REGULATORY AFFAIRS (RAFF)

Explanation of Course Numbers

- Courses in the 1000s are primarily introductory undergraduate courses
- Those in the 2000s to 4000s are upper-division undergraduate courses that also may be taken for graduate credit with permission and additional work assigned
- Those in the 6000s and 8000s are for master's, doctoral, and professional-level students
- The 6000s are open to advanced undergraduate students with approval of the instructor and the dean or advising office

RAFF 3101. Introduction to Regulatory Affairs. 3 Credits.
Introduction to the field of regulatory affairs to regulations, strategies, and laws that apply to safe and effective product development.

RAFF 5099. Variable Topics. 1-99 Credits.

RAFF 6201. Introduction to Global Regulatory Affairs. 3 Credits.
Foundations of regulatory affairs, including U.S. and international legislation and regulatory processes guidelines. Roles of leaders of regulatory affairs in developing products, navigating the regulatory review and approval process, and contributing to keeping products on the market.

RAFF 6202. Regulatory Drug Biologics. 3 Credits.
Development and evaluation of the regulatory affairs strategies that support drug and biologic development. Research science, study design, master file, risk/benefit analyses, product specifications and milestone identification, IND and NDA.

RAFF 6203. Regulatory Device Diagnostics. 3 Credits.
Development and evaluation of the regulatory affairs strategies that support device and diagnostics development. Research science, study design, master file, risk/benefit analyses, product specifications and milestone identification, IDE, 510K, PMA.

RAFF 6204. Clinical Research for Regulatory Affairs. 3 Credits.
The planning and conduct of clinical trials. Topics include protocol development, study design, post-marketing surveillance, and evaluation and assessment of regulatory submissions. Strategies for achieving clinical development goals.

RAFF 6205. Regulatory Affairs Compliance. 3 Credits.
Analysis and evaluation of regulatory affairs compliance strategies and guidelines. Pre and post marketing compliance of medical products, oversight, labeling, advertising and use.

RAFF 6206. International Regulatory Affairs. 3 Credits.
International regulatory requirements for the development and approval of new pharmaceuticals around the world. Prerequisites: RAFF 6201.

RAFF 6207. Advertising and Promotion of Regulated Medical Products. 3 Credits.
Exploration of FDA-regulated advertising and promotion of pharmaceutical drugs. Focus on pre- and post-market issues for prescription drugs and management of risks and compliance surrounding medical and commercial communications. Prerequisites: RAFF 6201 and RAFF 6202.

RAFF 6275. Leadership in Regulatory Affairs. 3 Credits.
Theories of leadership and change are integrated in the development of change proposals for the regulatory affairs field. The development of leadership solutions to problems in leading regulatory strategic change; integration of all field coursework into implementation plans for health care system changes.