CALIFORNIA STATE UNIVERSITY CHANNEL ISLANDS

NEW COURSE PROPOSAL

PROGRAM AREA _____BIOLOGY_____

1. Catalog Description of the Course.

BIOL 503 BIOTECHNOLOGY LAW AND REGULATION (3)
Three hours lecture per week

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.

2. Mode of Instruction.

	Units	**Hours per Unit**	**Benchmark Enrollment**
Lecture	_____3___	____1____	___15_____
Seminar	_____	_____	_____
Laboratory	_____	_____	_____
Activity	_____	_____	_____

3. Justification and Learning Objectives for the Course. (Indicate whether required or elective, and whether it meets University Writing, and/or Language requirements) *[Use as much space as necessary]*

This course is required element of the core curriculum for the proposed Professional Science Masters degree in Bioinformatics

Upon completion of this course, students 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

4. Is this a General Education Course NO
If Yes, indicate GE category:

A (English Language, Communication, Critical Thinking)	
B (Mathematics & Sciences)	
C (Fine Arts, Literature, Languages & Cultures)	
D (Social Perspectives)	
E (Human Psychological and Physiological Perspectives)	

5. Course Content in Outline Form. *[Be as brief as possible, but use as much space as necessary]*

Biotechnology: History and Trends (Evolution of biotech industry, agricultural and food products, pesticides and herbicides, drugs, medical products, GMOs)
Public policy and ethical issues
Regulation of Biotechnology (Food and Drug Administration, US Department of Agriculture, U.S. Environmental Protection Agency, International)
Protecting Biotechnology Products (property rights, technology transfer, patents)
Liability Risks

6. References. *[Provide 3 - 5 references on which this course is based and/or support it.]*

Biotechnology, Law, Business and Regulation. Michael J. Malinowski, Beth E. Arnold, eds. Aspen Law & Business Publications, 1999.
Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology. Thomas H. Murray, Maxwell J. Mehlman, eds. New York : John

Wiley & Sons, 2000.
Biotechnology and the Federal Circuit. Kenneth J. Burchfield. BNA Books, 1995.
Valuation and Pricing of Technology-Based Intellectual Property. Richard Razgaitis, Wiley, John & Sons. 2002.

7. List Faculty Qualified to Teach This Course.

Faculty to be hired.

8. Frequency.

a. Projected semesters to be offered: Fall _X ____ Spring _ ____ Summer _____

9. New Resources Required.

a. Computer (data processing), audio visual, broadcasting needs, other equipment
b. Library needs
c. Facility/space needs

None.

10. Consultation.

Attach consultation sheet from all program areas, Library, and others (if necessary)

11. If this new course will alter any degree, credential, certificate, or minor in your program, attach a program modification.

____Amy Denton 31 October 2003_____
Proposer of Course Date