

WINTER 2012

UCSC Silicon Valley
@extension



2505 AUGUSTINE DRIVE, SUITE 100, SANTA CLARA, CA 95054

of development as both elements

Biosciences



ucsc-extension.edu/biosciences



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Free Program Overview



Biotechnology and Bioinformatics

Are you interested in learning about the Bioinformatics and Biotechnology certificate programs, and about careers in these fields?

This special free information session provides an opportunity to 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.

SANTA CLARA CLASSROOM

Monday, 6–8:30 pm, January 9.

No fee, but enrollment required.

To enroll, use Section number 16649.(014)

Free Program Overview



Clinical Trials, Regulatory Affairs, and Medical Devices

This special information session provides an opportunity to meet instructors and other students, learn about program prerequisites, program philosophy, course content and program requirements, and gain insights into careers in clinical research, regulatory affairs, and medical devices.

SANTA CLARA CLASSROOM

Wednesday, 6–8:30 pm, January 11.

No fee, but enrollment required.

To enroll, use Section number 16650.(014)



Bioinformatics

Certificate Program

Bioinformatics

CERTIFICATE CONTACT

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

PROGRAM OVERVIEW

Biological data continue to accumulate at a phenomenal rate. UCSC Silicon Valley Extension'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 **3 required courses** and **7 units of electives**, for a minimum total of **16 units**. For GPA requirements and program time limits, go to ucsc-extension.edu.

To pursue two bioscience-related certificates in parallel or in sequence, see the chart on this page.

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, 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 "Statistics," or "Statistical Design of Experiments: A Practical Approach," or "General Statistics I" and "General Statistics II," or the equivalent prior to taking "Statistical Analysis and Modeling for Bioinformatics and Biomedical Applications."

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.

FOR MORE INFORMATION

Current and future course schedules can be found at ucsc-extension.edu/biosciences. For more information on this program or to be added to our mailing list, please call (408) 861-3860 or contact program@ucsc-extension.edu.

FOR INFORMATION ON CERTIFICATE APPLICATIONS AND TRANSFERRING CREDIT FROM OTHER SCHOOLS, GO TO UCSC-EXTENSION.EDU.

Prerequisite Courses

Molecular Biology, Introduction

X425.9 NATSC (3.0 quarter units) 30.0 hours CA BRN/LVN
Credit—Provider #CEP13114

This course provides a comprehensive introduction to molecular biology for nonbiologists and a review for those who want to refresh and update their knowledge of this subject. Topics include fundamental concepts of genes and proteins, central dogma and the genetic code; structure and function of genes; gene expression, transcription and translation; protein structure and function; introduction to genetics; Mendelian analysis; molecular and population genetics, genetic markers and maps; and the impact of modern molecular biology on science and medicine. The course also includes an overview of experimental methods used in molecular biology.

Prerequisite(s): College-level biology is recommended.

RAXIT J. JARIWALLA, Ph.D.

SANTA CLARA CLASSROOM

10 meetings: Tuesdays, 6–9 pm, January 17–February 28;

Saturdays, 1–4 pm, January 21–March 3

(no meeting Feb. 18 and 3 no meetings TBA).

Fee: \$675 (\$607.50 through Jan. 3).

To enroll, use Section Number 4213.(075)

Statistics

X400.102 AMS (5.0 quarter units)

This course explores the fundamentals of statistical methods and reasoning. Topics include descriptive methods, data gathering, probability, interval estimation, significance tests, one- and two-sample problems, categorical data analysis, correlation and regression. The instructor will demonstrate the use of spreadsheets and statistical software to analyze and interpret data. Examples are drawn from a variety of fields, including biology, business and marketing. While not too mathematically rigorous for the novice, the course provides some mathematical detail to illustrate basic concepts. No prior background in calculus or statistics is required.

ROBERT KNIGHT, M.S., DPM.

ONLINE, January 10–March 31.

Enrollments accepted through Feb. 29.

Fee: \$860 (\$774 through Dec. 27).

To enroll, use Section Number 23588.(002)



Featured Winter Courses

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Clinical Trials Essentials: An Intensive Course.....	8
Electronic Data Capture for Clinical Trials	10
Human Factors in Medical Device Development ..	13
Human Physiology in Health and Disease	8
Interacting with the FDA	12
Molecular Diagnostics	6
Risk Management for Regulated Industries.....	13
SAS Programming for Clinical Trials	10
<i>New!</i> Solid Oral Dosage Forms	6

The Bioscience Industry Is Thriving in the Bay Area

Regional studies predict that in the coming years, the shift from development to commercialization will continue to fuel significant growth in Bay Area life science companies. The availability of a highly skilled workforce will undoubtedly be a key component of this success.

UCSC Silicon Valley Extension offers a full complement of bioscience programs and courses designed to meet the needs of Bay Area companies and new and experienced industry professionals. Taught by experts from Silicon Valley's thriving biotechnology, pharmaceutical, and medical device sectors, our courses offer participants the knowledge base, industry perspectives, and important connections needed to build a strong career.

Whether you are interested in learning about the scientific, clinical, computational or regulatory aspects of the bioscience field, UCSC Silicon Valley Extension can help you succeed.

Learn More for Less

Do you know that you can complete **two bioscience certificate programs** at UCSC Extension, simultaneously or in sequence, with fewer units than if the programs were taken individually?

Students pursuing two certificates need to complete the total number of units indicated in the table below, including all the required courses for both programs. In order to obtain two certificates with the fewest number of units, students must select some electives that are common to both programs. Please contact program@ucsc-extension.edu or call (408) 861-3860 if you need more information or would like assistance creating a study plan.

	Biotechnology	Clinical Trials	Regulatory Affairs	Bioinformatics	Bioscience Business
Biotechnology	19 units	32 units	32 units	30 units	27 units
Clinical Trials	32 units	19 units	32 units	X	27 units
Regulatory Affairs	32 units	32 units	19 units	X	27 units
Bioinformatics	30 units	X	X	16 units	X
Bioscience Business	27 units	27 units	27 units	X	10 units

BIOINFORMATICS CERTIFICATE

16-unit minimum

PREREQUISITE COURSES

	Units	Course	F	W	Sp	Su
Molecular Biology, Introduction	3.0	4213	■	■	■	
AND						
Statistics OR	5.0	23588	○	○	○	
General Statistics I AND	2.5	5620	■		■	
General Statistics II, OR	2.5	6538		■		■
Statistical Design of Experiments: A Practical Approach	2.0	23096				■

REQUIRED COURSES

	Units	Course	F	W	Sp	Su
Bioinformatics Tools, Databases and Methods	3.0	2447	■		■	
Experimental Methods in Molecular Biology	3.0	1912		■		■
Statistical Analysis and Modeling for Bioinformatics and Biomedical Applications	3.0	1032	■		■	

ELECTIVE COURSES (7 units required)

	Units	Course	F	W	Sp	Su
Take required courses before electives.						
Cellular Biology	3.0	3383	■			
Computational Biology with Java	3.0	0266	■			
* Computational Intelligence	1.5	19951		■		■
DNA Microarrays: Principles, Applications and Data Analysis	3.0	2183				■
Drug Discovery, Introduction	3.0	4853	■		■	
Gene Expression and Pathways	2.0	6020		■		
Molecular Diagnostics	1.5	21972		■		■
Perl for Bioinformatics	2.0	19971				
* Sequence Analysis in Bioinformatics, Advanced	2.0	0036		■		
Structure Analysis of Biological Molecules	2.0	5925	■			

* Suggested electives for computer scientists and IT professionals

■ held in classroom ○ offered online □ both classroom and online sessions are available

Visit ucsc-extension.edu for the most current program schedule.

Experimental Methods in Molecular Biology

X446.5 NATSC (3.0 quarter units)

This lecture-based course provides a theoretical overview of the key molecular biology techniques used in basic life science research and by the biotechnology and biopharmaceutical industry for the discovery of novel therapeutics. Topics include gene cloning, manipulation and sequencing; PCR; RNA interference; gene expression analysis; protein expression, engineering, and structure determination; and the fundamentals of experimental design. Also addressed are high-throughput sequencing and microarray expression analysis and the types of data these techniques generate.

Prerequisite(s): "Molecular Biology, Introduction" or an equivalent course.

INSTRUCTOR: TBA.

SANTA CLARA CLASSROOM

8 meetings: Saturdays, 1–5 pm,
January 21–March 24 (2 no meetings TBA).
Fee: \$765 (\$688.50 through Jan. 7).

To enroll, use Section Number 1912.(039)

Elective Courses

Computational Intelligence

For course description, go to ucsc-extension.edu.

Gene Expression and Pathways

X426.2 NATSC (2.0 quarter units)

This course provides a solid foundation in the molecular concepts and cutting-edge technologies that are central to the understanding of gene expression pathways in simple cells and complex multicellular organisms. Topics include gene structure; regulatory proteins and transcriptional control; inheritance of states of gene expression; and post-transcriptional control of gene activity. Abnormalities in gene expression are discussed in relation to human disease states as well as drug discovery and diagnostic medicine.

Prerequisite(s): "Molecular Biology, Introduction" or equivalent or basic knowledge of foundation concepts in molecular biology.

RAXIT J. JARIWALLA, Ph.D.

SANTA CLARA CLASSROOM

8 meetings: Tuesdays, 6–9 pm, March 20–April 17;
Saturdays, 1–4 pm, March 24–April 21 (2 no meetings TBA).
Fee: \$715 (\$643.50 through Mar. 6).

To enroll, use Section Number 6020.(023)

Molecular Diagnostics

For course description, see page 6.

Biotechnology

Certificate Program

Biotechnology

CERTIFICATE CONTACT

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

PROGRAM OVERVIEW

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 bio-science 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 **4 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, go to ucsc-extension.edu.

To pursue two bioscience-related certificates in parallel or in sequence, see chart on page 3.

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 (see page 6).

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.

FOR MORE INFORMATION

Current and future course schedules can be found at ucsc-extension.edu/biosciences. For more information on this program or to be added to our mailing list, please call (408) 861-3860 or contact program@ucsc-extension.edu.

FOR INFORMATION ON CERTIFICATE APPLICATIONS AND TRANSFERRING CREDIT FROM OTHER SCHOOLS, GO TO UCSC-EXTENSION.EDU.

Prerequisite Course

Molecular Biology, Introduction

For course description, see page 3.

BIOTECHNOLOGY CERTIFICATE

19-unit minimum

PREREQUISITE COURSE	Units	Course	F	W	Sp	Su
Molecular Biology, Introduction	3.0	4213	■	■	■	
REQUIRED COURSES A AND B (four)	Units	Course	F	W	Sp	Su
Core A—Both required						
Drug Discovery, Introduction	3.0	4853	■		■	
Drug Development Process.....	2.0	6559	■	■	■	■
Core B—Choose 2 of 3 (The remaining core B may be used as an elective.)						
Cellular Biology.....	3.0	3383	■			
Experimental Methods in Molecular Biology	3.0	1912		■		■
Immunology, Principles.....	3.0	2257		■		■
ELECTIVE COURSES	Units	Course	F	W	Sp	Su
(8 units required; a minimum of 1 of the 8 units must be from each track.)						
Track 1: Discovery						
Bioinformatics Tools, Databases and Methods	3.0	2447	■		■	
Biology of Cancer	2.0	6630			■	
DNA Microarrays—Principles, Applications and Data Analysis	3.0	2183				■
Gene Expression and Pathways	2.0	6020		■		
Human Physiology in Health and Disease	3.0	6999	■	■		
Mass Spectrometry in Drug Discovery	2.0	4887				■
Neurobiology, Introduction	3.0	20042			■	
Pharmacology, Principles	2.0	5596				■
Stem Cell Biology	1.5	13567				■
Structure Analysis of Biological Molecules	2.0	5925	■			
Toxicology Basics for Biotechnology	1.5	2310				■
Viruses, Vaccines and Gene Therapy	1.5	6974			■	
Track 2: Development						
Biopharmaceutical Project Management and Leadership	1.5	4490				
Clinical Statistics for Non-Statisticians	2.0	2345		■		■
Good Manufacturing Practices	3.0	6328		■		■
Intellectual Property Essentials for the Life Science Industry.....	1.0	1942			■	
Medical Device Design and Development	2.0	19977	■		■	
Medical Devices: Regulatory Strategies and Marketing Pathways.....	1.5	5939		■		■
Molecular Diagnostics	1.5	21972		■		■
Nanotechnology, Introduction	1.0	4820				■
Regulation of Drugs and Biologics	3.0	19007	■		■	
Regulation of Medical Devices and Diagnostics.....	3.0	19071		■		■
Risk Management for Regulated Industries	3.0	22631		■		■
Solid Oral Dosage Forms: Development to Registration.....	3.0	4452		■		
Statistical Design of Experiments: A Practical Approach	2.0	23096				■

■ held in classroom ○ offered online □ both classroom and online sessions are available

Visit ucsc-extension.edu for the most current program schedule.

YOU MAY BE CLOSER TO A CERTIFICATE THAN YOU REALIZE



Are you just a few courses away from earning a bioscience certificate? Let us review your academic record and help to fast track your goals.

Contact us to develop a personalized study plan: biosciences@ucsc-extension.edu.

Enrollment

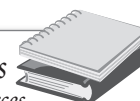
- **Early Enrollment Discount:** Save 10 percent when you enroll more than 14 days before the first day of class.
- **Courses may be taken individually or as part of the certificate program.**



Wireless Access at UCSC Extension Silicon Valley

Wireless Internet access is provided throughout our Santa Clara facility. Students may need to install protective software on their laptops to use our wireless network.

Course Readers, Textbooks and Other Instructional Resources



Students are responsible for obtaining the required instructional materials for all courses. A variety of media may be used. Please review the section details at the bottom of the course description pages on our Web site.

- Instructors may specify any of the following:
- Printed course readers from our on-demand service provider, **Content Management Corporation (CMC)**
 - Electronic course materials from our online learning platform, **UCSC Extension Online**
 - Textbooks (required and recommended). Purchasing information can be found at: ucsc-extension.edu/bookstore.
 - Other materials distributed via e-mail either by the Academic Department or the instructor

Students should acquire or access their materials prior to the first class meeting. For full instructions, go to ucsc-extension.edu/course-materials.

Required Courses

Drug Development Process

X428.2 NATSC (2.0 quarter units) 24.0 hours CA BRN/LVN
Credit—Provider #CEP13114

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. The course provides an important foundation in drug development for professionals from all disciplines who are currently working in, or are considering a move to, the biopharmaceutical industry.

EDWARD ROZHON, Ph.D.

SANTA CLARA CLASSROOM

10 meetings: Thursdays, 6–9 pm, January 19–April 5;
Saturday, 9 am–4 pm, March 31 (3 no meetings TBA).
Fee: \$765 (\$688.50 through Jan. 5).

To enroll, use Section Number 6559.(041)

Experimental Methods in Molecular Biology

For course description, see page 4.

Also of Interest

Biotechnology Basics for Non-Scientists

X426.8 NATSC (0.5 quarter unit)
6.0 hours CA BRN/LVN Credit—
Provider #CEP13114

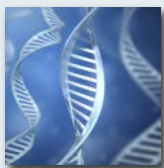
Designed for non-scientists, this one-day course begins with an accessible overview of the basic concepts in molecular biology and genetics that serve as a foundation for biotechnology. The instructor then highlights gene-based technology and important biotechnology breakthroughs, especially as they relate to Bay Area companies. He explores the impacts and the future of this cutting-edge discipline, and students leave the course with a new vocabulary and a solid understanding of the power and potential of biotechnology.

RAXIT J. JARIWALLA, Ph.D.

SANTA CLARA CLASSROOM

Saturday, 9 am–4 pm, January 14.
Fee: \$325 (\$292.50 through Dec. 31).

To enroll, use Section Number 6163.(025)



TO PURSUE TWO BIOSCIENCE-RELATED CERTIFICATES IN PARALLEL OR IN SEQUENCE, SEE PAGE 3.

Immunology, Principles

X426.3 NATSC (3.0 quarter units) 30.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Explore the fundamental principles of immunology along with recent developments in the field and their implications for drug discovery and development, as well as disease treatment. Topics include innate, humoral and cell-mediated immunity; the clonal selection of lymphocytes; antigens, antibodies and their interactions; antibody gene rearrangement; lymphocyte development; and aspects of clinical immunology such as inflammation. Also covered are the immune response to bacterial, viral, fungal and parasitic diseases; vaccines; AIDS and other immunodeficiencies; autoimmune diseases; allergies; transplantation immunology; and cancer. Throughout the course, immunological techniques important in research and clinical laboratories are highlighted.

Prerequisite(s): Knowledge of general microbiology and basic chemistry. Knowledge of cell biology is recommended.

MONICA RANES-GOLDBERG, Ph.D.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

9 meetings: Mondays, 6–9:30 pm,
January 23–March 26 (no meeting Feb. 20).
Fee: \$765 (\$688.50 through Jan. 9).

To enroll, use Section Number 2257.(024)

Elective Courses

Clinical Statistics for Non-Statisticians

For course description, see page 9.

Gene Expression and Pathways

For course description, see page 4.

Good Manufacturing Practices

For course description, see page 12.

Human Physiology in Health and Disease

For course description, see page 8.

Medical Devices: Regulatory Strategies and Marketing Pathways

For course description, see page 8.

Molecular Diagnostics

X400.414 BIOL (1.5 quarter units) 15.0 hours CA BRN/LVN
Credit—Provider #CEP13114

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.

Prerequisite(s): College-level biology.

BINAYA PANDA, Ph.D.

SANTA CLARA CLASSROOM

2 meetings: Friday–Saturday, 9 am–5 pm, March 16–17.
Fee: \$580 (\$522 through Mar. 2).

To enroll, use Section Number 21972.(006)

Regulation of Medical Devices and Diagnostics

For course description, see page 12.

Risk Management for Regulated Industries

For course description, see page 13.

✓NEW

Solid Oral Dosage Forms: Development to Registration

X427.6 NATSC (3.0 quarter units) 15.0 hours CA BRN/LVN
Credit—Provider #CEP13114

This course provides comprehensive knowledge of the scientific principles and regulatory requirements that guide each phase of the development of solid oral dosage forms, including preformulation, formulation and process development, scale-up, technology transfer, clinical and commercial manufacturing, and testing. You will gain the background knowledge necessary to effectively design and execute a development plan for tablets and capsules, leading to drug product registration. You will also acquire insight into the development of specialized dosage forms and modified release drug products.

Prerequisite(s): “Drug Development Process” or equivalent experience.

SREEKANT R. NADKARNI, Ph.D.

SANTA CLARA CLASSROOM

10 meetings: Thursdays, 6–9 pm, January 19–March 29.
Fee: \$825 (\$742.50 through Jan. 5).

To enroll, use Section Number 4452.(011)

Also of Interest

Clinical Trials Essentials: An Intensive Course

For course description, see page 8.

ACCESS TO ONLINE RESOURCES

WEB COMPONENT indicates that classroom instruction is supplemented with online materials or activities. Students enrolling in one of these courses for the first time will receive an e-mail with logon information within 24 hours. However, access to course resources may not be active until one day prior to the course’s start date.

Clinical Trials

Certificate Program

Clinical Trials Design and Management

CERTIFICATE CONTACT

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

PROGRAM OVERVIEW

The Bay Area and Silicon Valley are leaders in the global biopharmaceutical and medical device industries. The continued success of these industries relies on clinical trials—the complex process of ensuring the safety and effectiveness of new and existing medical products.

The Certificate in Clinical Trials Design and Management helps professionals gain a solid and practical understanding of the entire clinical trials process, from drug and device development to monitoring, 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 intense focus on best practices in the clinical trial process, this certificate is appropriate for current professionals—clinical research associates and 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 CCRAs and CCRCs through ACRP. Most courses also grant BRN credit for nursing professionals.

CERTIFICATE REQUIREMENTS

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

To pursue two bioscience-related certificates in parallel or in sequence, see page 3.

COURSES MAY BE TAKEN INDIVIDUALLY OR AS PART OF THE CERTIFICATE PROGRAM.

PREREQUISITES

Successful completion of “Medical/Clinical Terminology,” an equivalent course, or medical training. 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” after completing the prerequisites. You may then take courses in any sequence, unless otherwise specified.

FOR MORE INFORMATION

Current and future course schedules can be found at ucsc-extension.edu/biosciences. For more information on this program or to be added to our mailing list, please call (408) 861-3860 or contact program@ucsc-extension.edu.

FOR INFORMATION ON CERTIFICATE APPLICATIONS AND TRANSFERRING CREDIT FROM OTHER SCHOOLS, GO TO UCSC-EXTENSION.EDU.

CLINICAL TRIALS DESIGN AND MANAGEMENT CERTIFICATE

19-unit minimum

PREREQUISITE COURSES

Units	Course	F	W	Sp	Su
0.7 CEU	Medical/Clinical Terminology	■	■		■
3.0	Human Physiology in Health and Disease (Recommended)	■	■		

REQUIRED COURSES (six)

Units	Course	F	W	Sp	Su
2.0	Drug Development Process	■	■	■	■
1.5	Medical Devices: Regulatory Strategies and Marketing Pathways		■		■
3.0	Good Clinical Practices	■	■	■	
2.0	Clinical Trials Site Monitoring I	■	■	■	
2.5	Science of Clinical Trials Design	■		■	■
2.0	Clinical Statistics for Non-Statisticians		■		■

ELECTIVE COURSES (6 units required)

Units	Course	F	W	Sp	Su
Adverse Event and Medication Coding:					
1.5	An Introduction to MedDRA, COSTART, and WHO-Drug				■
1.0	Case Report Forms Development		■		
2.0	Clinical Data Management			■	
2.0	Clinical Project Management			■	
1.5	Clinical Research: The Study Site Perspective	■		■	
1.5	Clinical Trials Site Monitoring II			■	
1.5	Contracting with Contract Research Organizations (CROs)		■		
1.5	Development of Clinical Standard Operating Procedures		■		
1.5	Document Preparation: Protocols, Reports, Summaries	■			
1.0	Drug Safety and Adverse Events Reporting	■	■		
1.0	Electronic Data Capture for Clinical Trials		■		
Electronic Records for Regulated Environments:					
1.5	Cost-Effective Approaches to Compliance	■		■	
1.5	Global Conduct of Clinical Trials	■		■	
3.0	Good Manufacturing Practices		■		■
2.0	Medical Device Design and Development	■		■	
2.0	Medical Writing		■		■
1.5	Molecular Diagnostics		■		■
Preparing for FDA Inspections and Conducting Sponsor Audits					
1.5	Sponsor Audits			■	
3.0	Regulation of Drugs and Biologics	■		■	
3.0	SAS Programming for Clinical Trials		■		
3.0	SAS for Clinical Trials for the Non-Programmer, Introduction	■			
1.5	Toxicology, Basics for Biotechnology				■

■ held in classroom ○ offered online □ both classroom and online sessions are available

Visit ucsc-extension.edu for the most current program schedule.

ACRP Contact Hours

Many of the required and elective courses in UCSC Extension’s Clinical Trials Certificate Program qualify as contact hours toward ACRP recertification. See the Association of Clinical Research Professionals Web site at acrnet.org for certification information.

BRN: Board of Registered Nursing

All courses designated BRN are approved for continuing education hours for RNs and LVNs (Provider #CEP13114).

RAPS Credit

Many of the required and elective courses in UCSC Extension’s Clinical Trials and Regulatory Affairs Certificate Programs qualify for points toward recertification for RAC. See the Regulatory Affairs Professionals Society Web site at www.raps.org for details.

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 research setting. Space is limited. If you would like more information about these special opportunities and the application process, please e-mail program@ucsc-extension.edu.

Special Program

Clinical Trials Essentials: An Intensive Course

825. NATSC (3.5 CEU) 35.0 hours
CA BRN/LVN Credit—Provider #CEP13114



Well-planned, well-executed clinical trials are the cornerstones of effective drug and medical device development. Offered in an accelerated format taught by a team of biopharmaceutical industry leaders, this course provides a unique opportunity for professionals from all disciplines to learn about the many facets of clinical trials—the complex process that ensures the safety and effectiveness of medical products. Participants leave the program with an appreciation of the drug and device development process, as well as good clinical practice (GCP) and other regulations (ICH and FDA) that guide the conduct of trials and protect human volunteers. Also covered are clinical trial phases and design strategies; the importance of informed consent and the role of the IRB; investigator selection and responsibilities; study site management and trial monitoring; statistical data analysis; and regulatory responsibilities and the role of the FDA.

The course benefits anyone working in the biopharmaceutical and medical device industries and the biomedical community who is interfacing with or conducting clinical research, including new clinical research associates and study coordinators; medical directors, physicians, nurses, pharmacists, and other health professionals; biomedical scientists; statisticians and database administrators; and business professionals.

EXPERT INSTRUCTION TEAM: Taught by a team of clinical research experts, including many from UCSC Extension's Clinical Trials Design and Management Certificate. Visit ucsc-extension.edu/cti for speaker biographies and detailed course description.

SANTA CLARA CLASSROOM

5 meetings: Monday–Friday, 8:30 am–5 pm, March 12–16.

Fee: \$1865 (\$1678.50 through Feb. 27).

To enroll, use Section Number 5433.(010)

ACCESS TO ONLINE RESOURCES

WEB COMPONENT indicates that classroom instruction is supplemented with online materials or activities. Students enrolling in one of these courses for the first time will receive an e-mail with logon information within 24 hours. However, access to course resources may not be active until one day prior to the course's start date.

Prerequisite Course

Medical/Clinical Terminology

814. NATSC (0.7 CEU)

A basic understanding of medical and clinical terminology is essential in clinical trials design and management. This interactive workshop, for individuals with no background in medical/clinical terminology or for those who would like a refresher, reviews common terms associated with medical research and development and clinical trials. Participants review both the meaning of each term and how it is applied within a practical context.

ADDY ALSUMDE, M.D., Ph.D.

SANTA CLARA CLASSROOM

Saturday, 9 am–5 pm, January 21.

Fee: \$325 (\$292.50 through Jan. 7).

To enroll, use Section Number 2928.(061)

Recommended Prerequisite Course

Human Physiology in Health and Disease

X400.001 BIOL (3.0 quarter units)

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 have no 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.

Prerequisite(s): High school or college-level chemistry and biology.

LAWRENCE BASSO, M.D.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

12 meetings: Thursdays, 6–9 pm, January 19–April 5.

Fee: \$765 (\$688.50 through Jan. 5).

To enroll, use Section Number 6999.(012)



Required Courses

Drug Development Process

For course description, see page 6.

Medical Devices: Regulatory Strategies and Marketing Pathways

X425.6 NATSC (1.5 quarter units) 15.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Medical devices are uniquely different from drugs and biologics in their regulation and paths to market. Effective clinical trial conduct for devices requires a solid understanding of these issues. This course provides a foundation in the regulation of medical devices, and it includes discussions of device classification, investigational device exemptions (IDE), 510(K) and PMA submissions, and managing and reporting adverse device events (MDRs). Students pursuing the Clinical Trials Certificate who are also interested in the Regulatory Affairs Certificate may take "Regulation of Medical Devices and Diagnostics" to fulfill the "Medical Devices: Regulatory Strategies and Marketing Pathways" requirement in the Clinical Trials Program.

INSTRUCTOR: TBA.

SANTA CLARA CLASSROOM

5 meetings: Tuesdays, 6–9 pm, January 17–March 6 (3 no meetings TBA).

Fee: \$605 (\$544.50 through Jan. 3).

To enroll, use Section Number 5939.(028)

Good Clinical Practices

X424.1 NATSC (3.0 quarter units) 30.0 hours CA BRN/LVN
Credit—Provider #CEP13114

History, ethics, and regulations provide a context for the responsible conduct of clinical research. This course focuses on the timely, thorough and ethical conduct of clinical studies. Participants explore the translation of ethical principles into regulations (federal, state and local); recruitment and consent of research subjects; roles and responsibilities of sites, sponsors and institutional review boards; study monitoring; and auditing for compliance.

JACQUIE MARDELL, B.A.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

10 meetings: Wednesdays, 6–9 pm, January 18–March 28 (1 no meeting TBA).

Fee: \$800 (\$720 through Jan. 4).

To enroll, use Section Number 0458.(044)

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

10 meetings: Wednesdays, 6–9 pm, April 4–June 13 (1 no meeting TBA).

Fee: \$800 (\$720 through Mar. 21).

To enroll, use Section Number 0458.(045)

Clinical Trials Site Monitoring I

X424.3 NATSC (2.0 quarter units) 21.0 hours CA BRN/LVN
Credit—Provider #CEP13114

This course introduces the essential elements of monitoring a clinical trial and delineates the roles and responsibilities of the sponsor, study site and the FDA. Participants gain insight into the interactions between sponsors and study sites. They are exposed to the process of site selection, budgeting, initiation visits, source documentation, regulatory documentation, and adverse event reporting. Also addressed are some practical tools for use in tracking compliance, product accountability and medical record review.

Prerequisite(s): "Good Clinical Practices" or equivalent course or experience.

PATTY KASPER, M.S.

SANTA CLARA CLASSROOM

4 meetings: Fridays, 2–6 pm, January 27, February 17; Saturdays, 9 am–5 pm, February 4, 11.
Fee: \$750 (\$675 through Jan. 13).

To enroll, use Section Number 0608.(046)

SANTA CLARA CLASSROOM

4 meetings: Fridays, 2–6 pm, April 27, May 18; Saturdays, 9 am–5 pm, May 5, 12.
Fee: \$750 (\$675 through Apr. 13).

To enroll, use Section Number 0608.(047)

Science of Clinical Trials Design

X424.2 NATSC (2.5 quarter units) 25.0 hours CA BRN/LVN
Credit—Provider #CEP13114

This course addresses science that forms the basis of effective clinical trial design. Topics include classifying and describing trial design by stage in drug and device development; reasons for clinical trials; types of trial designs; defining the hypothesis and study objectives; determining the population and sample size; stopping rules; standards of practice versus FDA requirements; safety information and data safety monitoring boards; scientific and ethical considerations; validity of design, execution, analysis, and reporting.

Prerequisite(s): "Drug Development Process" and "Good Clinical Practices."

MICHAEL HUSTON, M.B.A., B.S.

SANTA CLARA CLASSROOM

6 meetings: Monday, 5:45–10 pm, April 2–May 21 (2 no meetings TBA).
Fee: \$765 (\$688.50 through Mar. 19).

To enroll, use Section Number 3657.(049)

Clinical Statistics for Non-Statisticians

X424.8 NATSC (2.0 quarter units) 24.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Clinical studies succeed or fail on the strength of their statistics. This course takes a practical approach to fundamental statistical concepts essential for non-statisticians involved in clinical research. Through lectures, discussions and in-class exercises, the instructor explores clinical study designs, hypothesis testing, sample size calculations, assumptions, controls, endpoints, data-management principles, data presentations and analysis plans, methods of analysis, and conclusions. Participants learn how to interpret statistics commonly encountered in clinical research as well as how to communicate effectively with

statisticians. The approach is practical, simple and qualitative. No previous background in statistics is required.

G. PETER SHABE, M.S.

SANTA CLARA CLASSROOM

8 meetings: Mondays, 6–9 pm, January 23–March 26 (no meeting Feb. 20 and 1 no meeting TBA).
Fee: \$750 (\$675 through Jan. 9).

To enroll, use Section Number 2345.(037)

Elective Courses

Case Report Forms Development

X425.1 NATSC (1.0 quarter unit) 10.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Case report forms (CRFs) are the tools used in clinical trials to collect data about subjects from investigator sites. A CRF must translate the clinical protocol in such a way as to collect data that will support the planned analyses. The CRF must also accommodate the many problems that arise in the "real world" of clinical sites and subjects. We will discuss how the industry CDISC data standards can assist with CRF development and throughout the clinical research process. Students will view and discuss many concrete examples and options for CRF modules that demonstrate how the CRF impacts all of the groups involved in the conduct of the clinical trial.

Prerequisite(s): Familiarly with the fundamentals of clinical trials, either from experience or the "Drug Development Process" course.

LAURA GARDNER, M.S., M.N.S., CCDM.

SANTA CLARA CLASSROOM

2 meetings: Friday–Saturday, 9 am–3 pm, February 24–25.

Fee: \$495 (\$445.50 through Feb. 10).

To enroll, use Section Number 5544.(021)

Clinical Data Management

X425.2 NATSC (2.0 quarter units) 21.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Taking a hands-on approach, this course provides a solid understanding of the steps involved in clinical data management from study site data collection through data extraction for analysis. Topics include a planned approach to clinical data management; basic design and specification of the database and cleaning rules; required documentation, standard operating procedures (SOPs), and quality control; compliance with FDA/ICH guidelines; working with other clinical groups and CROs; using electronic data capture; and data security and confidentiality. No previous data management experience is necessary.

LAURA GARDNER, M.S., M.N.S., CCDM.

SANTA CLARA CLASSROOM

3 meetings: Friday, 9 am–5 pm, April 13; Saturdays, 9 am–5 pm, April 14, 21.

Fee: \$825 (\$742.50 through Mar. 30).

To enroll, use Section Number 6291.(020)

Free Program Overview



Clinical Trials, Regulatory Affairs, and Medical Devices

This special information session provides an opportunity to meet instructors and other students,

learn about program prerequisites, program philosophy, course content and program requirements, and gain insights into careers in clinical research, regulatory affairs, and medical devices.

SANTA CLARA CLASSROOM

Wednesday, 6–8:30 pm, January 11.

No fee, but enrollment required.

To enroll, use Section Number 16650.(014)

Contracting with Contract Research Organizations (CROs)

X477.9 BUSAD (1.5 quarter units) 15.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Pharmaceutical and biotechnology companies are more and more frequently using the services of contract research organizations (CROs) to access expertise or technology not available in-house for key clinical services. This course takes a practical look at the identification, selection, and management of CROs in the performance of clinical projects. Other topics of discussion include selecting the best CRO for a project; request for proposal (RFP) components; bid review and negotiation; types of agreements; defining roles and responsibilities; and managing the work once the contract is signed.

NANETTE NANJO-JONES, M.B.A.

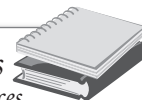
SANTA CLARA CLASSROOM WITH A WEB COMPONENT

2 meetings: Friday–Saturday, 8:30 am–5 pm, March 9–10.

Fee: \$580 (\$522 through Feb. 24).

To enroll, use Section Number 5479.(018)

Course Readers, Textbooks and Other Instructional Resources



Students are responsible for obtaining the required instructional materials for all courses. A variety of media may be used. Please review the section details at the bottom of the course description pages on our Web site.

Instructors may specify any of the following:

- Printed course readers from our on-demand service provider, **Content Management Corporation (CMC)**
- Electronic course materials from our online learning platform, **UCSC Extension Online**
- Textbooks (required and recommended). Purchasing information can be found at: ucsc-extension.edu/bookstore.
- Other materials distributed via e-mail either by the Academic Department or the instructor

Students should acquire or access their materials prior to the first class meeting. For full instructions, go to ucsc-extension.edu/course-materials.

Development of Clinical Standard Operating Procedures

X428.7 NATSC (1.5 quarter units) 15.0 hours CA BRN/LVN
Credit—Provider #CEP13114

The U.S. federal regulations and ICH guidelines for good clinical practice require that all institutions and entities involved in research with human subjects develop and maintain written standard operating procedures (SOPs). However, many companies do not develop policies and SOPs until after human clinical trials are well under way. This course examines the regulatory requirements and the differences between regulations, guidelines, policies and SOPs, and evaluates the components of a well-constructed SOP. Participants develop SOPs for important clinical functions.

Prerequisite(s): "Good Clinical Practices" or equivalent course or experience.

JACQUIE MARDELL, B.A.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

2 meetings: Monday–Tuesday, 8:30 am–5 pm,
March 26–27.

Fee: \$580 (\$522 through Mar. 12).

To enroll, use Section Number 1270.(016)

Drug Safety and Adverse Events Reporting

X427.2 NATSC (1.0 quarter unit) 10.0 hours CA BRN/LVN
Credit—Provider #CEP13114

This course introduces fundamental concepts essential to drug safety and adverse event reporting and how to apply them to situations encountered during clinical trials and post-marketing reporting. Students learn why safety reporting is crucial; the definitions of an adverse event and the key reporting issues of seriousness, expectedness, and relationship to the study drug. The course includes a brief overview of reporting requirements in the U.S. and abroad and the documents associated with these reports. The content is appropriate for CRAs, CRCs, Drug Safety Associates, and Regulatory Affairs personnel.

Prerequisite(s): "Good Clinical Practices" and "Medical/Clinical Terminology" or equivalent.

JEAN MASONEK, RN, B.S.N., B.A.

SANTA CLARA CLASSROOM

2 meetings: Saturdays, 9:30 am–3:30 pm, March 17–24.

Fee: \$495 (\$445.50 through Mar. 3).

To enroll, use Section Number 3990.(018)

Electronic Data Capture for Clinical Trials

X400.036 NATSC (1.0 quarter unit) 10.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Taking a practical approach, this course examines key issues surrounding the industry's adoption of electronic data capture (EDC). The instructor highlights the major differences between paper and electronic systems; explores benefits associated with EDC; and systematically examines the costs, risks, related process changes, and other business and regulatory implications of this shift. Interactive discussions address the process of selection, implementation and maintenance of EDC software, both for in-house and outsourced systems.

The course benefits professionals with roles in data management, biostatistics, clinical management, and clinical IT and IS.

JEFFREY SONAS, B.S.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

2 meetings: Friday, 6–9:30 pm, March 2;

Saturday, 9 am–4:30 pm, March 3.

Fee: \$580 (\$522 through Feb. 17).

To enroll, use Section Number 20777.(005)

Global Conduct of Clinical Trials

X400.038 NATSC (1.5 quarter units) 15.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Using the U.S. and E.U. as points of reference, the instructor and guest speakers help students develop a framework for examining issues and challenges related to the conduct of clinical trials in established and emerging foreign markets, including Eastern Europe, India, China, and South America. Lectures and case studies explore the current regulatory environment; the impact of local laws and requirements; cultural challenges and procedural differences in trial conduct; how to ensure that useful data are collected; and important implications for human subject protection.

Prerequisite(s): An understanding of Good Clinical Practice (GCP) regulations and the clinical trials process, at least at the level that is covered in "Drug Development Process."

JACQUIE MARDELL, B.A.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

5 meetings: Tuesdays, 6–9 pm,

April 10–May 15 (1 no meeting TBA).

Fee: \$580 (\$522 through Mar. 27).

To enroll, use Section Number 20787.(010)

Good Manufacturing Practices

For course description, see page 12.

Medical Writing

For course description, see page 13.

Molecular Diagnostics

For course description, see page 6.

SAS Programming for Clinical Trials

X429.4 NATSC (3.0 quarter units)

SAS is the primary software standard in the biopharmaceutical industry for the storage, management and manipulation of clinical data and its presentation to the FDA in clinical trials. Processing clinical data in FDA-regulated industries has specific requirements. This course prepares individuals with SAS programming experience to process clinical-trials data to meet the increasing demand for these skills in the biotech and pharmaceutical industries.

Through lectures and labs, participants learn about various aspects of SAS programming related to processing clinical data; understanding clinical-trial terminology; preparing data for submission using CDISC SDTM standards, tables, listings and figures for electronic submission; and managing regulatory considerations such as software-development life cycle and related documentation.

Prerequisite(s): Experience in SAS programming or "SAS for Clinical Trials for the Non-Programmer, Introduction."

LINDLEY C. FRAHM, B.S., M.B.A.

SANTA CLARA CLASSROOM

10 meetings: Tuesdays, 6–9 pm, January 17–March 27.

Fee: \$875 (\$787.50 through Jan. 3).

To enroll, use Section Number 4670.(010)

Medical Devices

Medical Devices

PROGRAM CONTACT

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

PROGRAM OVERVIEW

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 provide information on the principles underlying the design of medical devices and the regulations governing the manufacturing of diverse biomedical products.

Human Factors in Medical Device Development

For course description, see page 13.

Human Physiology in Health and Disease

For course description, see page 8.

Medical Devices: Regulatory Strategies and Marketing Pathways

For course description, see page 8.

Molecular Diagnostics

For course description, see page 6.

Regulation of Medical Devices and Diagnostics

For course description, see page 12.

Regulatory Submissions: Devices and Diagnostics

For course description, see page 12.

Risk Management for Regulated Industries

For course description, see page 13.



Regulatory Affairs

Certificate Program

Regulatory Affairs

CERTIFICATE CONTACT

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

PROGRAM OVERVIEW

Regulatory affairs professionals play critical roles in ensuring compliance with the laws and regulations guiding the development and commercialization of health care products. As Bay Area bioscience companies grow and mature, their need for trained regulatory personnel intensifies. Recent industry studies cite regulatory affairs as one of the most crucial human resource needs in the coming decade. However, there are currently few options available in our region for formal, in-depth training for early-stage regulatory professionals.

The Regulatory Affairs Certificate was developed under the guidance of industry and government experts to provide a broad regulatory foundation; exposure to practical, real-world applications of the regulations; and an appreciation of the important roles that regulatory affairs professionals play in the bioscience industry. Courses are taught by experienced regulatory professionals currently working in the device, diagnostic, pharmaceutical and biologic sectors. Instructors bring the regulations to life with relevant examples and hands-on exercises designed to prepare students for rewarding careers in regulatory affairs.

CERTIFICATE REQUIREMENTS

To obtain the Certificate in Regulatory Affairs, students 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, go to ucsc-extension.edu.

To pursue two bioscience-related certificates in parallel or sequence, see page 3.

COURSES MAY BE TAKEN INDIVIDUALLY OR AS PART OF THE 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 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."

FOR MORE INFORMATION

Current and future course schedules can be found at ucsc-extension.edu/biosciences. For more information or to be added to our mailing list, please call (408) 861-3860 or contact program@ucsc-extension.edu.

FOR INFORMATION ON CERTIFICATE APPLICATIONS AND TRANSFERRING CREDIT FROM OTHER SCHOOLS, GO TO UCSC-EXTENSION.EDU.

REGULATORY AFFAIRS CERTIFICATE

19-unit minimum

REQUIRED COURSES (seven)	Units	Course	F	W	Sp	Su
Drug Development Process.....	2.0	6559	■	■	■	■
Regulation of Medical Devices and Diagnostics	3.0	19071		■		■
Regulation of Drugs and Biologics	3.0	19007	■		■	
One of the following*						
Regulatory Submissions: Drugs and Biologics OR	2.0	19067	■		■	
Regulatory Submissions: Devices and Diagnostics	2.5	19315		■		■
One of the following*						
Good Manufacturing Practices OR	3.0	6328		■		■
Regulatory Compliance for Medical Devices	2.5	19029	■		■	
Interacting with the FDA	1.5	19318		■		■
RA Professional's Toolbox	1.5	19317	■		■	
*The remaining submissions or compliance courses may be used as electives.						
ELECTIVE COURSES (4 units required)	Units	Course	F	W	Sp	Su
Regulatory						
Design Control for Product Development	2.0	21973	■		■	
Drug Quality Fundamentals	1.5	23400	■			
Electronic Records for Regulated Environments:						
Cost-Effective Approaches to Compliance	1.5	19362	■		■	
Global Medical Device Submissions and Strategy	1.5	20343			■	
Human Factors in Medical Device Development	2.0	23097		■		
Medical Writing	2.0	4451		■		■
Post-Market Regulatory Obligations for Medical Devices	1.5	22414			■	
Regulation of Biomedical Product Advertising, Promotion and Labeling	1.5	20756				■
Regulatory Intelligence	1.0	20341				■
Risk Management for Regulated Industries	3.0	22631		■		■
Value-Added Quality Audits	1.5	19073				■
Clinical						
Adverse Event and Medication Coding:						
An Introduction to MedDRA, COSTART, and WHO-Drug	1.5	19976			■	
Clinical Statistics for Non-Statisticians	2.0	2345		■		■
Drug Safety and Adverse Events Reporting	1.0	3990	■	■		
Electronic Data Capture for Clinical Trials.....	1.0	20777		■		
Global Conduct of Clinical Trials	1.5	20787	■		■	
Good Clinical Practices	3.0	0458	■	■	■	
Preparing for FDA Inspections and Conducting Sponsor Audits	1.5	5168			■	
Science of Clinical Trials Design	2.5	3657	■		■	■
Discovery/Development (A maximum of 1.5 units may be applied toward the elective requirement.)						
Intellectual Property Essentials for the Life Science Industry.....	1.0	1942			■	
Medical Device Design and Development	2.0	19977	■		■	
Molecular Diagnostics	1.5	21972		■		■
Pharmacology, Principles	2.0	5596				■
Toxicology Basics for Biotechnology.....	1.5	2310				■

■ held in classroom ○ offered online □ both classroom and online sessions are available

Visit ucsc-extension.edu for the most current program schedule.

Regulatory Affairs Advisory Board

ERIC ANDERSON, Supervisory Investigator,
Food and Drug Administration

MEREDITH BROWN-TUTTLE, RAC, Consultant,
Regulatory Affairs

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Practice, Wilson Sonsini Goodrich & Rosati

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West Coast Operations, SciLucent

KATHY NUSSER, CQA, RAC, Corporate Regulatory
Affairs Manager, Varian Medical Systems, Inc.

VIRGINIA PERRY, RAC, CQE, Partner, Regulatory
Affairs/Medical Devices, Perry-D'Amico & Associates

MICHELLE ROEDING, RAC, Section Manager,
Regulatory Affairs, Abbott Diagnostics Division—
Santa Clara

ROBERT I. ROTH, M.D., Ph.D., Medical Director,
The Weinberg Group Inc.

RAPS Credit

Many of the required and elective courses in UCSC Extension's Clinical Trials and Regulatory Affairs Certificate Programs qualify for points toward recertification for RAC. See the Regulatory Affairs Professionals Society Web site at www.raps.org for details.

Course Readers, Textbooks and Other Instructional Resources



Students are responsible for obtaining the required instructional materials for all courses. A variety of media may be used. Please review the section details at the bottom of the course description pages on our Web site.

Instructors may specify any of the following:

- Printed course readers from our on-demand service provider, **Content Management Corporation (CMC)**
- Electronic course materials from our online learning platform, **UCSC Extension Online**
- Textbooks (required and recommended). Purchasing information can be found at: ucsc-extension.edu/bookstore.
- Other materials distributed via e-mail either by the Academic Department or the instructor

Students should acquire or access their materials prior to the first class meeting. For full instructions, go to ucsc-extension.edu/course-materials.

Required Courses

Drug Development Process

For course description, see page 6.

Regulation of Medical Devices and Diagnostics

X400.017 NATSC (3.0 quarter units)

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. 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 the investigational device exemption (IDE) application and process.

INSTRUCTOR: TBA.

SANTA CLARA CLASSROOM

10 meetings: Tuesdays, 6–9 pm,
January 17–April 10 (3 no meetings TBA).
Fee: \$825 (\$742.50 through Jan. 3).

To enroll, use Section Number 19071.(013)

Regulatory Submissions: Devices and Diagnostics

X400.022 NATSC (2.5 quarter units)

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.

This hands-on course requires substantial out-of-class work on a submission project, where you will be crafting a 510K.

Prerequisite(s): "Regulation of Medical Devices and Diagnostics" or equivalent experience.

CRAIG J. COOMBS, RAC.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

8 meetings: Thursday, 6–9:15 pm,
January 19–March 29 (3 no meetings TBA).
Fee: \$860 (\$774 through Jan. 5).

To enroll, use Section Number 19315.(010)



**TO PURSUE TWO BIOSCIENCE-RELATED
CERTIFICATES IN PARALLEL OR IN
SEQUENCE, SEE PAGE 3.**

Good Manufacturing Practices

X479.6 BUSAD (3.0 quarter units) 30.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Familiarity with the Good Manufacturing Practices (GMP) regulations is a necessity for employees engaged in the manufacture, regulation, 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. While primarily aimed at the manufacturing, quality control and quality assurance worker, the course is also useful for those in regulatory affairs and clinical research. It is beneficial for those who wish to understand which regulatory controls apply to the manufacture of drugs and biopharmaceuticals for human use.

STEVEN KUWAHARA, Ph.D.

SANTA CLARA CLASSROOM

5 meetings: Saturdays, 9 am–4:30 pm, January 21–
March 3 (no meeting Feb. 18 and 1 no meeting TBA).
Fee: \$825 (\$742.50 through Jan. 7).

To enroll, use Section Number 6328.(023)

Interacting with the FDA

X400.027 NATSC (1.5 quarter units)

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 learn how to prepare for these important events. The course highlights the structure, mission, jurisdiction and roles of the FDA, reviews centers within the agency and field offices, and examines key societal, political, industrial and biomedical drivers that impact policies, priorities, and the current U.S. regulatory environment. This course benefits new and experienced regulatory professionals or anyone who interfaces with the FDA.

ELIZABETH LEININGER, Ph.D.

SANTA CLARA CLASSROOM

5 meetings: Mondays, 6–9 pm, February 13–March 26
(no meeting Feb. 20 and 1 no meeting TBA).
Fee: \$700 (\$630 through Jan. 30).

To enroll, use Section Number 19318.(010)



Elective Courses: Regulatory

Human Factors in Medical Device Development

X400.440 CMPE (2.0 quarter units)

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 use 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.

MERRICK KOSSACK, M.S.
ERIC BERGMAN, Ph.D.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

7 meetings: Wednesdays, 6–9 pm,
January 18–March 7 (1 no meeting TBA).
Fee: \$775 (\$697.50 through Jan. 4).

To enroll, use Section Number 23097.(002)

Medical Writing

X493.5 BUSAD (2.0 quarter units) 24.0 hours CA BRN/LVN
Credit—Provider #CEP13114

Biopharmaceutical companies must produce scientific reports and summary documents for regulatory agencies. Good documentation should be scientifically sound, and also clear, effective and concise. This hands-on 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.

INSTRUCTOR: TBA.

SANTA CLARA CLASSROOM

8 meetings: Mondays, 6–9 pm, January 23–March 26
(no meeting Feb. 20 and 1 no meeting TBA).
Fee: \$750 (\$675 through Jan. 9).

To enroll, use Section Number 4451.(011)

ACCESS TO ONLINE RESOURCES

WEB COMPONENT indicates that classroom instruction is supplemented with online materials or activities. Students enrolling in one of these courses for the first time will receive an e-mail with logon information within 24 hours. However, access to course resources may not be active until one day prior to the course's start date.

Risk Management for Regulated Industries

X400.045 NATSC (3.0 quarter units)

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.

BARRY CRANER, M.A., M.B.A.

SANTA CLARA CLASSROOM WITH A WEB COMPONENT

10 meetings: Tuesdays, 6–9 pm,
January 17–March 27 (1 no meeting TBA).
Fee: \$825 (\$742.50 through Jan. 3).

To enroll, use Section Number 22631.(005)

Elective Courses: Clinical

Clinical Statistics for Non-Statisticians

For course description, see page 9.

Drug Safety and Adverse Events Reporting

For course description, see page 10.

Electronic Data Capture for Clinical Trials

For course description, see page 10.

Global Conduct of Clinical Trials

For course description, see page 10.

Good Clinical Practices

For course description, see page 8.

Science of Clinical Trials Design

For course description, see page 9.

Elective Courses:

Discovery/Development.

A maximum of 1.5 units may be applied toward the elective.

Molecular Diagnostics

For course description, see page 6.

Bioscience Business

UCSC Extension's Bioscience Business and Marketing Program provides a solid foundation in business and marketing principles and the unique ways they are applied to the bioscience industry. Taught by and designed with input from industry experts, the curriculum benefits professionals from within the industry, allied service firms (law, finance, consulting), and those from other industries who are looking to apply their skills in the burgeoning bioscience arena. More specifically, the program is geared for scientific personnel seeking to understand the role of their business and marketing colleagues and the industry environment in which they work; entry to mid-level business and marketing professionals from all backgrounds; scientists considering a move to the business and marketing side of the industry; and professionals from service firms who want to better understand how bioscience differs from other industries.

Certificate Program

Bioscience Business and Marketing

Certificate Contact

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

Program Overview

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 **4 required courses** and a minimum of **3 units (30 hours) of elective course work**. For GPA requirements and program time limits, go to 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 (or who have not taken a course in the past five years) 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.

For More Information

Current and future course schedules can be found at ucsc-extension.edu/biosciences. For more information on this program, or to be added to our mailing list, please call (408) 861-3860 or contact program@ucsc-extension.edu.