



UCIRVINE | EXTENSION

Life Sciences

Clinical Trials: Medical Device and Drug Development Certificate Program

Accelerate Your Career

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Improve Your Career Options with a Professional Certificate

In today's competitive business environment, leaders are appointed

based on credentials and experience.

To stay ahead of the competition,

advance your career and increase your

earning potential, enroll in one of

University of California, Irvine Extension's professional certificate programs.

Convenient and affordable, UC Irvine

Extension makes it easy to learn on your

own time, in your own way. Courses are

designed to ensure you gain mastery of a particular topic, and instructors are highly

qualified leaders in their professions.

UC Irvine Extension is the only continuing education provider in Orange County that represents the University of California.

A certificate bearing the UC seal signifies a well-known, uncompromising standard of academic excellence.



Clinical Trials: Medical Device and Drug Development Certificate Program

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. UC Irvine Extension's 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 Attend

- Working professionals 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

UC Irvine Extension is approved by the California Board of Registered Nursing (BRN) for contact hours (provider number 00093).

For more information:

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Certificate Requirements

A certificate is awarded upon completion of 16 credit units (10.5 required and a minimum of 5.5 elective credit units), with a grade point average of "B" or better. It is recommended that candidates complete the required courses prior to the elective courses. All requirements must be completed within five (5) years after the student enrolls in his/her first course.

Note: Six credit units may be counted toward the Medical Product Development Certificate Program.

Transfer Credit

Graduates from UC Irvine Extension's Clinical Trials program are eligible to transfer credits to *Keck Graduate Institute's Masters of Bioscience program* and *Northeastern University's Masters of Regulatory Affairs program*.

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
- Earn credits to qualify for RAC recertification. UC Irvine Extension is a RAPS registered provider for professional development
- Learn from instructors seasoned in practical industry experience who share their knowledge effectively

On-Site Training

Through Corporate Training, we can deliver this program or customize one that fits your organization's specific needs. Visit extension.uci.edu/corporate or call (949) 824-1847 for information.

Curriculum

 Certificate Program Online

Required Courses (10.5 units)

Regulatory Requirements for Medical Devices

EECS X445.2 (3 units)

Increase your understanding of the essential U.S. medical device regulations, including device classification, organizing pre-market notification 510(k), and planning and submitting a Pre-market approval (PMA). Enhance your knowledge of topics that include: global vigilance requirements and labeling requirements, European Medical Device Directive 93/42/EEC (MDD), E.U. conformity assessments, meeting E.U. essential requirements, and developing a technical file for the E.U. Get a review of device registrations in Canada, Australia, Japan and Latin America.

↕ OR

Regulatory Requirements for Pharmaceutical Products

EECS X445.26 (3 units)

This course presents a detailed overview of the regulatory requirements for the development and manufacture of pharmaceutical products. Individuals involved in manufacturing, quality control, research and development, and clinical studies will learn the latest information. Explore topics that include the product development process through commercialization; product characterization and pre-clinical evaluation; pharmaceutical industry requirements; clinical trial requirements, good manufacturing practices (GMPs); good laboratory practices (GLPs); FDA inspections, labeling, and advertising of medical products; and preparing Food and Drug Administration (FDA) submissions.



Fundamentals of Clinical Trials

BIO SCI X450 (3 units)

Clinical trials are designed to answer questions concerning the safety and effectiveness of medical products. Get an overview of clinical trials regulated by the FDA. Learn about the planning process underlying the Strategic Clinical Plan and regulatory submissions to the FDA. Explore topics including protocol development and implementation, i.e. study site selection, financial controls, timelines, and management of the site's operations; proper informed consent; Good Clinical Practices compliance; HIPAA; FDA regulations and guidelines; and post-market support studies.

Application of Good Clinical Practices

MED X413.4 (3 units)

Gain an understanding of the accepted good principles and practices applicable to the development and implementation of drugs and medical devices in a research environment. Enhance your knowledge of topics including: definition of GCPs; the affect of GCPs on the conduct of a clinical trial; applicable regulations from ICH, HHS, FDA, and the state; obligations of investigators, sponsors, monitors, SMOs, CROs, and IRBs in a research environment; and compliance and accountability during a clinical trial. Learn about the basic elements of the clinical data management process.

Human Subjects Safety in Clinical Trials

BME X403 (1.5 units)

The use of human subjects in clinical trials for drug and device development requires sound ethical practices. Explore topics that include FDA regulations and guidance, informed consent process, the make-up and function of Institutional Review Boards (IRB), the IRB review process, and basic biomedical ethics. Course topics are enhanced by guest case studies, small group discussions, and research document reviews.



Elective Courses (Choose a minimum of 5.5 units)

Applied Anatomy and Physiology for Clinical Studies BME X405 (4 units)

Whether designing investigational drugs and medical devices or conducting clinical trials, it is important to have a basic understanding of the form and function of the human body. Learn about human anatomy and physiology as related to pharmaceuticals and medical device design for clinical studies. Clinical examples and modeling techniques are used to demonstrate the applications of anatomy and physiology in the development of investigational drugs and medical devices. Course focus is on human safety in clinical studies.

Good Laboratory Practices

MED X413.41 (1.5 units)

Gain the knowledge to understand and comply with FDA Good Laboratory Practice (GLP) regulations for the conduct of animal/in vitro safety studies. Enhance your understanding of topics including: regulations from the Code of Federal Regulations (CFRs), European and Japanese regulations, typical methods of compliance, how GLP fits into the drug/device/biologic development process, and ethics regarding animal care. Learn about sponsor obligations and how to evaluate a contract laboratory. Visit a clinical research center to reinforce the importance of GLP guidelines and compliance.

Clinical Data Management

MED X413.43 (1.5 units)

Learn about the handling, processing, storage, retrieval, and electronic submissions of clinical data. Gain an understanding of the issues and implications surrounding database setup and the data management process. Enhance your knowledge of applicable FDA regulations (Part 11), and guidelines and the documentation necessary to achieve FDA compliance. The course will be of interest to clinical data management professionals, clinical research coordinators, clinical research associates, project managers, and programmers who support the design and development of clinical databases.

Clinical Trials Project Management

MED X413.45 (3 units)

Structuring the knowledge and expertise to conduct a clinical trial is instrumental in establishing your project plan. Learn how to organize your clinical trials project teams, define specific responsibilities for each team member, and create a project plan for either U.S. trials or Global trials. Participants will evaluate clinical and regulatory strategies for U.S. and Global approvals and become familiar with common standards of operation (SOPs) for clinical trials. Also addressed is the financial management of a clinical trial, negotiating contracts, and understanding how to interact with contract research organizations (CRO's). Hands-on lab exercises reinforce code writing skills.

Clinical Trials Internship

MED X413.44 (3 units)

Gain a working knowledge of the clinical trial researcher's role through an internship position. Interns must attend three meetings with the internship coordinator, work in a UC Irvine clinical research setting for 60 hours, and submit a report of their internship experience based on a daily log kept throughout the quarter. All candidates must attend the Information Meeting on September 26 to obtain the application packet and eligibility requirements. For more information contact Dave Dimas at (949) 824-5380.



Advisory Committee

- **Amy L. Batoosingh**, Director, Clinical Research, Allergan, Inc.
- **Ginger Clasby**, VP, Clinical Affairs, Transcend Medical
- **Ruth Mulnard**, Associate Professor of Nursing Science, Associate Director, UC Irvine
- **Richard Nichol**, President, Nichol Clinical Technologies Corp.
- **Albert Rego**, Scientific Consultant to the Life Science Industry
- **Nancy Schwartz**, Principal, SearchLight Consulting
- **Maribelle G. Sunga**, Director-Clinical Trials, Clinical Trials & Research, Inc.
- **John Thropay**, President & Medical Director, Beverly Oncology & Clinical Trials & Research Associates, Inc.

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