KGI HENRY E. RIGGS SCHOOL OF APPLIED LIFE SCIENCES

Master of Science in Human Genetics and Genomic Data Analytics (MSGDA) Curriculum

Students in the MSGDA program are required to take a minimum of **63.5 credits** over the course of two years of study. This coursework is comprised of required courses, a capstone project, as well as the following:

- 1. 5 credits of Ethics (Either **PDEV 5230** or **PDEV5240)**
- A **400-hour Internship**
- 6 credits of Electives to be chosen from 3 offered concentrations and will be taken in Year 2 **(Clinical Decision Support, Clinical Trial Support, Assay Development).**

Year 1 FALL CORE COURSES – 13.5 Credits

BUS5000: Introduction to Bioscience Industries (3 credits)

Instructor: Steven Casper PhD

The course will introduce students to industry dynamics within the bioscience industries, with a particular emphasis on commercialization dynamics and entrepreneurship. We will examine industry dynamics within different segments of the life science industries, such as therapeutics, diagnostics, and medical devices. Students will learn to evaluate common business models employed by life science firms, and will learn how to employ a variety of analytical tools used to assess the attractiveness of a variety of life science marketplaces. Common tools used for market research, such as survey methods and qualitative interview-based techniques, will be introduced. The course will introduce these topics to students through case studies of bioscience firms. Assessment of learning will be achieved through class participation, reflective essays and business memos, problem sets, and, most importantly, a team-based, client sponsored market research project. (ALS/MEB 359)

GENE 5120: Bioinformatics in Python (3 Credits)

Instructor: J. Cesar Ignacio Espinoza PhD

This course provides an introduction to bioinformatics, emphasizing sequence analysis. By the end of the course, students will comprehend the role of bioinformatics in addressing both hypothesis-driven and hypothesis-generating questions within the life sciences. Covered topics

include various algorithms for sequence alignment and deriving biological insights from them. Additionally, the course goes beyond mere sequence comparisons to explore certain aspects of proteomics. A substantial coding component is incorporated into the curriculum, allowing students to experience the process of building a software tool from scratch, given that it is a project-oriented class.

GENE 5190: MSGDA Journal Club (0 Credits)

Instructor: Barbara K. Fortini PhD

This journal club is a one-hour, weekly course with student-led presentations on timely topics in this rapidly evolving field. The intent is to raise the academic interest and scholastic skills of students through critical review of the literature and presentations. The series encourages life-long learning, critical analysis of the literature, and serves as preparation for capstone projects and development of presentation skills. This course will continue for two years, giving first and second-year students the opportunity to increase interaction, learn from each other, hear varied perspectives, and build professional and collegial bonds. The colloquium is not graded but students will be evaluated on their active participation and attendance. We will also be discussing professional development and the clinical genomics industry landscape.

GENE 5200: Human Molecular Genetics (3 Credits)

Instructor: Barbara K. Fortini PhD

Human Molecular Genetics will explore the structure and function of human genes and the connection of genotype to phenotype. The scope of this course will include DNA structure, chromosome structure, DNA replication and repair, the cell cycle, meiosis, mitosis, and gene expression and regulation. Mendelian and non-Mendelian inheritance will be discussed on the scale of individuals and populations. We will examine the role of mutation and variation in the etiology and diagnosis of disease, especially identifying and mapping causal genes. This course will also feature molecular biology techniques used to replicate DNA sequence, modify DNA molecules and genotype individuals.

GENE 5240: Genetic Disease Mechanisms (1.5 Credits)

Instructor: Barbara Bailus PhD

Genetics plays a fundamental role in the pathogenesis of most human disorders. This course is designed to provide an overview of genetic mechanisms that lead to human disorders, including their etiology, molecular basis, and mode of inheritance. For each mechanism, representative disorders will be presented including key symptoms and genetic testing. (GENE 340)

MATH 5020: Clinical Biostatistics (3 Credits)

Instructor: Rachaline Napier PhD

This course provides a basic primer in statistical methods commonly used in the design of clinical trials. Topics covered include data reporting and descriptive statistics, probability, estimation, hypothesis testing (parametric, non-parametric, and categorical), multi-sample inference, regression and correlation. Sample size and power estimation methods will be developed for various hypothesis testing scenarios. (ALS 434)

MATH 5100: Data Analytics in Python (1.5 Credits)

Instructor: Anna Iwaniec Hickerson PhD

Using the Python programming language, students will gain practical skills in processing and analyzing applied bioscience data, for the purpose of extracting meaningful information from publicly available and other datasets. A series of practical exercises will cover (a) processing data using mathematical tools to isolate relevant information, (b) analyzing processed data to generate insights using algorithms, (c) comparing data sets to determine statistical significance, and (d) creating visualizations to communicate results of processing and analysis.

Year 1 SPRING CORE COURSES – 18.5 Credits

GENE 5130: Bioinformatics in R (1.5 Credits)

Instructor:

Bioinformatics integrates core principles from biology, computer sciences, and statistics to extract meaningful information from large-scale genomic data. This course explores the fundamental principles of bioinformatics using the R software environment. Although the course focuses on transcriptomic data analysis, the principles covered can be applied to many other types of large-scale data encountered in the life science industries. Students will gain hands-on experience retrieving information from biological databases, data cleaning for bioinformatic workflows, executing bioinformatic packages, and visualizing genomic data.

GENE 5150: Human Genomics NGS Lab (2 Credits)

Instructor:

This course is a companion to the Human Genomics lecture and literature-based course GENE 5250. In this lab, students will prepare genomic DNA extractions from human cells and quantify the amount and quality of nucleic acid preparations. Students will identify variants within DNA sequencing reads. Students will carry out an RNA-seq experiment and perform the downstream data analysis pipeline to identify differentially expressed genes. Lastly, students will conduct a human genome sequencing project, including sequence alignment and variant calling. In addition to laboratory skills, students will gain experience in sample documentation, pipeline documentation, and scientific report writing.

GENE 5191: MSGDA Journal Club (0 credits)

Instructor: Barbara K. Fortini PhD

This journal club is a one-hour, weekly course with student-led presentations on timely topics in this rapidly evolving field. The intent is to raise the academic interest and scholastic skills of students through critical review of the literature and presentations. The series encourages life-long learning, critical analysis of the literature, and serves as preparation for capstone projects and development of presentation skills. This course will continue for two years, giving first and second-year students the opportunity to increase interaction, learn from each other, hear varied perspectives, and build professional and collegial bonds. The colloquium is not graded but students will be evaluated on their active participation and attendance. We will also be discussing professional development and the clinical genomics industry landscape.

GENE 5250: Human Genomics (3 Credits)

Instructor: Barbara K. Fortini PhD

Human Genomics will explore the structure and function of the human genome. This course will begin by examining the sequence of the human genome and the dynamic structure of chromatin in human cells. It will also focus on technologies used to determine the DNA sequence and functional state of chromatin regions in living cells, including next generation sequencing, GWAS, and ChIP-seq. Furthermore, students will explore genome-wide data sets in order to predict phenotypes in populations and individuals. Variation in the population will be explored for the purposes of mapping complex traits, variant curation and genetic anthropology. (GENE 360)

GENE 5260: Clinical Cancer Genomics (3 Credits)

Instructor(s): Rachelle Manookian & Lauren Gima

Genetic cancer risk assessment is an interdisciplinary standard-of-care practice that uses a growing arsenal of genetic and genomic tools and empiric risk models to provide precision prevention and management for individuals and their families. Identifying hereditary cancer predisposition through genomic cancer risk assessment allows for intensified measures to prevent cancers or detect them at an earlier, more treatable stage, and both germ line and somatic/tumor testing may guide precision cancer therapies. This course provides a foundation of knowledge and skills in the multidisciplinary specialty practice of genetic cancer risk assessment and counseling. The course designed is a blended, flipped-classroom model that combines recorded core distance-learning didactic modules developed by recognized experts in the field of cancer genomics with topic-specific discussion board engagement between learners and faculty, and weekly face-to-face application of new knowledge into practice through individual and team-centered case-based learning and cancer risk counseling skills development. (GENE 370)

GENE 5270: Medical Genetics (3 Credits)

Instructor(s): Melissa Randall Chan & Katheryn Grand

This course is intended to provide the trainee with a comprehensive curriculum on major topics in medical genetics. Various applications of genetics to human health, including studies of the inheritance of diseases in families, mapping of disease genes to specific locations on chromosomes, analyses of the molecular mechanisms through which genes cause disease, diagnosis and treatment of genetic disease, and genetic counseling, in which information regarding risks, prognoses, is communicated to patients and their families. This course will also cover the social implications of genetic disease and diagnosis. These principles will be illustrated using examples from clinical practice. Emphasis in lectures will be placed on molecular medicine with discussion of the most up-to-date clinical diagnostics and therapeutics. (GENE 380)

GENE 5280: Biochemical Genetics (1.5 Credits)

Instructor(s): Nicole Choy & Kayla Lam-Little

Metabolic disorders and biochemical disorders are an area of clinical genetics that is increasing in importance and complexity. This course provides an overview of the major groups of metabolic disorders, specific metabolic disorders, their metabolic pathways, the genes involved, and treatment. This course utilizes lectures and case-based examples and learning assignments. There will be an emphasis on how a diagnostic process unfolds, understanding the entire picture, what characteristics lead the clinician to certain tests and studies, what does the results mean, where do you go next. This course will focus on modes of inheritance, recurrence risks, pathogenesis, screening options, diagnostic testing, natural history, treatment options, psychosocial and genetic counseling implications.

MATH 5220: Data Analytics in R (1.5 Credits)

Instructor:

Students will learn the fundamentals of the R programming language through practical exercises using applied life science data. Major concepts covered include: (a) fundamentals of programming including syntax and data types, (b) importing data from varying sources, (c) sorting and filtering data to extract relevant information, (d) applying statistics and mathematical tools to analyze the data, and (e) creating visualizations to communicate results of processing and analysis.

REG 6520: Clinical Trial Design and Literature Evaluation (3 Credits)

Instructor: Barbara Bailus PhD

This course is a practical application of biostatistics in the context of designing clinical or research protocols and reading research literature. (ALS 436)

KGI HENRY E. RIGGS SCHOOL OF APPLIED LIFE SCIENCES

Year 2 FALL CORE COURSES – 12 to 13.5 Credits

GENE 6130: DNA Sequencing and Variant Analysis (3 Credits)

Instructor: Barbara Bailus PhD

This course provides a detailed understanding of DNA sequencing technologies and genome sequence interpretation. Students will learn about the variety of sequencing techniques and platforms, including generated data types and file formats. Emphasis will be placed on the relative strengths of genotyping arrays, targeting sequencing, whole genome sequencing, and whole exome sequencing strategies in study design and clinical practice. The second half of the course will focus on individual and family-based sequencing projects, including the identification of single nucleotide polymorphisms, indels, copy number variants, and chromosome rearrangements and the determination of variant significance. Other topics may include personal identity testing, molecular anthropology, and somatic single cell sequencing. (GENE 430)

GENE 6140: Functional Genomics (3 Credits)

Instructor(s): Barbara K. Fortini PhD & J. Cesar Ignacio Espinoza PhD

This course will provide in-depth and hands-on training in using genome-wide data to answer functional questions in human biology. Topics will include GWAS, transcriptomics, ChIP-seq, and chromatin conformation capture techniques. The course will also include a discussion of discoveries made through major genomics initiatives such as the ENCODE project, TCGA, and the Epigenetics Roadmap.

GENE 6190: MSGDA Journal Club (0 Credits)

Instructor: Barbara K. Fortini PhD

This journal club is a one-hour, weekly course with student-led presentations on timely topics in this rapidly evolving field. The intent is to raise the academic interest and scholastic skills of students through critical review of the literature and presentations. The series encourages life-long learning, critical analysis of the literature, and serves as preparation for capstone projects and development of presentation skills. This course will continue for two years, giving first and second-year students the opportunity to increase interaction, learn from each other, hear varied perspectives, and build professional and collegial bonds. The colloquium is not graded but students will be evaluated on their active participation and attendance. We will also be discussing professional development and the clinical genomics industry landscape.

GENE 6900: MSGDA Capstone Project I

Instructor: Barbara K. Fortini PhD

This sequential course is designed to help students successfully complete the capstone requirement for the MSGDA program. In this course, students will gain an understanding of how to conduct genomics research through designing a research project, conducting the research, analyzing collected data, and presenting a written summary and poster presentation to document the study findings. Capstone projects are designed and completed under the guidance of a capstone advisor and capstone committee. (GENE 490)

PDEV 5230: Healthcare Ethics (FALL ONLY) (1.5 Credits)

Instructor: Joshua Morris

As practitioners and leaders of tomorrow's healthcare systems, KGI graduates will be at the forefront in the application of new treatments, diagnostics, pharmaceuticals, biologics, and medical devices. They will be confronted with ethical issues concerning the research and use of related treatments and products. Stakeholders in the health systems that KGI students will lead—including clinical trial participants, patients, partners, employees, investors, activist groups, and the media—will be paying close attention to the ethical behavior of those health systems and their leaders. This course therefore explores the ethical challenges for commerce in healthcare systems as it will be increasingly important for healthcare leaders to consider the ethical ramifications of their work. The class will focus more on the practical application of ethical principles through real-world case studies, rather than emphasizing theories.

Year 2 SPRING CORE COURSES – 12 to 13.5 Credits

GENE 5290: Pharmacogenomics (1.5 Credits)

Instructor: Martin Zdanowicz PhD

This course will give students a broad perspective on the field of pharmacogenomics and provide them with insight into the growing importance it will play in clinical therapeutics and future drug design. The first part of the course will examine some of the common methodologies used in the application of pharmacogenomics along with role pharmacogenomics can play in altering drug pharmacokinetics and pharmacodynamics. The second part of the course will focus on the role of pharmacogenomics in the pharmacotherapy of area such as cardiovascular, hematologic, CNS, Cancer, and the immune system. Part three

of the course will address the ethical, legal and social issues involved the application of pharmacogenomics to clinical practice.

GENE 6135: Genomic Knowledge Translation (1.5 Credits)

Instructor(s):

This course will focus on the translation of genomic data into actionable clinical information. Students will use role-playing and written reports to gain experience conveying genomic analysis results to genetic counselors and clinicians. Special attention will be paid to crafting variant significance reports using HGVS nomenclature. Case studies and team-based learning activities will be used to follow patients from sample collection, test selection, data acquisition, results determination, to suggested clinical action. Best practices for genomic variant curation and patient documentation will be emphasized. (GENE 435)

GENE 6145: Genomic Data Visualization and Management (3 Credits)

Instructor:

This course is designed to train students in best practices in genomic data management and documentation, including data storage requirements, file formats, and HIPAA considerations. Students will learn theories and practices of data visualization, experiencing making figures and graphics (i.e., Circos plots, Manhattan plots, genome browser tracks, haplotype networks, heat maps, etc.) to represent the results of various genomic analyses through various visualization technologies. Students will also practice making analysis pipelines and protocol figures or infographics for publication and educational materials. Additionally, students will learn and refresh their knowledge of how to use Python as a programming language to automate routine data management tasks in genomics research. The main topics of this course include basic concepts of information visualization, best practices for data extraction, transformation and loading process, fundamentals of data preparation and understanding, and an overview of the data analysis pipeline.

GENE6191: MSGDA Journal Club (0)

Instructor: Barbara K. Fortini PhD

This journal club is a one-hour, weekly course with student-led presentations on timely topics in this rapidly evolving field. The intent is to raise the academic interest and scholastic skills of students through critical review of the literature and presentations. The series encourages life-long learning, critical analysis of the literature, and serves as preparation for capstone projects and development of presentation skills. This course will continue for two years, giving first and

second-year students the opportunity to increase interaction, learn from each other, hear varied perspectives, and build professional and collegial bonds. The colloquium is not graded but students will be evaluated on their active participation and attendance. We will also be discussing professional development and the clinical genomics industry landscape.

GENE 6901: MSGDA Capstone Project II (6 Credits)

Instructor: Barbara K. Fortini PhD

This sequential course is designed to help students successfully complete the capstone requirement for the MSGDA program. In this course, students will gain an understanding of how to conduct genomics research through designing a research project, conducting the research, analyzing collected data, and presenting a written summary and poster presentation to document the study findings. Capstone projects are designed and completed under the guidance of a capstone advisor and capstone committee. (GENE 491)

PDEV 5240: Life Sciences Industry Ethics (SPRING ONLY) (1.5 Credits)

Instructor(s): Joshua Morris

As practitioners and leaders of tomorrow's healthcare systems and bioscience industries, KGI graduates will be at the forefront in the development and application of new diagnostics, pharmaceuticals, biologics and medical devices. They will be confronted with ethical issues concerning the research, development, marketing and sale of related products. Stakeholders in the health systems and companies that KGI students will lead—including clinical trial participants, patients, partners, employees, investors, activist groups, and the media—will be paying close attention to the ethical behavior of those health systems and companies and their leaders. This course therefore explores the ethical challenges for commerce in healthcare systems and biosciences industry as it will be increasingly important for healthcare and bioscience leaders to consider the ethical ramifications of their work. The class will focus more on the practical application of ethical principles through real-world case studies, rather than emphasizing theories. (ALS/MEB 341)

Clinical Decision Support Concentration – 6 Credits

GENE 5020: Human Embryology and Prenatal Diagnosis (FALL ONLY) (3 Credits)

Instructor: Melissa Randall Chan

The course will focus on developmental mechanisms clinically oriented to human genetic disease and birth defects. We will explore the process of human development from gametogenesis, fertilization, gastrulation, to birth. The course will take a systematic approach to human embryonic and fetal development with early focus on the stages of embryological development, signaling pathways, and the establishment of germ layers and eventually weaving in complex body systems and their intricate relationships with one another. The discussion of major body systems will begin with their organogenesis and anatomy throughout normal development, followed by case studies analyzing potential developmental anomalies, effects of teratogens, and practice in differential diagnosis. Online lectures including information relevant to required textbook readings as well as video animations will enable the student to be exposed to a deep understanding of human embryological development as it relates to clinical findings and research. Class time will incorporate a review of online lectures, clinical case studies, group work, and literature review to enhance and strengthen understanding of developmental concepts. (GENE 320)

GENE 6447: Microbiomics and Pathogen Genomics (SPRING ONLY) (1.5 Credits)

Instructor: Angelika Niemz PhD

This course focuses on the use of next generation sequencing to identify microorganisms, pathogens, and antimicrobial resistance based on genotype. The Human Microbiome Project will serve as a roadmap for understanding the purpose of metagenomics and microbiome analysis in healthcare. We will further discuss the role of sequencing in infectious disease diagnostics and in responding to disease outbreaks such as COVID-19. During the course you will be able to take a deep dive into a relevant topic of interest to you, and learn how to use various bioinformatic tools for data analysis and visualization.

GENE 6446: Genetic Engineering (FALL ONLY) (1.5 Credits)

Instructor: Barbara Bailus PhD

This course is designed as an in-depth exploration of the genetic engineering field. The course will cover the history of genetic engineering, the evolution of different genetic engineering technologies (i.e. Zinc Fingers, TALENs and CRISPR), the current use of genetic engineering, and human clinical trials. Emphasis will be placed on how genetic engineering tools are designed and used to model, diagnose and treat human disease. Other potential topics include how genetic engineering impacts drug discovery, agriculture, and lifestyle.

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SCI 5100 Molecular Basis of Disease (SPRING ONLY) (1.5 Credits)

Instructor: Animesh Ray PhD

This course examines the role of genes, proteins and RNA in causing or combating diseases, and emphasizes the current conceptual and analytical tools that are brought to bear, and their limitations, on our understanding. (ALS 402)

SCI 5240 Medical Terminology (FALL ONLY) (3 Credits)

Instructor: Nichol Graffeo

This course is an introduction to the use and meaning of the medical terminology used in various allied health fields. Students are introduced to the fundamentals medical terminology in order to build an extensive medical vocabulary for a range of body systems. (ALS 380)

SCI 6410 Fundamental Papers in Applied Medicine (SPRING ONLY) (1.5 Credits)

Instructor(s):

This course delves into a few ground-breaking original research papers that have shaped the concepts and technologies of modern biomedical research, with a special focus on cancer. The research contributions discussed here start with the discovery of oncogenes and quickly gathers pace to discuss paradigm-shifting research papers published within the last few years. The goal is to understand the logic and principles of doing biological experiments: the importance of models and hypotheses, testable versus untestable hypotheses, controls, the limits of interpretation dictated by the results, how changing paradigms influence the progress of science. A few of the chosen publications are considered classic; their approaches to addressing the unknown questions of the day and their conceptual contributions remain valid even today. Others, those focusing on deep sequencing of cancer genomes and single-cell studies, are more recent but have already begun to impact our understanding of cancer biology. (ALS 481B)

MATH 5120: Machine Learning in the Life Sciences (SPRING ONLY) (1.5 Credits)

Instructor: Animesh Ray PhD

Data science is an exciting field of inter-disciplinary science, with a wide range of applications in marketing, finance, life sciences, healthcare as well as technology. This course is designed to provide a practical understanding of key concepts in data analytics and hands-on experience with real data from various sources. Topics covered include methods of data gathering, data

processing, data exploration, visualization, classification, and network analysis. Students will gain a deeper understanding by working with data using open source software tools, such as R, R Studio, and Cytoscape. Application areas will emphasize life sciences and biotechnology. (ALS 413)

Clinical Trial Design Concentration – 6 Credits

GENE 6446: Genetic Engineering (FALL ONLY) (1.5 Credits)

Instructor: Barbara Bailus PhD

This course is designed as an in-depth exploration of the genetic engineering field. The course will cover the history of genetic engineering, the evolution of different genetic engineering technologies (i.e. Zinc Fingers, TALENs and CRISPR), the current use of genetic engineering, and human clinical trials. Emphasis will be placed on how genetic engineering tools are designed and used to model, diagnose and treat human disease. Other potential topics include how genetic engineering impacts drug discovery, agriculture, and lifestyle.

REG 5000: Introduction to US Food and Drug Law (1.5 Credits)

Instructor: Larry Davis PharmD

This course is designed to provide a broad overview of the United States regulatory system, with some European Union structure and regulation highlights. Students will gain a basic understanding of how the FDA regulates the approval of various products and how this has changed over time, as well as the necessary inputs companies must be aware of when applying for regulatory approvals in the USA. (ALS 362)

REG 6510: Design of Clinical Trials (SPRING ONLY) (1.5 Credits)

Instructor(s):

This course will provide students with a more in-depth understanding of clinical trial design, conduct and strategy for therapeutic products. Clinical trial design elements will be examined in the context of their impact on clinical trial outcomes. Emphasis will be placed upon trial designs that reflect the biological nature and mechanism of action of the therapeutic product being tested, rather than a cookbook approach. Design elements related to small molecules, antibodies, therapeutic proteins, therapeutic vaccines, and cell and gene therapies will be

discussed. Discussions will include operational issues impacting execution of clinical trials and why they are critical elements of successful clinical development programs. Students will gain an understanding of the principles for use of particular biostatical testing procedures and in what context certain methods should be used. There will be an emphasis on clinical development problem solving as students work on team projects and defend their own clinical development solutions in the context of product profiles, strategy and timelines. (ALS 433)

SCI 5300: Pharmaceutical Discovery (FALL ONLY) (1.5 Credits)

Instructor: Derick Han PhD

This course is designed to provide you with an understanding of how pharmaceutical and biotechnology companies discover new drugs. This course will focus on the discovery of small molecule drugs. (ALS 330)

SCI 5310: Pharmaceutical Development (FALL ONLY)(1.5 Credits)

Instructor: Larry Gill PhD

This course is designed to provide an understanding of how pharmaceutical companies discover, develop, and bring drugs and biopharmaceuticals to market. This course will focus on the development of traditional and biological drugs. The course will follow the process of drug development, taking the drug substance through the process of becoming a drug product, and then into clinical development and commercialization. (ALS 333)

SCI 6310: Biotechnology-based Therapeutics (SPRING ONLY) (3 Credits)

Instructor: Larry Gill PhD

This course will provide students with a background of the scientific basis of some key aspects of biotechnology based drug, biologic and vaccine design, discovery and development process. Students will learn about therapeutic and vaccine targets, and how the drugs and vaccines are designed, tested and produced. (ALS 401)

SCI 6710: Technologies for Biomarker and Drug Discovery (SPRING ONLY) (1.5 Credits)

Instructor: Angelika Niemz PhD

This course focuses on the use of high throughput technologies in biomarker discovery, small molecule drug discovery, and basic research. In the context of biomarker discovery, we will cover proteomics based on mass spectrometry and other methods. Relevant to nucleic acid biomarkers, we will discuss next generation sequencing based approaches for genomic, epigenomic, and transcriptomic analyses, in addition to microarray and PCR based methods. Relevant to drug discovery, we will discuss disease model systems and high throughput as well as high content (i.e. cell-based) methods for compound library screening and lead optimization. The trend towards personalized medicine has encouraged the pharmaceutical and diagnostics industries to partner more closely. Biomarkers discovery and validation is of central importance in advancing personalized medicine. The course consists of class discussions, assigned readings and computer exercises, in addition to student presentations.

Assay Development Concentration – 6 Credits

GENE 6446: Genetic Engineering (1.5 Credits)

Instructor: Barbara Bailus PhD

This course is designed as an in-depth exploration of the genetic engineering field. The course will cover the history of genetic engineering, the evolution of different genetic engineering technologies (i.e. Zinc Fingers, TALENs and CRISPR), the current use of genetic engineering, and human clinical trials. Emphasis will be placed on how genetic engineering tools are designed and used to model, diagnose and treat human disease. Other potential topics include how genetic engineering impacts drug discovery, agriculture, and lifestyle.

GENE 6447: Microbiomics and Pathogen Genomics (SPRING ONLY) (1.5 Credits)

Instructor: Angelika Niemz PhD

This course focuses on the use of next generation sequencing to identify microorganisms, pathogens, and antimicrobial resistance based on genotype. The Human Microbiome Project will serve as a roadmap for understanding the purpose of metagenomics and microbiome analysis in healthcare. We will further discuss the role of sequencing in infectious disease diagnostics and in responding to disease outbreaks such as COVID-19. During the course you will be able to take a deep dive into a relevant topic of interest to you, and learn how to use various bioinformatic tools for data analysis and visualization.

BUS 6600: Business Operations (FALL ONLY) (3 Credits)

Instructor(s): Ed Arnheiter PhD

Operations Management is concerned with the production and delivery of goods and services to meet customers' demands. It is one of the central functions of every business, government agency, and non-profit organizations.(ALS 424)

MATH 5120: Machine Learning in the Life Sciences (SPRING ONLY) (1.5 Credits)

Instructor: Animesh Ray PhD

Data science is an exciting field of inter-disciplinary science, with a wide range of applications in marketing, finance, life sciences, healthcare as well as technology. This course is designed to provide a practical understanding of key concepts in data analytics and hands-on experience with real data from various sources. Topics covered include methods of data gathering, data processing, data exploration, visualization, classification, and network analysis. Students will gain a deeper understanding by working with data using open source software tools, such as R, R Studio, and Cytoscape. Application areas will emphasize life sciences and biotechnology. (ALS 413)

REG 5000: Introduction to US Food and Drug Law (1.5 Credits)

Instructor: Larry Davis PharmD

This course is designed to provide a broad overview of the United States regulatory system, with some European Union structure and regulation highlights. Students will gain a basic understanding of how the FDA regulates the approval of various products and how this has changed over time, as well as the necessary inputs companies must be aware of when applying for regulatory approvals in the USA. (ALS 362)

SCI 5000: Molecular Biotechnology (FALL ONLY) (1.5 Credits)

Instructor: Animesh Ray PhD

Students will be exposed to the conceptual foundations of biotechnology and the role played by discoveries and applications of molecular biology principles in advancing biotechnology industry horizons. This is a case-based course in which students will read landmark original papers that shaped (or are shaping) biotechnology, and discuss these in the class. The first half of the course explores targeted editing of the genome using CRISPR/Cas9 through the critical analysis of a landmark research report, and explores the foundational basis of present and

future directions of biotechnology. The second half of the course will explore the role of the microbiome in human health and potential therapies. (ALS 300)

SCI 5240: Medical Terminology (FALL ONLY) (3 Credits)

Instructor: Nichol Graffeo

This course is an introduction to the use and meaning of the medical terminology used in various allied health fields. Students are introduced to the fundamentals medical terminology in order to build an extensive medical vocabulary for a range of body systems. (ALS 380)

SCI 5700: Medical Diagnostics (FALL ONLY) (3 Credits)

Instructor: Angelika Niemz PhD

The In Vitro Diagnostics (IVD) industry focuses on developing methods for the diagnosis, screening, monitoring, and prognosis of human diseases and to aid in therapy selection. IVDs identify and quantify biomarkers that can entail small molecules, proteins, DNA/RNA, or pathogens as well as cells and tissues of a certain phenotype. Developing diagnostic assays, instrumentation and devices requires input from many disciplines such as biochemistry, molecular biology, engineering, and computer science. This course provides an overview of the in vitro diagnostics industry and will enable students to acquire the basic knowledge and skills needed to understand and ultimately design diagnostic assays and devices. The course also features aspects of user research, marketing / competitor analysis, device regulatory affairs and program management. Through a semester long project that involves the entire section, students will learn how to develop an IVD in a complex team environment.

SCI 6401: Fundamental Papers in Molecular Biology and Biotechnology (SPRING ONLY) (1.5 Credits)

Instructor(s):

This course delves into a few ground-breaking original research papers that have shaped the concepts and technologies of modern biomedical research, with a special focus on cancer. The research contributions discussed here start with the discovery of oncogenes and quickly gathers pace to discuss paradigm-shifting research papers published within the last few years. The goal is to understand the logic and principles of doing biological experiments: the importance of models and hypotheses, testable versus untestable hypotheses, controls, the limits of interpretation dictated by the results, how changing paradigms influence the progress of science. A few of the chosen publications are considered classic; their approaches to

addressing the unknown questions of the day and their conceptual contributions remain valid even today. Others, those focusing on deep sequencing of cancer genomes and single-cell studies, are more recent but have already begun to impact our understanding of cancer biology. (ALS 481B)

SCI 6410: Fundamental Papers in Applied Medicine (SPRING ONLY) (1.5 Credits)

Instructor(s):

This course delves into a few ground-breaking original research papers that have shaped the concepts and technologies of modern biomedical research, with a special focus on cancer. The research contributions discussed here start with the discovery of oncogenes and quickly gathers pace to discuss paradigm-shifting research papers published within the last few years. The goal is to understand the logic and principles of doing biological experiments: the importance of models and hypotheses, testable versus untestable hypotheses, controls, the limits of interpretation dictated by the results, how changing paradigms influence the progress of science. A few of the chosen publications are considered classic; their approaches to addressing the unknown questions of the day and their conceptual contributions remain valid even today. Others, those focusing on deep sequencing of cancer genomes and single-cell studies, are more recent but have already begun to impact our understanding of cancer biology. (ALS 481B)

SCI 6710: Technologies for Biomarker and Drug Discovery (SPRING ONLY) (1.5 Credits)

Instructor: Angelika Niemz PhD

This course focuses on the use of high throughput technologies in biomarker discovery, small molecule drug discovery, and basic research. In the context of biomarker discovery, we will cover proteomics based on mass spectrometry and other methods. Relevant to nucleic acid biomarkers, we will discuss next generation sequencing based approaches for genomic, epigenomic, and transcriptomic analyses, in addition to microarray and PCR based methods. Relevant to drug discovery, we will discuss disease model systems and high throughput as well as high content (i.e. cell-based) methods for compound library screening and lead optimization. The trend towards personalized medicine has encouraged the pharmaceutical and diagnostics industries to partner more closely. Biomarkers discovery and validation is of central importance in advancing personalized medicine. The course consists of class discussions, assigned readings and computer exercises, in addition to student presentations.

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