

CTSC 5025

Introduction to Regulatory Science

Faculty: Anthony Windebank, M.D. and Alexandra Greenberg, Ph.D., M.P.H.

Credits: 1

Quarters: Summer

Prerequisites: No required prerequisites. CTSC 5020: Regulatory Issues in Clinical Research and 6120: Case Studies in Translational recommended.

Overview

As medical treatments and technologies continue to advance at an unparalleled pace, there is a need to develop new scientifically-based standards and metrics to assess the safety, efficacy, and quality of diagnostic and therapeutic products. Development of techniques and measurements to assess these characteristics of clinical products is known as “regulatory science.” In this in-person course, participants will learn about critical areas of regulatory science, as defined by the FDA’s “Advancing Regulatory Science” report. This will include: the role of bioethics in regulation; toxicology and product safety; innovations in the science and conduct of clinical trials; product manufacturing and quality; evaluating emerging technologies; using informatics to improve health outcomes; and understanding regulatory processes, including the role of advisory committees and meetings. Evaluation will include attendance and participation in class discussion, online quizzes, and a final paper determining what methods of safety, efficacy, and quality assessment would be necessary from a regulatory standpoint for a new treatment or technology.

Course Objectives

Upon completion of the course, students will be able to:

- Define “regulatory science”
- Recognize differences between “regulatory science” and “regulatory affairs”
- Explain each of the eight priority areas identified by the FDA for advancing regulatory science
- Determine what bioethical and safety concerns need to be considered and addressed by regulatory science tools in a case study
- Summarize what regulatory standards, tools, and approaches are used in a given case study, and evaluate whether the underlying science supports the use of those tools

Evaluation

This course will evaluate students on class participation, quizzes, a research proposal, and final paper.

Students will be expected to spend approximately two to four hours per week on content from this one-credit course.

Additional online modules related to this topic are available through the [Continuous Professional Development website](#).