PARTICIPANTS will learn the fundamentals of regulatory affairs, gain exposure to industry practices, and discover practical applications to develop the interpretive and analytical skills required of a regulatory affairs professional.

This program offers two-tracks: pharmaceuticals (drugs and biologics) or medical devices. With unique products, organizations, regulations, and industry standards, pharmaceuticals and medical devices are often treated as distinct industries. The specialized coursework provides the focused training needed to understand regulatory expectations and to apply this regulatory knowledge in pharmaceutical and medical device organizations.

WHO SHOULD ENROLL
This program offers a path for students new to the pharmaceutical and/or medical device industries and to individuals currently employed within these industries who are new to the field of pharmaceutical or medical device regulatory affairs. Additionally, this program benefits current industry professionals with focused regulatory or compliance experience who are seeking a change in practice setting or job function.

PROGRAM BENEFITS
- Gain knowledge on the product development process and the product lifecycle for pharmaceuticals and medical devices
- Understand FDA and regulatory agencies in other major international markets in terms of structure, regulations, and enforcement
- Learn requirements and approaches to create and maintain compliance with quality systems, including strategies for minimizing and handling potential crises
- Earn professional development credits to maintain your RAC Credential with RAPS – Regulatory Affairs Professional Society
- Establish an educational pathway for advanced education in FDA regulations, compliance, and policy

CERTIFICATE ELIGIBILITY AND REQUIREMENTS
A certificate is awarded upon completion of 15 credit units (10 required from chosen track [pharma or device] and 5 elective credit units), with a grade of “C” or better in each course. NOTE: Six credit units may be counted towards the Clinical Trials: Medical Device and Drug Development or Medical Device Development Certificate Program when courses are shared.

All requirements must be completed within 5 years after the student enrolls in his/her first course. Students not pursuing the certificate are welcome to take as many individual courses as they wish.
PROGRAM FEES
The total cost of the program varies depending on the electives chosen. Actual fees may differ from the estimate below. Fees are subject to change without prior notice.
Course Fees (10 required and 5 elective units) $4,295
Candidacy Fees $125
Textbook Fees $350
Total Estimated Cost $4,770

TO ENROLL
Visit ce.uci.edu/rac for full course descriptions, instructor biographies, and to enroll.

TRANSFER CREDIT
Graduates from UCI Division of Continuing Education's Regulatory Affairs and Compliance program are eligible to transfer credits to:
• Northeastern University, Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices OR Master of Science in Project Management
• Rutgers School of Health Professions, Master of Science in Clinical Research Management

Note: Any student wishing to transfer credits must obtain a “B” or better in each course.

FOR MORE INFORMATION:
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