



ONLINE
CREDIT COURSES

Clinical Trials Project Management

Online Courses Focusing on Product Development for FDA Approval

The Clinical Trials Project Management Online Courses are graduate level academic credit courses that will be offered in a cohort-based format. Each course consists of 3 units of credit; students completing all 4 courses will receive a California State University Certificate Program in Clinical Trials Project Management and 12 units of academic credit.

The courses are designed to meet the high demand for project management personnel for human clinical trials involving medical devices, in vitro diagnostics, biologics, pharmaceuticals and combination products, with the focus on managing biomedical product development for FDA approval.

The courses are ideal for professionals interested in pursuing a clinical development career. They are designed to help clinical research associates, health care and allied health professionals and professionals involved in the development of a medical product to refine their skills or expand their knowledge. The online format allows for a more flexible schedule for those already in the workforce. Even though the courses take place outside of the traditional classroom, they offer real-world experiences involving team projects and case studies.

The four courses incorporate several overall themes: project management, ethics in biomedical product development, data management and global regulatory affairs.

REQUIREMENTS

Students must have successfully completed an undergraduate degree; it is preferred that students have a Bachelor's degree in science or a healthcare related field. Students must maintain a GPA average of 3.0 or above throughout all course work.

This program is a collaboration among Cal Poly Pomona, Cal State Los Angeles and Cal State Fullerton



BENEFITS

- Learn the process for managing biomedical product development for FDA approval
- Gain an in-depth understanding of the clinical trials process through a modular, operations-focus approach
- Acquire project management skills needed to successfully manage human clinical trials
- Gain a global perspective on clinical trials management to better respond to the growing industry across the globe
- Learn how to respond to ethical issues inherent in clinical trials
- Discover how to use statistical methods to monitor clinical trial outcomes and make decisions
- Gain practical knowledge through real-world case studies and team projects in product development
- Learn from instructors with industry expertise in clinical trials management

SCHEDULE

The courses will begin in Fall 2011. All four courses can be completed in less than a year if classes are taken continuously. Please note, Course 1 is the prerequisite for the rest of the courses. **See www.fullerton.edu/clinicaltrials for registration instructions.**

Course 1: RA 602 - Intro to Food & Drug Law – Aug. 22 to Oct. 30

Course 2: BIOL 537 - Setting Up Clinical Trials – Nov. 7 to Jan. 8*

Course 3: BIOL 538 - Managing Clinical Trials – Jan. 16 to Mar. 11

Course 4: BIOL 539 -Pre-market Submission Process – Mar. 19 to May 20**

*Holiday break – no classes the week of Dec. 26th

**Spring break – no classes the week of Mar. 26th

Please note: The first course is offered online through San Diego State University (SDSU), however, the remaining three courses will be offered online through Cal State Fullerton (CSUF).

Clinical Trials Project Management

THE COURSES

The first course is the prerequisite for the rest. The courses are listed in the order they will be offered. This is a cohort-based program – you will go through the four courses with the same group of students.

Introduction to Food and Drug Law - RA 602 (3 units)

Please note: This first course will be offered online through San Diego State University but the three remaining courses will be offered online through Cal State Fullerton.

An overview of:

- Regulatory requirements in the U.S. for drugs, biologics, in vitro diagnostics, devices, combination products, dietary supplements and cosmetic products
- Regulations in other countries
- Food and Drug Administration's (FDA) organization, structure and history
- Medical product development process
- Good Clinical Practices (GCP) – standards and regulations, pre-market and post-market
- Requirements and best practices for post market clinical trials
- Ethical concerns and examination of the role of statistics in clinical studies

Required textbook: A Practical Guide to Food and Drug Law Regulation, 3rd edition

Author(s): Pina, K.R. and Pines, W.L.

Publisher: Washington, D.C.: Food and Drug Law Institute, 2008
ISBN: 9781935065029

Ordering Information: This book is only available through the Food and Drug Law Institute (FDLI). To receive the book through FDLI at the discounted price, place your order by phone at (800) 956-6293 and ask for the student discount.

Clinical Trials Project Management:

Setting Up Clinical Trials - BIOL 537 (3 units)

Prerequisite: BIOL 576 or RA 602 or equivalent

A comprehensive overview of:

- Types and phases of clinical trials
- Implementation of Good Clinical Practices (GCP)
- Development of clinical study documents
- Interactions with Institutional Review Board (IRB)
- Identification and qualification of study sites
- Insurance requirements and needs
- Statistical considerations in study design
- Ethical issues
- Setting up clinical trials globally
- Investigator and subject matter recruitment issues
- Inclusion and exclusion criteria
- Project management skills and best practices

Clinical Trials Project Management:

Managing Clinical Trials - BIOL 538 (3 units)

Prerequisite: BIOL 537

A comprehensive overview of project management issues such as:

- Successful management, monitoring and closure of human clinical trials
- Preparing for and managing regulatory agency audits
- Balancing business goals with ethical issues
- Managing regulatory and statistical issues related to data management
- Monitoring best practices, from a global perspective
- Maintaining a budget and schedule to meet business goals
- Crisis management and conflict resolution

Clinical Trials Project Management:

Pre-Market Submission Process - BIOL 539 (3 units)

Prerequisite: BIOL 538

A comprehensive overview of the report process for pre-market submission to the FDA, such as:

- Development of timelines for submissions
- Project management principles followed by Regulatory Affairs professionals employed in the biomedical industry
- Incorporation of clinical data into product labeling
- Best practices for negotiating with regulatory agencies
- Ethical considerations
- Statistical issues in submissions
- Post-market clinical study scenarios.
- Global perspective on the premarket submissions process

COST

The cost of the first course will be \$522 per unit for a total of \$1566. The remaining three courses will be \$495 per unit or \$1,485 per course.

REGISTRATION

Online registration for the Fall 2011 session is now open. Visit www.fullerton.edu/clinicaltrials for complete registration details.

If you have questions regarding these courses, please contact Pat Lussier at plussier@fullerton.edu.

Registering in these courses does not guarantee admission to either a CSUF or other graduate programs. Credits earned may be applied toward a master's degree, depending upon program approval. Approval is currently pending for the 12 units to be accepted as part of the Program for Applied Biotechnology Studies (PABS) graduate study plan at Cal State Fullerton, Cal Poly Pomona or Cal State Los Angeles.