Fall 2013
Professional Advancement Courses
Regulatory & Clinical Research Management

(RA 633) Chinese Medical Device Regulation
This course introduces the student to the basics of Chinese regulations for medical devices and in vitro diagnostic (IVD) reagents. Subjects will include product registration, quality systems, manufacturing and distribution licenses and post market surveillance regulations. The course will discuss the strategy issues in planning a China submission and the process and requirements of product approvals by the China State Food & Drug Administration (SFDA). The instructor, Chang-Hong Whitney, has been in the medical device industry for more than 30 years and manages a China RA firm.

4 Monday Evenings, 6pm-9pm: September 9, 16, 23, 30

(RA 630) Combination Products and Advanced Product Regulation
Combination products where a medical device is used in combination with drugs and biologics are increasingly being developed. During this interactive course, participants will be exposed to examples of combination products on the market and under development and discuss the regulatory issues related to these products. The instructor, Michael Drues, has worked for and consulted with medical device, pharmaceutical, biotech and regulatory agencies on a regular basis.

4 Monday Evenings, 6pm-9pm: October 7, 21, 28, November 4

(RA 634) Advanced Regulatory Strategy
As medical products become more and more complex, the regulatory strategies and clinical trials necessary to successfully bring these products to market will become similarly complex. Being able to design, implement and defend these strategies is a required and valuable skill for regulatory and clinical trial professionals. Using case studies from a range of clinical specialties, participants will discuss a variety of regulatory strategies and clinical trial options. Michael Drues is the instructor.

4 Monday Evenings, 6pm-9pm: November 11, 18, 25, December 2

Who should take these courses?
Industry professionals working in the device, and pharmaceutical industries - Regulatory and Quality System Professionals - Graduate Students in Regulatory and Clinical Research Management

Tuition for 1 credit professional advancement courses:
$1000/course
(Virtual Classroom access will be available)

To register for courses, or for more information, please contact:
The Office of Graduate Admission - 781.768.7330, or graduatedepartment@regiscollege.edu