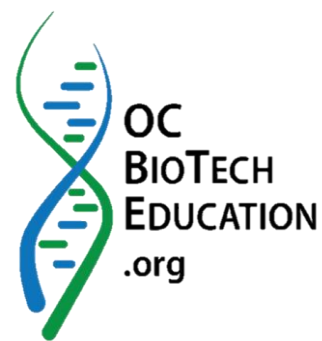


OC BIOTECH EDUCATION PARTNERSHIP

Advisory Board Meeting Minutes

Regional Biotech Program:

Santiago Canyon College, Santa Ana College,
Fullerton College, Irvine Valley College



Friday, February 22, 2019
Santiago Canyon College

Advisory Members Present:

OC Biotech Education Partnerships Representatives

Jo Wen Wu, PhD	Fullerton College	<i>Professor of Biology</i>
Spiros Dimitratos, PhD	Fullerton College	<i>Associate Professor of Biology</i>
Emalee Mackenzie, PhD	Irvine Valley College	<i>Biology Instructor</i>
Kathy Takahashi, PhD	Santa Ana College	<i>Professor of Biology</i>
Charles Jang	Santa Ana College	<i>Associate Professor of Biology</i>
Jonae Varela	Santa Ana College	<i>Internship Coordinator</i>
Denise Foley, PhD	Santiago Canyon College	<i>Professor of Biology</i>
Anson Lui	Santiago Canyon College	<i>Associate Professor of Biology</i>

Attendees:

Wendie Johnston, PhD	Pasadena Bio Collaborative	Pasadena, CA
Jesse Ouwens	Northrop Grumman	Azusa, CA
Novy Bath	Santiago Canyon College	Orange, CA
Rosemarie Christopher	MEIRxRS	Glendale, CA
Karilyn Gonzales	Food Microbiological LABs Inc.	Cypress, CA
Jayne Hoo	Clinical Diagnostic Genetics	La Mirada, CA
Brent Hunter	North OC Community College	Orange, CA
Sara Kong	PYLUSD	Placentia, CA
Lorna Larson	AVID Bioservices	Tustin, CA
Esmeralda Martin	Career coach (SCC)	Orange, CA
Victor Pham, PhD	UCI	Irvine, CA
Terri Quenzer	SN CA Biotech	San Diego
Walid Sabbagh	So Cal Bio	Newport, CA
Donna Saito	Medtronic Inc.	Corona, CA
Danielle Torres	former student (SCC)	Orange, CA
Jessica Wu-Woods	ABE Biotech	Orange, CA
Chris Shumway	Avid Bioservices	Tustin, CA
Olga Figueroa Brito	BBraun Medical	Irvine, CA
Jose Cedano	Student (SAC)	Orange, CA
Michael Pecolar	former Student (SCC)	Orange, CA

Meeting Starts at 8:10 AM

Introductions

Dr. Jo Wu

- Four community colleges come together to become OCBE (Orange County Biotech Education)
- 9 full time faculty are involved in the Biotech program across the four schools. First biotech courses were launched in 2013
- All colleges have a shared certificate pathway; there are 3 levels of which a student can receive.
- Three certificates are Biotech lab assistant, manufacturing technician, and biotech technician; each college has their own specialized certificate. SCC: food safety, SAC: QC/QA microbiology FC: R&D, IVC: CQIA training
- Once students finish and receive first level certificate, they are eligible to connect with regional internship coordinator to try to get an internship; this could potentially turn into a job as well.
- Some students stay at their internship job site, others continue onto a 4 year program, while others complete a 4 year program and return to obtain a biotech certificate.
- In California, we have 2 community colleges that students can transfer to obtain a bachelor's degree in bio-manufacturing (Solano, Mira Costa)
 - 2 years for AS and then 2 more years for BS in biomanufacturing all for about \$10,000. Main selling point.
- Our program has a diverse student pool, many bachelor's and master's student from foreign countries enroll in the program to have a pathway to working in biotech in the US

Dr. Spiros Dimitratos

- Biotech lab assistant: introduction to biology and lecture, basic lab skills which is the the most popular courses which have post-bacc and master's occasionally. Serves as a good refresher. Intro to chemistry is also required for the entry level certificate.
- After getting first certificate, we encourage students to start searching for internship or position in the workforce.
- The second certificate, biomanufacturing technician certificate, requires the protein course, QC regulation compliance course and general chemistry.
- We have seen our students be successful with any of these certificates
- For the top level certificate, the have to take nucleic acids, tissue culture and any of the electives listed (microbio, biochem, etc.).

Anson Lui

- Refers to handout on hands-on training and skills obtained during coursework:

- Biotech courses emphasize soft skills. Every interaction is an intended simulation of a workplace (Instructor is the supervisor, students are the employees, etc). They have to clock in and out, do peer evaluations, and give leadership opportunities to students excelling in the course
- The equipment used in the biotech course are equal to those used in industry. Students are required to use equipment over and over to build competency. This prepares students for an industry position as they will know how to use many of the instruments
- Biotech course emphasize many laboratory operations in terms of safety and regulations. We have a cell culture, protein biochemistry and nucleic acids that really emphasize the lab operations that are used commonly in industry
- Question: "I'm from a pharmaceutical background, and I notice that you don't have much analytical skills (HPLC, UPLC)."
- Charles Jang: we have a LPLC, it's more for production/purification rather than analytical. We would like to expand with chemistry and have a chemistry based certificate for analytical techniques. We would love to get an LC-MS or GC.
- Dr. Jo Wu: Analytical techniques are being taught in organic chemistry courses and not part of the certificate.
- Questioner: it's very hard to get into R&D if you don't have basic HPLC skills and won't be able to use higher level equipment
- Dr. Takahashi: were trying to coordinate with chemistry to invoke more analytical techniques
- Question: "You mentioned GLP procedures, but are GMPs also part of the curriculum, things like change control, are those aspects that you touch on?"
- Anson Lui: we try to integrate that where we can. Recording equipment they use and the conditions
- Charles: I have my students write SOPs for all the equipment we use and go through the change control process where they submit changes, and its reviewed and the other various levels to that.
- Question: "My focus is on quality control and regulatory aspects, and often on their end they submit documents to regulatory agencies and often times they submit documents that are poorly written. Do you have anything that talks about technical writing at all levels?"
- Aside from SOPs, we also have our students do batch records, and when they email [professor] they practice emailing outside contacts.
- Q: And you mentioned change control, is that something you emphasize? Or like teach emphasize technical writing so that a third party could understand a change in the future?
 - We haven't yet gone as far to implement communication with someone who is not in the class

- The initial idea was to overlap the quality regulatory compliance class with the manufacturing and have the quality class inspect the manufacturing class documentation, but we don't have enough people in the pipeline
 - Students need to be aware of the need to elevate an issue in the work environment. Troubleshooting without elevating the issue to supervisor not permitted.
- Question to industry: who writes the planning for procedures/SOPs, etc?
 - Biotech tech/associates and upper lever associates write the SOPs and is side by side with a compliance specialist
- Dr. Takahashi: we would like to have updated templates of SOPs and batch records to use as examples to teach in our courses; the examples we know can get outdated.
- FDA needs to understand the records years from when it happens; it's very important to emphasize technical writing.
- Question to industry: "what was your career path, how did you get to where you are right now?
 - "I am a chemical engineer by education, Lafayette college. Started at BMS. Had to learn a lot on the job like GMPs and all the equipment. Went back to school to continue education. A lot of training is on the job. Biotech program is great to fill in learning gaps on the way to industry.
- Question: is there a way to get hands on the documentation for the food safety curriculum?
 - We haven't been able to offer the class because not enough students.
 - Community colleges are prime to train students on FDA documentation.
 - Even BS holders from UCs can't write documentation because those skills aren't emphasized.
 - Documentation is killer in industry.
 - BS isn't required PCQI positions but an AS is and few additional certificates.
 - "You have (biotech program) what we need in industry"

Tissue Culture:

- Denise talks about tissue culture. Explains that the Dean will like them to have at least 20 students. Denise had a class with 14 students and 2 hoods. Students set up entry way to gown up before they went in.
- Michael: Talks about Vector Control and how the program helped with techniques in the workforce.
- Wendie: 14 students are a lot for tissue culture class. Wendie had 12 students and 4 hoods. She discusses with her advisory meeting that the max of students for 4 hoods is 12. Suggest that we can discuss with the advisory and dean about having less students for the tissue culture class.

Emalee poses a question to industry- "Is there a need to train students in sequencing or genotyping?"

- Individuals from Ambry replied- DNA Sequencing is important. If students taught to perform and analyze with the Sanger method, which is still the gold standard, they have an advantage over many. Next Gen is expensive. If students know the theory behind Next Gen, that will help.

Kathy presents Internships and new internship coordinator

- We wish to place biotech students to internships. Students need at least the lab certificate to earn the right to access the job developer and be recommended by faculty for an internship. Jonae Varela is the new coordinator. Our previous has moved on to get more education.
- The companies that have given us a chance to place interns, have been pleased with our interns.
 - Our interns have more of the training that we have been talking about, more than just the text book and simulation of an industry environment. More of a regulatory background and at least knowledge of this. They have been pretty pleased with our CC students so far, a lot have been offered jobs. A lot have accepted. But many have wanted to go on and pursue higher education degrees.
- Question from audience referring to figure-- Does the number represent the number of non-high school graduates? Is that what the 18% means?
 - Denise: No. 18% of the companies surveyed do not have internship opportunities in place. The vast majority of companies do have internships but most take from the universities. Some come from the high school, and some from community college.
- Question from the audience inquiring as to length of internship course, pay, and student hours
 - Depends on if regular semester (16 weeks), intersession (4 weeks) summer session (8 weeks). Some students start in the summer and continue through the next Fall semester- or in intersession through Spring.
 - Starting in intersession or summer ensures lots of available hours to work for most students (could be full time during this period)
 - During the semester when students are enrolled in classes, they often work 20 hours or less in an internship each week
 - Internship coordinator ensures students have a good block of time available during several days a week before they try to place them. Students learn they can't be free only a few hours each day and get an internship

- Students are enrolled in the course and are covered by the liability policy of the college
 - Some internships are unpaid but the paid internships vary from around \$11-\$18
 - Walid noted that UCI labs would very likely take interns, especially free internships. He also noted that priority registration for interns would be valuable so they can have the most ideal schedules for internships
 - Danielle Torres, former student: Shared about her internship experience. Working in QC/QA and R&D. Had positive experiences and enjoyed her internship. Wasn't paid and quit her 3 year job. Company told her they don't get paid because other biotech companies tend to hire their employees.
- Question from audience: Have you seen companies that are interested in the apprenticeship programs?
 - Rosemary Christopher: Yes and no. The STEM apprenticeship is new to the USA. Switzerland, France, Germany, Ireland have multinational corps have programs for 50 years. It can be a challenge, but can be done. It may be something they have in the HQ. Through the state and feds we are able to host apprenticeships. Mentors are provided but they mentor has to be only one step or a half step above that person and age is another important factor to consider. Food industry is ideal for the Biotech program. Big pharma apprenticeship custom and 40 hours a week. People with BA/BS get bored of the apprenticeship. Get recent BS/BA grads and have them certified. CC students typically have a better attitude about the work of apprenticeship. This was echoed by Terri Quenzer's experience in industry. The CC students typically have better attitudes.
- Walid posed a question: Do labs only hire BA/BS or AA/AS? What about interns working on the product line? Multi-million dollar product
 - Lorna, Avid Biosciences: We hire AA. Interns cannot sign batch records. FDA compliance prevents. Internships in manufacturing can be difficult for this reason.
 - Training for the manufacturing floor means reviewing all the SOPs. It would take a month of reading just to do this. Internships are not appropriate for this.
 - When hiring, we need someone for 4 years to get our investment in them worthwhile.
 - Terri Q (state sector navigator). When at Pfizer, would take a freshman intern, especially from a CC, and keep them through the educational journey. Then we would hire them right out of college. They were then experienced and part of the culture
 - Rosemary: Some internships can be 12-24 months, depending. The BA/BS holders often want to jump the line and leave or move ahead (her experience) and it is difficult to work with these students. The CC students are easier to work with. For CC students they can have the experience as a pre-apprentice before they graduate.

- Rosemary: In answer to the concern on the manufacturing floor-- The apprentice/intern is not signing off on the batch records of the QC/QA or any documentations. They are there to implement the law and regulation. So the mentors understand that the apprentice is under certain regulations as well.
- Wendie: I have trained apprentices of all types. The “sweet spot” is the students that are recent graduates with good grades and no skills. They are able to learn the skills quickly.

Announcement: Our regional collaboration is going to have a new position opening. The OC Biotech and manufacturing Sector Navigator who is on track to start July. The grant just got approved. So hopefully they will be starting soon. We will post information when the job is officially open for applicants.

- Terri Q. posed question to industry: Do you have any thoughts how this person (OC Biotech Navigator) would best fit the job for the industry? Do we need more curriculum?
- Lorna: The curriculum is there. The best thing I think this person would be able to help some in industry would be a liaison to speak to hiring managers and convey to them the capabilities of your students. I only know your program so much but having someone who can come in and convince these managers that your program prepares students, I think that would be very helpful. They want to see BA/BS but we need someone to come in and be another voice to talk about the program.

Novy: Talked about alumni stories.

- Michael Pecolar: Talked about his alumni experience from the program. CSUF BA in Public Health then enrolled in the biotech program. He admitted it taught him a lot. He was able to move into a position to investigate an outbreak in the county and this work will be published in September. He is co-author
- Jessica: Lab tech for Amgen experience. Talked about her biotech experience.
- Ed Kim: Talked about experience in the program and current position
- Danny: Talked about her experiences in biotech certificate. Earned the second level certificate.. While her current work does not seem linked to her biotech lab skills, the confidence she gained while in the program has allowed her to take advantage of new opportunities including the work she now does with computational biology at CSUF.

Charles: Closed the meeting with a general thank you and a request for the industry to continue to engage with us and our students in the various ways (internships, workshops, tours, mock interviews) He also requested they finish filling out the paper survey and turn it in as they leave. **Meeting Ends at 10:00 AM**