

Free Program Overviews

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Meet instructors and other students, learn about program prerequisites, course content and program requirements, and see how these programs can help you advance your current career or break into a new field. These sessions are free but enrollment is required.

Biotechnology, Bioinformatics, Bioscience Business and Marketing

Offered January and August
Course 16649

Clinical Trials and Regulatory Affairs

Offered January and August
Course 16650

Bioscience Program Information and Q&A Session

Led by the director of the Bioscience programs, this event begins with short overviews of the six bioscience programs followed by an open-floor segment for audience questions.

Offered March and June
Course 22402

All courses held in Santa Clara



Silicon Valley's Leading Bioscience Educator

Nearly 2000 professionals enroll in our bioscience programs each year—making us Silicon Valley's leading provider of professional education for the bioscience industry.

Rigorous Preparation Delivered by Experienced Professionals

Well-educated and well-connected instructors provide a rich learning environment and help to reveal opportunities in the highly interconnected Bay Area bioscience industry. UCSC Extension's bioscience instructors have extensive practical experience addressing real-world industry challenges, strong academic credentials and a passion for teaching.

Dynamic, Highly Educated Student Body

Virtually all of the students who enter our programs have Bachelor's degrees—and many have advanced degrees. Our highly-motivated student population brings a diversity of experience and an energy that enhance the learning environment.

Develop State-of-the-Art Expertise

Courses address the full range of activities—from basic research to non-clinical and clinical to commercialization—in the highly knowledge-based bioscience industry. The curriculum is constantly updated to reflect the latest technological advances, regulatory changes, ethical issues, business trends and standards of practice for U.S. and global markets. Professionals from biotechnology, pharmaceutical, medical device, diagnostics, and tool sectors alike benefit from the breadth and depth of our bioscience course offerings.

Programs That Build Careers

Working professionals come to UCSC Extension to build their careers rather than earn a degree. Students develop practical skills and gain exposure to tools and high-end resources that they can immediately put to work in their current job or to facilitate a career transition. Course projects offer hands-on experience in the development of documentation and strategy. Students hone their analytical skills and, in many of the programs, produce a portfolio of work that can be used to demonstrate their capabilities to potential employers. UCSC Extension has a track record rich with inspiring stories of successful career transitions in the life sciences industry.

Program Contact

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

Explore UCSC Extension's Bioscience Programs

- **Bioinformatics**
- **Biotechnology**
- **Clinical Trials Design and Management**
- **Medical Devices**
- **Regulatory Affairs**
- **Bioscience Business and Marketing**



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.

Bioinformatics

Biological data continue to accumulate at a phenomenal rate. UCSC Extension in Silicon Valley's Bioinformatics Certificate Program was created in consultation with industry leaders to meet the need for biologists and computer scientists with the ability to analyze and interpret this deluge of biological information. Courses in this program are taught by experienced molecular biologists and bioinformatics professionals who bring real-world perspectives and cutting-edge technologies into their classrooms.

The Bioinformatics Certificate provides theoretical foundations and practical skills in bioinformatics. The required courses provide the necessary computational and scientific foundations. A range of electives allows individuals to tailor their studies to their particular needs and interests. Life scientists learn how to effectively use the tools and methods of bioinformatics to enhance their work, while computer scientists gain a background in molecular biology and important bioinformatics methods and tools.

This program is designed for students who have a degree in biology, biochemistry, or computer science who want to enrich their careers by learning and applying the key principles and practices of bioinformatics.

Certificate Requirements

To satisfy the requirements for the Certificate in Bioinformatics, you must complete **three required courses** and **7 units of electives**, for a minimum total of **16 units**. For GPA requirements and program time limits, see ucsc-extension.edu.

Prerequisites

Familiarity with the principles of modern molecular biology is required. Completion of "Molecular Biology, Introduction" or an equivalent course within the last five years at another institution, or equivalent experience satisfies this requirement. An understanding of probability and statistics is required for "Statistical Analysis and Modeling for Bioinformatics and Biomedical Applications." Students without this background should first complete "Probability and Statistics, Introduction" or the equivalent.

Recommended Course Sequence

Those new to the field of bioinformatics should start with "Bioinformatics Tools, Databases and Methods" and "Experimental Methods in Molecular Biology" (after completing the prerequisites). Courses may then be taken in any sequence unless otherwise specified in the individual course description.

Biotechnology

The Bay Area is at the forefront of the global biopharmaceutical industry, one of the fastest growing sectors of California's economy. Local companies and research institutions are setting the pace in the discovery and development of biopharmaceuticals to target major unmet medical conditions such as cardiovascular disease, cancer, AIDS and other degenerative diseases.

The Biotechnology Certificate equips professionals with a rich background in the principles, processes and cutting edge technologies central to biotechnology. This combination of general and practical knowledge enhances the skills of professionals currently working in this industry and helps prepare others to enter this dynamic field. The certificate program provides a solid understanding of the scientific disciplines that underlie the industry's activities, a foundation in the principles that guide drug discovery and development, an appreciation of cutting-edge bioscience research and technology, and a broader awareness of today's biopharmaceutical industry.

This program benefits professionals from all disciplines who want to develop a solid scientific foundation in the principles and applications of biotechnology, in order to work more effectively in or transition into the biopharmaceutical sector.

Certificate Requirements

To satisfy the requirements for the Certificate in Biotechnology, you must complete the **four required courses** as indicated in both Core A and B, and **8 units of electives** from Track 1 and Track 2, for a minimum total of **19 units**. For GPA requirements and program time limits, see ucsc-extension.edu.

Prerequisites

Familiarity with the principles of modern molecular biology is required. Completion of "Molecular Biology, Introduction" or an equivalent course taken within the last five years, or equivalent experience satisfies this requirement. Please direct questions about the suitability of a prerequisite to program@ucsc-extension.edu. For those new to the industry, we recommend that "Biotechnology Basics for Non-Scientists" be taken prior to starting other course work.

Recommended Course Sequence

We recommend that you begin with "Drug Discovery, Introduction" or "Drug Development Process." After that, you may take courses in any sequence, unless otherwise specified.

Clinical Trials Design and Management

The Bay Area is a hot spot for the global biopharmaceutical and medical device industries. Their continued success relies on the clinical trial—the complex process of ensuring the safety and effectiveness of new and existing medical products.

UCSC Extension's Certificate in Clinical Trials Design and Management helps professionals gain an in-depth and practical understanding of the entire clinical trials process as well as a foundation in the scientific principles, regulations, and ethics that are vitally important to the conduct of clinical research.

Because of its comprehensive curriculum and its intense focus on best practices in the clinical trials process, our certificate is appropriate for current professionals—clinical research associates and study coordinators, clinical program managers and physicians, biomedical and research scientists, nurses, IRB members and administrators, and pharmacists—as well as those new to the field.

Many courses in this program qualify for re-certification CEUs for those certified as CCRA's and CCRC's through ACRP. Most courses also grant BRN credit for nursing professionals and RAC recertification points for regulatory professionals.

Certificate Requirements

To obtain the Certificate in Clinical Trials Design and Management, you must complete **six required courses** and **6 units of elective courses**, for a minimum total of **19 units**. For GPA requirements and program time limits, see ucsc-extension.edu.

Prerequisites

A familiarity with medical terminology is required. Successful completion of "Medical/Clinical Terminology," or an equivalent course, satisfies this requirement. We strongly recommend that students without a medical background take "Human Physiology in Health and Disease" early in their studies.

Recommended Course Sequence

We recommend that you begin the program with "Drug Development Process."

Clinical Research Internship Program

Qualifying students and alumni from the Clinical Trials Design and Management Certificate Program have the opportunity to bring their course work to life and gain valuable experience in a clinical setting. Space in the program is limited. If you would like more information about the program and application process, please e-mail program@ucsc-extension.edu.



Certificates and Programs

Regulatory Affairs

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.

Many 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 for details.

Certificate Requirements

To obtain the Certificate in Regulatory Affairs, students must complete the **seven 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.

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 benefit most from this program.

Recommended Course Sequence

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

Bioscience Business and Marketing

Reports frequently praise the enormous economic potential of the bioscience industry in the Bay Area and beyond. However, lengthy development timelines and unique financial, legal, regulatory, social, and political challenges impose constraints that impact every aspect of the business. Novel business approaches, well-informed analyses of business opportunities, and sound risk-management strategies are critical in this dynamic industry. Bioscience leaders and innovators need to be fluent in new technologies and understand how they impact traditional business models.

This program is designed to help individuals, from within and outside the bioscience sector, rapidly gain the knowledge, skills, and insight necessary to understand and work effectively in this growing, highly competitive, and global industry.

Certificate Requirements

To obtain the Certificate in Bioscience Business and Marketing, participants must complete the **four required courses** and a minimum of **3 units of elective courses**. For GPA requirements and program time limits, see ucsc-extension.edu.

Prerequisites

Given the scientific foundations of the bioscience industry and the value it places on the scientific and technical literacy of its employees, it is strongly recommended that individuals without a background in the life sciences take a basic science course early in their studies. "Biology, An Introduction" or "Molecular Biology, Introduction" can be used to satisfy 1.5 elective units in this program.

Recommended Course Sequence

Those individuals without a background of recent work or study in the life sciences should take the "Drug Development Process" and "Bioscience Business and Marketing Essentials" courses early in the certificate program. After that, you may take courses in any sequence, unless otherwise specified.



Medical Devices

The Bay Area has the highest concentration of medical device startup companies in the United States. UCSC Extension has developed an array of cutting-edge courses for professionals currently working in this growing industry and for those interested in taking their skills and career in a new direction.

Our courses can help you gain a solid foundation in the principles underlying the design of biomaterials and medical devices, and an understanding of the regulations governing the manufacturing and marketing of diverse biomedical products.



Program Contact

Enroll online or contact the Applied and Natural Sciences Department for more information: (408) 861-3860 or e-mail program@ucsc-extension.edu.

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.

Bioinformatics	Biotechnology	Clinical Trials	Regulatory Affairs	Bioscience Business	Medical Devices
REQUIRED COURSES					
<p>Bioinformatics Tools, Databases and Methods</p> <p>Experimental Methods in Molecular Biology</p> <p>Statistical Analysis and Modeling for Bioinformatics and Biomedical Applications</p>	<p>Core A—Discovery Drug Development Process Drug Discovery, Introduction</p> <p>Core B—Development Cellular Biology Experimental Methods in Molecular Biology Immunology, Principles</p>	<p>Clinical Statistics for Non-Statisticians</p> <p>Clinical Trials Site Monitoring</p> <p>Drug Development Process</p> <p>Good Clinical Practices</p> <p>Medical Devices: Regulatory Strategies and Marketing Pathways</p> <p>Science of Clinical Trials Design</p>	<p>Drug Development Process</p> <p>Regulation of Medical Devices and Diagnostics</p> <p>Regulation of Drugs and Biologics</p> <p>Regulatory Submissions: Drugs and Biologics</p> <p>OR Regulatory Submissions: Devices and Diagnostics</p> <p>Good Manufacturing Practices</p> <p>OR Regulatory Compliance for Medical Devices</p> <p>Interacting with the FDA RA Professional's Toolbox</p>	<p>Drug Development Process</p> <p>OR Biopharmaceutical Fundamentals</p> <p>Bioscience Business and Marketing Essentials</p> <p>Bioscience Business Development: Building Value</p> <p>Bioscience Product Marketing</p>	<p>Required courses pending approval of new certificate program.</p>
ELECTIVE COURSES					
<p>Cellular Biology</p> <p>Computational Intelligence*</p> <p>DNA Microarrays: Principles, Applications and Data Analysis</p> <p>Drug Discovery, Introduction</p> <p>Gene Expression and Pathways</p> <p>Molecular Diagnostics</p> <p>Perl for Bioinformatics</p> <p>Sequence Analysis in Bioinformatics, Advanced</p> <p>Structure Analysis of Biological Molecules*</p> <p>* Suggested electives for computer scientists and IT professionals</p>	<p>Track 1: Discovery Bioinformatics Tools, Databases and Methods Biology of Cancer DNA Microarrays—Principles, Applications and Data Analysis Gene Expression and Pathways Human Physiology in Health and Disease Mass Spectrometry in Drug Discovery Neurobiology, Introduction Pharmacology, Principles Stem Cell Biology Structure Analysis of Biological Molecules Toxicology Basics for Biotechnology Viruses, Vaccines and Gene Therapy</p> <p>Track 2: Development Biopharmaceutical Fundamentals Biopharmaceutical Project Management & Leadership Bioscience Business and Marketing Essentials Bioscience Business Development: Building Value Bioscience Product Marketing Clinical Statistics for Non-Statisticians Drug Development: Formulation Design, Manufacture and Control Good Manufacturing Practices Intellectual Property Essentials for the Life Science Industry Medical Device Design and Development Medical Devices: Regulatory Strategies and Marketing Pathways Molecular Diagnostics Nanotechnology, Introduction Regulation of Drugs and Biologics Regulation of Medical Devices and Diagnostics Risk Management for Regulated Industries Statistical Design of Experiments</p>	<p>Adverse Event and Medication Coding</p> <p>Case Report Forms Development</p> <p>Clinical Data Management</p> <p>Clinical Project Management</p> <p>Clinical Research: The Study Site Perspective</p> <p>Clinical Trials Site Monitoring II</p> <p>Contracting with Contract Research Organizations (CROs)</p> <p>Development of Clinical Standard Operations Procedures</p> <p>Document Preparation: Protocols, Reports, Summaries</p> <p>Drug Safety and Adverse Events Reporting</p> <p>Electronic Data Capture for Clinical Trials</p> <p>Electronic Records for Regulated Environments: Cost-Effective Approaches to Compliance</p> <p>Global Conduct of Clinical Trials</p> <p>Good Manufacturing Practices</p> <p>Medical Device Design and Development</p> <p>Medical Writing</p> <p>Molecular Diagnostics</p> <p>Preparing for FDA Inspections and Conducting Sponsor Audits</p> <p>Regulation of Drugs and Biologics</p> <p>SAS Programming for Clinical Trials</p> <p>SAS for Clinical Trials for the Non-Programmer, Introduction</p> <p>Toxicology, Basics for Biotechnology</p>	<p>Regulatory Design Control for Product Development Drug Safety and Adverse Events Reporting Electronic Records for Regulated Environments: Global IND Submissions Global Medical Device Submissions Strategy Human Factors in Medical Device Development Medical Writing Post-Market Regulatory/ Medical Devices Regulation of Biomedical Product Marketing Regulatory Intelligence Risk Management for Regulated Industries Value-Added Quality Audits</p> <p>Clinical Adverse Event and Medication Coding: Clinical Statistics for Non-Statisticians Contracting with CROs Electronic Data Capture Global Conduct of Clinical Trials Good Clinical Practices Preparing for FDA Inspections Science of Clinical Trials Design</p> <p>Discovery/Development Biopharmaceutical Fundamentals Biopharmaceutical Project Management Drug Development: Design, Manufacture and Control Intellectual Property Essentials for the Life Science Industry Medical Device Design Molecular Diagnostics Pharmacology, Principles Product Development Life Cycle for Medical Devices Statistical Design of Experiments Stem Cell Biology Toxicology Basics for Biotechnology Viruses, Vaccines and Gene Therapy</p>	<p>Biopharmaceutical Project Management and Leadership</p> <p>Drug Development: Formulation Design, Manufacture and Control</p> <p>Gene Expression and Pathways</p> <p>Global Medical Device Submissions and Strategy</p> <p>Intellectual Property Essentials for the Life Science Industry</p> <p>Medical Device Design and Development</p> <p>Medical Devices: Regulatory Strategies and Marketing Pathways</p> <p>Molecular Biology, Introduction</p> <p>Molecular Diagnostics</p> <p>Regulation of Biomedical Product Advertising, Promotion and Labeling</p> <p>Stem Cell Biology</p> <p>Viruses, Vaccines and Gene Therapy</p> <p>Also of Interest Biotechnology Basics for Non-Scientists</p>	<p>Design Control for Product Development</p> <p>Electronic Records for Regulated Environments: Cost-Effective Approaches to Compliance</p> <p>Global Medical Device Submissions and Strategy</p> <p>Human Factors in Medical Device Development</p> <p>Human Physiology in Health and Disease</p> <p>Intellectual Property Essentials for the Life Science Industry</p> <p>Medical Device Design and Development</p> <p>Medical Devices: Regulatory Strategies and Marketing Pathways</p> <p>Molecular Diagnostics</p> <p>Nanotechnology, Introduction</p> <p>Post-Market Regulatory Obligations for Medical Devices</p> <p>Product Development Life Cycle for Medical Devices</p> <p>Regulation of Biomedical Product Advertising, Promotion and Labeling</p> <p>Regulation of Medical Devices and Diagnostics</p> <p>Regulatory Compliance for Medical Devices</p> <p>Regulatory Submissions: Devices and Diagnostics</p> <p>Risk Management for Regulated Industries</p> <p>Statistical Design of Experiments: A Practical Approach</p> <p>Value-Added Quality Audits</p>

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**SEE UCSC-EXTENSION.EDU/
BIOSCIENCES FOR
COURSE DESCRIPTIONS
AND PREREQUISITES.**