



SAN JOSÉ STATE
UNIVERSITY



Channel Islands
CALIFORNIA STATE UNIVERSITY

California State University
SAN MARCOS

Extended
Learning

Online **BIOTECHNOLOGY COURSES**

These online courses were developed through a three campus collaboration involving San Jose State University, CSU San Marcos, and CSU Channel Islands with funding from the CSU Commission on Extended University



COURSES

Designed for both continuing graduate students as well as professionals in the field. The following courses represent the latest in biotechnology education delivered in a convenient online format.

BIOL 601 SEMINAR IN BIOTECHNOLOGY AND BIOINFORMATICS (1)

Latest Technological Developments (Winter 2010)

Stem Cell Research (Summer 2010)

Discussion of up-to-date research and development findings with guest speakers, visiting scientists and industry professionals.

Students who successfully complete this course will be able to:

- Discuss up-to-date issues in the biotechnology field.
- Formulate cogent questions related to biotechnology research.
- Identify emerging fields of study in biotechnology.

Scheduled Speakers: TBA

BIOL 503 BIOTECHNOLOGY LAW AND REGULATION (3)

Individual and organizational responsibility in R&D and commercial aspects of biotechnology. Topics include: intellectual property, privacy, government and industrial regulation, liability, ethics, and policy responses to societal concerns in the U.S. and abroad. Case studies involving gene therapy, cloning, and biomaterials in the medical and health sector, and farming and crop modification in the agricultural sector will be explored in detail.

Participants who successfully complete this course will be able to:

- Describe Federal laws governing biotechnological issues and the associated regulatory agencies.
- Describe California laws governing biotechnological issues and the associated regulatory agencies.
- Discuss current issues and debates in cloning, gene therapy, crop modification.
- Outline the technology transfer process for commercially valuable biotech products.

MGT 471 PROJECT MANAGEMENT

(3)

Presents the principles of project management, which is a special form of work organization, that focuses on a one-time objective. Discusses all aspects of project management: definition of objectives, selection of team and other resources, establishing of timing and sequences, creation of monitoring and control processes, and development of analysis and reporting mechanisms.

Participants who successfully complete this course will be able to:

- Read cases and describe (orally and in writing) the project management issues of the cases.
- Describe (in writing) project management approaches and their organizational implications for scientific managers.
- Analyze project management issues related to scientific projects and offer recommendations for effective corrective actions.
- In writing, demonstrate an understanding of the inter-relationships among the disciplines of science, basic management and project management.

BIOL 227T PHARMACOLOGY AND TOXICOLOGY

(3)

Principles of pharmacology, especially as related to the pharmaceutical industry and clinical applications.

BIOL 500 INTRODUCTION TO BIOPHARMACEUTICAL PRODUCTIONS (3)

An introduction to biopharmaceutical production systems and processes. Topics include manufacturing, unit operations and supporting infrastructures, product distribution, quality assurance and control, facility engineering and maintenance, utility operations, regulatory compliance, and laboratory support.

Students who successfully complete this course will be able to:

- Describe the processes, the facilities, the regulations, and the systems that are necessary for the production and supply of biopharmaceuticals.
- Communicate with experts in the domains of recombinant DNA technology, the unit operations associated with cell culture and fermentation, upstream recovery and downstream purification, formulation, and filling and packaging.
- Describe the international regulations associated with the industry, the scientific principles and rationale of the regulations, and draw the connections between the regulations, scientific principles and the quality systems that are put in place to assure the safety of the patients.
- Describe the concepts around the design and operation of facilities and the infrastructures that support their operation.

BINF 500 DNA & PROTEIN SEQUENCE ANALYSIS

(3)

This course will introduce the computational aspects of biological inference from nucleic acid and protein sequences. Pairwise sequence comparison and multiple sequence alignment will be studied in detail. Additional topics include: RNA structure prediction, conserved sequence pattern recognition (sequence profile analysis), phylogenetic analysis algorithms, sequence data as a means to study molecular evolution, models and algorithms for genetic regulation, contig assembly, PAM and BLOSUM matrices, protein three dimensional structure prediction.

Students who successfully complete this course will be able to:

- Explain the algorithms used in DNA sequence alignment.
- Explain the significance of scoring in DNA sequence alignment.
- Write Perl scripts that perform basic manipulations of nucleic acid and protein sequence data.
- Evaluate the merits and disadvantages of probabilistic and non-probabilistic tree-finding methods.
- Use a profile hidden Markov model to score how well an unknown protein sequences fits a family motif.
- Demonstrate facility using BLAST and PSI-BLAST.

BIOL 516 CLINICAL TRIALS AND QUALITY ASSURANCE

(3)

An introduction to the foundational knowledge and skills necessary to successfully conduct clinical trials for new drugs, biologics, and medical devices, including in vitro diagnostics. Topics include a broad overview of the product development process in the pharmaceutical, biopharmaceutical, and medical device industries, the regulatory and operational requirements for clinical study setup, management, monitoring, and closure of clinical trials, the principles of Good Clinical Practice (GCP), and the applications of quality control and quality assurance. The integration of quality assurance throughout the medical product development process will be discussed.

Student Learning Outcomes:

- Explain the structure and function of the U.S. Food and Drug Administration (FDA) and its history
- Describe the medical product development process
- Explain ethical considerations in clinical trials, incorporating current and historical perspectives
- Describe the U.S. regulatory requirements for clinical testing of new drugs, biologics, and medical devices, including in vitro diagnostics, and combination products

- State the application and importance of Good Clinical Practice (GCP)
- Describe the clinical trials process from planning to study close-out
- State clinical trial monitoring, study and data management best practices
- Identify the concepts of quality control and assurance as related to GCP and other areas of medical product development

PROFESSIONAL BIOTECHNOLOGY PROJECT MANAGEMENT CERTIFICATE IN QUALITY ASSURANCE

The certificate is being jointly offered by the Divisions of Extended Studies at CSU Channel Islands, CSU Dominguez Hills and San Diego State University.

This graduate certificate focuses on the skills and tools required to successfully manage product development and quality assurance projects in the life sciences industry including medical device, pharmaceutical, and biopharmaceutical companies. Participants will learn the importance of leadership and effective communications in managing and implementing process changes and improvements, while complying with regulatory requirements.

Who Will Benefit

- Quality assurance, manufacturing and regulatory affairs professionals
- Scientists involved in research programs and product development in the life sciences industry

To earn this certificate, students must complete the following four courses: Quality Function Management and TQM, Regulatory Affairs & Ethics, Good Manufacturing Practices and Project Management. Courses are taught online to provide flexibility to working professionals.

Please note: Students should hold a bachelors degree to qualify for the professional certificate. A science or engineering background is also strongly suggested.

Phone: (619) 594-3954

Email: rbhathal@mail.sdsu.edu.

(These online educational programs are partially funded by a grant from the CSU Commission on the Extended University.)



These online courses were developed through a three campus collaboration involving San Jose State University, CSU San Marcos, and CSU Channel Islands with funding from the CSU Commission on Extended University.

FOR COURSE SCHEDULE AND REGISTRATION:

Phone: 805.437.2748

E-mail: exed@csuci.edu

Current CSU Students: Contact your home campus for enrollment information.



Channel Islands

CALIFORNIA STATE UNIVERSITY

EXTENDED UNIVERSITY

2109 Sage Hall
One University Drive
Camarillo, CA 93012

NONPROFIT ORGANIZATION

U.S. POSTAGE

PAID

OXNARD, CA
PERMIT NO. 2323