REGULATION (REG)

REG 510 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. Taught by: Emma Meagher, MD Course usually offered in fall term Also Offered As: MTR 510 Activity: Lecture 1.0 Course Unit

REG 590 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 in Environmental and Occupational Health, and professional masters students (MPH and MTR). Taught by: Dr. Trevor M. Penning Course usually offered in spring term Also Offered As: PHRM 590 Activity: Lecture 1.0 Course Unit

REG 602 Proposal Development
Focuses on study design and proposal development as they relate to studies that probe the mechanism of disease. Discusses concepts such as writing a background section, asking a research question, designing a study, use of biomarkers, writing a research proposal, overview of study designs addressing feasibility issues. Development of thesis proposal starts during this course and concludes with each student submitting and presenting their proposal to the MTR faculty panel for critique and feedback. Taught by: Anil Vachani, MD Two terms. student must enter first term. Also Offered As: MTR 602 Activity: Seminar 1.0 Course Unit

REG 604 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. Taught by: Emma Meagher, MD Course usually offered in spring term Also Offered As: MTR 604 Activity: Lecture 1.0 Course Unit

REG 610 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. Taught by: Monica Ferrante Course usually offered summer term only Activity: Lecture 1.0 Course Unit
REG 611 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. Taught by: Megan Kasimatis Singleton, JD
Activity: Lecture
1.0 Course Unit

REG 612 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. Taught by: Eileen Doyle
One-term course offered either term
Activity: Lecture
1.0 Course Unit

REG 614 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. 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 Germany (bgermany@upenn.edu) to request a permit.
Taught by: Marcia Federici, PhD
Course usually offered in fall term
Activity: Lecture
1.0 Course Unit

REG 615 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. Taught by: Ajay Parashar, BPharm, MS, MDD, RAC
Course usually offered in spring term
Activity: Lecture
1.0 Course Unit

REG 616 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, GTP, GMP and Pharmacovigilance regulatory rules in product development and manufacturing will also be addressed. Taught by: Dawn Lundin
Course usually offered in fall term
Activity: Lecture
1.0 Course Unit

REG 618 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. Taught by: Jeff Barrett
Activity: Lecture
1.0 Course Unit
REG 621 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 therapies clinical trials, and key regulatory issues. Entrepreneurial considerations will be discussed as well. By the end of this course, students will understand the basic technologies employed for 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.
Taught by: Michael C. Milone, MD, PhD, Elizabeth Hexner, MD, MSTR
Course usually offered in spring term
Also Offered As: CAMB 707, MTR 621
Activity: Lecture
1.0 Course Unit

REG 622 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.
Taught by: Claudine Bruck, PhD
Course usually offered in fall term
Also Offered As: MTR 622
Activity: Lecture
1.0 Course Unit

REG 623 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
Taught by: Dr. Jeffrey Field and staff
Course usually offered in fall term
Also Offered As: PHRM 623
Activity: Lecture
1.0 Course Unit

REG 630 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.
Taught by: Farrar
Course usually offered in spring term
Also Offered As: EPID 630
Prerequisite: EPID 510 AND EPID 526
Activity: Lecture
1.0 Course Unit