

TECH 508: Regulatory Affairs and FDA Regulation

The FDA regulates, to differing extents, drugs, biologics, medical devices, foods, cosmetics, and tobacco. The Federal Food, Drug & Cosmetic Act (FD&C Act) gives FDA authority to regulate these products. Students will gain familiarity with FDA's regulatory authority under the FD&C Act. The course will begin with an overview of the United States Government and Administrative Law. Then, it will provide an overview of drug, biologic, and medical device approval processes. It will also cover how FDA regulates food, dietary supplements, cosmetics, and tobacco. Students will learn how FDA enforces its regulations. Individual and/or group projects may be assigned. This course is an elective for Advanced Studies in Technology Transfer.

Learning Objectives

- Become familiar with the U.S. legal system and FDA's administrative regulatory authority
- Learn about FDA's regulatory oversight over drugs, biologics, medical devices, foods, cosmetics, and tobacco
- Gain an understanding of current FDA news

Credits: 2

Class Type: Graduate Course

Program: Technology Transfer, Business, and Industry