AS.410 (BIOTECHNOLOGY)

AS.410.011. Managing the Medical School Portfolio. 4 Credits.
This year-long course leads students through a series of topics and exercises designed to identify strengths and weaknesses, develop of plan to cultivate skills and ultimately prepare a successful medical school portfolio. To be eligible for this course, students must be officially accepted and enrolled in the MS Biotechnology, concentration in Health Science Intensive Program. You must sign up for this course each semester it is required.

AS.410.302. Bio-Organic Chemistry. 4 Credits.
This course provides a foundation in structural organic chemistry, acid-base chemistry, chemical thermodynamics, and reaction mechanisms. Subjects include Lewis structures, atomic and hybridized orbitals, stereochemistry, inter- and intramolecular forces of attraction, nucleophilic reaction mechanisms, functional groups, and the organic chemistry of biological molecules. Please note that this course does not count toward requirements for the master's degree in biotechnology. Prerequisite: two semesters of college chemistry.

AS.410.303. Foundations in Bioscience. 4 Credits.
This course examines the fundamental underlying scientific concepts utilized in the creation and development of biomedical products. Topics to be covered include the structure and function of biomolecules, such as proteins, enzymes, carbohydrates, lipids, and DNA, as well as the structure and function of cellular components, such as membranes, vesicles, organelles, and the cytoskeleton. In addition, students will examine the complexities of metabolism, DNA replication, transcription, translation, signal transduction mechanisms, apoptosis, the cell cycle, and cancer. Please note that this course does not count toward requirements for the master's degree in either biotechnology or regulatory science and is required as a prerequisite course for some students entering the Master of Science in Regulatory Science. Pre-requisites: one year of college chemistry and one year of college biology or permission of program director. S

AS.410.601. Biochemistry. 4 Credits.
This course explores the roles of essential biological molecules, focusing on protein chemistry while also covering lipids and carbohydrates. It provides a systematic and methodical application of general and organic chemistry principles. Students examine the structure of proteins, their function, their binding to other molecules, and the methodologies for the purification and characterization of proteins. Enzymes and their kinetics and mechanisms are covered in detail. Metabolic pathways are examined from thermodynamic and regulatory perspectives. This course provides the linkage between the inanimate world of chemistry and the living world of 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 I. 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. Advanced Cell Biology II. 4 Credits.
This course is a continuation of 410.603 Advanced Cell Biology and further explores cell organization and subcellular structure. 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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

AS.410.605. Life Science Entrepreneurial Ventures. 4 Credits.
This course focuses on the knowledge, skills, and attitudes that enable entrepreneurs to pursue opportunities in life sciences. Students form teams to experience each step of the entrepreneurial process. The end result is an opportunity assessment of a business idea and the opportunity to pitch the opportunity to an active Venture Capital firm. Emphasis is placed on a hands-on approach with learning supplemented by cases appropriate to each phase of the course. Entrepreneurs and subject experts provide students with an experiential and in-depth examination of the challenges involved in identifying and assessing an opportunity for an entrepreneurial venture, whether in business-to-business or business-to-consumer settings. By entrepreneurial, we refer to those ventures that are high risk/high reward, capital intensive, scalable, and attractive targets for at-risk capital investment. The course's focus is specific to Life Sciences, including biotherapeutics, medical devices, diagnostics, health care information technology (HCIT) and digital health.

AS.410.607. Proseminar in Biotechnology. 4 Credits.
The Biotechnology Proseminar introduces students to issues and challenges facing leaders of public and private-sector organizations as well as t0 communities seeking to achieve shared goals within the biotechnology industry. The course brings together diverse academic, science, and business disciplines (science, regulatory affairs, marketing, finance, legal, ethics, communications, etc.). It explores how these disciplines can be used as powerful tools to create effective leadership and productive collaborations within the industry while improving managerial decision-making.

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: All four core courses; 410.628 Neurobiology.

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: 410.601 Biochemistry, 410.602 Molecular Biology. S
Area: A, A, P

AS.410.611. Vaccinology. 4 Credits.
This course will cover the biological development of vaccines a well as the immunologic concepts and methods for vaccine delivery. Specific topics include new technologies for vaccine development, such as DNA vaccines, recombinant mucosal vaccines, dendritic cells for antigen delivery, novel adjuvants, and methods to increase vaccine stability. Both time-tested and new vaccine delivery systems, such as lipid-based systems, needle-free injection systems, and the use of genetically modified foods, will be discussed. The underlying biological role of the innate and adaptive immune systems will be explored in light of new types of vaccines and delivery systems. Finally, the process of bringing vaccines to market will be covered, including government oversight and licensure. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I, 410.613 Principles of Immunology, or undergraduate 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. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology. S

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: 410.601 Biochemistry; 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

AS.410.614. Pathogenic Bacteriology. 4 Credits.
Lecture and discussion are augmented by guided readings on pathogenic bacteria, with special attention being given to the microorganisms that cause human disease. The course is designed to impart to the student an appreciation and knowledge of the history, epidemiology, cultivation, morphology, serology, biochemistry, and clinical description of the major disease-producing bacteria. Discussion of therapeutic considerations and vaccination will also be included in this course. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, undergraduate microbiology course, or permission of program committee.

AS.410.615. Microbiology. 4 Credits.
This course is an overview of microorganisms 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. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

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. S

AS.410.618. Parasitology. 4 Credits.
The field of parasitology is immense. It covers a plethora of organisms and a multitude of disciplines. This course focuses on the parasites of medical importance that causehuman morbidity and mortality throughout the world. It also introduces the student to the general aspects of parasitology. The developmental biology, natural history, and cell and molecular biology of the major eukaryotic parasites will be discussed. Also, the fundamental mechanisms of host-parasite relationships, diagnosis, pathogenesis, epidemiology, and control strategies will be emphasized. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I. S

AS.410.620. Advanced Topics in Immunology. 4 Credits.
This course integrates and expands concepts learned in an introductory immunology course. Students will be presented with advanced topics in immunology through literature reviews, clinical case studies, and basic science and clinical research papers. Students will also receive support from leading-edge webinars. Topic areas may include, but are not limited to: acellular and cellular innate immunity, adaptive immunity, immune regulation, autoimmunity, immunosuppression, inflammation, neuroimmunology, immunobiology of pregnancy, immunogenomics, tumor immunology, standard and developing therapies for immunopathologies, and immunotherapies. Students will also be introduced to immunological tests used for disease screening and diagnoses. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cellular Biology I, and 410.613 Principles of Immunology or an undergraduate immunology course.

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: All four core courses.

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: 410.303 Bioscience for Regulatory Affairs, OR 410.601 Biochemistry and 410.603 Advanced Cell Biology I or admission to the MS in Regulatory Science OR Master of Biotechnology Enterprise and Entrepreneurship 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: All four core courses.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I. S

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 as well as about the bioethical concerns involved with this field of research and medicine. Pre-requisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Cell Biology I.

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 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 to on an ongoing basis. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

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. Prerequisites: 410.601 Biochemistry. Corequisite: 410.602 Molecular Biology. S

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: 410.601 Biochemistry, 410.602 Molecular Biology.

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: 410.601 Biochemistry; 410.602 Molecular Biology; 410.633 Introduction to Bioinformatics or equivalent.

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. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cellular Biology I , 410.604 Advanced Cell Biology II. S

AS.410.639. Protein Bioinformatics. 4 Credits.
Because the gap between the number of protein sequences and the number of protein crystal structures continues to expand, protein structural predictions are increasingly important. This course provides a working knowledge of various computer-based tools available for predicting the structure and function of proteins. Topics include protein database searching, protein physicochemical properties, secondary structure prediction, and statistical verification. Also covered are graphic visualization of the different types of three-dimensional folds and predicting 3-D structures by homology. Computer laboratories complement material presented in lectures. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.633 Introduction to 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: 410.601 Biochemistry, 410.602 Molecular Biology, 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. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology.

AS.410.642. Economic Dynamics of Change in Biotechnology. 4 Credits.
Governments around the world are beginning a long-term process that reviews and redesigns their health care systems, addressing concerns of innovation, cost, equitable access, and sustained quality of health care. As a result, health care is undergoing significant changes globally in R&D, marketing, pricing, sales, and distribution. This course helps students to understand these processes and the new business opportunities and new business models they will create. It provides some of the basics of macro and microeconomics to clarify how economic and social forces drive changes in the pharmaceutical, biotech, and genetic industry. Emphasis will be placed on the application of economics.

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. Prerequisites: Basic mathematics (algebra).

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.410.647. Research Ethics. 4 Credits.
This course covers the basic ethical issues associated with the responsible conduct of biomedical research using animals and human subjects. Students explore ethical dilemmas and decisions central to these issues, such as the appropriate use of animals in research, misconduct in science, informed consent for human subjects, the role of institutional review boards (IRBs), authorship, data integrity, peer review, intellectual property, and biosecurity.

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. Prerequisites: 410.645 Biostatistics or equivalent (recommended), 410.651 Clinical Development of Drugs and Biologics (recommended).

AS.410.649. Introduction to Regulatory Affairs. 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.410.650. Legal Aspects of Biotechnology. 4 Credits.
This course is a survey of legal topics relevant to a biotech enterprise as it is established, conducts research, and brings innovative products to market. These include property, contracts, regulatory compliance, and patents. Students will be able to analyze common business situations and understand how associated legal risks are managed. Students who have taken 410.687 Ethical, Legal and Regulatory Aspects of the Biotechnology Enterprise will also benefit from this course, as they will analyze contracts, patents, and various statutes and court decisions that impact the biotechnology sector.

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: 410.303 Foundations of Bioscience OR 410.601 Biochemistry and 410.603 Advanced Cell Biology OR admission to the MS in Regulatory Science Program OR Master of Biotechnology Enterprise and Entrepreneurship programs.

AS.410.652. Cell Culture Techniques. 4 Credits.
This laboratory course illustrates the use of basic cell culture techniques for bioscience research and commercial applications. Students are introduced to cell cultivation methods, including proper use of a biological safety cabinet, sterile technique, cell enumeration and media preparation, cultivation of cell lines, detection of contamination, cryopreservation, transfection, cell culture scale-up, and bioassays. This course is designed for students with no prior knowledge or with limited knowledge of cell culture methods. Prerequisites: 410.601 Biochemistry, 410.603 Advanced Cell Biology I.

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. Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology; 410.603 Advanced Cell Biology I.

AS.410.655. Radiation Biology. 4 Credits.
This course will review types of ionizing radiation and their differences, physical and chemical interactions of radiation with key biological molecules, and effects on living matter beginning with molecular and cellular interactions and proceeding to tissue, organ, and organism levels, emphasizing the human system. Radiation's beneficial effects in cancer therapy and medicine, as well as its detrimental and carcinogenic effects, will be discussed. Specific units will consider food irradiation, nuclear power plant accidents, radiation terrorism, everyday sources exposure to the U.S. population, and other practical situations involving radiation. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

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. Prerequisites: 410.602 Molecular Biology. S

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I, undergraduate microbiology or 410.615 Microbiology, or approval of program committee.

AS.410.659. Advanced Recombinant DNA Lab. 4 Credits.
This course is a continuation of Recombinant DNA Laboratory (410.656), intended for those who have completed the introductory course or who have extensive molecular biology laboratory experience. This second course consists of a series of integrated laboratory exercises designed to give students hands-on experience with a variety of molecular techniques. Exercises include molecular cloning, PCR optimization, quantitative real-time PCR, control of gene expression by RNA interference (RNAi), CRISPR, and DNA sequencing. Students will be introduced to microarray analysis and utilization of bioinformatics pipelines. Prerequisites: 410.601 Biochemistry; 410.602 Molecular Biology; 410.656 Recombinant DNA Laboratory; or consent of program committee.

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: 410.601 Biochemistry, 410.6 Molecular Biology, 410.603 Advanced Cell Biology I, 410.613 Principles of Immunology or undergraduate immunology course highly recommended, or consent of program committee. S

AS.410.662. Epidemiology: Diseases in Populations. 4 Credits.
Epidemiology is the study of the patterns and determinants of disease in populations. It constitutes a basic science for public health and biomedical sciences, and its influence can be felt daily through the presentation of data by government, academic, and industry sources. The goal of this course is to present an introduction to epidemiological methods and inferences to biotechnology professionals with little prior experience in public health. Issues in epidemiological inference and the assessment of causal relationships from epidemiological studies will be discussed, introducing the issues of bias and confounding. Throughout the course, emphasis will be placed on the practical use of epidemiology, and lectures will be complemented by case studies and published literature. Examples will be drawn from contemporaneous issues in chronic and infectious diseases. At the conclusion of the course, students should have a greater appreciation for the role of the epidemiologic method and be able to evaluate a basic epidemiologic study, including how the study goals and research questions relate to the design, measures, and inferences. Recommended prerequisites: undergraduate statistics course or 410.645 Biostatistics.

AS.410.663. Current Topics in Molecular & Cellular Biology. 4 Credits.
This course is a literature-driven exploration of current topics and methodologies employed in cell biology research. By closely examining both fundamental and innovative experimental approaches as well as cutting-edge technologies, we will explore a broad range of cell biology topics, many of which most students have previously encountered, at least at some level, in the core courses. The particular subjects and technologies discussed may vary widely from semester to semester; topics may include but are not limited to expression profiling (microarray analysis), "knock-down" with RNAi, the use of transgenic and knockout mice, proteomics and mass spectrometry, microscopy applications (epifluorescence, confocal, and/or EM), characterizing protein/protein interactions, and detection methods for the movement of small molecules and ions. Students enrolling in this course are expected to already have some experience in critical reading and evaluation of the primary scientific literature. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I, 410.604 Advanced Cell Biology II.

AS.410.665. Bioscience Communication. 4 Credits.
Researchers must communicate effectively so their discoveries can be shared with others. In this course, students learn how to communicate their ideas to other researchers, their scientific peers, and investment communities. Students master both written and verbal communication skills, hone their expertise at making both formal and informal oral presentations, prepare poster presentations, and develop their own public speaking strategies. The course also presents personal strategies for improving daily communications, cross-cultural communications, and nonverbal skills. Students improve their written communication, editing, and informal writing skills.Participants also learn effective email strategies for getting their message across and learn how effective writing can improve their chances of getting grant applications approved. Class assignments include preparation of scientific papers, general science writing, oral presentations, PowerPoint presentations, and scientific posters.

AS.410.666. Next Generation DNA Sequencing and Analysis. 4 Credits.
The recent revolution in DNA sequencing technologies has transformed biology within a few short years, decreasing the cost and difficulty of sequencing dramatically to the point where the "$1,000 human genome" is in sight. Armed with complete genome sequences, biologists need to identify the genes encoded within and the variation in these genes between individuals, assign functions to the genes, and put these into functional and metabolic pathways. This course will provide an overview of next-generation sequencing technologies in the historical context of DNA sequencing, the pros and cons of each technology, and the bioinformatics techniques used with this sequence information, beginning with quality control assessment, genome assembly, and annotation. Prerequisites: 410.602 Molecular Biology, 410.633 Introduction to Bioinformatics, 410.634 Practical Computer Concepts for Bioinformatics.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.645 Biostatistics, 410.634 Practical Computer Concepts for Bioinformatics, or an undergraduate computer programming course.

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: 410.303 Bioscience for Regulatory Affairs, OR 410.601 Biochemistry and 410.603 Advanced Cell Biology OR admissions to the MS in Regulatory Science OR Master of Biotechnology Enterprise and Entrepreneurship 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.

AS.410.682. Validation in Biotechnology. 4 Credits.
Understanding validation and applying a comprehensive validation philosophy are essential in today's biotechnology industry. First and foremost, validation allows a company to operate in compliance with the regulations and guidance set forth by the FDA. Perhaps more importantly, it results in equipment assays and processes that are well-understood and robust, less prone to failure, and more cost-effective. This course will introduce the fundamentals of validation, validation master planning, resource management, types of validation and the associated documentation, departmental roles and interactions, and the differences between commissioning and validation. Students will have the opportunity to solve real-world problems, generate actual validation documents, and develop validation program elements that balance regulatory requirements, operational needs, and business expectations.

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.410.685. Emerging Issues in Biotechnology. 4 Credits.
Biotechnology impacts the world and our social, political, and physical environment in ways that many both inside and outside the industry may not fully understand or appreciate. It is critical to ensure that advances in biotechnology be accompanied by important public, political, and social considerations and discussions. This course will cover issues including domestic and global public perception of biotechnology, its benefits and risks, advances in bio-agriculture and genetically modified food, the impact of recombinant therapeutics on the pharmaceutic and health care industry, ways in which advances in biotechnology have and will continue to change our views of what life is, and how the political climate impacts advances in biotechnology discoveries. This highly interactive course will include thought-provoking debate and discussion with industry leaders, both proponents and opponents of biotechnology.

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. Discussions will address the leadership needs of organizations from early-stage, research-based companies through fully integrated biopharmaceuticals. General leadership practices and strategies, moving ideas from the research bench to the consumer, and strategies to prevent failure will all be discussed.

AS.410.690. International Food Regulations. 4 Credits.
As the U.S. food industry expands into international markets, the same companies hoping to sell their products abroad find themselves forced to source ingredients and finished products from foreign suppliers to reduce costs and remain competitive, and to do so, they must comply with a myriad of rules and regulations in both the United States and elsewhere. The most visible enforcement agency at any U.S. border is Customs and Border Protection. However, food importers must also comply with regulations enacted by a host of other government agencies, most notably the FDA, USDA Food Safety and Inspection Service, USDA Animal and Plant Health Inspection Service, and U.S. Fish & Wildlife Service. Food exporters have an even tougher burden, as they need to comply with Customs and food safety, quality, and labeling regulations and certification requirements in both the U.S. and the country that is receiving the goods; this is to mention nothing of the international regulatory infrastructure to which manufacturers must adhere when shipping food internationally. This course will cover each step of the importing and exporting process in detail and explain where to go for key information and guidance.

AS.410.692. Biological & Chemical Threat Response & Forensics. 4 Credits.
This course introduces the methods and techniques used for biological and chemical threat agent characterization; methods of detection, identification, medical intervention, and forensic attribution are also discussed. Lectures cover a broad variety 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, decontamination and remediation, health and safety of responders and analysts, and risk assessments. Laboratory methods employed in the characterization and forensic analysis of biological (bacterial, viral, biological toxins, agricultural threats) and chemical agents (classic military chemical agents, toxic industrial chemicals, and materials) will also be discussed. The course will also provide general overviews of techniques and sample collection for classic biological and chemical agents (PCR, DNA sequencing methods, immunological analyses) and for chemical agents (gas chromatography and mass spectrometry). Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I, undergraduate microbiology, or 410.615 Microbiology.

AS.410.693. Science, Medicine & Policy in Biodefense. 4 Credits.
This course provides a comprehensive introduction to the Concentration in Biodefense. Biological warfare is introduced in its historical context, followed by the properties of the most important biological threat agents, their medical consequences and treatment, diagnostics, and forensics. Relevant international and domestic policy issues are explored, along with defense strategies and the nature of existing dangers to national security. Students should leave the class with a deep understanding of biological warfare and terror agents, the consequences of their potential use, and the available means of protection. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I, undergraduate microbiology, or 410.615 Microbiology.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

AS.410.698. Bioperl. 4 Credits.
This course builds on the Perl concepts taught in 410.634 Practical Computer Concepts for Bioinformatics. Perl has emerged as the language of choice for the manipulation of bioinformatics data. Bioperl, a set of object-oriented modules that implements common bioinformatics tasks, has been developed to aid biologists in sequence analysis. The course will include an overview of the principal features of Bioperl and give students extensive opportunity to use Perl and the tools of Bioperl to solve problems in molecular biology sequence analysis. Prerequisites: 410.601 Biochemistry, 410.60 Molecular Biology, 410.634 Practical Computer Concepts for Bioinformatics.

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 as well as 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 is designed for biotechnology majors and 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: 410.601 Biochemistry; 410.602 Molecular Biology; 410.603 Advanced Cell Biology I.

AS.410.700. Food Labeling and Packaging Regulations. 4 Credits.
The Nutrition Labeling and Education Act of 1990, which amended the FD&C Act, requires most foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. The NLEA and the final regulations to implement the NLEA provide for a number of fundamental changes in how food is labeled, including requiring that nutrition labeling be placed on most foods, requiring that terms that characterize the level of nutrients in a food be used in accordance with definitions established by the FDA, and providing for the use of claims about the relationship between nutrients and diseases or health-related conditions. These changes apply to virtually all foods in the food supply, including, in large measure, to foods sold in restaurants. Food labeling is required for most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, drinks, etc. Nutrition labeling for raw produce (fruits and vegetables) and fish is voluntary.

AS.410.701. Introduction to Food Safety. 4 Credits.
This course is designed to help students understand the legal and regulatory complexities of the regulation of food products in the United States. The prone issues, including regulatory compliance in food safety and Hazard Analysis and Critical Control points (HACCP), are among major issues to control the food-supply. The FDA and the U.S. Department of Agriculture (USDA) have primary responsibility for the safety of meat and food products. Based on the principles of HACCP, FDA-issued seafood regulations went into effect in December of 1997. However, the regulation of food additives, labeling, dietary supplements, genetic modifications, and the protection of the food supply account for the majority of the in-depth food regulation in the United States. The FDA and USDA regulate the safe practice of primary and secondary food products to the American public. Depending upon the source and nature of food product, the method of shipment, advertisement of nutritional values, etc., are being governed by FDA and USDA jurisdictions. The Food Safety Modernization Act overhauls the FDA in food surveillance, enforcing regulations on specific targets, inspection records examination, and exemptions. In this course, students will learn the existing food regulations and safety net by examining the product tracing, performance standards, and preventive control plans toward food safety, security, genetic modifications, dietary supplements, and food labeling. Students will have the option to design projects to propose an effective food safety net that can assist in the supply chain of the nation's food safety and security.

AS.410.702. Biomedical Software Regulation. 4 Credits.
Software continually grows more complex and is becoming relied upon by health care professionals in the treatment of patients. This course describes how the U.S. government regulates software used in delivering health care, including the regulations utilized by the FDA and the Centers for Medicare and Medicaid Services. This course covers a wide range of topics, including FDA regulation of software as a medical device and software validation, medical imaging software regulation, electronic record keeping and software used in clinical trials, laboratory information management systems, and HIPAA privacy rules and security standards.

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.410.704. Social Entrepreneurship in BioScience. 4 Credits.
This course will explore how biotechnology innovators are solving social issues, including developing medical diagnostics, discovering effective and safer medicine, producing cleaner energy, remediating environmental contamination, and improving crop yields. Students will think broadly in terms of the roles required to tackle these social, economic, health, and environmental issues and how these roles can add value to society. <o:p></o:p> This course will cover social entrepreneurship principles and practices in a range of sectors, including corporate social responsibility and public value missions in emerging markets. Students will have the opportunity to define their role in advancing biotechnology as it relates to the top global challenges. <o:p></o:p>

AS.410.705. Problem-solving for Innovation in Health Care. 4 Credits.
Whether tackling small business challenges in a clinic or creating global initiatives, being a health care provider means being a problem-solver. This course focuses on helping students develop the problem-solving strategies and innovation development models necessary for every health care provider to more effectively tackle challenges. Students will develop a working knowledge of design thinking principles and techniques as well as an understanding of how they can be utilized 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. Students will work collaboratively on real-world projects, turn their ideas into practical action, and demonstrate their ability to leverage health care and social innovation to bring change 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.410.708. Medical Product Reimbursement. 4 Credits.
Medical products brought to market need to have a sound payment, coding, and coverage strategy. Medicare covers over 100 million Americans and leads the way in all United States insurance policies. This course will provide insight into how medical product reimbursement works and allow students to understand how the Centers for Medicare & Medicaid Services (CMS) considers medical products for coverage, coding, and payment. We'll review the history of Medicare coverage and the regulations. We'll focus primarily on strategies used to get reimbursement for medical products—both at the national and local levels.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cellular Biology I. 410.638 Cancer Biology is recommended.

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: 410.601 Biochemistry; 410.602 Molecular Biology; 410.634 Practical Computer Concepts. S

AS.410.713. Advanced Genomics and Genetics Analyses. 4 Credits.
The next generation of array and sequencing technologies provides the ability to investigate large quantities of genomics information with higher sensitivity, greater throughput, and lower costs. This also introduces new challenges in data management, novel algorithmic approaches, and general interpretation. This course builds on the topics in 410.671 Gene Expression Data Analysis and Visualization to address analysis of both genetic variation and genomics content, including splice variants, single nucleotide polymorphisms (SNPs) with family-based and case/control genome-wide association, copy number variation, somatic and germline single nucleotide variants, tumor clonality and ploidy estimates, and transcription factor binding sites. Data types will include array, RNA sequencing, and DNA sequencing (targeted and whole exome) with sequence assembly methods?presented,?such as de novo and reference-based.?Prerequisites: 410.602 Molecular Biology, 410.633 Introduction to Bioinformatics, 410.671 Gene Expression Data Analysis and Visualization.

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. Postmarket Surveillance. 4 Credits.
While review of devices prior to marketing plays a significant role in ensuring that patients and providers have access to safe and effective medical devices, continued post market surveillance of devices after they reach the market is crucial to protecting public health. The Office of Surveillance and Biometrics (OSB) within the FDA's Center for Devices and Radiologic Health (CDRH) is responsible for overseeing the continued post market surveillance of medical devices. This course covers regulatory requirements for industry once a device reaches the market as well as the post market surveillance requirements and activities performed by the FDA. Students will discover the multifaceted approach to medical device post market surveillance through topics including Post market Surveillance Studies, 522 Studies, Registries, Medical Device Reporting (MDR) & Complaint Handling, the MedSun Program, Medical Device Tracking, Unique Device Identification (UDI), MDEpiNet, and Real-World Data/Evidence & the National Evaluation System for health Technology (NEST).

AS.410.720. USDA Regulation of Food Safety, Wholesomeness, and Labeling. 4 Credits.
This course addresses the USDA, FSIS regulatory processes that ensure a safe, wholesome, properly labeled food supply. Students will (1) review the history of applicable food law and the rise of the Food Safety Inspection Service as a regulatory agency, (2) evaluate the statutory definitions of adulterated and misbranded as the basis for regulatory requirements, and (3) apply those regulatory requirements to the preparation, packaging, and holding of meat and poultry products. Coursework is built around a project in which students prepare a series of documents required to meet food safety, wholesomeness, and labeling requirements. Course work concludes with a review of FSIS enforcement authority and state inspection programs.

AS.410.721. In Vitro Diagnostic Regulation. 4 Credits.
This course provides a comprehensive overview of in vitro diagnostic (IVD) devices and how they are regulated by the U.S. Food and Drug Administration (FDA) and by international organizations such as the European Union (E.U.). Topics that will be covered include: (1) a summary of the U.S. and international laws, regulations, and policies that govern IVD devices, (2) administrative and legal requirements and resources for IVD devices throughout the full product life-cycle, (3) types of IVD devices, (4) coverage and reimbursement of laboratory tests, and (5) current issues and developments. Upon completion of this course, the student will have a working knowledge of the requirements and policies of the regulation of IVD devices.

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.410.728. Managing Innovation in the Life Sciences. 4 Credits.
Innovation is the creation of value from new ideas, concepts, methods, materials, and organizational structures. Life sciences organizations that seek to create value for their stakeholders must do so using available capital resources, including financial capital, human capital, intellectual capital, and physical capital. They should manage those resources to gain leverage and maximize value realized. They then seek to defend and control the value created. Why, then, do most organizations treat innovation (and innovators) in ways similar to the body's immune system (i.e., by identifying the innovators, isolating them, "killing" them, and ejecting them from the organization? This course will explore innovation, invention, and value creation as a driving force in the biotechnology or life sciences enterprise as well as the ways in which managers should plan to take full advantage of innovation as the only true competitive weapon for long-term success. A special emphasis will be placed on innovation as applied to life science applications (biotechnology, medical devices, health care delivery, drug discovery, development and packaging, bioinformatics, etc.). Topics include invention, ROI, disruption, creative destruction, types of innovation, technology brokering, organizational structures that foster innovation, planning, and managing for innovation. Students are required to read extensively, participate actively in discussions, do case studies, and develop a convincing pitch for an innovation project.

AS.410.731. Bioprocessing and Scale-up Laboratory. 4 Credits.
This course will provide students with hands-on experience in the process development of biological products from a cell bank through purification. Students will develop two products: one produced in bacteria and the other in a mammalian cell culture system. Students will optimize growth conditions on a small scale and then produce the biologic in a bioreactor. Students then purify the product after optimizing purification conditions. Topics to be covered include microbial fermentation, cell cult production, bioassays, product purification, and the regulatory, engineering, and business principles associated with the scale-up of a biologic product. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

AS.410.732. Funding a New Venture. 4 Credits.
In this course, we study the nuts and bolts of putting together a new company and explore financial markets and the economics of life science companies. The course includes weekly discussions based upon textbook and outside reading materials; the latter are often topical and speak to the issues of the day and how they may affect investor's confidence and funding. Video presentations on the part of all students are required. We will examine the roles of corporate officers and the venture community. The students will learn what makes the startup process both attractive and difficult, and will work through that process in a realistic manner.

AS.410.733. Comparative Animal Physiology. 4 Credits.
This class examines animal physiology from an evolutionary and comparative viewpoint. The goal is to examine the commonalities and unique differences in how various animal organisms address the necessary life functions. Topics will include homeostatic mechanisms as an overarching theme, integrating the following systems: nervous, endocrine, muscle, circulatory, defense, respiratory, excretory, fluid and acid-base balance, digestive, energy balance and thermal, and reproductive.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 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; 410.633 Introduction to Bioinformatics.

AS.410.737. Promotion of Biomedical Products: Regulatory Considerations. 4 Credits.
This course will provide students with knowledge of the basic laws and regulations affecting the advertising and promotion of drugs, biologics, and medical devices. This course is specifically designed to illustrate how the law and regulations are applied on an everyday basis using case study examples as well as to provide historical context on regulations and strategies used in the past.

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: 410.601 Biochemistry, 410.602 Molecule Biology, 410.603 Advanced Cell Biology I. Recommended: 410.604. Advanced Cell Biology II.

AS.410.751. Chemical Libraries & Diversity. 4 Credits.
Chemical diversity and "pharmacological space" will be studied, with emphasis being placed on disciplines related to drug discovery. Medicinal chemistry, natural product chemistry, focused synthetic libraries, and combinatorial chemistry will be covered. Lipinski's rules for 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. In addition, techniques used for assessing and harnessing chemical diversity for drug discovery will be discussed. Prerequisites: All four core courses or approval of program committee.

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: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology, 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. Current peer-reviewed literature and guest experts in the field will provide up-to-date information for discussion. Prerequisites: 410.601 Biochemistry, 410.602 Molecule Biology, 410.603 Advanced Cell Biology I, 410.604 Advanced Cell Biology II. S

AS.410.756. Grants and Federal Funding for Biotechnology Enterprises. 4 Credits.
This course is designed to help students working for life sciences companies understand the fundamentals of obtaining government funding for product/technology research and development. While the emphasis will be on grant funding from the National Institutes of Health, other Federal and state funding mechanisms will also be covered. Students will learn how to search for funding opportunities and receive an overview of the NIH funding mechanisms as well as explore the background and history of the Small Business Innovation Research (SBIR) program. The course will provide insights on preparing an SBIR proposal and submission procedure. Fundamentals of government contracting law will also be covered.

AS.410.777. Next Generation Alternative Energies. 4 Credits.
In this course, students are introduced to the current technologies used in the production of alternative energies. These technologies include first and second-generation biomass biofuels, carbon-neutral synthetic fuels, microbial fuel cells, algae fuel, and biological hydrogen production. The study of biomass biofuels will include technologies using agriculture, cellulosic, and waste feedstocks. Carbon-neutral synthetic fuels will include biobutanol, acetone-butanol-ethanol, methane, and biogas. Students will study the methods used to produce these types of fuels, the by-products produced, and the sustainability of energy production. In addition to studying the techniques used to produce alternative energy, students will also discuss the economic and environmental impacts of producing and using alternative energy sources. Prerequisites: 410.601 Biochemistry, 410.602 Molecular Biology, 410.603 Advanced Cell Biology I.

AS.410.780. Stem Cell Culture Laboratory Methods. 4 Credits.
This laboratory course introduces students to the cultivation and differentiation of stem cells. Students are introduced to cell cultivation methods for three types of stem cells 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: 410.601 Biochemistry; 410.602 Molecular Biology; 410.603 Advanced Cell Biology I; 410.652 Cell Culture Techniques or permission of program committee.

AS.410.799. Current Topics in Regulatory Policy. 4 Credits.
The ability to successfully navigate the intersections of law, regulation, guidance, and policy has never been more critical to the success of entities engaged in medical product development and commercial marketing. The entities that make up this industry are very sophisticated in their abilities to innovate at a blazing speed. In contrast, regulators must use a regulatory model that evolves and adapts much slower than their industry counterparts. As a result, regulators are relying more heavily on policy to drive their strategy, actions, and outcomes. Therefore, a clear understanding of regulatory policy is an essential consideration for individuals engaged in the medical product development industry. <o:p></o:p> This course provides an introduction to several key areas of government regulatory policy (both old and new) and regulatory science. The topics covered in this course will serve as a road map for students who want to successfully navigate within this complex and changing regulatory model. <o:p></o:p>

AS.410.800. Independent Research in Biotechnology. 4 Credits.
Students in the biotechnology program 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 Advanced Academic Programs office no later than one month prior to 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 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. Prerequisite: All core courses and four additional courses.

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 410.645 Biostatistics.

AS.410.802. Independent Studies in Regulatory Science. 4 Credits.
This course is open only to students in the MS in Regulatory Science program or the MS in Biotechnology with a concentration in Regulatory Affairs and may be taken only after the student has completed 5 courses and has compiled a strong academic record. Prior to proposing a project, interested students must have identified a study topic and a mentor who is familiar with their prospective inquiry and who is willing to provide guidance and oversee the project. The study project must be independent of current work-related responsibilities as determined by the project mentor. The mentor may be a faculty member, a supervisor from the student's place of work, or any expert with appropriate credentials. The goal of the study project should be a 'publishable' article. Students are required to submit a formal proposal for review and approval by the regulatory science program committee. The proposal must be received by the Advanced Academic Programs office no later than one month prior to the beginning of the term in which the student wants to enroll in the course. Students must interact with a member of the program committee periodically for discussion of the project's progress, and a written document 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.

AS.410.803. Regulatory Science Thesis. 4 Credits.
Students wishing to complete a thesis may do so by embarking on a two-semester thesis project, which includes the 410.802 Independent Studies in Regulatory Science Project and 410.8 Biotechnology Thesis courses. This project must be either a hypothesis-based or research question-based original research study. The student must complete 410.802 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 410.802 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: All required regulatory science courses and three elective courses, which must include 410.802 Independent Studies in Regulatory Science and, if hypothesis-driven, 410.645 Biostatistics.

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.410.806. Independent Studies in Biotechnology Enterprise and Entrepreneurship. 4 Credits.
This course is open only to students in the MBEE or the MS in Biotechnology with a concentration in Enterprise and may be taken only after the student has completed five courses and has compiled a strong academic record. Prior to proposing a project, interested students must have identified a study topic and a mentor who is familiar with their prospective inquiry and who is willing to provide guidance and oversee the project. The study project must be independent of current work-related responsibilities as determined by the project mentor. The mentor may be a faculty member, a supervisor from the student's place of work, or any expert with appropriate credentials. The goal of the study project should be a 'publishable' article. Students are required to submit a formal proposal for review and approval by the enterprise/regulatory program committee. The proposal must be received by the Advanced Academic Programs office no later than one month prior to the beginning of the term in which the student wants to enroll in the course. Students must interact with a member of the program committee periodically for discussion of the project's progress, and a written document 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.