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.
Taught by: Emma Meagher, MD
Course usually offered in fall term
Also Offered As: MTR 510
Activity: Lecture
1 Course Unit
Notes: This course requires permission to register. Please contact Anna Greene (acgreene@upenn.edu) to register.

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.
Taught by: Monica Ferrante
Course usually offered summer term only
Prerequisites: Permission needed to register. Contact Anna Greene (acgreene@upenn.edu) to register.
Activity: Lecture
1 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.
Taught by: Emma A. Meagher, MD
Activity: Lecture
1 Course Unit
Notes: Permission needed to register. Contact Anna Greene (acgreene@upenn.edu) to register.

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.
Taught by: Jeffrey S. Barrett, PhD, FCP
Course usually offered in spring term
Prerequisites: Undergraduates and graduate students from other departments are welcome. Please contact acgreene@upenn.edu to request permission to register.
Activity: Lecture
1 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 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.
Taught by: Marcia Federici, PhD
Course usually offered in fall term
Activity: Lecture
1 Course Unit
Notes: Permission required to register. Please contact Anna Greene (acgreene@upenn.edu) to request a permit.

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.
Taught by: Ajay Parashar, BPharm, MS, MDD, RAC
Course usually offered in spring term
Activity: Lecture
1 Course Unit
Notes: Contact Anna Greene (acgreene@upenn.edu) to receive a permit.
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.
Taught by: Michael C. Milone, MD, PhD
Course usually offered in spring term
Prerequisites: At least one course in immunology.
Activity: Lecture
1 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.
Taught by: Claudine Bruck, PhD
Course usually offered in fall term
Activity: Lecture
1 Course Unit
Notes: Permission required to register. Please contact Anna Greene (acgreene@upenn.edu) to request a permit.