PROFESSIONAL PROGRAM IN

Regulatory Affairs

Regulatory affairs personnel are the first-line assurance that company products and documentation are in accordance with regulatory bodies worldwide. The Professional Program in Regulatory Affairs provides the training to manage these activities and reviews FDA regulations and other guidelines, Good Pharmaceutical Practice (GXP) principles and ethical considerations covering the development of drugs and dossiers for clinical trials and licensure. Additional coursework draws from the related functional areas of clinical research, product and process development, manufacturing and supply chain, and quality and compliance. Many required courses apply to multiple programs, allowing you to earn credit while you find the curriculum that’s right for you.

6 Required Courses, Minimum 2 Electives*
9 Semester Units, 135 Hours of Instruction

Principles of Regulatory Affairs  PB HLTH X401.3 (1 semester unit)
Get an introduction to the regulatory authorities whose regulations and requirements must be met to ensure compliance with the industry's laws.

BLA/NDA/MAA Submissions and Commercialization  PB HLTH X402.2
(2 semester units)
Master the components and processes for successful licensure of a biotechnology product.

Harmonization Across Worldwide Applications  PB HLTH X402.1 (1 semester unit)
Understand the role of regulatory affairs in worldwide requirements for product licensure.

IND/CTA Enabling Studies and Agency Interfaces  PB HLTH X402.4 (1 semester unit)
Learn the initial steps taken in the product development life cycle, including the responsibilities as facilitators and conduits between companies and regulatory agencies.

IND/CTA Preparation and Submission  PB HLTH X402.3 (1 semester unit)
Examine the processes in the preparation, development, submission and approval of the IND/CTA.

Post-Approval Activities  PB HLTH X403.1 (1 semester unit)
Discern the role of regulatory affairs after licensure and commercialization of a biopharmaceutical product.

* See the website for a complete list of available electives. Course availability is subject to change.

Learn more at extension.berkeley.edu/spos/regulatory.html (continued)
Prerequisites for Admission
There are no prerequisites for the Professional Program in Regulatory Affairs, but a bachelor’s degree is recommended.

Curriculum and Completion Requirements
The curriculum comprises 6 required courses and a minimum of 2 electives for a total of 9 semester units (135 hours of instruction). Candidates must pay a nonrefundable program registration fee.

You must take all courses for a letter grade. To receive the Award of Completion, you must maintain an overall minimum 2.5 grade point average, with a grade of C or better in each course.

All coursework must be completed within five years of registering for the program. However, requirements may be updated based on new developments in the field of study; we recommend completing the curriculum in a timely fashion.

How to Register for This Specialized Program of Study
Register for the Professional Program in Regulatory Affairs at extension.berkeley.edu/cert/register.html. Click on the More Information button next to the program title to begin the registration process. Complete your student account profile if you are a new student, and pay the nonrefundable program registration fee.

You may enroll in individual courses without registering for the Professional Program in Regulatory Affairs.

Value of a UC Berkeley Extension Specialized Program of Study
As the continuing education arm of the University of California, Berkeley, UC Berkeley Extension is a respected provider of adult and professional education. Fulfilling the requirements for a UC Berkeley Extension specialized program of study reflects the successful completion of a high-caliber, in-depth sequence of courses.

Learn More
For additional information about the Professional Program in Regulatory Affairs, visit extension.berkeley.edu/spos/regulatory.html, email extension-science@berkeley.edu or call (510) 642-1062.