Los Angeles/Orange County Regional Consortia Endorsement Template

Biotechnology	**Denise Foley, Ph.D.**
PROPOSED PROGRAM TITLE	**CONTACT PERSON**
Santiago Canyon College	**Associate Professor/co-chair Biology**
COLLEGE	**TITLE**
Rancho Santiago Community College District	**714-628-4920**
DISTRICT	**PHONE NUMBER**
Fall 2014	**Foley_denise@sccollege.edu**
PROJECTED PROGRAM START DATE	**E-MAIL ADDRESS**

GOAL(S) OF PROGRAM (CHECK ALL THAT APPLY):

☑ CAREER TECHNICAL EDUCATION (CTE)

☑ TRANSFER and CAREER TECHNICAL EDUCATION (CTE)

TYPE OF PROGRAM (CHECK ALL THAT APPLY):

☑ A.S. Degree

☑ Certificate of Achievement: ☑ 18+ semester units ☐ 09-17 semester units

☑ New Program

☐ Substantial Change

☑ Locally Approved

APPLICATION FOR APPROVAL—NEW and SUBSTANTIAL CHANGE PROGRAM TEMPLATE

1. *SP02 Program Award*	*A.S./ Cert of Achievement*	*11. New Faculty Positions*	*none*
2. *Program Title*	*Biotechnology*	*12. New Equipment*	*$179,493*
3. *Program Goal*	*CTE & transfer*	*13. New/Remodeled Facilities*	*$0*
4. *SP01: Program TOP code*	*0430.00*	*14. Library Acquisitions*	*$0*
5. *Effective Date:*	*Fall 2014*	*15. Program Review Date*	*Fall 2016*
6. *Units for Degree Major or Area of Emphasis (Minimum)* *Units for Degree Major or Area of Emphasis (Maximum)*	*31* *38*	*16. Gainful Employment*	☑ *Yes* ○*No*
7. *Total Units for Degree (Minimum)* *Total Units for Degree (Maximum)*	*38 (cert of achievement)* *61 (A.S.)*	*17. Apprenticeship*	○ *Yes* ☑*No*
8. *Annual Completers*	*20*	*18. Distance Education*	☑*Hybrid* ☐ *0-49%* ☐*50-99%* ☐*100%*
9. *Net Annual Labor Demand (CTE Only)*	*377*	*19. CTE Regional Consortia Approval*	○ *Yes* ○*No*
10. *Faculty Workload (total cert) (biotech-specific)*	*3 faculty loads* *0.79 faculty*	*20. District Governing Board Approved*	○ *Yes* ○*No*
The fall 38.4, the spring 30.3, the summer 20.65 89.35 the/30 the= 3 8.55 fall, 5.5 spring, 9.55 summer =23.65 the =0.79 faculty		*21. District Governing Board Approval Date*	

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)

California Community Colleges Chancellor's Office Program and Course Approval Handbook, 5th Edition, VII Draft

NARRATIVE TEMPLATE (for Traditional Degrees and Certificates)

Please adhere to the following format conventions:

- Use the heading (item) and numbering convention (for example: Item 1. Program Goals and Objectives).
- Ensure the description provided under each criteria/item is removed from the narrative prior to submission.

Item 1: Programs Goals and Objectives (page 142)
Item 2: Catalog Description (page 143)
Item 3: Program Requirements (page 144-146)
Item 4: Master Planning (page 146)
Item 5: Enrollment and Completer Projections (pages 148)
- **A. Enrollment Data**
- **B. Survey**

Item 6: Place of Program in Curriculum/similar Programs (page 148-149)
Item 7: Similar Programs at Other Colleges in Service Area (page 149)

SUBMISSION CHECKLIST

This submission checklist provides a quick reference check for traditional associate degree proposal requirements; please refer to sections 1-3 of this Program Course Approval Handbook 5th Edition – Draft guide for a detailed discussion of each requirement.

✓ **Proposal fields #1-21** – All fields are complete, no fields are left blank. Please refer to section one of this Guide for a detailed description of requirements unique to each field.

1. SP02: Program Award: A.A. or A.S. is selected as the program award.

2. Program Title: Entered as it will appear in the catalog; does not include descriptors, such as "with an emphasis," "degree," "certificate," "transfer" or "for transfer."

3. Program Goal: Career Technical Education (CTE), Transfer, Career Technical Education (CTE) and Transfer, or Other – Designed to meet community needs is selected; refer to section two (Comprehensive Curriculum Topics) of the Program and Course Approval Handbook 5th Edition - Draft for a detailed discussion of each.

For a proposed program that is categorized by a TOP code that is designated as vocational or Career Technical Education (CTE) as denoted with an asterisk (*), the program goal selected must be "Career Technical Education (CTE)" or "Career Technical Education (CTE) and Transfer."

4. SP01: Program TOP Code: An appropriate TOP code is selected.

5. Effective Date: A future date is entered. **Important Note:** The desired action will be made effective in the CCC Curriculum Inventory immediately after Chancellor's Office approval; the "effective date" entered in the proposal field is for record keeping purposes only.

6. Units for Degree Major or Area of Emphasis – Minimum & Maximum: The (minimum and maximum) number of semester or quarter units for the major or area of emphasis including course requirements, restricted electives, and other completion requirements is entered. If the units required are the same (not a range), then enter the same number in both (min/max) fields.

7. Total Units for Degree – Minimum & Maximum: The total (minimum and maximum) units required to complete the degree including the units for the major or area of emphasis, the general education pattern units, any other graduation requirements, and electives is entered. If the units required are the same (not a range), then enter the same number in both (min/max) fields.

8. Annual Completers: The number of students projected to be awarded the degree each year after the program is fully established is entered and reconciles with the Narrative Item 5. Enrollment and Completer Projections. The number entered is greater than zero.

9. Net Annual Labor Demand: For programs with a selected program goal of "Career Technical Education (CTE)" or "Career Technical Education (CTE) and Transfer," the estimated number of annual job openings, minus the annual number of program completers of other programs within the counties in the college service areas is entered. The number is explicitly stated and

consistent with the Labor Market Information and Analysis provided as Supporting Documentation. The figure entered is greater than zero.

10. Faculty Workload: The number of full-time equivalent faculty (FTEF) that will be dedicated to teaching in the degree during the first full year of operation, regardless of whether they are new or existing faculty is entered as a decimal.

11. New Faculty Positions: The number (not FTEF) of separately identified new faculty positions, both part- and full-time is entered.

12. New Equipment: If new equipment will be acquired for the degree, an estimate (in dollars) is provided. If no new equipment will be acquired for the degree, zero (0) is entered.

13. New/Remodeled Facilities: If new or remodeled facilities will be acquired for the degree, an estimate (in dollars) is provided. If no new or remodeled facilities will be acquired for the degree, zero (0) is entered.

14. Library Acquisitions: If new library and learning resources materials will be acquired for the degree, an estimate (in dollars) is provided. If no new library and learning resource materials will be acquired for the degree, zero (0) is entered.

15. Program Review Date: A future date is entered; for a degree with a program goal of "Career Technical Education (CTE)" or "Career Technical Education (CTE) and Transfer," pursuant to Education Code section 78016, the degree must be reviewed every two (2) years.

16. Apprenticeship (yes/no): "No" is selected if the program is not an apprenticeship. "Yes" if the program is an apprenticeship with approval from the Division of Apprenticeship Standards (DAS) and the following additional proposal fields are complete:

Employer or Joint Apprenticeship Committee (JAC) Sponsor: The Name, Address, and Telephone Number of the Sponsor are entered.

RSI - Year & Hours: The estimated total number of related and supplemental instruction (RSI) hours the program is likely to generate in the first three years is entered.

Year 1	[Whole Number]
Year 2	[Whole Number]
Year 3	[Whole Number]
Total	[auto total]

It is important to note that a credit apprenticeship proposal must also have a corresponding program goal (selected in field #3 above) of "Career Technical Education (CTE)" or "Career Technical Education (CTE) and Transfer."

17. Distance Education: The extent to which the courses associated with the degree are conducted via distance education is indicated.

18. Gainful Employment (yes/no): If the program meets U.S. Department of Education gainful employment criteria is indicated.

19. CTE Regional Consortium Approved (yes/no) – For programs with a selected program goal of "Career Technical Education (CTE)" or "Career Technical Education (CTE) and Transfer," "Yes" is selected. For programs with a selected goal that does not include Career Technical Education (CTE), "No" is selected.

20. District Governing Board Approved (yes/no): "Yes" is selected.
21. District Governing Board Approval Date: A historical date is entered.

✓ **Course Report** – The course report reflects all courses listed in the Narrative Item 3. Program Requirements (general education courses are not required to be attached to the proposal).

✓ **Supporting Documentation – Course Outlines of Record (CORs);** a COR is attached for each course listed in the Narrative Item 3. Program Requirements (general education courses are not required to be attached to the proposal).

✓ **Supporting Documentation – Transfer Documentation**; If applicable, articulation and transfer reports downloaded from ASSIST website at www.assist.org (ASSIST is the official online repository of articulation for California's public colleges and universities and provides the most accurate and up-to-date information about student transfer in California.) are attached.

✓ **Supporting Documentation – Narrative Items #1-7** are complete; refer to the aforementioned discussion for details.

If the program goal (selected in field #3 above) is "Career Technical Education (CTE)" or "Career Technical Education (CTE) and Transfer" and the program is NOT an apprenticeship, then the following additional supporting documentation is attached:

✓ **Supporting Documentation – Labor Market Information (LMI) & Analysis** is complete and demonstrates that jobs are available for program completers within the local service area of the individual college and/or that job enhancement or promotion justifies the proposed curriculum.

✓ **Supporting Documentation – Advisory Committee Recommendations** including (1) a list of advisory committee members, (2) minutes of committee meetings highlighting the action to approve the proposed program, and (3) a description of how program design aligns with committee recommendations.

✓ **Supporting Documentation – Regional Consortia Approval Meeting Minutes** clearly indicating the action to approved the proposed program.

If the program is an **apprenticeship**, then the following additional supporting documentation is attached:

✓ **Supporting Documentation – Labor Market Information (LMI) & Analysis** is complete and demonstrates that jobs are available for program completers within the local service area of the individual college and/or that job enhancement or promotion justifies the proposed curriculum.

✓ **Supporting Documentation – California Division of Apprenticeship Standards (DAS) Approval Letter** is attached indicating the "file number" assigned to the program by the DAS.

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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Item 1: Programs Goals and Objectives

Goals:

- Offer a layered certificate of achievement in biotechnology at Santiago Canyon College in collaboration with Santa Ana College and Fullerton College
- Develop further industry involvement and internship opportunities for students

Objectives:

- Have 20 student completers for each layer by 2016.
- Offer the courses for the first layer in 2014-2015 year.
- Offer second and final layer in 2015-2016 academic year

Santiago Canyon College and our collaborators met with a biotechnology advisory committee in June 2012 which recommended developing a stackable certificate that would provide new students and incumbent workers with skills to enter and advance in this growing industry. Since that meeting, Santiago Canyon College and our collaborators have researched and planned for the implementation of such a certificate. The certificate will be comprised of courses intended to develop and ensure proficiency in specific lab-based skills as well as more traditional basic biology and chemistry courses (see section 13). We have proceeded in developing this program with the support of colleagues at Santa Ana College, Fullerton College and Wendie Johnson, director of the Pasadena City College LA/OC Biotechnology Economic Workforce Development Program. Considering the new biotechnology courses, the program will work with the campus articulation officer to determine the course transferability and articulation to CSU/UC.

The certificate comprises a mix of courses that are a blend of skills-intensive biotechnology courses and UC/CSU transferable courses, some of which are required of biology majors. This blend will allow students who are job-oriented to acquire skills and theory-based knowledge needed to enter a growing and high-wage field but also take courses that can be applied to a science/biology degree should they decide to pursue more education.

The major goal of the Biotechnology certificate is to provide students with information and skills which will provide employment and advancement opportunities in the biotechnology sector, which includes many industries from food processing to medical device manufacturing (for examples, see section 8 table 1). The stackable certificate will provide first, basic laboratory skills and related theory. The middle layer will focus on protein-related work, and the final layer will provide training in the booming field of nucleic acids but also allow the student flexibility in choosing courses that align best with their interests and opportunities in the industry. For example, a student completing the final layer must take biotech C: Nucleic acids and upstream development but may decide to concentrate on chemistry and take the second semester of general chemistry (which would also complete the UC/CSU transfer requirement for general chemistry in the biology and chemistry majors). Another student may want to focus on food safety and take microbiology and the food safety and food microbiology course. Internships will be encouraged for all students. While SCC has already established internship agreements at three Orange County sites for up to 15 students a year, we will continue to expand and diversify the internship opportunities for students within the program.

The program goals include integrating existing courses and programs (e.g. biology and chemistry) with the biotechnology program to support the industry needs and provide students with multiple opportunities. They may initially choose only to complete the certificate to obtain good-wage employment but may later use the completed coursework in biology and chemistry to complete a pathway to transfer to a University in a STEM major. Similarly, a biology major may decide to take the biotechnology-specific skills courses in order to obtain employment in the field of interest while simultaneously pursuing their degree.

The proposed certificate includes an introductory hybrid course (Intro to Biotechnology which covers the history, scope, and basic theories and processes of the industry as well as Biotechnology A the introductory lab skills course. The intermediate level includes Biotechnology B the protein lab skills course as well as a second chemistry (Chem. 219, General Chemistry) and the cellular and molecular biology course (Biology 211) taken by beginning students who wish to major in biology. The final and 3rd layer includes the nucleic acid course, Biotechnology C, the Quality and Regulatory Compliance in Bioscience course and opportunities for students to take courses of most benefit to them, including internship opportunities. Our campuses (Santiago Canyon College, Santa Ana College and Fullerton College) will offer various specialty courses at the different campuses which will allow students to pursue a more focused specialties or more than one specialty as their needs change. Our intention is to offer skills-based training to students to enter or retrain for the biotechnology manufacturing and product development industry for a variety of entry-to mid-level positions. This certificate is meeting the needs of the industry and the desire of students to obtain the training necessary to enter the field.

Students who complete this certificate will obtain a certificate of achievement in biotechnology, will have obtained proficiency in basic and more advanced laboratory skills, and will have been exposed to various aspects of the industry through school-sponsored events and coursework. By having a coordinated collaboration between three campuses in Orange County, students will benefit by having multiple opportunities to seek additional specializations within the field of biotechnology. Additionally, they will obtain real-life experience through internship opportunities. This certificate meets the needs of the emerging and growing biotechnology sector in Orange County.

Item 2: Catalog Description

This certificate program is designed for students who wish to obtain the skills required to gain employment in industries influenced by biotechnology as well as for incumbent workers seeking career opportunities. Upon completion of this certificate program, students will be eligible to obtain employment as laboratory assistants, biomanufacturing technicians, or research and development technicians.

Item 3: Program Requirements (NEW PROGRAM)

Several new courses are being developed for the program. The courses are skills-based. Students will be graded on the acquisition and proficiency in specific laboratory skills in addition to basic scientific theory. Standard operating procedures (SOPs), laboratory notebooks, concepts of bioethics, and an integration of regulation and compliance into these courses will occur.

Facilities on the Santiago Canyon College campus are adequate to host this program. Equipment is being purchased with Perkins funding as well as SB1070 funding. We will continue to pursue other grant sources as well as industry contributions to enhance the basic equipment acquired for the program.

Certificate of Achievement: Biotechnology Laboratory Technician

Requirements	Dept/Name#	Name	Units
Required Core (31 units)	**Biology 190**	**Introduction to Biotechnology**	3
	Biology 191	**Biotechnology A: Basic Lab Skills**	4
	Biology 192	**Biotechnology B: Protein Biomanufacturing**	4
	Biology 193	**Biotechnology C: Nucleic Acid upstream processing**	4
	Biology 211	**Cellular and Molecular biology**	5
	Biology 194	**Quality & Regulatory Compliance in Bioscience**	2
	Chemistry 209	**Introduction to Chemistry General**	4
	Chemistry 219	**General Chemistry & Quantitative Analysis**	5
General (7 units)	Biology 177	Human Genetics	3
	Chemistry 229	General Chemistry and Quantitative analysis	5
	Biology 229	General Microbiology	5
	or	or	
	Biology 139	Health Microbiology	4
	Biol 290	Biochemistry and Molecular Biology	5
	Internship	Internship	1-4

38 Total Units

Certificate of Achievement: Biotechnology Laboratory Technician: Food Safety Focus

Requirements	Dept/Name#	Name	Units
Required Core (31 units)	**Biology 190**	**Introduction to Biotechnology**	3
	Biology 191	**Biotechnology A: Basic Lab Skills**	4
	Biology 192	**Biotechnology B: Protein Biomanufacturing**	4
	Biology 193	**Biotechnology C: Nucleic Acid upstream processing**	4
	Biology 211	**Cellular and Molecular biology**	5
	Biology 194	**Quality & Regulatory Compliance in Bioscience**	2
	Chemistry 209	**Introduction to Chemistry General**	4
	Chemistry 219	**General Chemistry & Quantitative Analysis**	5

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)

Food Safety Focused (7 units)	Biology 229 or Biology 139	General Microbiology or Health Microbiology	5 or 4
	Biology 196	Food Safety& Microbiology (required)	2
	Internship	Internship	1

38 Total Units

In the future we envision a potential to develop short 1-2 unit courses focused on these topics
Bioinformatics
Proteomics
RT PCR
DNA barcoding
HPLC
Mammalian cell culture
Specialized Microscopy

Item 4: Master Planning
In keeping with the California Community College Mission Statement focus being on basic skills, transfer and career technical education, this proposed stackable certificate meets the standard for both transfer and career technical education.

In June 2012, the Biotechnology Advisory Committee met to investigate the need and interest in developing a program to train students for employment in the industries related to biotechnology in Orange County. The meeting was attended by 13 individuals not affiliated with SCC. Nine of these were from local biotechnology employers and 4 from academic programs at Santa Ana College, Fullerton College, and Pasadena City College. Since the last advisory committee meeting, we have made additional industry contacts and have sought their input. The consensus is that students graduating with B.S. in a STEM major have a good grasp of scientific theory but lack the skills necessary for even basic employment. In addition, there is a lack of training opportunities in biotechnology for students in the Orange County area. Fullerton College does currently offer an AS in biotechnology with emphasis in training students for research positions.

In June 2013, a report by Jonathan Rothwell of the Brookings Institute on the "Sub-Bachelor STEM Economy" made several very important points regarding the wide availability of sub-bachelor STEM jobs in every major metropolitan area. One very important point is quoted below:

> **"Half of all STEM jobs are available to workers without a four-year college degree, and these jobs pay $53,000 on average—a wage 10 percent higher than jobs with similar educational requirements.** Half of all STEM jobs are in manufacturing, health care, or construction industries. Installation, maintenance, and repair occupations constitute 12 percent of all STEM jobs, one of the largest occupational categories. Other blue-collar or technical jobs in fields such as construction and production also frequently demand STEM knowledge."

http://www.brookings.edu/~/media/research/files/reports/2013/06/10%20stem%20economy%20rothwell/thehiddenstemeconomy610.pdf

Recommendations for developing a stackable certificate that included theory in biology and chemistry as well as basic laboratory skills proficiency were made for students seeking entry into the industry as well as incumbent workers seeking opportunities for career advancement. The goal was to provide industry with a skilled and knowledgeable workforce and achieve student success by offering stackable certificates that would enhance students' career options as they progressed through the layers to the final certificate of achievement. Additionally, completion of the certificate would also provide for the opportunity to complete a few science major courses, which would provide a bridge to the science B.S. degree. For example, students pursuing a biology major could simultaneously complete the certificate courses and thus opportunities for employment in the field, or students wishing mainly to obtain high-wage employment could gain entry to a high wage industry by pursuing the certificate and simultaneously complete key courses that may encourage them to continue and pursue the B.S. degree. The cooperation between campuses in Orange County support the *"Doing What Matters for Job and the Economy"* framework and allows students to specialize even further as they pursue training in this diverse technology-oriented field.

Item 5: Enrollment and Completer Projections

This biotechnology program is strongly supported by local industry. The advisory committee's recommendation was to create a stackable certificate design which was to include a significant amount of chemistry in addition to the biotechnology lab skills courses. The program anticipates 20 completing students within the first two years.

A. Enrollment Data

Below reflects the number of students who completed or are presently enrolled in existing required and/or transferable to the biology major courses and who may be encouraged to pursue the certificate to gain sub-degree employment in the STEM field.

Core Course Completers for Fall '12, Spring '13, Fall 13'/present

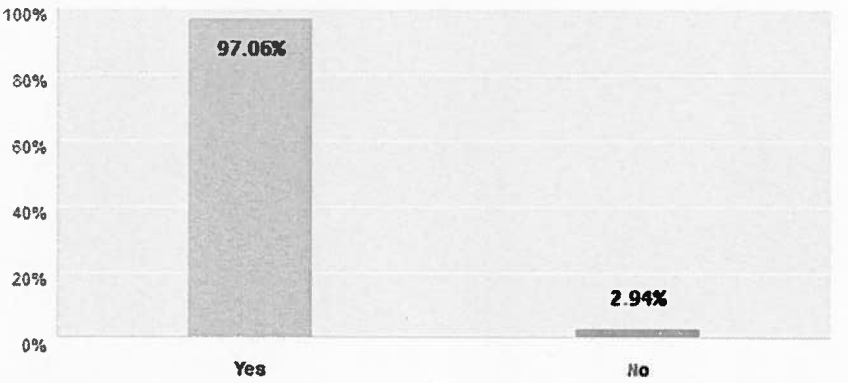
Courses	Fall 2012	Spring 2013	Summer 2013	Total '12-'13 completers	Fall 2013 (enrolled)
Chem 209	126	123	48	297	144
Biol 211	45	52	-	192	64
Chem 219	44	66	22	132	72

B. **Survey**

A 4-question survey was sent to the 40 industry-employed members of our advisory group. We received 34 responses (85%) which are summarized by question below. We are also including the optional comments made by the people who chose to use the opportunity to correspond with us. As you can see, they are very specific and helpful comments. Importantly, over 85% of the respondents indicated they would hire an individual with the certificate and laboratory skills even if they did not have a college degree. This mirrors what our original industry advisory committee told us in our inaugural meeting back in June 2012.

Our goal is to create a coordinated curriculum and a sequence of courses to teach fundamental biotechnology laboratory skills at several collaborating campuses. Also, additional specialized skills training will be offered with a different emphasis uniquely available at each campus. Do you see a benefit to this approach?

Answered: 34 Skipped: 0



Answer Choices	Responses	
Yes	97.06%	33
No	2.94%	1
Total		34

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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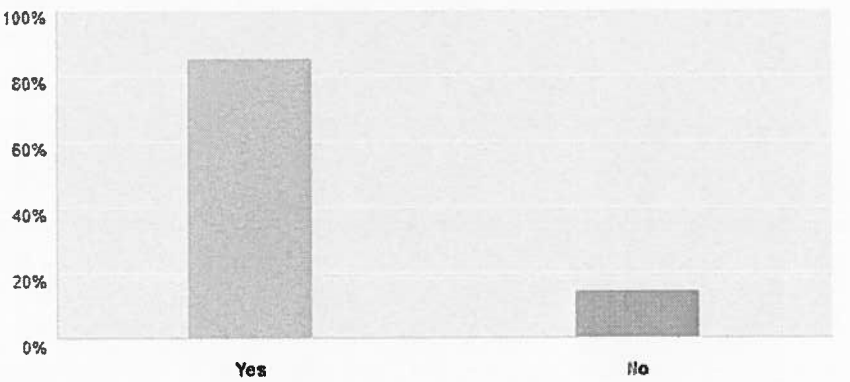
Would you anticipate hiring individuals without a college degree, but with a biotechnology certificate? Students completing the biotechnology certificate would have at minimum: Basic laboratory skills (such as preparation of solutions, reagents, and media), a proficiency in aseptic technique, a knowledge of laboratory safety regulations, an ability to work with standard operating procedures as well as possessing good documentation practices. In addition, they would be proficient in utilizing common laboratory instruments such as (but not limited to) spectrophotometers, analytical balances, micro-pipettors, and electrophoresis apparati.

Answered: 34 Skipped: 0

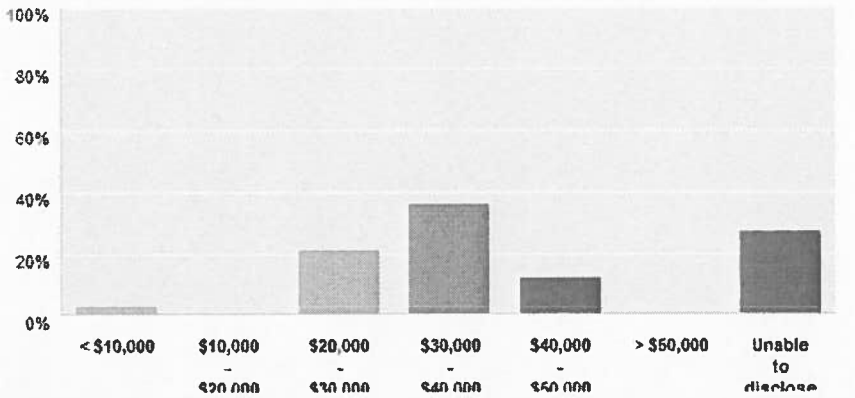


Answer Choices	Responses	
Yes	85.29%	29
No	14.71%	5
Total		34

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)

What would your company pay an individual with such a certificate anually?

Answered: 33 Skipped: 1



Answer Choices	Responses	
< $10,000	3.03%	1
$10,000 - $20,000	0%	0
$20,000 - $30,000	21.21%	7
$30,000 - $40,000	36.36%	12
$40,000 - $50,000	12.12%	4
> $50,000	0%	0
Unable to disclose	27.27%	9
Total		33

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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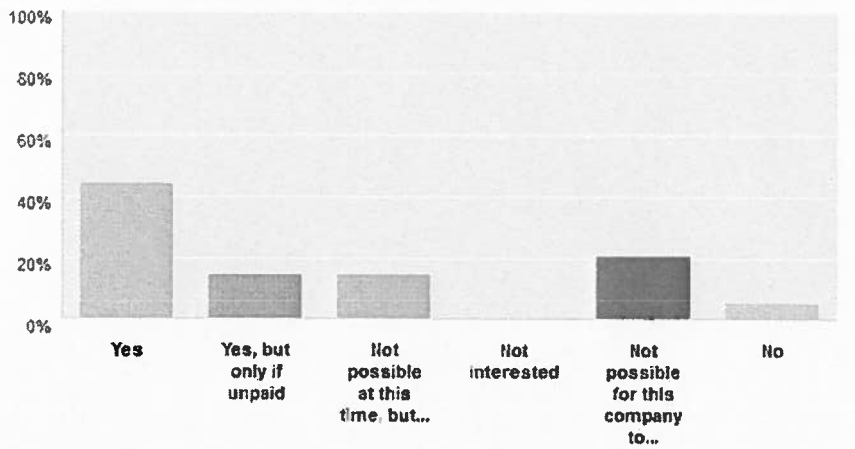
Would you be interested in paid or unpaid students as interns in your company?

Answered: 34 Skipped: 0



Answer Choices	Responses	
Yes	44.12%	15
Yes, but only if unpaid	14.71%	5
Not possible at this time, but perhaps in the future	14.71%	5
Not interested	0%	0
Not possible for this company to host student interns	20.59%	7
No	5.88%	2
Total		34

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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Please provide any further comments or thoughts. (OPTIONAL)

Answered: 11 Skipped: 21

Responses (11) | Text Analysis | My Categories

PRO FEATURE
Use text analysis to search and categorize responses; see frequently-used words and phrases. To use Text Analysis, upgrade to a GOLD or PLATINUM plan.

Upgrade | Learn more »

Categorize as... | Filter by Category | Search responses

Showing 12 responses

It will be useful for your graduates to learn some degree of lab managerial skills (ordering, keeping inventory and etc). This will be a good path for being promoted from a lab tech to a lab manager.
10/1/2013 9:09 AM View respondent's answers

Truer Medical manufactures disposable medical products that are primarily class II or Class I products. Regulatory classes that train students about design controls, the 510(K) process, Installation qualification (IQ), Operation qualification (OQ), & Product qualification (PQ) would be very beneficial.
9/27/2013 3:03 PM View respondent's answers

currently, and in the foreseeable future, I am working in virtual development stage environment. Such companies only hire, or more often contract with, highly experienced individuals. I am happy to provide input, but it will be based on my past experiences and not current situation.
9/27/2013 2:27 PM View respondent's answers

The market is in need of tech level scientific associates. Knowledge of basic chemistry and microbiology techniques and current regulatory standards (GMP, GLP, FDA, USP, etc.) is key. A focus on QC, QA and manufacturing is more needed than R&D.
9/13/2013 4:40 PM View respondent's answers

This program could benefit our company as we are looking to expand technical manufacturing to include more biological practices
9/12/2013 2:16 PM View respondent's answers

The market is in need of tech level scientific associates. Knowledge of basic chemistry and microbiology techniques and current regulatory standards (GMP, GLP, FDA, USP, etc.) is key. A focus on QC, QA and manufacturing is more needed than R&D.
9/13/2013 4:40 PM View respondent's answers

This program could benefit our company as we are looking to expand technical manufacturing to include more biological practices
9/12/2013 2:16 PM View respondent's answers

I think this is a fantastic program that will do great in the biotech industry. From the sounds of it, your graduates will have more of a working knowledge of laboratory practices than many Bachelor's students we hire straight out of college. Our company is somewhat unique due to what we work with, otherwise I would be very interested in having student interns.
9/12/2013 1:46 PM View respondent's answers

N/A
9/5/2013 11:59 PM View respondent's answers

I would be happy to provide expert assistance and guidance in the areas of Statistical Process Control, Six Sigma and Lean Production (minimizing waste and time), and ISO Documentation and Procedural Standardization as it applies to the completion and testing of a product in a commercial production facility.
9/3/2013 9:01 PM View respondent's answers

As a macro trend - the life sciences industry is requiring lesser and lesser wet-lab work within country. Outsourcing and contracting out is becoming bigger component. In current scenario - along with certain lab skills mastering - knowledge on computational skills, simulation modeling for chemistry and biology would be bigger need of the industry going forward.
9/3/2013 1:55 PM View respondent's answers

Outsourcing and contracting out is becoming bigger component. In current scenario - along with certain lab skills mastering - knowledge on computational skills, simulation modeling for chemistry and biology would be bigger need of the industry going forward.
9/3/2013 1:55 PM View respondent's answers

I am happy to provide info wherever I can in support of your program. I have been in biotech for more than 15 years working several capacities in QC (1992-1994) and Mfg (1994-1998) and then developed the Lab Services organization (1999-2006) for Amgen that has since evolved into a highly outsourced function. I currently work in Global Sourcing for Genentech in SF.
9/22/2013 2:09 PM View respondent's answers

I usually see people with certificates come into a biotech manufacturing role and the Bio-Rad Irvine campus has a small amount of manufacturing, but a lot of technical support roles. If you haven't contacted Beckman Coulter yet in Brea they would be a good company to get onboard since last time a visited they had a lot of manufacturing on site.
9/19/2013 5:57 PM View respondent's answers

I run an incubator, not a company, so it is difficult to answer these questions. I do personally use unpaid interns with certifications so they get work experience.
9/18/2013 4:42 PM View respondent's answers

Item 6: Place of Program in Curriculum/similar Programs
SCC currently offers AS degrees in biology and chemistry. Upon the advice of the advisory committee, a stackable certificate of achievement in biotechnology will provide new students and incumbent workers training in laboratory skills required of the industry. Students who complete the program will have new and accelerated opportunities for employment in the various types of companies influenced by and dependent upon biotechnology. We will work with the campus articulation officer to align course curriculum and programs to meet transfer requirements for new courses.

Item 7: Similar Programs at Other Colleges in Service Area
Orange County does not currently have a biotechnology program being offered to students. The only current active biotechnology-related program within the SCC service area is an A.S. degree in Biological Technician at Fullerton College (with a focus in training students as research technicians). Coastline College has a biological technical program on the books but it has not been offered for a number of years.

Our sister college, Santa Ana College, and Fullerton College are collaborators in the design and implementation of this certificate. SCC and SAC share courses between campuses and students often take classes on both campuses. Additionally, the proximity of Fullerton College to SCC makes it probable that students will travel to that campus if they can benefit from completing a specialty of interest there. The faculty members at the different campuses have different areas of expertise. For example, Santa Ana College will offer the Quality Control emphasis but Santiago Canyon College will offer the course specifically related to Food Safety and has lined up internship slots with that emphasis. Fullerton College will offer classes with an emphasis in training students for research programs, such as those within a university setting.

Kathy Takahashi, Ph.D is the faculty expert and biotechnology program coordinator at SAC and Jo Wen Wu, Ph.D is the faculty expert and biotechnology program coordinator at Fullerton College. Denise Foley, Ph.D. is a faculty expert and biotechnology program coordinator at SCC and will work with Anson Lui, M.S. another faculty expert in biotechnology at SCC. Together, we have established this multi-campus certificate to support the needs of the biotechnology industry in Orange County.

Supporting Documentation:

✓ **Course Report** – The course report reflects all courses listed in the Narrative Item 3. Program Requirements (general education courses are not required to be attached to the proposal).

Course outlines of record are included as an attachment and are included for:

Biotechnology Program-Specific Courses:

Biology 190 Introduction to Biotechnology – Approved/ Hybrid	3 units
Biology 191 Biotechnology A: Basic Laboratory Skills – Approved/Hybrid	4 units
Biology 192 Biotechnology B: Proteins – New/Hybrid	4 units
Biology 193 Biotechnology C: Nucleic Acids Upstream Processing- New/Hybrid	4 units
Biology 194 Quality & Regulatory Compliance in Bioscience New/online	2 units
Biology 196-Food safety & microbiology New/online	2 units
Biol 197-Internship (New)	1 unit

Biotechnology Program-Existing transferable/majors courses:

Chemistry 209/Chem 101 Introduction to Chemistry –	4 units
Chemistry 219/Chem 111A – General Chemistry-	5 units
Chem 229- General Chemistry & Quantitiative Analysis	5 units
Biology 211- Cellular and Molecular biology-	5 units
Biology 229- General Microbiology	5 units
Biology 139-health microbiology	4 units
Biology 177- Human Genetics	3 units

Diagram showing SCC Biotechnology program offerings and organization

Core Courses: Certificate of Achievement Biotechnology

Biotechnology Lab Assistant Certificate

- **Biology 190 Introduction to Biotechnology – New Hybrid** — **3 units**
- **Biology 191 Biotechnology A: Basic Laboratory Skills – New Hybrid** — **4 units**
- **Chemistry 209/Chem 101 Introduction to Chemistry – Existing** — **4 units**

Biotechnology Biomanufacturing Technician Certificate

- **Biology 192 Biotechnology B: Proteins - New Hybrid** — **4 units**
- **Biology 211- Cellular and Molecular biology- Existing** — **5 units**
- **Chemistry 219/Chem 111A – General Chemistry- Existing** — **5 units**

Biotechnology Technician Certificate

- **Biology 193 Biotechnology C: Nucleic Acids Upstream Processing- New/Hybrid** — **4 units**
- **Biology 194 Quality & Regulatory Compliance in Bioscience New/online** — **2 units**

31 units
= requirements for A.S. degree
+ 7 units from below categories= Certificate of Achievement (38 units)

Biotechnology laboratory technician: Food Safety

- **Biology 229-** General Microbiology (Existing) 5 units
  or
- **Biology 139**-health microbiology (Existing) 4 units
- **Biology 196-Food safety & microbiology** (New) 2 units
- **Biol 197**-Internship - 1 unit

Biotechnology laboratory technician:

- **Biology 177-** Human Genetics (Existing) 3 units
- **Biology 290-** Biochemistry and Molecular biology (Existing) 5 units
- **Biology 229-** General Microbiology (Existing) 5 units
  or
- **Biology 139**-health microbiology (Existing) 4 units
- **Chem 229-** General Chemistry & Quantitiative Analysis (Existing) 5 units
- **Biol 197-** Internship- 1-4 units

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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Diagram Showing the core curriculum plus specializations at the collaborating campuses:

PROPOSED CERTIFICATE:
Stackable

Core Courses: Certificate of Achievement Biotechnology

Biotechnology Lab Assistant Certificate

- **Biology 190** Introduction to Biotechnology – New Hybrid — 3 units
- **Biology 191** Biotechnology A: Basic Laboratory Skills – New Hybrid — 4 units
- **Chemistry 209/Chem 101** Introduction to Chemistry – Existing — 4 units

Biotechnology Biomanufacturing Technician Certificate

- **Biology 192** Biotechnology B: Proteins - New Hybrid — 4 units
- **Biology 211**- Cellular and Molecular biology- Existing — 5 units
- **Chemistry 219/Chem 111A** – General Chemistry- Existing — 5 units

Biotechnology Technician Certificate

- **Biology 193** Biotechnology C: Nucleic Acids Upstream Processing- New/Hybrid — 4 units
- **Biology 194** Quality & Regulatory Compliance in Bioscience New/online — 2 units

31 units

= requirements for A.S. degree

- **7 units from below categories= Certificate of Achievement (38 units)**

-QC Microbiology (SAC)

- **Biology 229** - General Microbiology (Existing) 5 units
  or
- **Biology 139** – Health Microbiology (Existing) 4 units
- **Biology 195** - QC Microbiology (New) 2 units
- **Internship** – 1 unit

-Food Safety (SCC)

- **Biology 229**- General Microbiology (Existing) 5 units
  or
- **Biology 139**-health microbiology (Existing) 4 units
- **Biology 196-Food safety & microbiology** (New) 2 units
- Internship - 1 unit

- Research (Fullerton College)

- **Biology 109**- Genetics and Biotechnology (Existing) 5 units
- **Biology 262**- General Microbiology (Existing) 5 units
- **Hort 205** - Applied Entomology (Existing) 3 units
- **Internship** – 1-4 units

-General (SCC/SAC/FC)

- **Biology 177**- Human Genetics (Existing) 3 units
- **Biology 290**- Biochemistry and Molecular biology (Existing) 5 units
- **Biology 229**- General Microbiology (Existing) 5 units
  or
- **Biology 139**-health microbiology (Existing) 4 units
- **Chem 229**- General Chemistry & Quantitative Analysis (Existing) 5 units
- Internship- 1-4 units

Plan for course offerings: The diagram below shows the plan for the rollout (years 1 and 2) and then starting in year 3 is the plan for the regular offerings each year.

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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biotech-specific	Fall	Spring	Summer		Fall	Spring	Summer		Fall	Spring	Summer
year 1	intro to biotech 3 units	Biotech A 4 units	(intro to biotech) 3 units	year 2	Biotech A 4 units	Biotech C 4 units		year 3	intro to biotech 3 units	Biotech A 4 units	Biotech C 4 units
	chem 209 4 units	chem 209 4 units	chem 209 4 units		Biotech B 4 units	internships	chem 209 4 units		Biotech B 4 units	internships	chem 209 4 units
	internships	internships	internships		internships	biol 211 5 units	internships		chem 209 4 units	biol 211 5 units	internships
	biol 211 5 units	biol 211 5 units	biol 139 health microbiology 4 units		biol 211 5 units	chem 229 5 units	biol 139 health microbiology 4 units		internships	chem 229 5 units	biol 139 health microbiology 4 units
	chem 219 5 units	chem 229 5 units	(food safety) 2 units		chem 219 5 units	biol 229 microbiology 5 units	food safety 2 units		biol 211 5 units	biol 229 microbiology 5 units	food safety 2 units
	biol 229 microbiology 5 units	biol 229 microbiology 5 units	quality reg & compliance 2 units		biol 229 microbiology 5 units	Biol 177 3 units	quality reg & compliance 2 units		chem 219 5 units	Biol 177 3 units	quality reg & compliance 2 units
		Biol 177 3 units							biol 229 microbiology 5 units		

starting yr 3								
	food safety ideal path	intro to biotech 3 units	Biotech A 4 units	biol 139 health microbiology 4 units		Biotech B 4 units	Biotech C 4 units	food safety 2 units
		chem 209 4 units	biol 211 5 units			chem 219 5 units	internship 1 unit	quality reg & compliance 2 units
	General biotech ideal path	intro to biotech 3 units	Biotech A 4 units	quality reg & compliance 2 units		Biotech B 4 units	Biotech C 4 units	
		chem 209 4 units	biol 211 5 units	internship 1 unit		chem 219 5 units	chem 229 5 units	

Survey of biotechnology programs in Southern California:
Biotechnology Offerings in So Cal Region

Fullerton College*
A.S. Biological Technician -18 units +GE

*The only biotechnology program in a community college in the SCC service area. Other biotechnology program in Southern California listed below.

Pasadena City College
Cert of Achievement. Biological Technology- Lab assistant 39-45 units
Cert of Achievement Biological Technology 49-55 units
Cert of Achievement Biological Technology-Stem Cell Culture 33-39 units
Occupational skills certificate- Biological Technology- laboratory Skills- 16 units

College of the Canyons
Cert of Achievement- Biotechnology- 24 units (+ 13 recommended units)

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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Moorpark
A.S. Biotechnology (48-49 specified units) +GE
Cert of Achievement- Biotechnology - 44 units
Cert of Achievement- Manufacturing Operator- 16-17 units

Ventura
Cert of proficiency- Biotechnician -17 units
AA/Cert of Achievement with biotechnology or plant biotechnology option - 35 units

MiraCosta College
AA research and development (see descriptor for AA degree)
Cert of Achievement Research and development -44 units
Cert of Achievement Bioprocess Technology:- 12 units
Cert of proficiency: Laboratory skills- 12 units

MiraMar College
Certificate of completion/proficiency biotechnology molecular biology -8 units
Certificate of completion/proficiency Analytical chemistry- 9 units
AS in applied biology- 35 units +GE

Southwestern College
Cert of Achievement biotechnology- 31 units
AS biotechnology- 31 units + GE

✓ **Supporting Documentation – Labor Market Information (LMI) & Analysis**

Biotechnology is a term that often brings to mind genetic engineering. This is a very narrow view of the term as it really touches very many industries. The skills acquired by students completing this program will enable them to enter a large number of fields, some of which are noted below along with typical education levels. As is typical, pay depends on education level, experience, and geographic location. Of particular note is that while the typical education level for some positions is a bachelor's degree, the lack of specific skills-based training in Orange County means employers have less options for employing individuals with the knowledge needed to function in the industry. Our interaction with industry indicates that they would hire certificated individuals with skills over an individual with a B.S. without the skill-based training.

Table 1. Staffing patterns in the county for some jobs related to biotechnology

Orange County Staffing Patterns for Selected Industries							
SOC Code	Occupation	Employed in Industry Group (2011)	Employed in Industry Group (2016)	Change	% Change	2011 Median Hourly Wage	Typical Education Level

51-2092	Team assemblers	859	1,025	166	19%	$12.20	Moderate-term on-the-job training
11-3051	Industrial production managers	183	204	21	11%	$38.87	Work experience in a related field
51-9082	Medical appliance technicians	216	273	57	26%	$15.25	Long-term on-the-job training
51-2023	Electromechanical equipment assemblers	116	107	(9)	(8%)	$13.65	Short-term on-the-job training
51-9011	Chemical equipment operators and tenders	72	79	7	10%	$19.98	Moderate-term on-the-job training
43-6013	Medical secretaries	13	17	4	31%	$14.99	Moderate-term on-the-job training
17-3023	Electrical and electronic engineering technicians	56	46	(10)	(18%)	$24.86	Associate's degree
19-4031	Chemical technicians	141	158	17	12%	$18.84	Associate's degree
29-2012	Medical and clinical laboratory technicians	19	23	4	21%	$17.95	Associate's degree
11-9121	Natural sciences managers	98	112	14	14%	$58.27	Degree plus work experience
19-2031	Chemists	221	245	24	11%	$34.57	Bachelor's degree
17-2031	Biomedical engineers	195	290	95	49%	$41.53	Bachelor's degree
17-2112	Industrial engineers	178	212	34	19%	$38.01	Bachelor's degree
19-4021	Biological technicians	77	91	14	18%	$16.80	Bachelor's degree
17-2041	Chemical engineers	25	28	3	12%	$42.57	Bachelor's degree

CALIFORNIA EMPLOYMENT OUTLOOK: Job availability can change with national and global economics, unexpected political events and natural disasters. Current events can change demand for jobs quickly. Check web sites, local newspapers, magazines and international news to help you make informed career decisions.

Outlook depends on economical conditions, changes in product technology, level of public and private support for research and development, and public interest in consumer protection and environmental control. The ability to do technical computations and to apply other mathematical principles is seen as an attractive skill by some employers. Technicians who are willing to relocate improve their chances for employment.

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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California Pay & Outlook:

Pay depends on type of employer and level of training.

Current Monthly Wage Data (2011) from California Labor Market Information (LMI) * indicates no data available			
LMI Occupation	**Entry/Low Pay**	**Average Pay**	**Top Pay**
Agricultural & Food Science Technicians	$2,236	$2,941	$3,352 & up
Biological Technicians	$2,866	$4,065	$4,989 & up
Chemical Technicians	$2,801	$3,853	$4,549 & up

Current Employment Projections to 2018 from California Labor Market Information (LMI) * indicates no data available						
LMI Occupation	**Expected Growth Rate**	**Estimated Jobs 2008**	**Expected Jobs 2018**	**Openings due to Growth**	**Openings due to Replacements**	**Expected Yearly Job Openings**
Agricultural & Food Science Technicians	Average (4.6%-13.8%)	3,100	3,400	30	110	140
Biological Technicians	Faster than average (13.9%+)	10,600	13,100	250	370	620
Chemical Technicians	Average (4.6%-13.8%)	7,500	8,200	80	150	230

Educational Program(s):

- Science Technologies

Related Majors/Programs: (offer some preparation in the field)

- Chemistry
- Food Science and Technology
- Life Sciences
- Physical Science

California Licensing:

Licensing not required in California.

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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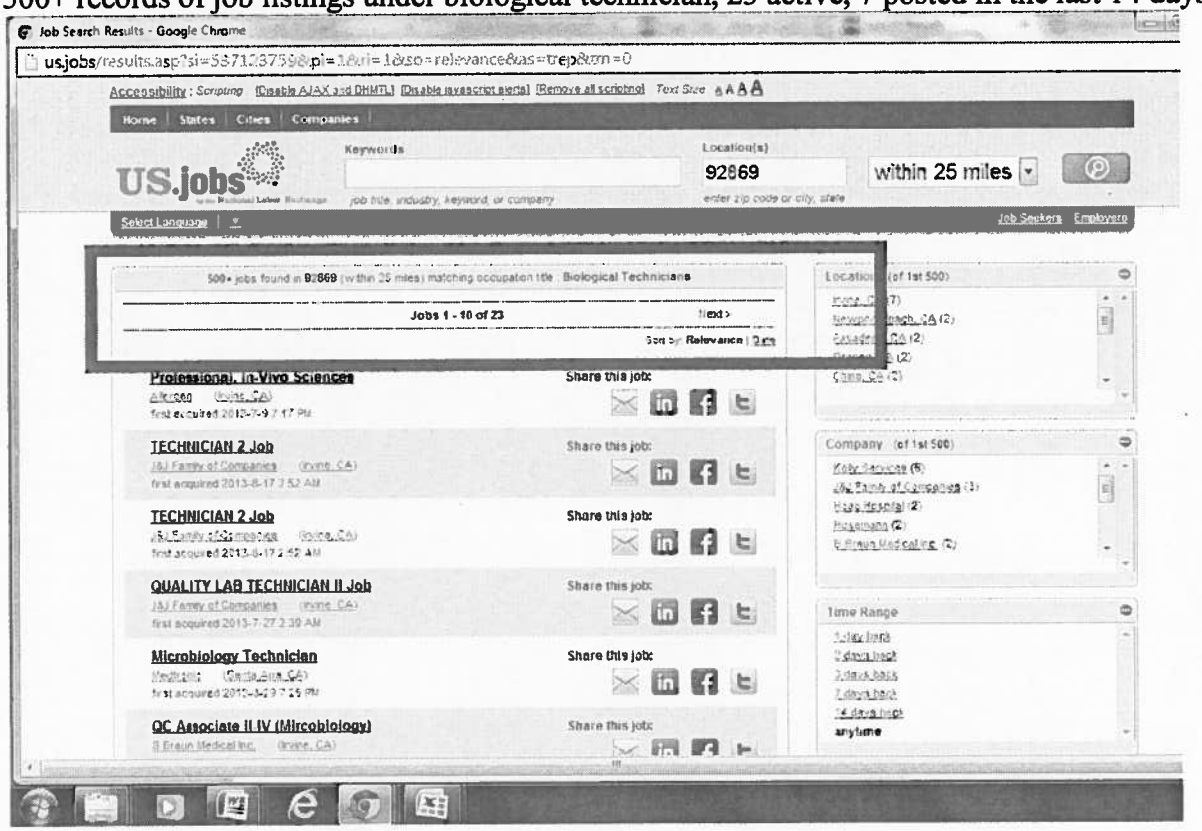
The above Regional Wage and Employment data is not a true representation of the jobs available in the region as demonstrated by the information below. The data in the table above is underreporting job openings as evidenced by the fact that there were 23 active job postings for biological technicians (7 posted in the last 14 days) within 25 miles of the SCC campus. Twenty-one biotechnology-related job announcements had been posted within the 14 days prior to 9-7-2013 on this one website and were readily identified by searching the terms illustrated below. Most of these recent entries were entry level positions. Therefore, if 21 jobs within 25 miles of SCC were posted on this website within two weeks in a date in August, the total of 50 total jobs listed in the table above must be inaccurate (see snapshots of screens below). In addition, Wendie Johnson, deputy sector navigator for biotechnology, provided documentation from recent work with the CoE that indicated that biotechnology-related jobs numbered over 4,900 in the state and in Orange County numbered 377/yr. This is the number used in section 9 of the front page.

Based on our own research and discussions with industry, it appears that training in several local and cooperating campuses would be justified and appropriate to meet local labor market demands for trained workers.

Snap shots taken 9/7/2013 of website: US jobs- by the national labor market exchange. A website sponsored by DirectEmployers Association, Inc., a non-profit consortium of global employers.
http://us.jobs/results.asp?si=537123759&pi=1&ri=1&so=relevance&as=trep&tm=0
search perameter---within 25 miles of SCC campus (zipcode 92869)
500+ records of job listings under biological technician, 23 active, 7 posted in the last 14 days.



Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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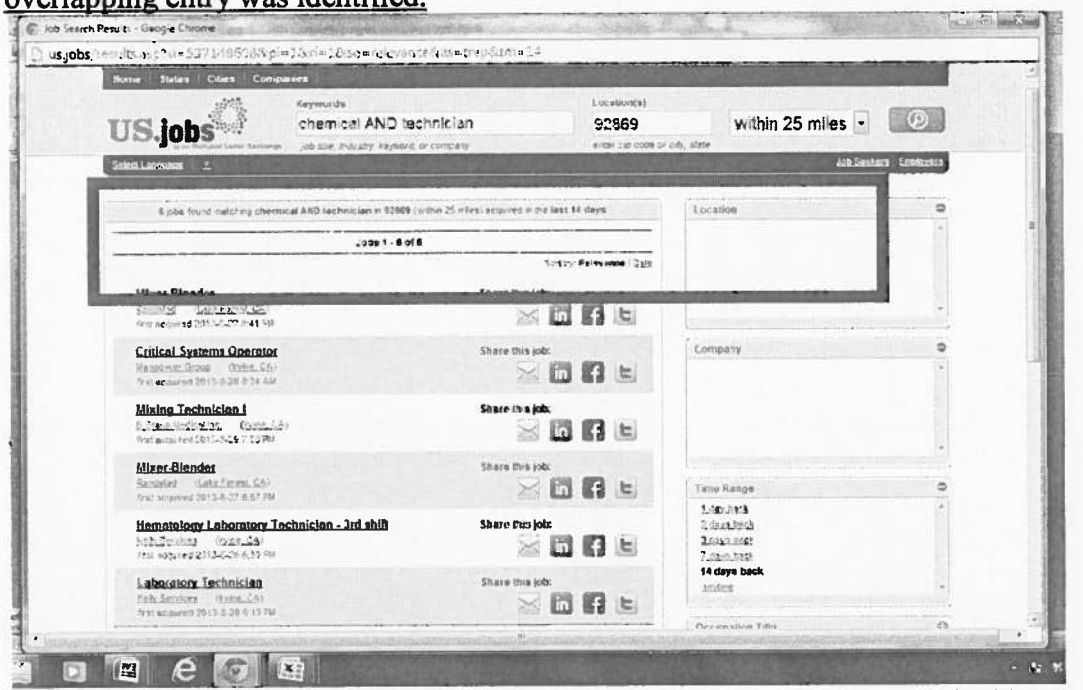
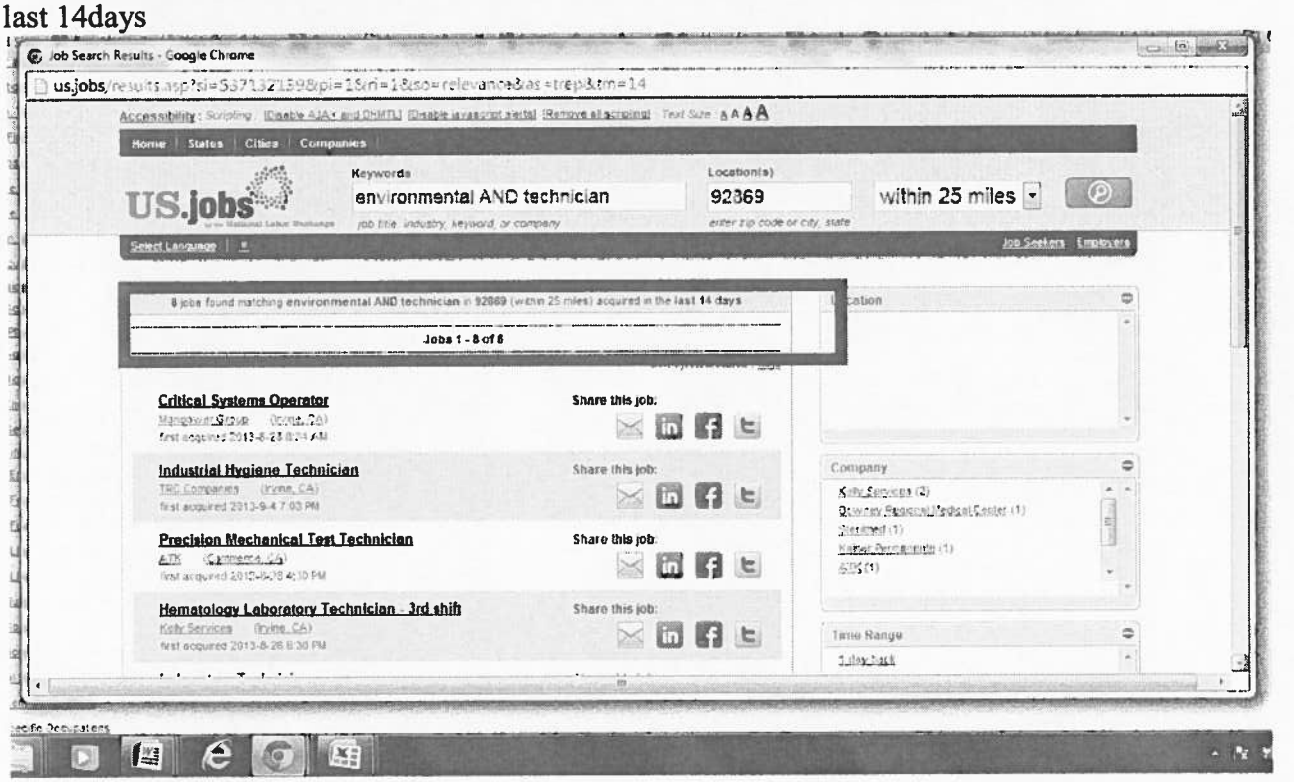
A search under chemical technician produced quite a few overlapping entries. 110 postings were active with 6 new postings (shown) within 14 days. At least one very relevant, recent, non-overlapping entry was identified.



A search under environmental technician produced 43 results, 8 of which had been posted in the last 14days



A search under food technician revealed 33 openings (see snapshot), 5 in the last 14 days

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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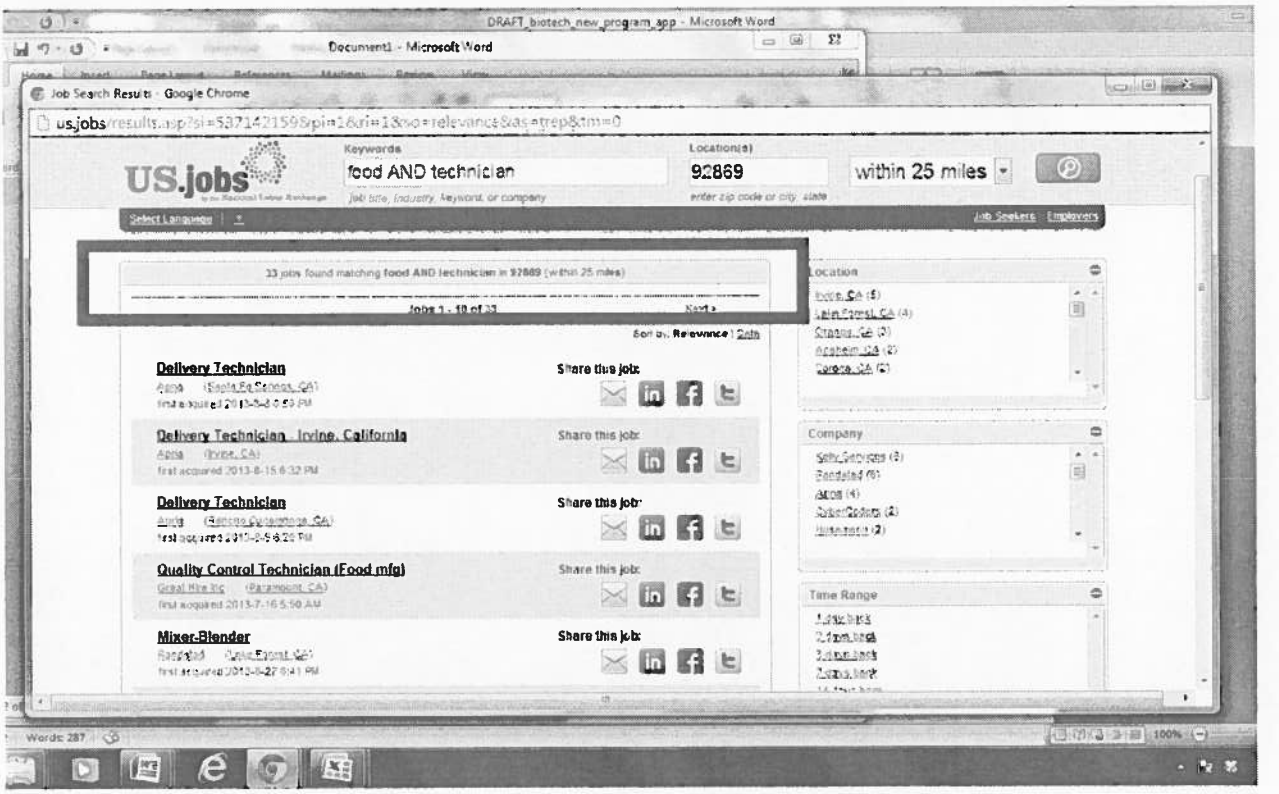

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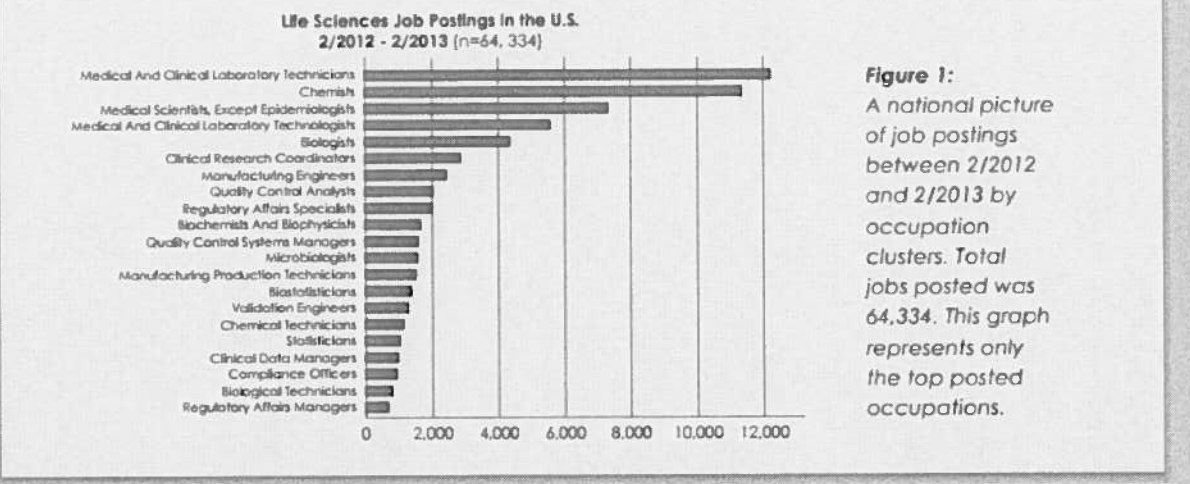

Figure 1: *A national picture of job postings between 2/2012 and 2/2013 by occupation clusters. Total jobs posted was 64,334. This graph represents only the top posted occupations.*

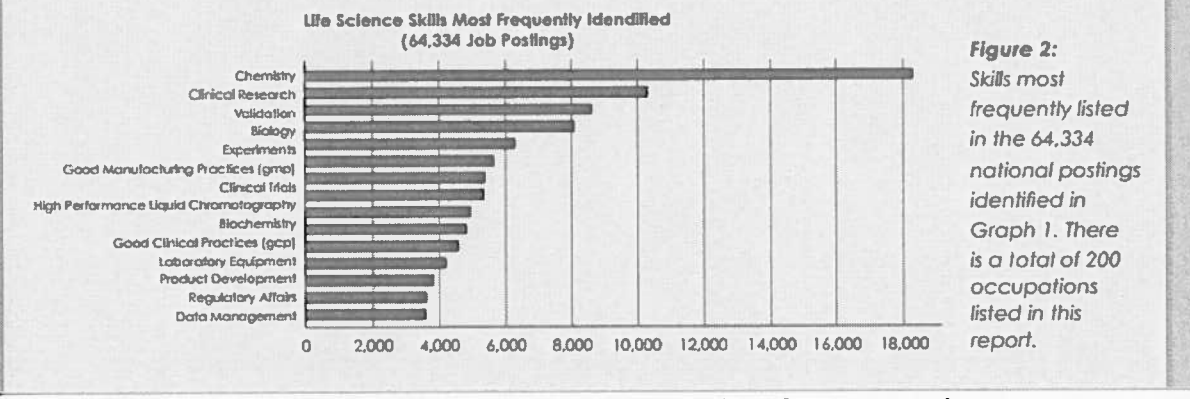

Figure 2: *Skills most frequently listed in the 64,334 national postings identified in Graph 1. There is a total of 200 occupations listed in this report.*

Demand for Talent: Current & Projected Workforce Trends in the Life Science Industry
a report of the Coalition of State Bioscience Institutes (CSBI) and Booz & Company (2013)

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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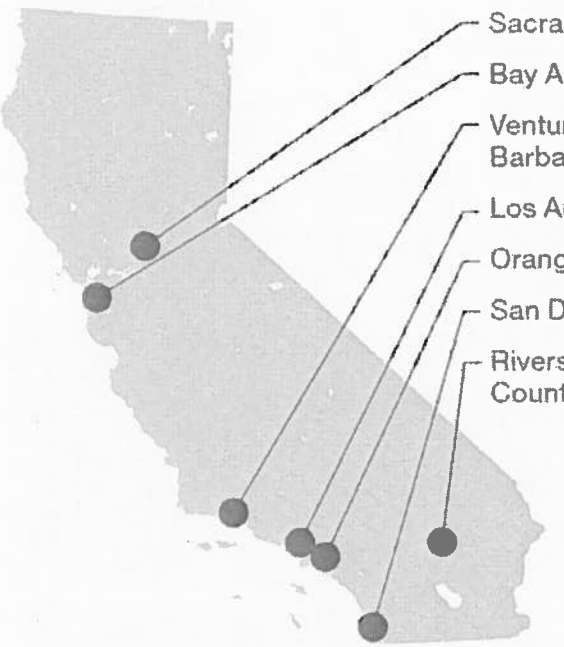
The life sciences clusters disperse jobs throughout the state and represent some of the country's – and the world's – most fertile environments for biomedical research and development.



Sacramento County:	2,990	1.1%
Bay Area:	51,255	19.2%
Ventura & Santa Barbara Counties:	9,463	3.5%
Los Angeles County:	42,383	15.9%
Orange County:	30,092	11.3%
San Diego County:	27,510	10.3%
Riverside/San Bernardino Counties:	6,338	2.4%

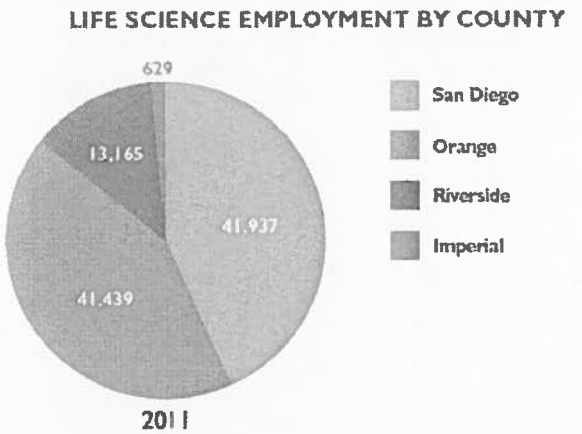
Note: Regional numbers do not add up to the total because of changes made at the Bureau to avoid identification through numbers reported.

Source: Bureau of Labor Statistics Quarterly Census of Employment and Wages and Company Specific SEC filings.

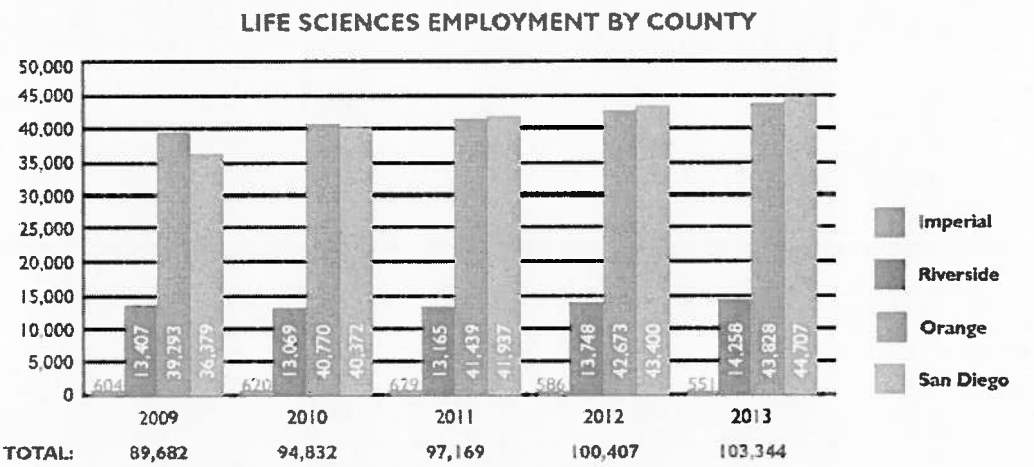
California Biomedical Industries Report 2012

"LIFE SCIENCES INDUSTRY

Southern California's life sciences cluster employs just over 97,000 in five sectors: biopharmaceuticals, industrial biotechnology and biofuels, life sciences trade, medical devices and diagnostics, and research and lab services. Medical devices and diagnostics is the region's largest life sciences sector, employing 33,871 and edging out research and lab services by 1,993 jobs. These two sectors account for 68 percent of the total employment in the cluster, with over 65,000 in the region. The life sciences trade and biopharmaceuticals sectors stand on relatively equal footing, employing 13,925 and 11,425 respectively. Industrial biotechnology and biofuels, still considered an emerging sector, employs 6,095 or 6 percent of the total employment in the cluster." (California Biomedical Industries Report 2012)



A region's specialization is measured by location quotient (LQ) analysis. If the LQ value is above 1.00, the region has a greater concentration of that sector than the nation. Conversely, if the LQ is below 1.00, the region has a lower concentration of that sector than the nation. Southern California has a 1.63 LQ, which means that the region's concentration of this industry is 63 percent greater than the nation's as a whole. Another way to say it is that there are 63 percent more life science jobs per capita than the national average.



In Orange County, in 2013, there are 43,828 jobs in the Life Sciences sector.

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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LIFE SCIENCES LOCATION QUOTIENT BY COUNTY

2009
1.52 Region

2011
1.63 Region

2013
1.70 Region

COUNTY	2009	2011	2013
Imperial	0.70	0.73	0.61
Orange	1.65	1.72	1.79
Riverside	1.14	1.13	1.17
San Diego	1.58	1.79	1.87
REGION	**1.52**	**1.63**	**1.70**

Source: EMSI Complete Employment, Hendershot Economics

A location quotient of 1 is equal to national profile for employment in biosciences per capita. Anything over 1 represents the % over the national figure. In 2013 there is a 79% greater employment in biosciences per capita in Orange County compared to the national figure.

NUMBER OF ESTABLISHMENTS BY INDUSTRY & COUNTY

SECTOR	IMPERIAL	ORANGE	RIVERSIDE	SAN DIEGO	REGION
Biopharmaceuticals	0	87	19	108	214
Industrial Biotechnology and Biofuels	105	84	189	308	686
Life Sciences Trade	1	377	105	228	711
Medical Devices & Diagnostics	1	388	86	240	715
Research and Lab Services	6	281	101	821	1,209
TOTAL	**113**	**1,217**	**500**	**1,705**	**3,535**

Source: EMSI Complete Employment, IMPLAN, Hendershot Economics

Above data figures taken from *Biocom 2012 Southern California Economic Impact Report:* http://www.biocom.org/bcq/archive/83/cover_story/

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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✓ **Supporting Documentation – Advisory Committee**

1. Current (as of 10-4-13) list of OC biotech/collaborative advisory committee members

Advisory member	Position	Company	Location
Abbasi, Taher taher@cellworksgroup.com	CEO	CellWorks Group	Irvine
Azimi, Nazli nazimi@bioniz.com	Founder & Pres.	Bioniz LLC	Irvine
Baklayan, George George.Baklayan@bausch.com	Director of Pharm Development	Bausch & Lomb	Irvine
Boyd, Nancy boyd_nancy@edwards.com 949.250.3401	Executive Recruiter	Edwards Life Sciences	Irvine
Dixon, Michael md@maxcelint.com (949) 855-3776	Molecular Biochemistry Reasearcher/Founder	Maxcelint Laboratories	Lake Forest, CA
Enany, Ahmed enany@socalbio.org	President	SoCalBio	LA
Gilbert, Dean dgilbert@ocde.us	Science Coordinator of Instructional Services	Orange County Department of Education	Costa Mesa
Gonzales, Karilyn M. M.S karilyn@foodmicrolabs.com	Laboratory Director	Food Microbiological Laboratories, Inc.	Cypress
Hamel, Jody Hamel_Jody@Allergan.com	Professional, Microbiology Biologics Development	Allergan Inc.	Irvine
Head, James James.head@sce.com	Business Readiness Manager	Southern California Edison	Pomona
Humpries, Valerie vjhumphries@hotmail.com	Clinical Lab	St. Jude Hospital	Fullerton

Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)

California Community Colleges Chancellor's Office Program and Course Approval Handbook, 5th Edition, VII Draft

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Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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Note: See Appendix C (pages 131-184): Proposal Development Guide for an Associate Degree: Associate in Arts (A.A) and Associate of Science (A.S)
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2. Recommendation of Advisory Committee (summary only)
Biotech advisory meeting 6-1-2012

- While manufacturing was moved offshore in many cases it is moving back due to quality control issues and government incentives to bring it back.
- There was noted a gap in training for people in entry-level type jobs. Firms would hire people with hands-on lab experience
- Internships were noted as exceptionally valuable. Everyone agreed it was almost a necessity for students to have that type of "real-world" experience to get hired
- Bioethics is important but a stand-alone class doesn't make the enrollment targets. Should incorporate key aspects into other courses or perhaps a 1u required online course will work
- A draft curriculum was discussed but modifications were suggested- especially the inclusion of more chemistry and microbiology.

1. Develop skills-based curriculum. Determine proficiency in skills
2. Industry would hire individual with laboratory skills as assistant laboratory technicians, manufacturing, filling, clean room, packaging, inventory control positions etc.
3. Besides a basic understanding of the science, a list of skills needed in this industry was developed and the plan is to incorporate training in as many as possible into the biotechnology-specific courses:
   a) Logic
   b) Basic knowledge of instrumentation
   c) Good documentation techniques
   d) GMP Good Manufacturing Process
   e) SOP Standard Operating Procedures
   f) Grasp of regulations and compliance
   g) Grasp of bioethics

4. The laboratory skill set should include:
   a) Basic Chemistry
   b) Microbiology
   c) Microscopy
   d) Protein chemistry
   e) Nucleic acid chemistry
   f) Working in a laminar flow hood
   g) ELISAs (enzyme linked immunosorbant assays)
   h) HPLC (High Performance Liquid Chromatography)skills
   i) Gas chromatograph, Mass spectrometer (GC/MS)
   j) Tissue culture (mammalian)
   k) PCR (polymerase chain reaction) assays and maybe ability to design a primer

l) Excel spreadsheet
m) Powerpoint usage
n) Inventory
o) Basic laboratory math
p) Good lab notebooks
q) Ability to make laboratory solutions
r) Ability to troubleshoot

3. How Curriculum Aligns with Recommendations

Since the advisory meeting in June 2012, the faculty at Santiago Canyon College, Santa Ana College and Fullerton College have met face-to-face and held several electronic discussions to implement the recommendations of the committee. The draft proposal discussed at the meeting in June 2012 has been revised and reshaped to incorporate the recommended skills and knowledge desired by industry. The major changes were to incorporate more chemistry and microbiology curriculum, both as required and optional stand-alone courses and as embedded curriculum in biotech-specific courses. Soft skills, ethics, regulations and compliance knowledge, and other desired skill sets have been incorporated into one or more courses. We carefully considered the recommendations and how we could achieve the desired outcome by placing the curriculum in the proper sequence while layering knowledge to allow for students to gain employment early, if desired, while continuing to build knowledge and skills for advancement as they continued to take courses in the certificate. Additionally, we created several groupings of specializations located on the various campuses to enable students to take courses that most benefitted their career goals while taking advantage of the knowledge base available on that campus.

✓ **Supporting Documentation – Regional Consortia Approval Meeting Minutes** clearly indicating the action to approved the proposed program.

PROPOSED CERTIFICATE:
Stackable

Core Courses: Certificate of Achievement Biotechnology

Biotechnology Lab Assistant Certificate (SCC/SAC version)

- **Biology 190 Introduction to Biotechnology – New Hybrid** — **3 units**
- **Biology 191 Biotechnology A: Basic Laboratory Skills – New Hybrid** — **4 units**
- **Chemistry 209/Chem 101 Introduction to Chemistry – Existing** — **4 units**

Biotechnology Lab Assistant Certificate (Fullerton version)

- **Bio 105 Introduction to Biotechnology** — **3 units**
- **Bio 109L: Biotech Lab Skills** — **2 units**
- **Chem 107: Elementary Chemistry** — **5 units**

Biotechnology Biomanufacturing Technician Certificate

- **Biology 192/115 Biotechnology B: Proteins - New Hybrid** — **4 units**
- **Biology 211/272- Cellular and Molecular biology- Existing** — **5 units**
- **Chemistry 219/Chem 111A – General Chemistry- Existing** — **5 units**

Biotechnology Technician Certificate

- **Biology 193/120 Biotechnology C: Nucleic Acids Upstream Processing- New/Hybrid** — **4 units**
- **Biology 194/125 Quality & Regulatory Compliance in Bioscience New/online** — **2 units**

30/31 units
= requirements for A.S. degree

- **7 units from below categories= Certificate of Achievement (38 units)**

- QC Microbiology (SAC)

- **Biology 229** – General Microbiology (Existing) 5 units
  or
- **Biology 139** – Health Microbiology (Existing) 4 units
- **Biology 195** – QC Microbiology (New) 2 units
- **Internship** – 1 unit

SANTA ANA COLLEGE

-Food Safety (SCC)

- **Biology 229** – General Microbiology (Existing) 5 units
  or
- **Biology 139** – health microbiology (Existing) 4 units
- **Biology 196** – Food safety & microbiology (New) 2 units
- **Internship** – 1 unit

Santiago Canyon College

- Research (Fullerton College)

- **Biology 130** – Research Seminars (New) 1 unit
- **Biology 140** – Research skills (New) 2 units
- **Bio 276** – Genetics (Existing) 4 units
- **Internship** – 1-4 units

FULLERTON COLLEGE

-General (all 3 campuses)

- **Biology 177/109** – Human Genetics (Existing) 3 units
- **Biology** 290 – Biochemistry and Molecular biology (Existing) 5 units
- **Biology 229/**262 – General Microbiology (Existing) 5 units
  or
- **Biology 139/220** – health/medical microbiology (Existing) 4 units
- **Chem 229/**111B – General Chemistry & Quantitiative Analysis (Existing) 5 units
- **Internship** – 1-4 units

Biotechnology Certificate-Specific Courses

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date: 12/03/2012

Discipline, Number, Title: Biology 190, Introduction to Biotechnology

Units and Hours:

3.00 Units
48.00 Hours Lecture

Catalog Entry:

Introduction to the field of biotechnology including a history of its origin and development, a survey of modern industrial applications and accomplishments, ethical considerations, and career paths. Field trips may be required.

Requisites:

Prerequisite: *None*
Corequisite: *None*
Recommended Preparation: *None*

Repeatability: Non-Repeatable

Pass/No Pass Only: No

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course will define the field of biotechnology and provide students with a brief history of its development, an understanding of the foundational molecular biology principles relating to its modern industrial practices and applications, create an awareness of bioethics, and introduce students to the variety of jobs available in this field.
This course will allow student to acquire the basic foundational knowledge and skills for the biotechnology field. Industry practices and ethics will be emphasized.

Student Learning Outcomes:

1. Demonstrate knowledge of the fundamental biotechnology concepts that include basic molecular biology, industrial applications, a brief history of the field, and ethical considerations.
2. Demonstrate a proficiency in the techniques used for scientific communication.

General Education & Transfer:

Transfer Status: B. Transfers to CSU Only

Course Content and Objectives:

Lecture		
Approx. Hours	Content	Objective
3.00	Introduction to Biotechnology	• Define biotechnology • Describe the goals in this field
6.00	History of biotechnology	• Examine the ancient origins of biotechnology • List and describe the practices of the field • Discuss recent technological advancements

12.00	Basic Molecular Biology	• Define and describe the principles of basic molecular biology as they apply to biotechnology
		  ◦ Structure and replication of nucleic acids
		  ◦ Gene structure and function (Prokaryotic and Eukaryotic)
		  ◦ Proteins and enzymes
		  ◦ Restriction endonucleases
		  ◦ Reverse transcriptase
		  ◦ Polymerase chain reaction (PCR)
		  ◦ Sanger method of DNA sequencing
		  ◦ Bacterial plasmids and transformation

3.00	Industrial applications	• Discuss the scaling of biotechnology ideas and principles to large scale industrial applications
2.00	Plant biotechnology	• Explore the applications of plant biotechnology • Examine the careers available in this specialty of the field
2.00	Animal biotechnology and wildlife conservation	• Explore the applications of animal biotechnology and wildlife conservation • Examine the careers available in this specialty of the field

2.00	Environmental biotechnology	• Explore the applications of environmental biotechnology • Examine the careers available in this specialty of the field
2.00	Marine biotechnology	• Explore the applications of marine biotechnology • Examine the careers available in this specialty of the field
2.00	Medical biotechnology	• Explore the applications of medical biotechnology • Examine the careers available in this specialty of the field
2.00	Biopharmacy	• Explore the applications of biopharmacy • Examine the careers available in this specialty of the field
2.00	Food biotechnology	• Explore the applications of food biotechnology • Examine the careers available in this specialty of the field
2.00	Bioremediation	• Explore the applications of bioremediation • Examine the careers available in this specialty of the field
2.00	Nanobiotechnology	• Explore the applications of nanobiotechnology • Examine the careers available in this specialty of the field
2.00	Bioethics	• Identify and discuss the major public concerns related to biotechnology practices • Examine and discuss the potential benefits and dangers of gene manipulation and transgenic organisms • Discuss and relate the necessity of industrial regulations to ethical considerations

4.00	Scientific communication skills	• Describe and discuss importance and aspects of effective communication in science • Analyze and evaluate case examples of workplace communication • Examine the roles of leadership and good communication in effective teamwork

Course Materials:

- Thieman, W., M. Pallandino., *Introduction to Biotechnology*, 3rd Ed. Benjamin Cummings. 2013 **(Required)** ISBN:9780321766113 $130.60

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity
- Cooperative Learning
- Discussion
- Distance Education
- Field Trips
- Guest Lecturers
- Instructor-Prepared Materials
- Lecture
- Multimedia Presentations
- Observation and Demonstration
- Projects

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Exams/Tests
- Quizzes
- Oral Presentation
- Projects
- Field Trips
- Simulation
- Group Projects
- Class Participation
- Class Work
- Standardized instrument objectively measuring student knowledge
- Competency based written and practical tests which demonstrate the students' ability to apply skills and concepts learned to minimum standards established by the instructor

- Class Performance
- Computer Assignments
- Final Exam
- Laboratory Notebook/Reports

Outside of Class Assignments:

- Homework assignments including reading of the text and other materials, writing assignments, and preparation of presentations for class.

Outside Class Hours: 96 Hours

Grading Criteria:

- A: 90%-100%
- B: 80%-89%
- C: 70%-79%
- D: 60%-69%
- F: Less than 60%

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date:

Discipline, Number, Title: Biology 191, Biotechnology A: Basic Lab Skills

Units and Hours:

4.00 Units
48.00 Hours Lecture
48.00 Hours Laboratory

Catalog Entry:

Introduction to the fundamental skills necessary for any biotechnology laboratory. Skills include maintenance of an industry standard notebook; preparation and sterilization of solutions, reagents, and media; utilization of good aseptic technique; proper use and maintenance of laboratory equipment; adherence to quality control protocols and laboratory safety regulations. Compliance with industry standards and regulations will be incorporated into course procedures.

Requisites:

Prerequisite: *None*
Corequisite: *None*
Recommended Preparation: Mathematics 080

Repeatability: Non-Repeatable

Pass/No Pass Only: No

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course will allow students to acquire the basic foundational skills needed in a biotechnology laboratory. Industry standards and practices will be emphasized.

Student Learning Outcomes:

1. Demonstrate a proficiency in the techniques used for scientific analysis, documentation and communication in a laboratory and industrial setting.
2. Demonstrate the knowledge of fundamental biotechnology concepts including basic molecular biology industrial applications and ethical considerations.

General Education & Transfer:

Transfer Status: Transfers to CSU

Course Content and Objectives:

Lecture		
Approx. Hours	Content	Objective
6.00	Lab Safety and standard procedures	Students will: • Demonstrate proper procedures when performing basic laboratory activities to ensure safety and compliance with standard operating procedures employed in industry. • Demonstrate a knowledge of hazardous materials encountered in the biotechnology laboratory setting. • Maintain proper records for hazardous material storage and disposal.
9.00	The laboratory notebook and record keeping.	Students will: • Create and maintain an industry-standard notebook. • Create accurate records and logs for laboratory equipment and materials.
8.00	Solutions, buffers, and reagents.	Students will: • Mix accurate solutions, buffers, and reagents. • Employ basic laboratory math calculations to arrive at the proper formulation for the solution, buffer, or reagent. • Demonstrate an understanding of the function of the materials used to create the solutions, buffers and reagents.
9.00	Aseptic technique and decontamination	Students will: • Properly employ the methods of aseptic technique. • Properly employ the methods needed to decontaminate materials used in the laboratory. • Demonstrate a knowledge of the functions of the various equipment, methods and materials used to decontaminate and sterilize laboratory materials.

10.00	Basic Laboratory math including unit conversions, basic calculations, dilutions, charts and graphs.	Students will: • Employ basic math calculations to solve common laboratory problems. • Create accurate charts and graphs of laboratory-generated data. • Interpret data displayed in chart or graph format.
6.00	Inventory, supplies, and validating equipment and materials.	Students will: • Demonstrate a knowledge of the proper methods to label, organize and otherwise, maintain your inventory. • Demonstrate a knowledge of methods used to validate laboratory equipment and materials. • Perform inventory maintenance methodologies, and validation of equipment and materials exercises.

Laboratory		
Approx. Hours	Content	Objective
6.00	Lab Safety and standard procedures	Students will: • Demonstrate proper procedures when performing basic laboratory activities to ensure safety and compliance with standard operating procedures employed in industry. • Demonstrate a knowledge of hazardous materials encountered in the biotechnology laboratory setting. • Maintain proper records for hazardous material storage and disposal.
9.00	The laboratory notebook and record keeping.	Students will: • Create and maintain an industry-standard notebook. • Create accurate records and logs for laboratory equipment and materials.

8.00	Solutions, buffers, and reagents.	Students will: • Mix accurate solutions, buffers, and reagents. • Employ basic laboratory math calculations to arrive at the proper formulation for the solution, buffer, or reagent. • Demonstrate an understanding of the function of the materials used to create the solutions, buffers and reagents.
9.00	Aseptic technique and decontamination	Students will: • Properly employ the methods of aseptic technique. • Properly employ the methods needed to decontaminate materials used in the laboratory. • Demonstrate a knowledge of the functions of the various equipment, methods and materials used to decontaminate and sterilize laboratory materials.
10.00	Basic Laboratory math including unit conversions, basic calculations, dilutions, charts and graphs.	Students will: • Employ basic math calculations to solve common laboratory problems. • Create accurate charts and graphs of laboratory-generated data. • Interpret data displayed in chart or graph format.
6.00	Inventory, supplies, and validating equipment and materials.	Students will: • Demonstrate a knowledge of the proper methods to label, organize and otherwise, maintain your inventory. • Demonstrate a knowledge of methods used to validate laboratory equipment and materials. • Perform inventory maintenance methodologies, and validation of equipment and materials exercises.

Course Materials:

- Moore, Lisa A, *Basic Laboratory Methods for Biotechnology,* 1 Ed. Benjamin Cummins. 2008 **(Required)** ISBN:9780321570147 $86.00
- Laboratory Notebook (approximately $3)

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity
- Cooperative Learning
- Distance Education
- Instructor-Prepared Materials
- Lab
- Lecture
- Multimedia Presentations
- Observation and Demonstration
- Projects

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Exams/Tests
- Quizzes
- Projects
- Group Projects
- Class Participation
- Class Work
- Lab Activities/Exercises
- Standardized instrument objectively measuring student knowledge
- Competency based written and practical tests which demonstrate the students' ability to apply skills and concepts learned to minimum standards established by the instructor
- Class Performance
- Practicum
- Observation and evaluation of manipulative skills
- Computer Assignments
- Final Exam
- Laboratory Notebook/Reports

Outside of Class Assignments:

- Homework assignments including reading of the text and other materials, writing of standard operating procedures and laboratory reports.

Outside Class Hours: 96 Hours

Grading Criteria:

- **Laboratory Grade** – a minimum of 50% of the total course grade

Students will be graded on a standard grading scale as follows:

- 90-100% A
- 80-89% B
- 70-79% C
- 60-69% D
- below 60% F

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date:

Discipline, Number, Title: Biology 192, Biotechnology B: Proteins

Units and Hours:

4.00 Units
48.00 Hours Lecture
48.00 Hours Laboratory

Catalog Entry:

Fundamental skills in applied biotechnology necessary for any biotechnology laboratory but particularly focused on downstream manufacturing processes in biomanufacturing. Skills include maintenance of an industry standard notebook, preparation and sterilization of solutions, reagents and media; utilization of good aseptic technique, proper use and maintenance of laboratory equipment, adherence to quality control protocols, lab safety regulations, in vitro translation, large scale expression, purification, modificstion, western blot analysis, ELISA, antibody tagging, and flourescent microscopy. Compliance with industry standards and regulations will be incorporated into course procedures.

Requisites:

Prerequisite: Biology 191
Corequisite: *None*
Recommended Preparation: *None*

Repeatability: Non-Repeatable

Pass/No Pass Only: No

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course is designed to teach the students fundamental laboratory skills used in the biotechnology industry and will focus on protein biomanufacturing.

Student Learning Outcomes:

1. Students will be able to write and follow SOPs (standard operating procedures).
2. Students will know how to obtain a purified sample of a genetically engineered protein

Course Content and Objectives:

Lecture

Approx. Hours	Content	Objective
3.00	*in vitro* translation	Describe the process of protein production starting with a DNA sequence
10.00	Large scale protein expression and bioreactors	Explain protein production resulting in quantities suitable for industrial applications.
10.00	Protein purification and filtration	Summarize the methods needed for obtaining purified protein product. Describe filtration methodology for protein purification.
6.00	Post-translational modifications	Describe modifications made to proteins after translation in order to acheive fundtionality.
6.00	Protein and antibody tags	Explain methods for identifying and purifying proteins using linkages to other proteins, including antibodies.
6.00	Western blot analysis and ELISAs (Enzyme-linked immunosorbent assays)	Explain immunological methods for detecting proteins.
4.00	Fluorescent microscopy	Describe the visualization of protein location using flourescent microscopy.
3.00	Lab safety and quality control standard procedures.	Describe the proper protocols to ensure laboratory safety and quality of product.

Laboratory		
Approx. Hours	Content	Objective

3.00	*in vitro* translation	Demonstrate the pocess of protein production starting with a DNA sequence.
10.00	protein expression and bioreactors	Demonstrate the methods used in industry for protein production.
10.00	protein production and filtration	Demonstrate the methods needed for obtaining purified protein product. Demonstrate filtration methodology for protein purification.
6.00	Post-translational modifications	Demonstrate methods used to modify proteins after translation to achieve functionality.
6.00	Protein and antibody tags	Demonstrate methods for identifying and purifying proteins using linkages to other proteins, including antibodies.
6.00	Western blot analysis and ELISAs	Demonstrate immunological methods for detecting proteins.
4.00	Flourescent microscopy	Demonstrate the visualization of protein location using flourescent microscopy.
3.00	Lab safety and quality control standard procedures.	Demonstrate a knowledge of and employ the procedures necessary to ensure safety and quality product production in the laboratory.

Course Materials:

- Seidman, L.A., M.E. Kraus, D. Brandner, J. Mowery, *Laboratory Manual for Biotechnology and Laboratory Science: The Basics,* Benjamin Cummins. 2010 **(Required)** ISBN:978-032164402 $58.00

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity

- Cooperative Learning
- Distance Education
- Experiments
- Handouts
- Lab
- Lecture
- Observation and Demonstration
- Projects

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Exams/Tests
- Quizzes
- Projects
- Group Projects
- Homework
- Lab Activities/Exercises
- Competency based written and practical tests which demonstrate the students' ability to apply skills and concepts learned to minimum standards established by the instructor
- Practicum
- Observation and evaluation of manipulative skills
- Computer Assignments
- Laboratory Notebook/Reports

Outside of Class Assignments:

Homework assignments including reading and writing. The construction of Standard Operating Procedures (SOPs), laboratory reports and group projects will be assigned. Approximately 6 hours per week during a semester.

Outside Class Hours: 96 Hours

Grading Criteria:

A point scale will be used and a calculation of the overall percentage will be made.
100-90% =A
89-80% =B
79-70% =C
69-60% =D
below 60% =F

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date:

Discipline, Number, Title: Biology 193, Biotechnology C: Nucleic Acids

Units and Hours:

4.00 Units
48.00 Hours Lecture
48.00 Hours Laboratory

Catalog Entry:

This course introduces the fundamental skills in any biotechnology laboratory focusing on the upstream research and development process. Skills include the maintenance of an industry standard notebook, preparation and sterilization of solutions, reagents, and media, utilization of good aseptic technique, proper use and maintenance of laboratory equipment, adherence to quality control protocols, lab safety regulations, DNA/RNA extraction and purification, bioinformatics, polymerase chain reaction, electrophoresis, DNA sequencing, recombinant DNA technology, DNA cloning, fluoresence in situ hybridization, and Southern blot analysis. Compliance with industry standards and regulations will be incorporated into course procedures.

Requisites:

Prerequisite: Biology 191
Corequisite: *None*
Recommended Preparation: *None*

Repeatability: Non-Repeatable

Pass/No Pass Only: No

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course will cover the basic laboratory skills needed in the biotechnology industry and focus on work with nucleic acids.

Student Learning Outcomes:

1. Students will be able to maintain an industry standard notebook.
2. Students will know how to subclone a gene into a cloning vector.

General Education & Transfer:

Transfer Status: Transfers to CSU

Course Content and Objectives:

Lecture		
Approx. Hours	Content	Objective
8.00	DNA and RNA purification and isolation	Explain the process of obtaining pure nucleic acids.
4.00	Transformation	Explain the process of DNA uptake and incorporation.
4.00	Polymerase chain reaction (PCR)	Explain the process of PCR
4.00	Restriction Digest Analysis	describe the procedures and process for analyzing DNA restriction digests.
4.00	Cloning	Describe the process of cloning. Describe the uses for cloning.
4.00	bioinformatics	Explain the uses for bioinformatics.
4.00	DNA sequencing	Describe the method of sequencing a DNA fragment Describe the method for obtaining the sequence of an entire genome.
4.00	Flourescence in situ hybridization	Explain the use for flourescence in situ hybridization
4.00	*in vitro* transcription	Explain the process of obtaining RNA in the laboratory.
8.00	Hybridizations	Describe the methodologies for nucleic acid hybridization

Laboratory		
Approx. Hours	Content	Objective
8.00	DNA and RNA purification and isolation	Students will: • Be able to extract nucleic acids from cells. • Be able to purify extracted nucleic acids.
4.00	Transformation	Students will: • Be able to perform a tranformation. • Be able to isolate transformed cells.
4.00	Polymerase Chain Reaction (PCR)	Students will: • Be able to assemble a PCR master mix. • Be able to operate a thermal cycler. • Be able to verify PCR products.
4.00	Restriction Digest Analysis	Students will: • Be able to selectively digest DNA using restriction endonucleases. • Be able to interpret the results of the digests.
4.00	Cloning	Students will: • Be able to clone an entire gene or selected portions of a cloned gene. • Be able to relate this procedure to it applications.
4.00	Bioinformatics	Students will: • Be able to access databases such as Genbank. • Be able to use alignment tools such as BLAST to compare nucleic acid and/or amino acid sequences. • Be able to search for selected complete or partial sequences and related sequences.

		• Be able to interpret alignment and search results.
4.00	*In vitro* transcription	Students will: • Be able to selectively obtain RNA using the *in vitro* transcription procedure. • Be able to verify the RNA produced using this procedure.
4.00	Fluoresence *in situ* hybridization (FISH)	Students will: • Be able to hybridize fluoresently labeled probes to selected nucleic acid sequences. • Be able to interpret the results of this procedure.
4.00	DNA Sequencing	Students will: • Be able to perform a Sanger chain-termination sequencing reaction. • Be able to interpret the results of this procedure.
4.00	Hybridizations	Students will: • Be able to perform hybridizations of DNA and/or RNA probes to nucleic acid sequences. • Be able to interpret the results of the hybridization procedure(s).
1.00	Industry Standard Notebook and Standard Operating Procedures (SOPs)	Students will: • Be able to keep and maintain an industry standard notebook. • Be able to create, edit, and follow standard operating procedures.
1.00	Process Validation	Students will: • Be able to perform process validation.
1.00		

	Laboratory Safety	Students will: • Be able to observe and practice laboratory safety guidelines during all activities.
1.00	Good Laboratory Practices (GLPs) and International Organization for Standardization Standards (ISOs)	Students will: • Become familiar with and practice GLPs and ISOs as they relate to the lab and the workplace.

Course Materials:

- Seidman & Moore, *Basic Laboratory Methods for Biotechnology: Textbook and Laboratory Reference,* 2 Ed. Prentice Hall Inc.. 2009 **(Required)** ISBN:978032157014 $65.86
- Seidman & Moore, Laboratory Manual for Biotechnology and Laboratory Science: The Basics, Benjamin Cummings. (Jan 1, 2008).

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity
- Cooperative Learning
- Distance Education
- Experiments
- Handouts
- Lab
- Lecture
- Observation and Demonstration
- Projects

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Exams/Tests
- Quizzes
- Projects
- Group Projects
- Homework
- Lab Activities/Exercises
- Competency based written and practical tests which demonstrate the students' ability to apply skills and concepts learned to minimum standards established by the instructor

- Practicum
- Observation and evaluation of manipulative skills
- Computer Assignments
- Laboratory Notebook/Reports

Outside of Class Assignments:

- Howework assignments will include reading and writing.
- The writing of standard operating procedures (SOPs), laboratory reports, and group projects will be assigned.

Outside Class Hours: 96 Hours

Grading Criteria:

Grading will based on a point scale and the calculated percentage of total points earned.

- A = 90% - 100%
- B = 80% - 89%
- C = 70% - 79%
- D = 60% - 69%
- F = 59% or less

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date:

Discipline, Number, Title: Biology 194, Quality and Regulatory Compliance in Biosciences

Units and Hours:

2.00 Units
32.00 Hours Lecture
0 Hour Laboratory

Catalog Entry:

This course will cover quality assurance and regulatory compliance for the bioscience industries. Topics will span quality control and Federal Drug Administration (FDA) regulations for the biotechnology, biopharmaceutical, biomedical device and food industries. Theories and application of quality assurance and quality control will be presented and several different quality systems will be discussed such as cGMP (good maufacutring practices), ISO9000 (Internaltional Standards Organization), Six Sigma and Lean.

Requisites:

Prerequisite: *None*
Corequisite: *None*
Recommended Preparation: Biology 190

A general knowledge of the specific industries identified as biotechnology is recommended.

Repeatability: Non-Repeatable

Course Family: Biology, certificate of acheivement in biotechnology

Pass/No Pass Only: No

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course will cover the regulations that govern and the methods that ensure quality products in the bioscience industries.

Student Learning Outcomes:

1. Demonstrate knowledge of regulatory compliance in the bioscience industry.
2. Demonstrate knowledge of quality assurance in the bioscience industry.

Course Content and Objectives:

Lecture		
Approx. Hours	**Content**	**Objective**
3.00	Biotechnology Industry Overview and Production Considerations 1. research and development 2. manufacturing process	Sumarize the current state of the biotechnology industry.
2.00	Quality Regulations- Abbreviated History and Influences 1. Quality Evolution: Influntial People 2. Regulations Evolution: Landmark Laws and Origin of the FDA (Food and Drug Administration)	Demonstrate a knowledge of the history of regulations concernng product quality.
1.00	Variation- Impacts on Quality	Demonstrate a knowledge of managing variation.
3.00	Statistical Process Control Charts 1. Six Sigma 2. Lean	Properly employ statistical process control charts
1.00	Quality and Regulatory Relationships	Demonstrate an understanding of the relationshp between product quality and the regulatory environment.
6.00	Food and Drug Administration 1. overview 2. organization 3. biotech product jurisdiction	Explain the role of the FDA in the bioscience industry.

	4. regulated product approvals A. drugs B. medical devices a. classification b. substantial equivalence 5. FDA website resources 6. FDA Inspection	
5.00	The Laws (U.S. Code) and Federal Regulations 1. laws to regulations 2. laws impacting the FDA 3. FD&C Act overview 4. 21 CFR (Code of Federal Regulation) Overview A. summary of select CFR parts B. Good Practices (GXPs) C. Good Laboratory Practices (GLPs) D. Good Clinical Practices (GCPs) E. Good Manufacturing Practices (GMPs) a. Medical device GMPs (21 CFR 820) b. FDA QSR-Introduction c. GMP design controls	Summarize the laws, regulations, and good practices affecting the biotechnology industry.
3.00	ISO (International Organization for Standardization) 1. Governing body 2. 9000 Series Standards Family 3. ISO 9001:2008 Quality Managment System-requirements	Demonstrate a knowledge of the ISO as it applies to biotechnology

4.00	1. Quality Management System (QMS) A. key elements of quality B. controlling and improving quality C. vocabulary D. Plan-Do-Check-Act (PDCA) cycle E. quality activities 2. QMS Process Model 3. Understanding Teams A. Purpose of a Team B. Team member roles C. Team success D. Team Stages	Summarize the quality managment system and its components as it applies to biotechnology.
4.00	1. QMS documents A. types B. examples 2. Writing QMS documents A. SOPs (standard operating procedures) B. Considerations 3. Validating QMS documents (SOPs)	Demonstrate QMS documentation.

Course Materials:

- Allport-Settle, M.J., *Current Good Manufacturing Practices: Pharmaceutical, Biologics, and Medical Device Regulations and Guidance Documents Concise Reference*, PharmaLogika. 2009 **(Required)** ISBN:1449505236 $45.00

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity
- Discussion
- Distance Education
- Instructor-Prepared Materials
- Lecture
- Multimedia Presentations

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Exams/Tests
- Quizzes
- Research Papers/Projects
- Projects
- Class Participation
- Class Work
- Homework
- Computer Assignments
- Final Exam

Outside of Class Assignments:

Reading and writing assignments, including construction and evaluation of QMS documents is required. Approximately 2 hours per week during a semester.

Outside Class Hours: 64 Hours

Grading Criteria:

A point scale will be used and a percentae of the total calculated.
90-100% =A
80-89% =B
70-79% =C
60-69% =D
below 60% = F

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date:

Discipline, Number, Title: Biology 196, Food Safety and Microbiology

Units and Hours:

2.00 Units
32.00 Hours Lecture

Catalog Entry:

This course will cover the regulatory agencies that oversee, and the methodologies prescribed to ensure a safe food supply. The Food Safety Modernization Act, hazard analysis critical control points (HACCP), product traceability, food allergens, and food contaminants including microorganisms will be presented. Discussion of illnesses known to result from ingestion of contaminated foods will occur.

Requisites:

Prerequisite: *None*
Corequisite: *None*
Recommended Preparation: Biology 190 Biology 229

Repeatability: Non-Repeatable

Pass/No Pass Only: No

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course will summarize the various agencies and methods used to ensure a safe food supply in the U.S.

Student Learning Outcomes:

1. Demonstrate fundamental knowledge of regulations that apply to food production.
2. Demonstrate a knowledge of food contaminants and resulting illnesses associated with their ingestion.

Course Content and Objectives:

Lecture		
Approx. Hours	Content	Objective

3.00	Introduction to food safety 1. historical events 2. major influences on regulations	Summarize the major events and influences on the food safety regulations in the United States.
3.00	Food Safety Modernization Act 1. background 2. scope 3. implementation	Understand the food safety Modernization act and its application to different types of food products.
6.00	Government Regulations 1. United States Department of Agriculture 2. Food and Drug Administration	Demonstrate knowedge of the regulatory groups governing food production and their jurisdictions
2.00	Product Traceability	Explain the reasons for and methods employed to ensure a product is traceable to the source(s).
2.00	Hazard Analysis Critical Control Points (HACCP)	Apply the principles of HACCP to a given food product.
2.00	Macroanalytical Procedures 1. regulations 2. methodologies	Explain the various regulations concerning and macroanalytical procedures used to ensure food safety
2.00	Elemental analysis	Describe the regulation concerning and methods used to detect toxic elements within foods
2.00	Pesticide Residues 1. regulations 2. methods of detection	Describe the regulations concerning and methods used to detect traces of pesticide within foods

2.00	Drug and Chemical Residues	Demonstrate a knowledge of the regulations concerning drug and chemical residues in foods. Explain the methods employed to detect traces of drugs and chemicals in foods
2.00	Food Allergens	Demonstrate a knowlege of the common food allergens. Demonstrate a knowledge of the physiologic effect of an allergen on an allergic individual.
6.00	Microbial Contamination 1. Approved methods of detection (FDA-BAM; AOAC, USDA-FSIS) 2. types of microbial contamination A. microbial intoxinations B. prions and viruses C. bacteria D. protozoa E. parasites	Demonstrate a knowledge of the approved methods for detection of microorganisms Demonstrate a knowledge of the types of microbial contamination

Course Materials:

- King, H., *Food Safety Management: Implementing a Food Safety Program in a Food Retail Business (Food Microbiology and Food Safety / Practical Approaches),* Springer. 2013 **(Required)** ISBN:9781461462040 $57.00

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity
- Cooperative Learning
- Discussion
- Distance Education
- Instructor-Prepared Materials
- Lecture
- Multimedia Presentations
- Projects

1000

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Exams/Tests
- Quizzes
- Projects
- Group Projects
- Class Participation
- Homework
- Computer Assignments
- Final Exam

Outside of Class Assignments:

Reading and writing assignments, as well as case studies will be assigned. Approximately 2 hours per week during a semester.

Outside Class Hours: 64 Hours

Grading Criteria:

a point scale will be used and a percentage of the total calculated.
90-100% =A
80-89% = B
70-79% = C
60-69% =D
below 60% =F

Santiago Canyon College

Course Outline of Record
Curriculum Council Approval Date:

Discipline, Number, Title: Biology 197, STEM internship

Units and Hours:

1.00 - 4.00 Units
Increment: 1.00 Unit
60.00 - 240.00 Hours Laboratory

Catalog Entry:

Supervised paid or volunteer experience in student's major including new or expanded responsibilities. 75 hours paid work or 60 hours of un-paid work equals one unit. A maximum of 4 units is allowed per semester. Limitation of 16 units in occupational cooperative education courses.

Requisites:

Prerequisite:

Successful completion of 10 units within the Biotechnology Program.

Corequisite: *None*
Recommended Preparation: *None*

Repeatability: Non-Repeatable

Pass/No Pass Only: Yes

Open Entry/Open Exit: No

Credit by Exam: No

Course Purpose:

This course will allow students to gain experience in the scientific field where they can apply learned concepts and acquire new skills. This type of experience is valuable for gaining relevant employment.

Student Learning Outcomes:

1. Students will develop knowledge necessary to select and develop STEM careers.
2. Students will develop skills necessary to select and develop STEM careers.

General Education & Transfer:

Transfer Status: B. Transfers to CSU Only

Course Content and Objectives:

Laboratory		
Approx. Hours	Content	Objective
5.00	Orientation	Students will be able to: • Write measurable learning objectives related to personal and internship site needs including what is to be accomplished, how it will be accomplished, how it will be evaluated and completion date. • Identify an appropriate internship site. • Interview at an internship site and represent one's self professionally. • Dress appropriate for internship site and interview.
230.00	Complete Objectives	Students will: • Maintain a record of internship experiences and time. • Review achievement of learning objectives and effectiveness of internship site and program with instructor and work site supervisor. • Participate in all assignments related to the career/job.
5.00	Evaluation	Students will: • Evaluate their performance, and review the employer evaluation (must include both employer and student signature). • Discuss with the faculty the evaluation and experience who will then determine if credit should be granted and determine the final grade to be submitted to the Admissions office.

Course Materials:

- T. Morrison, W.A. Conaway , *Kiss, Bow, or Shake Hands,* 2 Ed. Adams Media. 2006

(**Recommended**) ISBN:1593373686 $19.95

- Stephan P Robbins and Phillip L Hunsaker, *Training in Interpersonal Skills,* 6th Ed. Prentice Hall. 2012 (**Required**) ISBN:0132551748 $20.00

Instructional Methods:
These measures are typical of the instructional methods of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Activity
- Critique
- Directed Study
- Discussion
- Field Experience
- Field Trips
- Guided Inquiry
- Individualized Instruction
- Journaling
- Multimedia Presentations
- Observation and Demonstration
- Projects
- Work Experience

Methods of Evaluation:
These evaluation methods are typical of this course; however, instructors may employ other related methods and not all methods listed are necessarily performed by each instructor:

- Research Papers/Projects
- Portfolios
- Papers
- Projects
- Field Trips
- Student satisfaction with their educational experience
- Journaling
- Observation and evaluation of attitudes and actions
- Observation and evaluation of manipulative skills
- Laboratory Notebook/Reports
- Open-ended and controlled dialogues
- Write a skills, knowledge and attitude summary, and/or a resume upon completion of the course.

Outside of Class Assignments:

- Research the company in which internship will be held and discover the history, purpose, and key markets for their services or products.
- Develop three written performance objectives that are specific, measurable, and achievable during the semester. Write a summary of the skills, knowledge and attitudes student should have for a career in STEM-related business and/OR construct a typed resume suitable for distribution.

- Complete 60 unpaid or 75 paid hours of work experience for each unit of credit.

Outside Class Hours: 15 Hours

Grading Criteria:

Pass/No Pass Only

- To receive credit, students must satisfactorily complete two objectives:
  - Write a skills, knowledge and attitudes summary or resume, and
  - Receive satisfactory employer and instructor evaluations on acheivement of their three objectves.

Proposed Biotech Programs: SCC

Santiago Canyon College

PROGRAM OF STUDY

Certificate of Proficiency in Biotechnology Lab Assistant

This certificate of proficiency program in biotechnology lab assistant is designed for students who wish to obtain the skills required to gain employment in industries influenced by biotechnology as well as for incumbent workers seeking career opportunities. Upon completion of this certificate program, students will be eligible to obtain employment as laboratory assistants.

Requirements for the certificate of proficiency:

		Units
BIOL 190	Introduction to Biotechnology	3
BIOL 191	Biotechnology A: Basic Lab Skills	4
CHEM 209	Introductory Chemistry	4
Total Units		**11**

Career Opportunities in Biology

Entry-level laboratory jobs in science-related industries.

Program Outcomes

1. Students will develop knowledge necessary to select and develop STEM careers.

Santiago Canyon College

PROGRAM OF STUDY

Certificate of Achievement in Biotechnology Biomanufacturing Technician

This certificate of acheivement in biotechnology technician is designed for students who wish to obtain the skills required to gain employment in industries influenced by biotechnology as well as for incumbent workers seeking career opportunities. Upon completion of this certificate program, students will be eligible to obtain employment as laboratory assistants or biomanufacturing technicians.

Requirements for the certificate of achievement:		Units
BIOL 191	Biotechnology A: Basic Lab Skills	4
BIOL 192	Biotechnology B: Proteins	4
BIOL 211	Cellular and Molecular Biology	5
CHEM 219	General Chemistry	5
Total Units		**18**

Career Opportunities in Biology

Entry-level laboratory jobs in science-related industries.

Program Outcomes

1. Students will develop knowledge necessary to select and develop STEM careers.

Santiago Canyon College

PROGRAM OF STUDY

Certificate of Achievement in General Biotechnology Technician

This certificate of acheivement in biotechnology laboratory technician is designed for students who wish to obtain the skills required to gain employment in industries influenced by biotechnology as well as for incumbent workers seeking career opportunities. Upon completion of this certificate program, students will be eligible to obtain employment as laboratory assistants, biomanufacturing technicians, or research and development technicians

Requirements for the certificate of achievement:

		Units
BIOL 190	Introduction to Biotechnology	3
BIOL 191	Biotechnology A: Basic Lab Skills	4
BIOL 192	Biotechnology B: Proteins	4
BIOL 193	Biotechnology C: Nucleic Acids	4
BIOL 194	Quality and Regulatory Compliance in Biosciences	2
BIOL 211	Cellular and Molecular Biology	5
CHEM 219	General Chemistry	5
Plus 7 units from the following list:		
BIOL 177	Human Genetics	3
BIOL 280	Biochemistry and Molecular Biology	5
BIOL 229	General Microbiology	5
	or	
BIOL 139	Health Microbiology	4
CHEM 229	General Chemistry and Qualitative Analysis	5
BIOL 197	STEM Internship	1 - 4
Total Units		**45 - 49**

Career Opportunities in Biology

Entry-mid level laboratory positions in science related industries.

Program Outcomes

1. Students will develop knowledge necessary to select and develop STEM careers.

Santiago Canyon College

PROGRAM OF STUDY

Certificate of Achievement in Biotechnology Laboratory Technician: Food Safety

This certificate of acheivement in biotechnology laboratory technician of food safety is designed for students who wish to obtain the skills required to gain employment in industries influenced by biotechnology as well as for incumbent workers seeking career opportunities. Upon completion of this certificate program, students will be eligible to obtain employment as laboratory assistants, biomanufacturing technicians, or research and development technicians.

Requirements for the certificate of achievement in Food Safety:		Units
BIOL 190	Introduction to Biotechnology	3
BIOL 191	Biotechnology A: Basic Lab Skills	4
BIOL 192	Biotechnology B: Proteins	4
BIOL 193	Biotechnology C: Nucleic Acids	4
BIOL 194	Quality and Regulatory Compliance in Biosciences	2
BIOL 211	Cellular and Molecular Biology	5
CHEM 219	General Chemistry	5
Plus 7 units from the following list:		
BIOL 196	Food Safety and Microbiology	2
BIOL 197	STEM Internship	1 - 4
BIOL 139	Health Microbiology	4
	or	
BIOL 229	General Microbiology	5
Total Units		**34 - 38**

Career Opportunities in Biology

Entry-level laboratory positions in science-related industries, especially those concerned with food manufacturing.

Program Outcomes

1. Students will develop knowledge necessary to select and develop STEM careers, espcelally those concerned with food manufacturing and safety.

Santiago Canyon College

PROGRAM OF STUDY

Associate in Science in Biotechnology

This associates degree in biotechnology is designed for students who wish to obtain the skills required to gain employment in industries influenced by biotechnology as well as for incumbent workers seeking career opportunities. Upon completion of this program, students will be eligible to obtain employment as laboratory assistants, biomanufacturing technicians, or research and development technicians.

Major requirements for the associate in biotechnology:		Units
BIOL 190	Introduction to Biotechnology	3
BIOL 191	Biotechnology A: Basic Lab Skills	4
BIOL 192	Biotechnology B: Proteins	4
BIOL 193	Biotechnology C: Nucleic Acids	4
BIOL 194	Quality and Regulatory Compliance in Biosciences	2
BIOL 211	Cellular and Molecular Biology	5
CHEM 209	Introductory Chemistry	4
CHEM 219	General Chemistry	5
Total Units		**31**

Career Opportunities in Biology

Entry-level laboratory positions in science-related industries.

Program Outcomes

1. Students will develop knowledge necessary to select and develop STEM careers.