharmaceuticals. 4 Credits.
Given the costly drug development process and the limited resources of emerging biopharmaceutical companies, developing an early regulatory strategy - starting well before clinical trials are initiated - is extremely important for the success of a company. This course will discuss different regulatory strategies that several players of the U.S. biopharmaceutical industry have employed. Students will learn about interacting with regulatory agencies, the orphan drug development, accelerated approval, fast track, priority review, and other regulatory mechanisms, pharmacogenomics and biomarkers, adaptive clinical trials, animal rule, generic drug development, and biosimilars. Using case studies, the impact of these regulatory strategies on drug development, and how these strategies have helped many biopharmaceutical companies will be discussed. At the end of this course, students will better understand federal regulations and the aspects involved in developing efficient regulatory strategies.

AS.410.731. Manufacturing and Processes for Biotherapeutics. 4 Credits.
This course examines manufacturing processes of current and emerging treatments that utilize therapies derived from biological sources as treatment for injury or disease, including cell and gene therapies. Students will become familiar with the state-of-the-art in biomanufacturing, stem cell differentiation, purification of biological materials, drug delivery, and explore challenges/gaps in current biological-based treatments. The course will explore processes at the development, pilot, and industrial scale. Prerequisites: 410.603 Advanced Cell Biology or equivalent; 410.653 Regenerative Medicine: from Bench to Bedside.

AS.410.734. Practical Introduction to Metagenomics. 4 Credits.
The emerging field of metagenomics allows for the study of entire communities of microorganisms at once, with far-reaching applications in a wide array of fields, such as medicine, agriculture, and bioremediation. Students will learn the principles of metagenomics through the exploration of published project data and guided readings of recent literature. Using data from the Human Microbiome Project, students will explore practical analysis tasks, including sequence assembly, gene prediction and annotation, metabolic reconstruction, taxonomic community profiling, and more. Prerequisites: 410.602 Molecular Biology or equivalent, 410.633 Introduction to Bioinformatics, 410.634 Practical Computer Concepts for Bioinformatics.

AS.410.736. Genomic and Personalized Medicine. 4 Credits.
With the advent of rapid, low-cost whole-genome sequencing, the field of personalized medicine is growing from a niche field to becoming the new standard of practice in medicine. Already, oncology makes use of genomic sequencing to inform treatment decisions based on tumor types, and patients are seeking knowledge about their genetic and environmental risk factors to make informed health decisions. This class explores the evolving field of personalized medicine, examining genomics as well as proteomics, metabolomics, epigenetics, and the microbiome. Students will read and discuss new developments in pharmacogenomics, rare and complex diseases, genomics for the healthy person, and the ethical, economic, and social implications of these new technologies. These topics will be approached with a view toward application in clinical practice. Prerequisites: 410.602 Molecular Biology or equivalent; 410.633 Introduction to Bioinformatics.

AS.410.739. Traceability Outbreaks and Recalls. 4 Credits.
When a food is adulterated or misbranded in the US, it needs to be recalled by the producing firm. If an outbreak of foodborne illness occurs, regulators seek to determine the associated food so that it can be recalled. Both outbreaks and recalls rely on records of production and distribution, and food traceability is term used to describe the system that documents the history of a product, from its raw materials through to the final product. This course?covers the principles, regulations, and practices involved in tracing outbreaks of foodborne illness and executing recalls, with a focus on the role that traceability plays. Students will be equipped with the awareness, knowledge and skills necessary to evaluate and use traceability systems in order to protect public health during outbreak and recalls.

AS.410.750. Molecular Targets & Cancer. 4 Credits.
This course will investigate current and potential molecular targets in cancer, including kinases, DNA repair pathways, epigenetic modifications, immunotherapy approaches, and hormonal, metastasis, and angiogenesis targets. Discussion will also include topics on what defines a molecular target and the methods by which they are evaluated. Prerequisites: 410.603 Advanced Cell Biology or equivalent, 410.604 Cellular Signal Transduction or equivalent.

AS.410.751. Drug Design and Chemical Libraries. 4 Credits.
Drug Design and Chemical Libraries explores pharmacological space with an emphasis on disciplines related to drug discovery, and an understanding of the properties desirable in a drug. Medicinal chemistry, natural product chemistry, focused synthetic libraries, and combinatorial chemistry will be covered. The application of Lipinski's rules for assessing drug-like molecules will be discussed in detail, as well as methods for chemical analysis, in silico drug design, molecular modeling, and compound storage and handling. Also, techniques used for assessing and harnessing chemical diversity for drug discovery will be discussed. Students will gain a fundamental understanding of small molecules at the atomic level as well as insights into the structure-activity relationship. Both are critical to the design and synthesis of chemical libraries that efficiently explore therapeutically useful chemical space and to drug design. Prerequisites: 410.603 Advanced Cell Biology or equivalent.

AS.410.752. High Throughput Screening & Automation Lab. 4 Credits.
This course will use hands-on instruction in automated bioassay systems for high-throughput screening as an entry point to covering pertinent aspects of HTS, such as data manipulation, storage, and analysis; liquid handling robotics, microtiter plate washing, manipulation, and barcoding; HTS assay detectors; and automated devices for assay setup, validation, and visualization. Cost considerations, HTS amenable assay systems, and miniaturization and scale-up will also be discussed. Prerequisites: 410.603 Advanced Cell Biology or equivalent, and 410.696 Bioassay Development.

AS.410.753. Stem Cell Biology. 4 Credits.
This course will involve discussion and debate on current topics concerning stem cell biology and the use of stem cells in biotechnology and therapeutics. Topics will include review and discussion of developmental and cell biology, stem cell characteristics, stem cell preparation and therapeutic uses, tissue engineering, global regulatory and ethical issues, and commercialization of stem cell therapy. The course will also detail state-of-the-art techniques for the experimental study of stem cells for biotechnology and biomedical applications. Current peer-reviewed literature and guest experts in the field will provide up-to-date information for discussion. Prerequisites: 410.603 Advanced Cell Biology or equivalent, 410.604 Cellular Signal Transduction or equivalent.

AS.410.780. Stem Cell Culture Laboratory Methods. 4 Credits.
This laboratory course introduces students to the isolation, cultivation, and differentiation of stem cells. Students are introduced to reprogramming and differentiation protocols for various stem cell and cell progenitor types and the basics of tissue engineering. Students will scale up cells into mini-bioreactors for large-scale use. The class will include industry-wide practices in cGMP. Prerequisites: 410.603 Advanced Cell Biology or equivalent, 410.604 Cellular Signal Transduction or equivalent, 410.652 Cell Culture Techniques or approval of academic advisor.

AS.410.800. Independent Research in Biotechnology. 4 Credits.
Students in Center for Biotechnology Education (CBE) MS programs have the opportunity to enroll in an independent research course. This elective course is an option after a student has completed at least eight graduate-level courses and has compiled a strong academic record. Prior to proposing a project, interested students must have identified a research topic and a mentor who is familiar with their prospective inquiry and is willing to provide guidance and oversee the project. The research project must be independent of current work-related responsibilities as determined by the project mentor. The mentor may be a faculty member teaching in the biotechnology program, a supervisor from the student's place of work, or any expert with appropriate credentials. Students are required to submit a formal proposal for review and approval by the biotechnology program committee. The proposal must be received by the instructors ideally one month prior to, and no later than one week after, the beginning of the term in which the student wants to enroll in the course. Students must meet with a member of the program committee periodically for discussion of the project's progress, and a written document, poster, and oral presentation must be completed and approved by the program committee and project mentor for the student to receive graduate credit. Additional guidelines can be obtained from the AAP administrative office. Prerequisites: Full-time students - six classes counting toward degree completion, Part-time students - eight classes counting toward degree completion

AS.410.801. Biotechnology Thesis. 4 Credits.
Students wishing to complete a thesis may do so by embarking on a two-semester thesis project, which includes the 410.800 Independent Research Project and 410.801 Biotechnology Thesis courses. This project must be a hypothesis-based, original research study. The student must complete 410.800 Independent Research Project and fulfill the requirements of that course, including submission of a project proposal, final paper, and poster presentation, before enrolling in the subsequent thesis course. For the thesis course, students are required to submit a revised proposal (an update of the 410.800 proposal) for review and approval by the faculty adviser and biotechnology program committee one month prior to the beginning of the term. Students must meet with the faculty adviser periodically for discussion of the project's progress. Graduation with a thesis is subject to approval by the thesis committee and program committee and requires the student to present his/her project to a faculty committee both orally and in writing. Prerequisites: Successful completion of 410.800 Independent Research Project and a biostatistics class

AS.410.802. Independent Studies in Biotechnology. 4 Credits.
This course is only open to students in one of the programs in the Center for Biotechnology Education and may be taken only after the student has completed seven classes toward degree completion (including all core classes). Before enrolling in this class, interested students must (1) identified a study topic, (2) secure a mentor who is familiar with the prospective inquiry, a recognized expert in the field, and has agreed to provide guidance and oversee the project, and (3) submit a proposal to the Center's program committee (Program Directors and the Center Director) at least one month before the start of the semester in which the student wants to enroll in the course. The study project must be independent of current work-related responsibilities as determined by the project mentor.The goal of the study project is to produce publishable quality data/information. During the semester, students must (1) meet often with the mentor to give updates on progress, (2) periodically interact with a member of the program committee to discuss the project's progress, and (3) submit a written document or file(s) containing the completed work, which must be approved by the program committee and project mentor for the student to receive any credit hours.

AS.410.804. Practicum in Biotechnology Enterprise & Entrepreneurship. 4 Credits.
This course synthesizes the knowledge and skills acquired in the Masters of Biotechnology Enterprise and Entrepreneurship program while offering a real-world examination of a bioscience organization and the issues it faces. Students will form interdisciplinary teams and work with faculty and industry professionals on an authentic and current project from a local bioscience public or private company, an entrepreneurial startup, or a nonprofit organization. This course is only open to students completing the Master of Biotechnology Enterprise and Entrepreneurship program.

AS.410.807. Independent Study in Biotechnology. 4 Credits.