

# REGULATORY AFFAIRS AND CLINICAL RESEARCH ADMINISTRATION (RCR)

## Explanation of Course Numbers

- Courses in the 1000s are primarily introductory undergraduate courses
- Those in the 2000s to 4000s are upper-level undergraduate courses that can also 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

### **RCR 6201. Introduction to Global Regulatory Affairs and Clinical Research. 3 Credits.**

Foundation of regulatory affairs and clinical research in therapeutic development in the United States, Japan, and EU. Roles in developing products, navigating the regulatory review and approval process, and maintaining products on the market. Credit cannot be earned for this course and CRA 6201.

### **RCR 6202. Regulatory Strategy in the Development of Therapeutics. 3 Credits.**

Overview of therapeutic development through analyses of the critical elements of the product lifecycle, assessment of non-clinical and clinical data, integration of strategic business needs, and post-marketing efforts in planning regulatory strategy. Prerequisites: RCR 6201.

### **RCR 6206. International Regulatory Affairs and Clinical Research. 3 Credits.**

International regulatory requirements for the development and approval of new medicinal products around the world. Prerequisites: RCR 6201.