

# TECH 588: FDA Regulatory Strategy in Medical Product Development

This course offers an overview of the historical development of food and drug laws and regulations as they apply to drugs, biologics, and medical devices, including radiological products, with an introduction to marketing clearance and approval processes, regulations covering import, export, current good manufacturing practices, labeling, reclassification, establishment registration, and medical device listing.

## Learning Objectives

- Gain an understanding of the history and development of food and drug laws and regulations as applied to drugs, biologics, and medical devices
- Get introduced to processes, regulations, manufacturing practices, reporting, listing, inspection involved in medical device and product development

**Credits:** 2

**Class Type:** Graduate Course

**Program:** Technology Transfer, Business, and Industry