



REGULATORY AFFAIRS AND COMPLIANCE CERTIFICATE PROGRAM • ONLINE

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.



www.ocra-dg.org
Members Save 10%
Email membership@ocra-online.org

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	\$4,295
Candidacy fee	\$125
Textbooks and Materials	\$350
Total Estimated Cost	\$4,770

TO ENROLL

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

FOR MORE INFORMATION:

EngineeringSciences@ce.uci.edu

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COURSE#	REQUIRED COURSES – PHARMA TRACK (10 units)	UNITS
PHRMSCI X480	Introduction to Regulatory Affairs and Compliance for Drugs, Biologics and Medical Devices	2
EECS X445.26	Regulatory Requirements for Pharmaceutical Products	3
BIO SCI X450	Fundamentals of Clinical Trials	3
PHRMSCI X481	Post-Approval Compliance Requirements for Pharmaceutical Products	2
COURSE#	REQUIRED COURSES – DEVICE TRACK (10 units)	UNITS
PHRMSCI X480	Introduction to Regulatory Affairs and Compliance for Drugs, Biologics and Medical Devices	2
EECS X445.2	Regulatory Requirements for Medical Devices	3
BME X413.2	Regulatory Affairs for Post-Market Approval	2
BME X412	Regulatory Affairs Planning and Management	3
COURSE#	ELECTIVE COURSES (Minimum 5 units)	UNITS
PHRMSCI X493	Drug Safety and Pharmacovigilance	2
MGMT X442.6	Medical Device Quality Systems	3
MGMT X445	Medical Device Marketing	3
PHRMSCI X490	Overview of Global Regulatory Affairs	3
BME X408	Medical Device Life-Cycle Management	3

Course schedules are subject to change. Individual courses may be taken without enrolling in the full certificate.

ADVISORY COMMITTEE

Michele Dishon, Pharm.D., Sr. Manager, Pharmacovigilance, Spectrum Pharmaceuticals

Albert Rego, Scientific Consultant to the Life Science Industry

Del Stagg, Ph.D., Regulatory Consultant, Founder of the Orange County Regulatory Affairs Society (OCRA)

Cristiana Zaharia, Ph.D., Manager, Drug Substance Regulatory Strategy, Gilead Sciences, Inc.