UCI Division of Continuing Education

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.

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**

OCRA Orange County Regulatory Affairs Discussion Group

www.ocra-dg.org
Members Save 10%

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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REGULATORY AFFAIRS AND COMPLIANCE CERTIFICATE PROGRAM

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: Concept Review and Evaluation	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
BME X417	Biological Product Regulation	3

ADVISORY COMMITTEE

Richard Chamberlin, Ph.D., Professor and Chair, Pharmaceutical Sciences, University of California, Irvine

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

Alexandre Chan, Pharm.D., MPH, FCCP, FISOPP, BCPS, BCOP, Professor and Founding Chair, Department of Clinical Pharmacy Practice, University of California, Irvine

Sumit Sen, Ph.D., Chemist (Technology-Based Expert), U.S. Food and Drug Administration

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.