BME 532 : Medical Device Regulation

This course provides an overview of regulations that guide the medical devices industry. Primary focus is on the Food, Drug and Cosmetic Act (FD&C Act) and its associated regulations. The course covers the FD&C Act, including definitions, prohibited acts, penalties and general authority. The course also covers regulations, including establishment registration, premarket approval (PMA) and current good manufacturing practices. Requirements of other federal agencies (NRC, FCC, EPA) will also be discussed.

Department
Biomedical Engineering

Credits 3.0