BTR-Biotechnology & Regulatory Affairs

BTR 605. Biotechnology Regulatory & Quality Systems. 3 Hours.
U.S. and European Union regulatory affairs frameworks and practices governing the development, approval, manufacturing and surveillance of pharmaceuticals and medical devices, including in vitro diagnostic products. Regulations covered include investigational new drug applications (IND), new drug applications (NDA), good laboratory practices (GLP), good clinical practices (GCP) and current good manufacturing practices (cGMP).

BTR 615. Applications of Biological Processes in Drug Development. 3 Hours.
Overview of biological processes and laboratory techniques for discovery, development and evaluation of therapeutic drugs. Focus on drug development processes such as gene cloning, culture scale-up, downstream processing, and product purification. Emphasis on theory and application of laboratory methods used in drug development.

BTR 620. Regulation of Food and Drugs. 3 Hours.
Administrative procedures followed by the FDA; enforcement activities of the FDA, including searches, seizure actions, injunctions, criminal prosecutions, and civil penalties authorized by statutes.

BTR 640. Clinical Development of Drugs, Biologics, Diagnostics, and Medical Devices. 3 Hours.
Major concepts under which clinical trials are designed and run. Focus on phases of clinical trial development, role of the U.S. Food and Drug Administration, Institutional Review Boards, and the Code of Federal Regulations and ethical principles.

BTR 675. Special Topics in Biotechnology Regulatory Affairs. 1-4 Hour.
Exploration of current issues in Biotechnology Regulatory Affairs.

BTR 690. Clinical Trial Implementation. 3 Hours.
Activities involved in running a clinical trial from study initiation to study close-out. Complex details and issues associated with study initiation, site and data management, preparation of the final report and study close-out.