



# 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. An internship course provides an invaluable capstone experience for the certificate.

### 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

**UCI Division of Continuing Education is approved by the California Board of Registered Nursing (BRN) for contact hours (provider number 00093).**

### 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
- UCI Division of Continuing Education is a Regulatory Affairs Professional Society (RAPS) Professional Development provider
- Earn credits to qualify for RAC recertification
- 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 Product 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.

## 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 (11 required and 5 elective units)	\$4,325
Candidacy Fees	\$125
Textbook Fees	\$600
<b>Total Estimated Cost</b>	<b>\$5,050</b>



## RAPS PROFESSIONAL DEVELOPMENT PROVIDER

UCI DCE is a Regulatory Affairs Professionals Society (RAPS) Professional Development provider. UCI DCE is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs UCI DCE has agreed to follow RAPS' established operational and educational criteria.

## TRANSFER CREDIT

Graduates from UCI Division of Continuing Education's Clinical Trials 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**
- **Keck Graduate Institute (KGI) Of Applied Life Science's: Part-Time Master of Bioscience (MBS) Program**

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

## TO ENROLL

Visit [ce.uci.edu/clinicaltrials](http://ce.uci.edu/clinicaltrials) for full course descriptions, instructor biographies, and to enroll.

## FOR MORE INFORMATION:

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## CLINICAL TRIALS: MEDICAL DEVICE AND DRUG DEVELOPMENT CERTIFICATE PROGRAM

Course BME X403 Human Subject Safety has been updated to BME X430. Students who have already taken BME X403 as their required course in the program will still need to complete a minimum of 5.5 elective units.

COURSE #	REQUIRED COURSES (11 units)	UNITS
EECS X445.2	Regulatory Requirements for Medical Devices**	3
EECS X445.26	OR Regulatory Requirements for Pharmaceutical Products**	3
BioSci X450	Fundamentals of Clinical Trials**	3
Med X413.4	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 X413.44	Clinical Trials Internship***	3
Med X413.45	Clinical Trials Project Management	3

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

†Courses EECS X445.2 and EECS X445.26 have been pre-approved by RAPS as eligible for up to 15 credits towards a participant's RAC recertification upon full completion.

\*\*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.

\*\*\*Email [j.mortensen@uci.edu](mailto:j.mortensen@uci.edu) for details.