REGULATORY (REG)

REG 5100 Introduction to Clinical and Translational Research
This introductory course lays the foundation for understanding practical aspects of conducting clinical research in an academic environment. The course is divided into two modules: Module 1: Research Methods & Protocol Development and Module 2: Regulatory Environment for Clinical Trials. The first module introduces clinical research, clinical protocols, study designs and biostatistics that underlie such studies. The second module covers ethical considerations in clinical research, study execution and oversight, and the regulatory environment for clinical research. Upon completion, students should have a strong foundation in the fundamentals of clinical research and should be able to apply contemporary research tools to clinically relevant areas of investigation. Prerequisite: This course requires permission to register. Please contact Bethany Germany at (bgermany@upenn.edu) to register.
Fall
Also Offered As: MTR 5100
1 Course Unit

REG 5900 Molecular Toxicology: Chemical and Biological Mechanisms
Course Goals: Exposures to foreign compounds (drugs, carcinogens, and pollutants) can disrupt normal cellular processes leading to toxicity. This course will focus on the molecular mechanisms by which environmental exposures lead to end-organ injury and to diseases of environmental etiology (neurodegenerative and lung diseases, reproduction disruption and cardiovascular injury). Students will learn the difficulties in modeling response to low-dose chronic exposures, how these exposures are influenced by metabolism and disposition, and how reactive intermediates alter the function of biomolecules. Mechanisms responsible for cellular damage, aberrant repair, and end-organ injury will be discussed. Students will learn about modern predictive molecular toxicology to classify toxicants, predict individual susceptibility and response to environmental triggers, and how to develop and validate biomarkers for diseases of environmental etiology. Students are expected to write a term paper on risk assessment on an environmental exposure using available TOXNET information. Pre-requisites: Must have taken or will take Fundamentals of Pharmacology concurrently. Undergraduate course work in biochemistry and chemistry essential. Exceptions allowed based on past course work. Please consult with students with required prerequisites; residents in Environmenal and Occupational Health, and professional masters students (MPH and MTR).
Spring
Also Offered As: PHRM 5900
1 Course Unit

REG 6000 Introduction to Biostatistics
This course prepares students understand and apply the necessary statistical methods to their thesis project, critically assess the application of statistical methods in the literature, and collaborate with biostatisticians.
Fall
Also Offered As: MTR 6000
1 Course Unit

REG 6020 Proposal Development and Study Design
This course has two primary areas of focus: (i) proposal development and enhancement; and (ii) a focus on research and study design. (i) Proposal Development and Enhancement: Students apply foundational concepts by revising and refining their written proposal and presenting their research project throughout the course. Students receive an overview of approaches to developing an effective proposal; and guidance on how to write and present their hypothesis, specific aims, research strategy, significance, innovation, and approach using the general NIH application format. (ii) Research and Study Design: Students receive an overview of translational research principals and clinical study design approaches relevant to thesis projects designed to probe mechanisms of disease and translate results in basic research into investigations in humans. Topics include clinical and translational research methods, and study design and execution. Students are introduced to these topics through asynchronous and synchronous learning environments. At the end of the course, each student submits and presents their written proposal to their peers and a panel of reviewers for critique and feedback. Members of the panel include the students’ research mentor(s), program mentor, and thesis committee. The panel provides feedback on the proposal which the student will then incorporate into the written proposal. Students submit their final revised proposal to be reviewed and graded by their program mentor.
Fall
Also Offered As: MTR 6020
1 Course Unit

REG 6040 Scientific & Ethical Conduct
In this course, students will learn the foundational principles of scientific, operational and ethical conduct of research, complete directed experience in evaluating ethical principles through IRB membership and ultimately be able to apply all principles to their own work. By the end of the foundational class sessions, students will understand scientific conduct, ethical considerations of human subject’s research, good clinical practices (GCP), good laboratory practices (GLP), conflict of interest, and budgetary concepts. The directed experience will include becoming a member of an Institutional Review Board (IRB) (Penn or CHOP) and participating as an active member in 6 meetings.
Spring
Also Offered As: MTR 6040
1 Course Unit

REG 6100 Fundamentals of FDA Regulation
This introductory course provides an overview of Regulatory Affairs in relation to three key areas of development: Drugs, Biologics, and Medical Devices. The course will look at the rules governing prescription and over-the-counter drugs as well as the changes introduced by the influence of genetic engineering and biological product development. Throughout the course, practical issues facing regulatory specialists as they work with the FDA and other international regulatory bodies to secure and keep product approval will be addressed. Prerequisite: Permission is needed to register. Contact Bethany Germany at (bgermany@upenn.edu) to register.
Summer Term
1 Course Unit
REG 6110 Clinical Study Management
This course will focus on the practical aspects of conducting clinical research in an academic environment. Upon course completion students will be able to apply scientific principles of research to the implementation and management of both investigator-initiated and industry-sponsored clinical research studies. Students will be guided through the operational aspects and regulatory processes for the three stages of study management: pre-study start-up, ongoing study management and study close out. Students will learn strategies for navigating the complex regulatory/operational clinical research environment and for successful protocol development and approval, subject recruitment, data management and IRB clinical practices guiding research in humans is a critical concept that will be integrated throughout each of the lectures. Prerequisite: Permission is needed to register. Contact Bethany Germany (bgermany@upenn.edu) to register. 1 Course Unit

REG 6120 Introduction to Drug Development
This introductory course lays the foundation for conducting pharmaceutical research in many ways. It begins with a brief review of the history of drug development and explains the phases of drug development in detail. The decision making process, drug development milestones and compound progression metrics are defined and explained with examples. At the conclusion of this course, students should have a working knowledge of the drug development process, understand the regulatory basis by which new chemical entities are evaluated and ultimately approved, and appreciate the time and expense of drug development. Undergraduates and graduate students from other departments are welcome. Please contact Bethany Germany (bgermany@upenn.edu) to request permission to register. Fall or Spring 1 Course Unit

REG 6140 Biopharmaceutical Product Development, Manufacturing and Regulatory Affairs
Biopharmaceutical protein products have been successfully used to treat a number of diseases and currently represent a large segment of the product pipeline in most major pharmaceutical companies. More than half of the current top 20 blockbuster drugs are biopharmaceuticals. Drugs like Activase, Humira, and Avastin have revolutionized the drug industry in treating the unmet medical needs of many patients. With innovation at the heart of the biopharmaceutical industry, this course is aimed at developing the student’s understanding of the application of basic research in molecular biology and genetics to the development of novel drugs for treating diseases. The course is designed to provide an overview of biopharmaceutical protein drug development and manufacturing processes with an emphasis on regulatory affairs activities. The class has been developed and is taught by a former VP of biopharmaceutical product development with over 30 years of experience in biotechnology and the biopharmaceutical industry. The course director will provide insights into the unique challenges and opportunities facing the biopharmaceutical industry and how they relate to regulatory affairs. Subject area experts from industry will also participate as guest lecturers. Prerequisite: Permission required to register. Please contact Bethany Garmany (bgermany@upenn.edu) to request a permit. Fall 1 Course Unit

REG 6150 Post-Approval Maintenance of Drugs, Biologics, and Devices.
The FDA regulates prescription drugs, biologics and medical devices for utilization in the United States. The approval of a marketing application is a major accomplishment; however, it comes with significant responsibilities for a sponsor including numerous reporting requirements and activities to maintain a license as well as a need for lifecycle maintenance activities to stay competitive. The purpose of this course is to provide an overview of post-approval activities required for drugs, biologics and devices. Prerequisite: Contact Bethany Germany (bgermany@upenn.edu) to request a permit for registration. Spring 1 Course Unit

REG 6160 Quality Assurance
Quality assurance (QA) plays a critical role in the reliability and reproducibility of product development and, manufacturing. As a component of the Quality Management System, quality assurance includes all activities performed by an organization for the prevention of errors and defects. This course intends to focus on QA principles, standards and requirements, with regard to the FDA-regulated product development lifecycle. Further, the course aims to offer examples of QA and quality control measures through auditing monitoring and risk management. Application of quality assurance and the interfaces between GLP, GTPGMP-and Pharmacovigilance regulatory regulated activities during product development and manufacturing will also be addressed. Fall 1 Course Unit

REG 6180 Introduction to Vaccine Development
Vaccine development is the process by which new vaccines are discovered, studied in laboratory and preclinical models and investigated clinically in patients to determine if they are safe and efficacious. Assuming the vaccine under investigation passes systematically defined milestones, submission of all documentation to regulatory authorities (e.g., US FDA and equivalent global regulatory authorities) can ensue and, pending a favorable review, market access can be granted. The process is highly regulated and there is significant cost involved for pharmaceutical sponsors to research and develop vaccines with the entire process averaging around 12 years once a product is discovered. This introductory course lays the foundation for conducting vaccine research in many ways. It begins with a brief review of the history of vaccine discovery and development and explains the phases of vaccine development in detail. Global Health history and impact of vaccines is described as well as the various stakeholders (e.g. WHO and World Bank) involved which distinguish vaccine from drug development. The decision-making process, vaccine development milestones and compound progression metrics are defined and explained with examples. At the conclusion of this course, students should have a working knowledge of the vaccine development process, understand the regulatory basis by which new vaccines are evaluated, ultimately approved and distributed around the world. Fall 1 Course Unit
REG 6210 Cell and Gene Therapy
This course will provide students with a general overview of translational research in the area of gene and cell therapy. This includes technical considerations, translating preclinical investigation into therapeutics, the execution of gene and cell therapy along with approaches and pitfalls to translating these therapies into clinical applications including regulatory and commercial aspects of this emerging area. Prerequisite: For graduate students, at least one prior course in immunology. An undergraduate-level or medical school immunology course is sufficient to meet the prerequisite.
Spring
Also Offered As: CAMB 7070, MTR 6210
1 Course Unit

REG 6220 New Trends in Medicine and Vaccine Discovery
Modern drug discovery has evolved to include human genetic diagnosis and various biological approaches which has enabled progress in a variety of fields, including rare diseases, immuno-oncology, precision medicine, and biomarkers. The goal of this course is for students to understand newer treatment modalities and approaches beyond one size fits all small molecule drugs, as well as the technologies that empower them. Students will learn regulatory processes that govern medicine discovery and development and also consider business and societal aspects of medical progress. Students will be able to apply concepts directly to work in the healthcare industry. Students will be taught by experts in the field internal and external to Penn. Prerequisite: Permission required to register. Please contact Rachel McGarrigle (rmcg@upenn.edu) to request a permit.
Fall
Also Offered As: MTR 6220
1 Course Unit

REG 6230 Fundamentals of Pharmacology
This course is designed to introduce students to basic pharmacological concepts with special emphasis on the molecular actions of drugs. Subject matter includes use of microcomputers to analyze pharmacological data. Prerequisite: Permission of course director
Fall
Also Offered As: PHRM 6230
1 Course Unit

REG 6240 Applied Regulatory Processes of Vaccines and Biologics
Drug development is at a turning point in human medicine. Over the past three decades, the development of biotherapeutics has revolutionized innovation in medicines. Efficiency and Quality Compliance are critical to achieving innovation and affordability. This course will provide an overview of the multi-dimensional nature of drug development, which involves regulatory, new technologies, statistical, and quality considerations. This 6-week course will introduce the concepts of drug development, which include, pharmacology, toxicology, product development, clinical trials. All of these topics will be addressed based on regulatory requirements by the FDA. Risk assessment and mitigation will be discussed using a role-play process. The content of the course includes seminars, case studies, project reports, and journal article-reviews.
Summer Term
1 Course Unit

REG 6250 Manufacturing Novel Therapies & Imaging Agents
Novel therapeutic and diagnostic agents (eg. CAR T cells, gene therapy for sickle cell disease, radionuclides etc.) have revolutionized modern clinical medicine. Historically, these agents were first developed in academia then transferred to industry for clinical scale manufacturing. Recently, however, some academic centers have developed clinical scale biomanufacturing facilities. Operation of these new facilities requires a unique blend of manufacturing, clinical, basic, regulatory and laboratory sciences. Examples of areas in which academic medical centers have developed in-house manufacturing include cell therapy, gene therapy and novel imaging agents. This course will cover manufacturing approaches, challenges, and controversies in each of these domains. At the completion of this course students will understand: -The general approach to development, manufacturing, quality control and regulatory compliance in academic manufacturing facilities -Critical steps in the manufacturing cycles of cell therapies, gene therapies and imaging agents -Current challenges in development, manufacturing, and maintaining regulatory compliance in academic manufacturing facilities -Key considerations and relative merits of different positions in the current controversies surround these agents Each week includes a combination of synchronous and asynchronous work. Synchronous sessions will include instructor led discussions based on pre-recorded lectures or case-based discussions. Asynchronous material includes pre-recorded lectures and discussion board prompts to which students will respond throughout the week. One unique aspect to this course are the debates. For each debate week, two students will be assigned as debaters and will represent opposing points of view. All students will be provided with required pre-reading and pre-recorded lectures relevant to the debate topic. Ahead of the debate, the debaters will meet with an assigned faculty advisor to help to prepare. Students who are not assigned as debaters for that week will post questions to the discussion board ahead of the debate. The debate will occur during a synchronous session. The debaters will deliver a short introductory statement. This will be followed by QA with the audience. Finally, the debates will deliver a closing statement. These debates are a fun and interactive way for students to engage with controversial and evolving topics in the field. By the end of the course, students will appreciate the academic perspective on core elements of therapeutic and diagnostic agent manufacturing.
Fall
1 Course Unit

REG 6300 Clinical Trials
This course is to serve as a general introduction to clinical trials, with emphasis on trial design issues. This is not a course on the biostatistics of clinical trials. It is expected that at the conclusion of the course, a student will be able to plan a clinical trial. Each class will consist of a two-hour lecture followed by a one hour discussion. Prerequisite: Permission of instructor.
Spring
Also Offered As: EPID 6300
Prerequisite: EPID 5100 AND EPID 5260
1 Course Unit

REG 6400 Capstone I
1 Course Unit

REG 6410 Capstone II
1 Course Unit

REG 9910 Thesis I
1 Course Unit

REG 9911 Thesis II
1 Course Unit