UCI Division of Continuing Education

CLINICAL TRIALS: MEDICAL DEVICE AND DRUG DEVELOPMENT

CERTIFICATE PROGRAM • ONLINE

Demonstrating the effectiveness and safety of new medical products is a critical part of the medical product development process and requires significant resources to accomplish. Our program fills a growing need for professional learning that ensures designing and implementing clinical trials for success. The curriculum provides comprehensive knowledge of coordinating, monitoring and managing a clinical trial within a framework of good clinical practices and regulatory requirements.

WHO SHOULD ENROLL

- Working professionals who are interested in transitioning into the clinical trials arena
- Nurses interested in expanding their career options
- Researchers and technologists seeking to increase earning power in the clinical research field
- Medical product development professionals who need working knowledge of clinical trials
- Healthcare professionals and allied health professionals

PROGRAM BENEFITS

- Gain the knowledge base needed to design and implement effective clinical trials
- Acquire a comprehensive knowledge of laws, regulations, guidance, and standard practices needed to surpass regulatory requirements
- Improve time-to-market by applying approved clinical research regulations and clinical research guidelines
- Learn from instructors seasoned in practical industry experience who share their knowledge effectively

CERTIFICATE ELIGIBILITY AND REQUIREMENTS

A certificate is awarded upon completion of 16 credit units (11 required and a minimum of 5 elective credit units), with a grade of "C" or better in each course.

Note: 6 credit units may be counted toward the Medical Device Development or Regulatory Affairs and Compliance 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 a certificate are welcome to take as many individual courses as they wish.

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PROGRAM FEES

The total cost of the certificate 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	$4,775
Candidacy fee	$125
Textbooks and Materials	$600
Total Estimated Cost	**$5,500**

TO ENROLL

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

FOR MORE INFORMATION:

EngineeringSciences@ce.uci.edu

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COURSE#	REQUIRED COURSES (11 units)	UNITS
EECS X445.2	Regulatory Requirements for Medical Devices*	3
EECS X445.26	Regulatory Requirements for Pharmaceutical Products*	3
BioSci X450	Fundamentals of Clinical Trials**	3
Med X413.4 OR	Application of Good Clinical Practices	3
BME X430	Human Subjects Safety in Clinical Trials	2
COURSE#	**ELECTIVE COURSES (Minimum 5 units)**	**UNITS**
BME X405	Applied Anatomy and Physiology for Clinical Studies	4
Med X413.41	Good Laboratory Practices	1.5
Med X413.43	Clinical Data Management	1.5
Med X413.45	Clinical Trials Project Management	3

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

* Candidates may take both courses and count one as an elective.

** Clinical Research Associates and Coordinators, Managers, or Investigators with at least two years work experience in clinical trials may substitute *BioSci X450, Fundamentals of Clinical Trials*, with a 3-unit elective course.

ADVISORY COMMITTEE

Maribelle Guloy, DHSc, CCRP, Director, Clinical Development, American Regent, Inc., a Daiichi Sankyo Group Company

Albert Rego, Scientific Consultant to the Life Science Industry

Charles Stark, PharmD, Sr VP, Research and Development, Emmaus Life Sciences, Inc.