UCI Division of Continuing Education

Life Sciences

- Regulatory Affairs and Compliance
- Clinical Trials: Medical Device and Drug Development
- Medical Product Development

Accelerate Your Career

ce.uci.edu/lifescience

University of California, Irvine
Improve Your Career Options with a Professional Certificate

UCI Division of Continuing Education’s professional certificate programs help you increase or enhance your current skills or prepare for a new career. Courses are highly practical and instructors are qualified leaders in their field. Convenient online courses make it easy to learn on your own time, in your own way. A certificate bearing the UC seal signifies a well-known, uncompromising standard of excellence.

Table of Contents
Regulatory Affairs and Compliance ........................................ 3
Clinical Trials: Medical Device and Drug Development .............. 8
Medical Product Development ........................................... 12
Pharmaceutical (drug and biologic) and medical device companies today are challenged with a stringent and continually evolving regulatory environment, together with changing technologies and global economic considerations. This program is designed to help meet the expanding need for regulatory affairs professionals who are able to understand and interpret regulations across the full spectrum of the product lifecycle and who can demonstrate both operational and strategic effectiveness. It covers a variety of key topics including regulatory requirements, submissions, strategy, compliance during pre-market and post-market phases, and also addresses requirements in the major international markets.

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
- Learn how to maintain regulatory compliance across the product lifecycle
- Further your career with a studies approach in regulatory intelligence by effectively utilizing key databases and resources to gather critical information relevant to the practice of regulatory affairs
- 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 credits to qualify for RAC® recertification
- 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. NOTE: Six credit units may be counted towards the Clinical Trials: Medical Device and Drug Development or Medical Product Development Certificate Program – course units need to be shared between programs.

To become an official candidate in the program, students pursuing the certificate must submit a Declaration of Candidacy. Students are encouraged to declare candidacy as soon as possible. To receive the certificate after completing all program requirements, students must submit a Request for Certificate. 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 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) | $3,990 |
| Candidacy Fees | $125 |
| Textbook Fees | $350 |
| **Total Estimated Cost** | **$4,465** |

OCRA Members receive a 10% discount.

For more information:
Jennifer Mortensen
j.mortensen@uci.edu
(949) 824-9722
## CURRICULUM

### REQUIRED COURSES (Pharm track)  

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHRMSCI X480</td>
<td>Introduction to Regulatory Affairs and Compliance for Drugs, Biologics, and Medical Devices</td>
<td>2</td>
</tr>
<tr>
<td>EECS X445.26</td>
<td>Regulatory Requirements for Pharmaceutical Products</td>
<td>3</td>
</tr>
<tr>
<td>BIO SCI X450</td>
<td>Fundamentals of Clinical Trials</td>
<td>3</td>
</tr>
<tr>
<td>PHRMSCI X481</td>
<td>Post-Approval Compliance Requirements for Pharmaceutical Products</td>
<td>2</td>
</tr>
</tbody>
</table>

### REQUIRED COURSES (Device track)  

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHRMSCI X480</td>
<td>Introduction to Regulatory Affairs and Compliance for Drugs, Biologics, and Medical Devices</td>
<td>2</td>
</tr>
<tr>
<td>EECS X445.2</td>
<td>Regulatory Requirements for Medical Devices</td>
<td>3</td>
</tr>
<tr>
<td>BME X413.2</td>
<td>Regulatory Affairs for Post-Market Approval</td>
<td>2</td>
</tr>
<tr>
<td>BME X412</td>
<td>Regulatory Affairs Planning and Management: Concept Review and Evaluation</td>
<td>3</td>
</tr>
</tbody>
</table>

### COURSE # ELECTIVE COURSES (Choose 5)  

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course Title</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHRMSCI X493</td>
<td>Drug Safety and Pharmacovigilance</td>
<td>2</td>
</tr>
<tr>
<td>MGMT X442.6</td>
<td>Medical Product Quality Systems</td>
<td>3</td>
</tr>
<tr>
<td>MGMT X445</td>
<td>Medical Product Marketing</td>
<td>3</td>
</tr>
<tr>
<td>BME X409</td>
<td>Medical Product Crisis Management</td>
<td>1.5</td>
</tr>
<tr>
<td>PHRMSCI X490</td>
<td>Overview of Global Regulatory Affairs</td>
<td>3</td>
</tr>
<tr>
<td>BME X414</td>
<td>Biomedical Business and Legal Management Essentials</td>
<td>3</td>
</tr>
<tr>
<td>BME X408</td>
<td>Medical Device Product Life-Cycle Management</td>
<td>3</td>
</tr>
<tr>
<td>PHRMSCI X495</td>
<td>Application of ICH Guidelines – Regulatory Strategy Development and Dossier Preparation</td>
<td>2</td>
</tr>
</tbody>
</table>

---

### Advisory Committee

- **Richard Chamberlin**, Ph.D., Professor and Chair, Pharmaceutical Sciences, University of California, Irvine  
- **Michele Dishon**, Pharm.D., Senior Manager, Pharmacovigilance, Spectrum Pharmaceuticals  
- **Jasmine Gupta**, Ph.D., Manager, Global Regulatory Affairs – CMC, Allergan, Inc.  
- **Dennis Hong**, J.D., RAC, Senior Director of Regulatory Affairs, AriCure  
- **Wen Liu**, Ph.D., Global Regulatory Leader, Genentech Inc.  
- **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 (OCRAS)  
- **Cristiana Zaharia**, Ph.D., Manager, Drug Substance Regulatory Strategy, Gilead Sciences, Inc.

### Required Course (both tracks)

**Introduction to Regulatory Compliance for Drugs, Biologics, and Medical Devices**  

PHRMSCI X480 (2.0 units)

This course presents an introduction to the field of regulatory affairs and to the laws and regulations governing healthcare products, including drugs, biologics, dietary supplements, and medical devices. Individuals from various disciplines who are new to the field of regulatory affairs will explore the regulatory pathways for each of these medical products and learn how to maintain regulatory compliance with U.S. regulations throughout the product lifecycle. Examine the structure of the FDA and the historical context of current FDA regulations governing healthcare products. Appreciate the complexities of global regulatory affairs through an introduction to the regulatory structure in the European Union. This course provides an introduction to the regulatory affairs profession, regulatory intelligence, and provides a framework for subsequent courses in the Regulatory Affairs and Compliance Certificate Program.
**Required Courses – Pharma Track**

**Regulatory Requirements for Pharmaceutical Products**
EECS X445.26 (3 units)
This course presents a detailed overview of the regulatory requirements for the discovery, development, and commercialization of pharmaceutical products (drugs and biologics). 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) and inspections, labeling medical products and writing 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.

**Post-Approval Compliance Requirements for Pharmaceutical Products**
PHRMSCI X481 (2 units)
Product approval is a crucial milestone in a product’s lifecycle, after which, the marketing phase begins and post-approval compliance requirements commence. This course explores the FDA regulatory requirements for drugs and biologics following product approval. Some of the areas covered include promotional labelling and advertising, post-marketing surveillance (e.g. adverse events, recalls), post-marketing commitments, post-approval manufacturing changes, post-approval submissions to the NDA/BLA, supply chain management, and quality systems, including compliance with 21 CFR 11 governing electronic records. Students who complete this course will be equipped with relevant knowledge and skills needed to meet post-approval regulatory requirements.

**Required Courses – Device Track**

**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.

**Regulatory Affairs for Medical Device Post-Market Approval**
BME X413.2 (2 units)
Learn how to continuously evaluate and perform periodic reporting on the safety, effectiveness, and reliability of a medical device for its intended use. Utilizing design controls practices and procedures, participants learn “design transfer” from research and development to manufacturing. Increase your knowledge on managing regulatory affairs activities for engineering design modifications, post approval studies, and after-market product changes. Participants learn how to recognize the regulatory pathway for changes in labeling, manufacturing process, design, sterilization, packaging, material and vendor; changes due to customer complaints, product recall or field corrective action.

*This course has been pre-approved by RAPS as eligible for credits towards a participant's RAC recertification upon full completion. The Regulatory Affairs Certification (RAC) is a professional credential offered through the Regulatory Affairs Professionals Society (RAPS). This professional credential is the only globally recognized certification for the regulatory profession. For more information, please visit www.raps.org/rac.*
Regulatory Affairs and Compliance
CERTIFICATE PROGRAM ONLINE

Regulatory Affairs Planning and Management:
Concept Review and Evaluation
BME X412 (3 units)
Learn how to organize your medical product design teams to meet the stringent FDA requirements and Regulatory Affairs. This course has two phases, concept review and evaluation review that provides a baseline knowledge on the role of regulatory affairs professional. Participants learn how to guide medical product designers through the design and development stages based on product classification to demonstrate safety and efficacy or performance for human use; and regulatory approval. Participants will be guided on how to conduct pre-submission meetings with the FDA, how to request meetings with the FDA, prepare and send pre-IDE packets, and how to record and document meetings with the FDA.

Elective Courses (choose 5 units)

Drug Safety and Pharmacovigilance
PHRMSCI X493 (2 units)
With increasing public and regulator focus on product and patient safety, regulatory requirements in this area have become more demanding. Regulatory Affairs professionals work closely with the pharmacovigilance team to comply with regulatory authority requirements and ensure product safety. Learn the essential elements of pharmacovigilance and managing risks/benefits of drugs and biologics throughout the product lifecycle. With focus on U.S. and EU requirements and international harmonization guidelines, explore topics that include pre-marketing and post-marketing adverse event surveillance and reporting, individual case safety reports, aggregate safety reports, safety operational units, MedDRA coding, quality systems, good pharmacovigilance practices, safety inspections, electronic records, safety labeling, signal detection, risk management (REMS, RMPs), and pharmacoepidemiology.

Medical Product Quality Systems
MGMT X442.6 (3 units)
Learn about the essential elements of Quality System Regulations (QSR's) and Good Manufacturing Practices (GMP's), how there is a commonality between them, and how to develop a global approach to Quality Systems in order to satisfy international requirements of ISO 9001:2000 and ISO 13485:2003. A detailed analysis of these systems and practical ‘how to’ recommendations and approaches are presented, with particular emphasis on the United States Food and Drug Administration (FDA) QSR's and GMP's.

Medical Product Marketing
MGMT X445 (3 units)
Getting your medical product to market successfully starts before product design and does not end with the product launch. This course focuses on what is needed to successfully market products within medical device and related industries. Learn how to analyze the market, identify and understand customers and users in medical marketing industries, and provide them with value through innovation, sales and service. Case studies and insights from practicing medical product professionals enhance the application of classroom concepts.

Medical Product Crisis Management
BME X409 (1.5 units)
Recent publicity involving medical device and pharmaceutical products has heightened public awareness and triggered changes in the regulation and marketing practices of many healthcare product companies. Learn how to analyze and review potential response scenarios to various threats impacting a medical company’s product, brand, marketing strategy and financial performance. Role play exercises and case study analysis prepare participants for real world medical product crisis management situations in the current and future regulatory and marketing environment.

For more information:
Jennifer Mortensen
j.mortensen@uci.edu
(949) 824-9722

ce.uci.edu/rac
Overview of Global Regulatory Affairs
PHRMSCI X490 (3 units)

With the expansion of global markets in the pharmaceutical industry, regulatory affairs professionals must be well-versed in multinational regulatory requirements. This course presents an overview of the regulatory agencies and regulations for drugs and biologics in the EU, Canada, and Japan in comparison with the U.S. regulatory system. Explore topics that include international harmonization efforts, premarket regulations, authorization requirements, and regulatory authority enforcement. Learn how to apply knowledge of international regulations to formulate a global regulatory strategy for product development.

Biomedical Business and Legal Management Essentials
BME X414 (3 units)

Increase your knowledge of business and legal issues in the biomedical industry. Participants will learn to discern the rationale behind policies and procedures in a highly regulated industry. A top-down approach is taken to introduce broad business and legal concepts and relating them specifically to design, development, and commercialization of medical device and pharmaceutical products. Topics include corporate structure, corporate formation; and early stage financing, contracts, licensing, formation, intellectual property, due diligence and sale.

Medical Device Product Life-Cycle Management
BME X408 (3 units)

From concept through development to approval, the Medical Product Life Cycle integrates design, development, validation, and commercialization. Further your understanding of the phases, requirements, and deliverables of the Product Life Cycle in order to manage projects and multifunctional teams. Topics covered include product development process, customer requirements, proof of concept, design control, design verification and validation, design transfer, product launch, risk management, regulatory strategy, intellectual property management, project management, start-up company experiences, and time to market.

Application of ICH Guidelines – Regulatory Strategy Development and Dossier Preparation
PHRMSCI X495 (2 units)

A well-planned regulatory strategy formulated in the early stages of product development is critical for a product’s success. This course will examine the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. Discover how ICH guidelines guide the development of regulatory strategies for product development. Learn how to apply ICH Guidelines for preparation of market authorization application dossiers. Exploration of ICH guidelines during this course will include those establishing the chemistry, manufacturing, and controls data needed to support investigational and marketing applications. The ICH guidelines establishing the required structure and content of the Common Technical Document (CTD) are also covered. This class emphasizes the practical application of ICH guidelines to help build a successful dossier for submission to regulatory authorities.
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.

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

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
- Earn credits to qualify for RAC* recertification
- Learn from instructors seasoned in practical industry experience who share their knowledge effectively

*This course has been pre-approved by RAPS as eligible for credits towards a participant’s RAC recertification upon full completion. The Regulatory Affairs Certification (RAC) is a professional certification offered through the Regulatory Affairs Professionals Society (RAPS). This professional credential is the only globally recognized certification for the regulatory profession. For more information, please visit: www.raps.org/rac.

Certificate Eligibility and 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 of “C” or better in each course. NOTE: Six credit units may be counted toward the Medical Product Development Certificate Program – course units need to be shared between programs.

To become an official candidate in the program, students pursuing the certificate must submit a Declaration of Candidacy. Students are encouraged to declare candidacy as soon as possible. To receive the certificate after completing all program requirements, students must submit a Request for Certificate. All requirements must be completed within 5 years after the student enrolls in his/her first course. Students not pursuing the certificate program are welcome to take as many individual courses as they wish.

Individuals seeking the designation of Certified Clinical Research Professional, “CCRP” from The Society of Clinical Research Associates (SoCRA), who hold an Associate’s Degree or Bachelor’s degree in science, health science, pharmacy, or a related (science/health-care) field, may complete the UC Irvine Extension Clinical Trials Certificate Program in lieu of one year of SoCRA’s eligibility requirement of two years’ work experience in clinical research. For more information about the CCRP designation, please visit the SoCRA website at http://www.socra.org/html/certific.htm.

Internship course available to students who are certificate candidates and have completed the required courses. Call Dave Dimas at (949) 824-5380 for details.

Transfer Credit
Graduates from UCI Continuing Education’s Clinical Trials Program are eligible to transfer credits to:
- Keck Graduate Institute, School of Applied Life Sciences, Master of Bioscience
- Northeastern University Master of Science in Regulatory Affairs for Drugs, Biologistics, and Medical Devices

NOTE: Any student wishing to transfer credits must obtain a “B” or better in each course.
### CURRICULUM

#### REQUIRED COURSES (10.5 units)

<table>
<thead>
<tr>
<th>COURSE #</th>
<th>COURSE NAME</th>
<th>UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EECS X445.2</td>
<td>Regulatory Requirements for Medical Devices*</td>
<td>3</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EECS X445.26</td>
<td>Regulatory Requirements for Pharmaceutical Products**</td>
<td>3</td>
</tr>
<tr>
<td>BioSci X450</td>
<td>Fundamentals of Clinical Trials***</td>
<td>3</td>
</tr>
<tr>
<td>Med X413.4</td>
<td>Application of Good Clinical Practices</td>
<td>3</td>
</tr>
<tr>
<td>BME X403</td>
<td>Human Subjects Safety &amp; Ethics in Clinical Trials</td>
<td>1.5</td>
</tr>
<tr>
<td>BME X405</td>
<td>Applied Anatomy and Physiology for Clinical Studies</td>
<td>4</td>
</tr>
</tbody>
</table>

#### ELECTIVE COURSES (Minimum 5.5 units)

<table>
<thead>
<tr>
<th>COURSE #</th>
<th>COURSE NAME</th>
<th>UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Med X413.41</td>
<td>Good Laboratory Practices</td>
<td>1.5</td>
</tr>
<tr>
<td>Med X413.43</td>
<td>Clinical Data Management</td>
<td>1.5</td>
</tr>
<tr>
<td>Med X413.44</td>
<td>Clinical Trials Internship</td>
<td>3</td>
</tr>
<tr>
<td>Med X413.45</td>
<td>Clinical Trials Project Management</td>
<td>3</td>
</tr>
<tr>
<td>BME X415</td>
<td>Ethical and Regulatory Aspects of Clinical Trials</td>
<td>3</td>
</tr>
</tbody>
</table>

---

*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 three-unit elective course.

† Call for details, Dave Dimas (949) 824-5380.

---

### 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 (10.5 required and 5.5 elective units) $4,515
- Candidacy Fees $125
- Textbook Fees $600

**Total Estimated Cost** $5,240

---

OCRA members receive a 10% discount!

---

**For more information:**
Jennifer Mortensen
j.mortensen@uci.edu
(949) 824-9722

---

**Advisory Committee**

Amy L. Batooosingh, Sr. Director, Core Project Team Lead, Allergan, Plc.
Patricia Beers Block, B.S., B.S., CCRP, Assistant Professor, Clinical Trial Sciences BioPharma Educational Initiative, SHP Rutgers, The State University of New Jersey
Ginger Glasby, Vice President, Clinical Affairs, Transcend Medical
Maribelle Guloy, Director, Clinical Trials, Clinical Trials & Research Associates, Inc.
Ruth Mulnard, Associate Professor of Nursing Science, Associate Director, University of California, Irvine
Richard Nichol, President, Nichol Clinical Technologies Corp.
Yutaka Niihara, MD, CEO, Emmaus Life Sciences, Inc.
Albert Rego, Scientific Consultant to the Life Science Industry
Nancy Schwartz, Principal, SearchLight Consulting
Charles Stark, PharmD, Senior Vice President, Research and Development, Emmaus Life Sciences, Inc.
John Thropay, President & Medical Director, Beverly Oncology & Clinical Trials & Research Associates, Inc.
Clinical Trials: Medical Device and Drug Development
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.

**Regulatory Requirements for Pharmaceutical Products**
EECS X445.26 (3 units)
This course presents a detailed overview of the regulatory requirements for the development and commercialization of pharmaceutical products (drugs and biologics). 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); inspections and labeling 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.

For more information:
Jennifer Mortensen
j.mortensen@uci.edu
(949) 824-9722

ce.uci.edu/clinicaltrials

*This course has been pre-approved by RAPS as eligible for credits towards a participant’s RAC recertification upon full completion. The Regulatory Affairs Certification (RAC) is a professional certification offered through the Regulatory Affairs Professionals Society (RAPS). The professional credential is the only globally recognized certification for the regulatory profession. For more information, please visit www.raps.org/rac.*
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)
Increase your understanding of the processes of application and compliance with FDA's Good Laboratory Practice (GLP) regulations for the conduct of animal/in-vitro (non-clinical) safety studies. Learn about sponsor obligations and important considerations to evaluate a contract laboratory. Develop new insights into topics that include the applicable regulations from the Code of Federal Regulations (CFRs) and their history; typical methods of compliance; process of GLP integration into the drug/device/biologic development process; ethics pertaining to animal care and use; applicable Quality Assurance (QA) and Quality Control (QC) processes; GLP documentation management; and the FDA's GLP inspection program. Gain an overview of the changing scope of the GLP regulations as well as its impact on biomedical research, and future trends.

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 apply the principles of project management to the implementation and evaluation of clinical trials. Gain an overview of fundamental project management concepts and methods, and then learn how to apply those concepts and methods to the unique characteristics of a clinical trial. Topics include organizing and planning the project, and recruiting participants, and analyzing the results.

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 Clinical Research setting for a minimum of 60 hours, and submit a report of their internship experience based on a daily log kept throughout the quarter. To obtain more information and schedule internship meetings with a UCI Continuing Education coordinator, please call (949) 824-5380.

Ethical and Regulatory Aspects of Clinical Trials
BME X415 (3 units)
Ethics and regulatory aspects of clinical trials are an important element of the scientific process. This course is intended to introduce students to the core ethical principles and regulatory standards for the protection of human subjects in research. Examples from prior clinical trials will guide the course content as to the responsibilities and expectations for an ethical clinical trial conduct. There will be considerable attention on addressing special ethical concerns in clinical research. Additionally, this course will cover the regulatory oversight of clinical trials and the guidance as outlined in Good Clinical Practice, and the implementation of the HIPAA Privacy Rule in Research.
Emerging technologies, ever-changing regulations, and increased competition create many challenges for the medical product industry. UCI Continuing Education’s program, developed with government and industry advisors, fulfills a recognized need for comprehensive professional learning in the successful design, development, and delivery of medical devices, pharmaceuticals, and other biomedical products. The curriculum addresses the breadth of the development process, including a thorough understanding of compliance, engineering for improved performance, how to mitigate commercial and financial risks, and building marketing success.

Who Should Enroll
- Regulatory professionals, such as those in regulatory affairs or quality assurance
- Engineers, such as those involved in biomedical product design and development
- Manufacturing professionals
- Clinical managers and other healthcare professionals
- Life science managers, such as research scientists and product managers

Program Benefits
- Gain the knowledge needed to design and create medical devices and pharmaceuticals
- Acquire an understanding of the medical device product development process and knowledge needed to manage medical device intellectual property rights
- Learn how to implement successful medical device design and manufacturing by avoiding common quality and regulatory pitfalls
- 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 15 credit units (9 required and 6 elective credit units), with a grade of “C” or better in each course. NOTE: Six credit units may be counted toward the Clinical Trials: Medical Device and Drug Development Certificate Program when courses are shared.

To become an official candidate in the program, students pursuing the certificate must submit a Declaration of Candidacy. Students are encouraged to declare candidacy as soon as possible. To receive the certificate after completing all program requirements, students must submit a Request for Certificate. All requirements must be completed within 5 years after the student enrolls in his/her first course. Students not pursuing the certificate program are welcome to take as many individual courses as they wish.

Transfer Credit
Graduates from UCI Continuing Education’s Medical Product Development Program are eligible to transfer credits to:
- Northeastern University Master of Science in Regulatory Affairs for Drugs, Biologistics and Medical Devices
- University of Nebraska-Lincoln Online Master in Engineering Management (MEM)
- University of Wisconsin-Platteville Online Master of Science in Engineering

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

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 (9 required and 6 elective units) $3,650
Candidacy Fees $125
Textbook Fees $560

Total Estimated Cost $4,335

*This course has been pre-approved by RAPS as eligible for credits towards a participant’s RAC recertification upon full completion. The Regulatory Affairs Certification (RAC) is a professional certification offered through the Regulatory Affairs Professionals Society (RAPS). This professional credential is the only globally recognized certification for the regulatory profession. For more information, please visit: www.raps.org/rac.

OCRA members receive a 10% discount!
CURRICULUM

COURSE #   REQUIRED COURSES (9 units)   UNITS
BME X408   Medical Product Life Cycle Management   3
EECS X445.2   Regulatory Requirements for Medical Devices*   3
OR
EECS X445.26   Regulatory Requirements for Pharmaceutical Products*   3
MGMT X442.6   Medical Product Quality Systems   3

COURSE #   ELECTIVE COURSES (Minimum 6 units)   UNITS
Regulatory Affairs
MGMT X446   Medical Product Marketing   3
MED X413.4   Application of Good Clinical Practices   3
BME X414   Biomedical Business and Legal Management Essentials   3
Quality and Compliance
EECS X445.22   Medical Product Manufacturing   3
BME X407   Process Validation for Medical Product Development   3
BME X406   Medical Device Risk Management   3
BIO SCI X450   Fundamentals of Clinical Trials   3
MED X413.41   Good Laboratory Practices   1.5

Engineering and Science
BME X405   Applied Anatomy and Physiology for Clinical Studies   4
EECS X445.23   Medical Device Design and Evaluation   3

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

Required Courses (9 units)
Medical Product Life-Cycle Management
BME X408 (3 units)
From concept through development to approval, the medical product lifecycle integrates design, development, validation, and commercialization. Further your understanding of the phases, requirements, and deliverables of the product lifecycle in order to manage projects and multifunctional teams. Topics covered include design control, FDA guidances, corporate procedures, start-up company experiences, marketing tools, concept generation, intellectual property, risk management, statistics, regulatory strategy, and time to market.

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

Elective Courses (6 units)

Medical Product Marketing
MGMT X445 (3 units)
Getting your medical product to market successfully starts before product design and does not end with the product launch. This course focuses on what is needed to successfully market products within medical device and related industries. Learn how to analyze the market, identify and understand customers and users in medical marketing industries, and provide them with value through innovation, sales, and service. Case studies and insights from practicing medical product professionals enhance the application of classroom concepts.

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 engagement; and compliance and accountability during a clinical trial. Learn about the basic elements of the clinical data management process.

Biomedical Business and Legal Management Essentials
BME X414 (3 units)
Increase your knowledge of business and legal issues in the biomedical industry. Participants will learn to discern the rationale behind policies and procedures in a highly regulated industry. A top down approach is taken to introduce broad business and legal concepts and relating them specifically to design, development, and commercialization of medical device and pharmaceutical products. Topics include corporate structure, corporate formation, early stage financing, contracts, licensing, intellectual property, due diligence, and sales.

Medical Product Manufacturing
EECS X445.22 (3 units)
Learn about the essential manufacturing principles for medical device and pharmaceutical products, and the regulations governing the medical product manufacturing process. Gain valuable knowledge in understanding the
key principles, challenges, and issues involved in good manufacturing practices (GMPs) of medical products. Topics include product development cycle, understanding the customer and their needs, material and process selection, packaging and sterilization, reliability testing, design validation, manufacturing process validation, and developing a manufacturing strategy.

Process Validation for Medical Product Development
BME X407 (3 units)
Enhance your understanding of process validation and how it is applied to the development of medical products. Learn how to assess an appropriate level of process scrutiny to provide a high level of confidence for process validation. Increase your knowledge of validation project management; basic approaches to process validation; validation criteria for facilities and utilities; sterilization techniques; use of controls; automated processes; and computer systems. Case studies illustrate how critical processes are validated in the development of cardiovascular, ophthalmic, and intravenous devices.

Medical Device Risk Management
BME X406 (3 units)
Risk management integrated into the overall quality management is one of the main components for global medical device compliance. To meet the approval requirements for almost every regulated market, a comprehensive implementation and documentation of a full risk management lifecycle has to be demonstrated. This course introduces the major components necessary to achieve global regulatory compliance and approvability. The main emphasis is on European and U.S. regulation. A practical path to implanting a successful risk management system across different subsystems will be presented. The main issues covered are risk management, compliance with IEC60601-1, usability engineering and software risk management.

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.

Good Laboratory Practices
MED X413.41 (1.5 units)
Increase your understanding of the processes of application and compliance with FDA’s Good Laboratory Practice (GLP) regulations for the conduct of animal/in-vitro (non-clinical) safety studies. Learn about sponsor obligations and important considerations to evaluate a contract laboratory. Develop new insights into topics that include the applicable regulations from the Code of Federal Regulations (CFRs) and their history; typical methods of compliance; process of GLP integration into the drug/device/biologic development process; ethics pertaining to animal care and use; applicable Quality Assurance (QA) and Quality Control (QC) processes; GLP documentation management; and the FDA’s GLP inspection program. Gain an overview of the changing scope of the GLP regulations as well as its impact on biomedical research, and future trends.

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.

Medical Device Design and Evaluation
EECS X445.23 (3 units)
Explore the opportunities and need for medical devices through the examination of mortality and morbidity with special attention to medical problems that affect patients’ productivity. A market and need-driven systems engineering approach is applied to the examination of medical device design. The designs of medical devices are then studied through a layered approach of examining the underlying physiological mechanisms, the applicable biomedical sensors and actuators, as well as the control processing power requirements. Exemplary medical device solutions are studied.
Academic Management

Dave Dimas, Ph.D., Director, Engineering, Sciences and Information Technologies

Corporate Training

Our Corporate Training specialists can deliver any of these programs or customize one that fits your company’s specific needs.

Visit ce.uci.edu/corporate or call (949) 824-1847 for information.

Life Sciences Programs

Jennifer Mortensen  ■  (949) 824-9722  ■  j.mortensen@uci.edu

ce.uci.edu/lifescience