

Free Program Overview

1 *Clinical Trials and Regulatory Affairs*

These special information sessions provide opportunities to meet instructors and other students, learn about program prerequisites, philosophy, requirements, and course content.

You will also gain insights into careers in clinical research and regulatory affairs.

Offered January and August

Courses 16650 and 22402

2 *Explore UCSC Extension's Other Bioscience Programs*

Bioinformatics

Biotechnology

Clinical Trials Design and Development

Medical Devices

Bioscience Business and Marketing

See ucsc-extension.edu/biosciences for more information.

Keep your RAC certification current

RAPS Credit: Many of the required and elective courses in UCSC Extension's Regulatory Affairs Certificate Program qualify for points toward recertification for RAC. See the Regulatory Affairs Professionals Society Web site at www.raps.org.



The San Francisco Bay Area's Only Comprehensive Regulatory Affairs Certificate Program

Regulatory affairs professionals play critical roles in ensuring compliance with the laws and regulations guiding the development and commercialization of health care products. Industry studies cite regulatory affairs as one of the most crucial human resource needs in the bioscience industry for the coming decade. UCSC Extension's Regulatory Affairs Certificate Program was developed with the guidance of industry and government experts to meet this need.

The Regulatory Affairs Certificate Program provides broad regulatory foundations, exposure to the practical, real-world applications of the regulations, and appreciation of the important roles that regulatory professionals play in the biomedical industry. Courses are taught by experienced regulatory professionals currently working in the device, diagnostic, pharmaceutical and biologic sectors. Instructors bring the regulations to life and infuse courses with relevant examples and hands-on projects designed to prepare students for rewarding careers in regulatory affairs.

Program Benefits

This highly-interactive program provides:

- An understanding of the complex processes central to developing and bringing new medical products to market
- In-depth coverage of U.S. and international laws and regulations governing the testing, manufacture and distribution of medical devices, diagnostics, pharmaceuticals, and biologics
- Hands-on experience with the documentation required for new product approval and product surveillance
- Grounding in the ethical, management and professional competencies needed to be effective in regulatory roles
- Strategic thinking and analytical skills applicable to regulatory functions in the biomedical industry

Who Should Attend This Program

Regulatory personnel come from a variety of backgrounds, including clinical, engineering, law, manufacturing, QA/QC, research, and medical and allied professions. The Regulatory Affairs Certificate builds on these foundations and overlays the regulatory principles, practices and strategies needed by professionals entering the field of regulatory affairs. It also increases the knowledge and competency of those already working in regulatory affairs, especially in entry-level or mid-level positions.

Program Contact

Applied and Natural Sciences Department
(408) 861-3860
program@ucsc-extension.edu

All courses held in Santa Clara



About UCSC Extension in Silicon Valley

The vital learning community at UCSC Extension in Silicon Valley is well known for its collegial atmosphere and rigorous preparation. Our faculty of expert practitioners teaches state-of-the-art solutions to the everyday problems confronting professionals working in Silicon Valley. The professional education programs we offer build expertise, open doors to new opportunity, and deliver tangible value. Our broad portfolio of open-enrollment courses and certificates, affordable pricing, experience-based instruction, and central location in Silicon Valley help turn jobs into careers.

Regulatory Affairs Certificate

Program Prerequisites

Given the scientific foundations of the bioscience industry and the importance of effective communication to the regulatory role, students who come to the program with a basic understanding of the life sciences and strong written and oral communication skills will gain the most from this program.

Certificate Requirements

To obtain the Certificate in Regulatory Affairs, you must complete the **7 required courses** and **4 units of elective courses**, for a minimum total of **19 units**. For GPA requirements and program time limits, see ucsc-extension.edu/regaffairs.

Recommended Course Sequence

We recommend that students begin the program with "Drug Development Process" or "Regulation of Medical Devices and Diagnostics."

Certificate Application

Students are encouraged to establish candidacy in a certificate program early in their studies. By doing so, they lock in program requirements, receive notification of updates to the program and priority enrollment in fully enrolled courses. Certificate applications can be submitted online. Visit ucsc-extension.edu/certificates.

Earn Two Certificates: Learn More for Less

Students pursuing the Regulatory Affairs plus Biotechnology or Clinical Trials Design and Management certificates need a minimum of 32 units, including all required courses and elective units for both programs. Please note that in order to complete two certificate programs with the minimum number of units, students must select some electives that are common to both programs. Contact us at program@ucsc-extension.edu or call (408) 861-3860 if you need more information or would like assistance creating a study plan.



Curriculum

Required Courses (seven)	Units	Course
Drug Development Process	2.06559
Regulation of Medical Devices and Diagnostics	3.019071
Regulation of Drugs and Biologics	3.019007
Interacting with the FDA	1.519318
RA Professional's Toolbox	1.519317
One of the following*		
Regulatory Submissions: Drugs and Biologics OR	2.019067
Regulatory Submissions: Devices and Diagnostics	2.519315
One of the following*		
Good Manufacturing Practices OR	3.06328
Regulatory Compliance for Medical Devices	2.519029
Elective Courses (4 units required)	Units	Course
Regulatory		
Design Control for Product Development	1.521973
Electronic Records for Regulated Environments: Cost-Effective Approaches to Compliance	1.519362
Global IND Submissions	2.022184
Global Medical Device Submissions and Strategy	1.520343
Human Factors in Medical Device Development	2.023097
Medical Writing	2.04451
Post-Market Regulatory Obligations for Medical Devices	1.522414
Regulation of Biomedical Product Advertising, Promotion and Labeling	1.520756
Regulatory Intelligence	1.020341
Risk Management for Regulated Industries	3.022631
Value-Added Quality Audits	1.519070
Clinical		
Adverse Event and Medication Coding: An Introduction to MedDRA, COSTART, and WHO-Drug	1.519976
Clinical Statistics for Non-Statisticians	2.02345
Contracting with Contract Research Organizations (CROs)	1.55479
Drug Safety and Adverse Events Reporting	1.03990
Electronic Data Capture for Clinical Trials	1.020777

Global Conduct of Clinical Trials	1.520787
Good Clinical Practices	3.00458
Preparing for FDA Inspections and Conducting Sponsor Audits	1.55168
Science of Clinical Trials Design	2.53657
Discovery/Development		
Biopharmaceutical Fundamentals	2.06659
Biopharmaceutical Project Management and Leadership	1.54490
Drug Development: Formulation Design, Manufacture and Control	1.54452
Intellectual Property Essentials for the Life Science Industry	1.01942
Medical Device Design and Development	2.019977
Molecular Diagnostics	1.521972
Pharmacology, Principles	2.05596
Product Development Life Cycle for Medical Devices	2.023084
Statistical Design of Experiments: A Practical Approach	2.023096
Stem Cell Biology	1.513567
Toxicology Basics for Biotechnology	1.52310
Viruses, Vaccines and Gene Therapy	1.56974

Courses may be taken individually or as part of the certificate program.

Required Courses

Drug Development Process

The development of new drugs is a complex, lengthy, and expensive process. In this course, we examine this process—from discovery to market and beyond—and see what makes the biopharmaceutical industry unique. Infused with real-world examples, lectures address drug discovery; preclinical characterization of new drug entities; the phases and purposes of both pharmacological and clinical development; regulatory filings, compliance and oversight; FDA jurisdiction; and strategic issues in drug development.

Course 6559

Explore UCSC Extension's Other Bioscience Programs

- Bioinformatics
- Clinical Trials
- Biotechnology
- Medical Devices
- Bioscience Business and Marketing



Course Descriptions

Regulation of Medical Devices and Diagnostics

Starting with the definition of medical devices, an overview of the medical device industry, and the historical roots of medical device regulation, the instructor lays a foundation for understanding the unique aspects of medical devices and the pathways through which various classes of products are moved into the U.S. marketplace. Students gain in-depth exposure to key routes to market, including 510(k) premarket notification and premarket approval applications (PMA). Students gain insight into the rationale and strategies for using each of these paths, as well as the clinical testing of devices, and investigational device exemption (IDE) application and process.

Course 19071

Regulation of Drugs and Biologics

Complex regulations govern the development, manufacture, and commercialization of biomedical products. This course helps participants understand the regulatory requirements, both U.S. and international, for patented and generic pharmaceuticals, over-the-counter drugs, and biological products. Students gain knowledge and insight into the regulatory agencies and their roles and responsibilities; regulatory applications and pathways; postmarketing requirements; the impact of regulatory differences between the U.S. and other countries; and how regulatory approval processes affect corporate strategy.

Course 19007

Regulatory Submissions: Drugs and Biologics

This course uses approved drug labels and summary basis of approvals to help students acquire the knowledge and insight needed to understand and begin to construct core U.S. drug and biologics submissions, including premarketing (IND), marketing (NDA/CTD) and postmarketing documents. Students learn how to work with the regulations, guidance documents and style guides to produce submissions that comply with the requirements and are clear to the reviewers.

Course 19067

Regulatory Submissions: Devices and Diagnostics

Designed for individuals who already have a strong foundation in medical devices, this course provides a unique opportunity to gain hands-on experience working with the regulations, guidance documents, and style guides to produce portions of key medical device submissions that both comply with the requirements and are clear to the reviewers. Students explore the content

and process of medical device submissions and gain insight into timelines, important strategic considerations, and business impacts.

Course 19315

Good Manufacturing Practices

Familiarity with the Good Manufacturing Practices (GMP) regulations is a necessity for employees engaged in the manufacture, regulation and quality assurance, and control of drugs and biologics. Through lectures, discussions and case studies, participants gain an understanding of the FDA GMP and Good Laboratory Practice (GLP) regulations. Emphasis is on drugs and biologics, with additional coverage of the regulations that apply to cell and gene therapies, including stem cells.

Course 6328

Regulatory Compliance for Medical Devices

Lectures, interactive discussions and case studies provide in-depth exposure to the fundamental concepts and major issues central to regulatory compliance in the medical device sector. Emphasis is placed on using the principles in the medical device quality system (QS) regulation and ISO 13485 as tools to take a process-oriented, risk-based approach to compliance, while achieving strategic business objectives in today's dynamic regulatory environment. Students learn about key quality system regulation processes and how to recognize noncompliance. The instructor provides insight into putting an effective CAPA system in place and using it as an improvement tool. Current industry trends, FDA initiatives and do's and don'ts when interacting with regulatory agencies are also discussed.

Course 19029

Interacting with the FDA

Regulatory affairs professionals interact with the U.S. Food and Drug Administration (FDA) throughout the life cycle of a biomedical product. Lectures, case studies and roleplaying are used to explore the range of interactions that industry has with the FDA, including inspections and key meetings. Students gain insight into how to prepare for these important events. The course highlights the structure, mission, jurisdiction and roles of the FDA, centers within the agency and field offices, and examines key societal, political, industry and biomedical drivers that impact policies, priorities, and the current U.S. regulatory environment.

Course 19318

RA Professional's Toolbox

This seminar-format course addresses important competencies for RA professionals, including negotiation and communication strategies, effective collaboration techniques, project management, and approaches to educating and motivating senior management and staff about compliance. Through discussions, real-world examples and case studies, senior regulatory professionals help students learn about regulatory strategy, how to work in the regulatory "gray zones," and the important legal and ethical responsibilities of regulatory affairs personnel. *Note:* This course should be taken toward the end of the Regulatory Affairs Certificate Program.

Course 19317

Select Elective Courses

Design Control for Product Development

The successful development of products, especially medical devices, requires that the design be controlled to ensure product safety and that the device can fulfill its intended use. This course provides practical understanding of the engineering value of design control as it pertains to product quality. Lectures, interactive discussions and real world examples help students use the nine elements of design control to make design objectives clearer, products more testable, and better satisfy customer requirements, thereby shortening the path to product and business success.

Course 21973

Drug Safety and Adverse Events Reporting

This course introduces the concepts of drug safety and adverse event reporting, in both clinical trials and the post-approval period. Students learn to assess individual adverse events, understand the information needed from reporting sources, and complete the U.S. primary safety report. Topics include why safety reporting is crucial; how to define an adverse event; safety databases; coding dictionaries; and reporting requirements in the U.S. and abroad.

Course 3990

Courses continue on reverse...

Electronic Records for Regulated Environments: Cost-Effective Approaches to Compliance

This interactive two-day course explores proven techniques for reducing costs associated with implementing, using, and maintaining computer systems in regulated environments. The instructor addresses the latest computer system industry standards for data security, data transfer, and audit trails. Students see how 21 CFR Part 11 (electronic records and signatures requirements) and the HIPAA electronic security regulations for medical records fit into the validation process. Finally, the instructor reviews recent FDA inspection trends and discusses how to streamline SOP production.

Course 19362

Global IND Submissions

This course surveys IND submission requirements and timelines for approval in Canada, EU, Eastern EU, Middle East, South Africa, Australia, Asia, and South America. Students develop a framework for understanding and working effectively in the dynamic global regulatory environment, and they have the opportunity to gain hands-on experience producing a clinical trial application for either Canada or the EU.

Course 22184

Global Medical Device Submissions and Strategy

The global nature of the medical device industry presents opportunities and challenges to medical device companies and regulatory affairs professionals who must navigate a diverse regulatory terrain. In this course, students gain a practical understanding of international medical device requirements and regulations for major and emerging markets around the world, including the EU, Canada, Japan, and China. A comparative approach highlights similarities and differences between countries and underscores the impact they have on global regulatory and business strategies.

Course 20343

Human Factors in Medical Device Development

Understanding and applying human factors is important for ensuring product usability and user satisfaction. Human factors are also critical to ensuring patient safety by minimizing risks introduced by user error. This course begins with the fundamental principles of human factors and builds on that foundation each week to cover core concepts and demonstrate how human factors fit into the larger context of medical device software and hardware development. Specifically, the instructors will address the integration of human factors into the product development lifecycle; regulatory considerations, including applicable FDA guidance and standards (IEC 62366, ANSI HE 74 and ANSI HE75); and human factors methods. The course will benefit professionals who already have a basic understanding of risk management and quality systems as well as those with no prior medical device experience.

Course 23097

Medical Writing

Biopharmaceutical companies must produce scientific reports and summary documents for regulatory agencies. Good documentation should be not only scientifically sound, but also clear, effective and concise. Taking a hands-on approach, this course builds the practical skills needed to write effective documents for the bioscience industry. Topics include a review of the essentials of good writing, including the correct use of grammar and punctuation; drafting user-friendly documents that comply with the regulations; and creating clear and concise content. Exercises are based on documentation used in pharmaceutical development.

Course 4451

Post-Market Regulatory Obligations for Medical Devices

After receiving regulatory approval or clearance within the United States, a medical device is subject to continuing regulation in the form of recordkeeping and reporting to federal agencies, including the FDA. This course provides a detailed overview of post-market regulatory obligations and offers practical insights for efficient and robust systems that can be implemented prior to market release. Discussion topics include complaint handling, adverse event reporting, device tracking, import/export requirements, and the conduct of mandatory and voluntary recalls.

Course 22414

Product Development Life Cycle for Medical Devices

This course explores the phases, development processes, and deliverables essential to developing a medical device from concept to production scale up. Using a stage-gate process as a framework, the instructor details the timing and deliverables for each phase of device development. Process inputs and outputs are explained to provide an integrated view of the development team's activities throughout the entire product lifecycle. In addition, the course highlights benefits and practical considerations related to concurrent development activity. The essential risk management and regulatory clearance aspects of the development process are also addressed.

Course 23084

Regulation of Biomedical Product Advertising, Promotion and Labeling

The biomedical industry offers numerous examples of what not to do when it comes to advertising, promotion, and labeling. Drawing on real-world cases in the public domain, this workshop-format course unravels the mysteries of advertising and promotional regulations and guidance documents, and provides hands-on experience with their interpretation and practical application. The instructor highlights the dynamic between regulatory professionals and the marketing, medical communications, and corporate communications departments, and offers tools for effective partnering around their joint advertising, promotion, and labeling activities.

Course 20756

Regulatory Intelligence

This course examines the fundamentals of regulatory intelligence, including what it is, how it is conducted, and how it can be used to inform non-clinical, clinical, manufacturing, and regulatory decision making throughout a development program for a biomedical product. The instructor takes a practical look at monitoring the regulatory landscape, addresses the range of available information sources and provides insight into how to collect, analyze and present regulatory intelligence. In doing so, the groundwork is laid for the use of regulatory intelligence in developing global regulatory strategy.

Course 20341

Risk Management for Regulated Industries

This course provides an in-depth look at risk management with a focus on how it is applied in the medical device, biotechnology, pharmaceutical and in vitro diagnostic (IVD) industries. Lectures and interactive workshop sessions delve into the major risk management concepts and tools, including hazard analysis, fault tree analysis, failure modes and effects analysis (FMEA), mitigation application, regulatory requirements, and the creation of risk management reports and files. By the end of the course, students will be able to conduct competent and complete risk management for a variety of products, processes and services within the biomedical industries and beyond.

Course 22631

Value-Added Quality Audits

By auditing to domestic and international quality system regulations, biomedical corporations can improve the effectiveness of their internal systems and those of their suppliers and corporate partners. Taking a hands-on approach, this course introduces participants to fundamental auditing principles and techniques, including planning, conducting, analyzing, and communicating audit results in terms that are meaningful to senior managers. Through understanding the psychology of audits and practice in questioning techniques, participants can take their organization's quality audit program to another level.

Course 19073

Additional Elective Courses

Please see the certificate table on page 2 for a complete list of applicable electives from the clinical and discovery/development programs areas.

Course descriptions and schedules can be found at ucsc-extension.edu/regaffairs.

Enrollment Information

Visit ucsc-extension.edu/biosciences, for the most up-to-date information about all our bioscience courses and programs, including instructor biographies, schedules and textbook requirements.

Enroll online at ucsc-extension.edu.