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

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 613 Drug Development Decision Criteria
This course reviews the critical junctures over which innovative and generic drugs are evaluated and the decision criteria used to judge performance and plan next steps. The nature of the collective data under review, the decision paths and the decision makers themselves often change depending on the stage of development. This course covers decision criteria from drug discovery through post marketing and even entertains decision points for generic drugs (pharmaceutical- and bio-equivalence). Metrics for evaluation, company and regulatory expectations and the tools used to facilitate decision (e.g., modeling and simulation techniques to generate what-if scenarios) making are all discussed in detail. A key feature of the course is 7 labs which involve instructor-led decision analysis role playing. The class will be divided into small teams that review data generated at different stages to examine the thought processes and decision criteria evaluable at different stages of drug development. Labs are constructed from actual case study examples and team performance will be evaluated at the conclusion of the lab session.

Taught by: Jeffrey S. Barrett, PhD, FCP
Course usually offered in fall term
Activity: Lecture
1 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.

Taught by: Michael C. Milone, MD, PhD
Course usually offered in spring term
Also Offered As: CAMB 707, MTR 621
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