

Free Program Overviews

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## 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

## Bioscience Program Information and Q&A Session

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

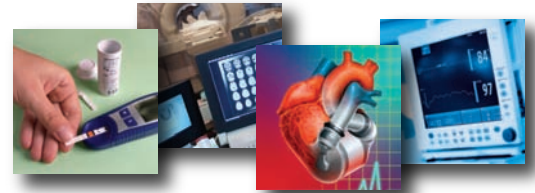
Offered March and June

Course 22402

Certificate Under Development

## Certificate Program in Medical Devices

Please e-mail [program@ucsc-extension.edu](mailto:program@ucsc-extension.edu) to be added to our mailing list and receive the latest information about this exciting new program. Include your name, current job title and e-mail address.



## Medical Device Training in the Heart of Silicon Valley

The Bay Area is home to the highest concentration of medical device startups in the US and a broad array of established companies that run the gamut in size, core technology and therapeutic focus.

The robust medical device industry offers exciting opportunities for professionals from a range of disciplines interested in working in a sector focused on innovative approaches to improving human health.

## Cutting-Edge Curriculum in Core Competencies

UCSC Extension in Silicon Valley offers an array of cutting-edge medical device courses, all taught by experts who bring many years of industry experience to the classroom. Our curriculum addresses topics that are critical to the development and commercialization of safe and effective medical devices. Taking a practical and hands-on approach, these courses build a solid foundation in core competencies in product design and development, regulatory and quality, innovation strategy and management, and more.

## Program Benefits Experienced and Aspiring Medical Device Professionals

Experienced and aspiring medical device professionals gain insight into the technological, regulatory and business aspects of the industry and learn what it takes to be successful in the dynamic and highly-regulated medical device industry. Courses in our medical device program benefit professionals from a wide range of disciplines: engineering (software, hardware, electrical, mechanical, biomedical, chemical and design); manufacturing; project and program management; regulatory affairs; quality; medical equipment testing and maintenance; and technical sales and marketing.

## Program Contact

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

## Explore UCSC Extension's Other Bioscience Programs

- Bioinformatics
- Biotechnology
- Bioscience Business and Marketing
- Regulatory Affairs
- Clinical Trials

All courses held in Santa Clara

[ucsc-extension.edu/meddevices](http://ucsc-extension.edu/meddevices)



## 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.

### Courses

#### Design Control for Product Development

The successful development of products, especially medical devices, requires that the design be controlled to assure product safety and that the device can fulfill its intended use. This course provides a 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 to better satisfy customer requirements; thereby shortening the path to product and business success. This course benefits new and experienced professionals in quality, engineering, regulatory, manufacturing, clinical, and project management functions.

Course 21973

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

Nearly every computerized system used in laboratory, clinical, manufacturing settings and in the quality process has to be validated. 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 industry standards for data security, data transfer, and audit trails. Students see how 21 CFR Part 11 (electronic records and signatures requirements) and 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. This course benefits anyone that uses computer systems to perform their job functions and is ideal for regulatory, clinical, and IT professionals working in the health care, clinical trial, biopharmaceutical, and medical device sectors.

Course 19362

#### Global Medical Device Submissions and Strategy

The global nature of the medical device industry presents both opportunities and challenges to medical device companies and regulatory affairs professionals who must navigate a diverse regulatory terrain. Through interactive lectures and facilitated group projects, students gain a practical understanding of international medical device requirements and regulations for major

and emerging markets around the world, with emphasis on the EU, Canada, Japan, and China. A comparative approach highlights regulatory and process similarities and differences between countries and underscores the impact they have on global regulatory and business strategies. This course will benefit regulatory affairs professionals who need to help their organizations understand the barriers to entry into global medical device market.

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 is beneficial for professionals who already have a basic understanding of risk management and quality systems, as well as a broad range of technical professionals, including those with no prior medical device experience.

Course 20397

#### Human Physiology in Health and Disease

This course introduces the fundamental principles of human physiology in health and disease, and provides insights into the cutting-edge and established therapies being developed and used to treat a range of disease processes. Designed for individuals who lack formal medical training, the course begins with an overview of the hierarchical organization of the body, from cells to coordinated organ systems, and continues with a discussion of the key integrative/homeostatic control mechanisms. With these topics as a foundation, the instructor progresses through the functions of major systems, including renal, cardiovascular, respiratory, neuromuscular, digestive, endocrine and reproductive. This course benefits clinical research, biopharmaceutical, and engineering professionals who need a basic understanding of the physiological processes and therapeutic approaches that underlie the biomedical projects or clinical trials on which they work.

Course 6999

#### Intellectual Property Essentials for the Life Science Industry

This course demystifies key intellectual property principles and applications, emphasizing topics of particular relevance to the biotechnology, pharmaceutical and medical device sectors. The instructor explains the basic principles of patents, and explores their strategic implications in a variety of contexts, such as securing funding, establishing barriers to competitor entry, achieving freedom to operate, technology transfer, and strategic alliances. Trade secrets, trademarks, copyrights and contractual agreements are also discussed, particularly as they apply to the life science industry. Scientific, engineering, regulatory and business professionals will benefit from this course.

Course 1942

#### Medical Device Design and Development

This introductory course provides insight into the entrepreneurial nature of the medical device industry, as well as a detailed look at the design and development process for new medical devices. Beginning with an overview of device terminology, applied pathophysiological concepts, and biocompatibility, the instructor and expert guest speakers move on to explore how technologies are translated into medical devices. Using case studies on numerous families of devices, the instructional team addresses hardware and software design as well as the importance of human factors. Brief coverage is also given to device manufacturing and testing, marketing pathways and strategies to navigate the regulatory bodies. This course will benefit professionals from all backgrounds who are working in or interested in exploring opportunities within the medical device arena.

Course 19977

#### Molecular Diagnostics

Rapid advancements in molecular diagnostics are the attention of the bioscience industry, regulatory agencies, clinicians, patients and insurers alike. This survey course provides a foundation in the basic science and technologies that underlie the emerging field of molecular diagnostics, and highlights the potential impact on the health care landscape. The instructor examines the role of pharmacogenomics in the development of new therapeutics and treatment options. He uses case studies to present the applications of molecular diagnostic tools in infectious disease identification and early detection and diagnosis of cancer. Also addressed are the regulatory challenges that face the new wave of diagnostic tests, and the changing dynamics of the molecular diagnostics global marketplace.

Course 21972

## Explore UCSC Extension's Other Bioscience Programs

- Bioinformatics
- Clinical Trials
- Biotechnology
- Regulatory Affairs
- Bioscience Business and Marketing



# Course Descriptions

## Nanotechnology, Introduction

This survey course provides a foundation in the basic principles of nanotechnology. The instructors highlight the recent advances in nanoscale science and engineering, drawing on examples and demonstrations from electronic, photonic, mechanical, chemical and biological systems. Participants learn, in each of these cases, how an understanding of the fundamental physical properties at the atomic level has permitted nanoscale engineering for specific applications. They gain an appreciation of the importance of reproducible manufacturing, in bottom-up and top-down approaches and self-assembly. The tools and methods used to characterize materials and devices at the nanoscale are explored. Instructors also discuss future prospects and possible roadblocks to implementation of nanotechnology, with reference to other technological advances in the last two centuries. Finally, local and national resources as well as key players are discussed. This course is intended for engineers, computer scientists, chemists, biologists, physicists, and other scientists and technology professionals who seek to gain insight into the emerging field of nanotechnology.

Course 4820

## Post-Market Regulatory Obligations for Medical Devices

Once a medical device has received regulatory approval or clearance, it is subject to continuing regulation in the form of record keeping and reporting to the FDA. Understanding and preparing for these obligations during the submission phase yields advantages in post-marketing. This course helps regulatory affairs professionals understand their post-market regulatory obligations and provides perspective on how efficient and robust systems can be put in place prior to market release. Topics of discussion include complaint handling, adverse event reporting, MDR/Vigilance Reporting, device tracking, post-market studies, annual reports, and the conduct of voluntary recalls. This course will focus primarily on the post-market regulatory obligations for medical device manufacturers distributing products within the United States. Requirements for other regulatory agencies will also be discussed, including reporting requirements to clinicaltrials.gov, reporting of financial arrangements to state and federal agencies, and the guidelines of industry trade organizations and the Office of the Inspector General.

Course 22414

## Product Development Life Cycle for Medical Devices

Medical devices that meet marketplace needs and satisfy business objectives require well-structured business and development processes. This course explores the phases, development processes, and deliverables essential to developing a medical device from concept to production scale up. Using a framework of gated stages and design review, 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. Throughout the course, emphasis is placed on maintaining business value through the phases of a product development process, and achieving the successful commercialization of a medical device.

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. Participants learn what gives regulators the grounds to take action on violative materials, and they gain an appreciation of the risk levels inherent in various promotional strategies. 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. This course will benefit regulatory, medical, legal, marketing, and sales professionals responsible for the review of materials used in the promotion of prescription and OTC drug, biologic, medical device and diagnostic products.

Course 20756

## Regulation of Medical Devices and Diagnostics

Medical devices encompass a broad array of products, ranging from the simple tongue depressor to surgically implanted stents and pacemakers. This course provides individuals from all backgrounds with a solid grounding in the laws, regulations and institutions that underlie the process of medical device and diagnostic product development and marketing. 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 product are moved into the U.S. marketplace. Through lectures and case studies, students gain in-depth exposure to key routes to market, including 510(k) premarket notification and premarket approval applications (PMA). The instructor provides insight into the rationale and strategies for using each of these paths and others, including product development protocol (PDP) and reclassification. Also addressed are the pre-clinical and clinical testing of devices, as well as the investigational device exemption (IDE) application and process. There will be some coverage of international laws and regulations, particularly as they relate to the U.S. counterparts.

Course 19071

## 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 non-compliance. 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 best practices when interacting with regulatory agencies are also discussed. This course is suitable for professionals in the medical device sector who are responsible for compliance, regulatory affairs, project planning, design and development, technology transfer, QA, R&D and manufacturing.

Course 19029

*Courses continue on reverse...*

## Regulatory Submissions: Devices and Diagnostics

This course is designed to provide individuals who already have a foundation in medical device terminology, classification, and pathways to market, with opportunities to gain a greater exposure to key medical device submissions. Through lectures, case studies, and hands-on exercises, new and experienced regulatory professionals learn how to work with the regulations, guidance documents, and style guides to write 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, as well as gain insight into timelines, important strategic considerations and business impacts. Topics include IDE; 510(k) (including unique features of in vitro diagnostics); PMA; brief coverage of HDE and PDP; combination products; foreign manufacturers filing in the U.S.; and global submissions.

Course 19315

## Risk Management for Regulated Industries

Risk management principles are widely used to identify and develop strategies to minimize risks related to products, processes and services. More than just a valuable skill set, risk management is now essential in product and process design and implementation. 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. Students explore the common risk-identification and risk-reduction methods applicable to biomedical industries, which are also relevant to many other 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, and regulatory requirements. The instructor will explain how to create a risk management report and build and maintain a risk management file. Assignments and in-class activities will be used to guide students through the creation of their own risk management file. By the end of the course, students will be able to conduct competent and complete risk management for a variety for products, processes and services within the biomedical industries and beyond.

Course 22631

## Statistical Design of Experiments: A Practical Approach

The Statistical Design of Experiment (DOE) is a powerful tool for systematically analyzing factors affecting processes and their outputs. This methodology is applicable to a wide range of research and development experiments, as well as manufacturing, quality and marketing. It can speed up research, increase productivity, and reduce costs. In this course, students learn how DOE can be used to simultaneously analyze multiple inputs and identify important interactions that might otherwise be missed. Topics include screening designs, factorial designs, fractional factorials, analysis of variance, regression, response surface methods, power and sample size. Instruction will include lectures and live classroom DOE experiments, all with a practical focus. Concepts are introduced at an elementary level, so no previous background in statistics is required. Examples and analyses will use Excel software. This course is designed for scientists and engineers working in high tech areas including biomedical research, material science, electronics and medical devices. No previous background in statistics is required.

Course 23096

## Value-Added Quality Audits

In today's dynamic business environment, every aspect of an organization needs to perform value-added activities that have a positive impact on the bottom line. Regulatory and quality units in more and more biomedical industry corporations are relying on quality audits as a means to improve operations. By auditing to domestic and international quality system regulations (GXP, QSR and ISO), these organizations are assessing and improving the effectiveness of their internal systems and those of their suppliers and corporate partners. This hands-on 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. By understanding the psychology of audits and practicing questioning techniques, participants will take their organization's quality audit program to another level.

Course 19073

**UCSC**extension  
Silicon Valley

**Silicon Valley's Leading  
Bioscience Educator**

### Premier 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 the 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.

### How To Get Started—Program Contact

Applied and Natural Sciences Department,  
(408) 861-3860 or e-mail  
[program@ucsc-extension.edu](mailto:program@ucsc-extension.edu).



### *Courses Coming Soon*

**Business Dynamics of  
Medical Device Development**

**Clinical Trial Fundamentals  
for Medical Devices**

**Medical Device  
Software Development**

**CE Marking**

**Medical Device Research  
and Development**

### **Enrollment Information**

Visit [ucsc-extension.edu/biosciences](http://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](http://ucsc-extension.edu).