

**Citrus Community College
Biotechnology Advisory Council
Tuesday, May 28, 2024
3:00-4:30 PM
via Zoom
Zoom ID: 811 8998 3669
Password: 439043**

Attendees: Dr. Eleanor Tsark, *Citrus College Biotechnology Faculty*; Dr. Katherine Harker, *Citrus College Biotechnology Faculty*; Dr. Wendie Johnston, *Laboratory Director of Pasadena Bio Collaborative*; Dr. Eric Rabbitoy, *Dean of Natural and Physical Sciences, Citrus College*; Willie Zuniga, *President Emeritus, Grifols Biologicals*; Maria Berry, *Microbiology Manager, Grifols Biologicals*; Scott Eaker, *Chief Operations Officer, Prolacta Bioscience*; Jorge Osuna, *Associate Director of Technical Services, Gilead Sciences, Inc*; Brad Pollak, *Director of the Long Beach Small Business Development Center*; Dr. Terri Quenzer, *Executive Director, Bioscience Workforce Development Hub hosted at MiraCosta College*; Natalie Desimone, *Citrus College Career Counselor*; Kevin Tapia (2019 Citrus biotech graduate), *Manufacturing Technician III, Gilead Sciences (Oceanside)*.

Agenda	Discussion	Summary/Recommendation
Meeting commenced at 3:00 PM with welcome and introductions.	<p>Eleanor thanked everyone who is in attendance since the biotech program requires the input of the advisory board members to constantly improve the program and ensure the training is relevant and current. If modifications to the program are recommended, then the biotech faculty will work to implement these changes.</p> <p>Advisory Committee members introduced themselves to the other participants providing their name and the organization they work for. During her introduction, Dr. Wendie Johnston thanked Scott for the donation of the Opentron pipetting module that Prolacta recently donated to PBC which, in turn, Wendie donated to Pierce College for use in their program to train their students in the use of this vital piece of equipment. In addition, a new member of the advisory council introduced himself (Jorge Osuna) who is replacing Gerard Jensen of Gilead Sciences in La Verne. As Associate Director of Technical Services, Jorge has many roles to support the manufacturing of parenteral drugs at the La Verne facility.</p>	<p>The Advisory Committee meeting was convened to allow industry partners and Citrus biotech faculty to come together to review the program at the present time and to discuss the proposed curriculum for the new EM course.</p>
Eleanor asked industry partners: What are your current needs with respect to employment and positions that need to be filled projecting	<p>Scott Eaker of Prolacta Bioscience shared that the company has undergone some recent restructuring with new investors towards the end of last year so the beginning of this year has been focused on projecting forward 3-5 years for what is on the horizon for the company. Although this year will remain fairly flat with respect to headcount in the lab and in manufacturing, next year will see exciting things happening with the planned launch of Prolacta's product in Japan towards the end of next year as a pharmaceutical product. So, there will not be an increase in hiring in the upcoming year due to the work required for the product launch in Japan. Eleanor inquired if there would be additional QA positions needed to support the launch in Japan and Scott indicated that there will be increased focus on regulatory since pharmaceutical quality is</p>	<p>Hiring at Prolacta and Gilead will remain flat in 2024 but hiring will ramp up again when production increases next year. The launch of Prolacta's product in Japan will likely require additional regulatory personnel and the shift to</p>

<p>forward? Are we addressing these employment needs?</p>	<p>different from what is required for a nutritional infant formula type product in the United States. Prolacta has added some staff to support that need and existing staff do come from Baxter and Grifols so do possess that regulatory experience, but it is more work and more will have to be done with respect to the launch in Japan. So, more has been added to the regulatory team and a partner in Japan will be holding the authorization there and will also be providing regulatory support. Batches will be under Japan pharmaceutical regulations which will prompt increased QA needs such as floor QA so Scott does anticipate ramping that up towards the middle to the end of next year.</p> <p>Jorge discussed the closing of the San Dimas facility which happened in August of last year. From a manufacturing perspective, some contractors were let go due to this closure and consolidation to La Verne. With respect to the La Verne facility, Jorge shared that both the site and the company of Gilead are in an interesting place due to the future closure of the biologics R & D site in Oceanside which corporate announced last year. As a result of this impending closure, those roles are going to move to corporate in Foster City which means new openings in Foster City but, at the same time, there is closure and not hiring at Oceanside. Last year, it was also announced that Kite, a company owned by Gilead, was letting go of about 7% of workers. Though Kite works independently, you can still find the same positions within the Gilead website. So, the company is going through a lot of changes as it continues to move more towards the production of biologics. So, currently hiring needs remain flat until the company can see where the need is and then it will ramp up. At the La Verne site where parenterals are manufactured, another fill line has just been completed. In the future, there will be more activities in the fill flex line for biologics production and to support more clinical programs. Jorge anticipates that by the end of this year and early next year, Gilead will see where the hiring demand is in manufacturing and QA/QC to support the increased production of biologics. There will be increased need in the company and at the La Verne site for biologics which, historically, Gilead hasn't really been involved in. The focus was mostly small molecules (solid and oral dose). So, it's interesting that the La Verne site is going to see more work and need for workers come out of it. Eleanor asked if, with these company changes, Jorge foresees the company having a need for students who receive training at biotech programs and have certificates and A.S. degrees. Jorge said yes and that tech roles that once only required a high school diploma now need some college education and that it definitely will be helpful to have a certificate or associates degree from a biotech program. Eleanor shared that Citrus biotech has had students in the program who work at Gilead as manufacturing technicians and have a desire to receive targeted training to have a competitive edge and secure additional roles at the company.</p> <p>Maria Berry, representative of Grifols, was unable to provide an update due to an audio technical difficulty.</p> <p>Terry Quenzer shared that there are grant funds to support student internships. Terry shared there is an NSF grant to support student internships with our partner companies. Though positions have been filled this year, this grant could support internships with companies for next year. So, student interns would be unpaid by the company but paid by the grant. This year, the grant is supporting 19 students at 4 different colleges. Students are paid for work experience college credits and MiraCosta pays them off of the grant where they earn \$25/hr for 400 hours of work for their internship. They participate in this internship while</p>	<p>biologics manufacturing from Oceanside to Gilead's corporate office in Foster City may impact hiring in the areas of manufacturing and QA/QC at the La Verne site.</p> <p>Terry Quenzer, Executive Director of the Bioscience Workforce Development Hub, shared that her organization has grant funds to support student internships at partner companies. If company representatives are interested in hosting student interns, the grant would pay their salary.</p>
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	<p>they are pursuing their education at the college. The internships are supported by an NSF EXLENT Grant (EXperiential learning in EMerging and NOvel Technologies). The supported students are traditionally community college students working towards a certificate or A.S. degree, but they are also able to support students pursuing their bachelor's since these students were included in the grant proposal with the intent to support students completing the biomanufacturing bachelor's degree at MiraCosta College. They have completed year one of a three-year grant. It's intended to be full time over the summer, but they are also allowing some part time roles for students who are proximal to a company to help them participate in a part-time internship while they continue to go to school.</p>	
<p>Eleanor asked for an approval of the minutes from the last Advisory meeting (May 2023)</p>	<p>Several advisory members approved the 2023 minutes.</p>	<p>Minutes from May 2023 Biotech Advisory Committee meeting were approved.</p>
<p>Program enrollment and completion was discussed and strategies to increase enrollment were shared.</p>	<p>Eleanor discussed enrollment trends for current and previous cohorts. For the current year, 12 students completed the fall 2023 BIOT 110 course and all enrolled in spring 2024 BIOT 150 and are on track to graduate in June. The program has done well with retaining students. Registration for fall 2024 is currently open and there is hope the class fills to the maximum of 16 students. High school outreach events to help advertise the program include the following: 1) Kathy and Eleanor along with a former student attended a tabling event during the fall semester at Bonita Unified school district; 2) Kathy presented at Baldwin Park High School where she gave an in-person presentation to 75 juniors and seniors; 3) Attendance at the SoCal Trades Tour this spring semester for an entire week in March which allowed Kathy and Eleanor to go to five different high schools and meet with students interested in biotechnology. The five high schools included Claremont High, Glendora High, Northview, Covina High and South Hills. Following this event, Kathy followed up with 92 students via email to provide these students with information about the biotech program and information about how to register as a student at Citrus. Additionally, to help spread the word to our Citrus students, Eleanor continued to showcase former biotech students and their successes by using the Citrus social media accounts and time these posts prior to fall registration in the spring to inform our students about the program. These posts are particularly effective for students enrolled in asynchronous courses who may not attend classes in-person on campus.</p> <p>Biotech posters and flyers are also strategically placed throughout campus to increase visibility of the program for those students who are on campus for classes.</p> <p>Eleanor shared program completion and awards data:</p> <ul style="list-style-type: none"> • For the 2022-2023 year, all 8 students who completed fall 22 BIOT 110 enrolled in spring 23 BIOT 150 and successfully completed the program. • For the 2022-2023 year, we had 11 total awards (6 certificates and 5 A.S. degrees). Although 8 students graduated from the 2022-2023 cohort, students from previous cohorts likely completed their chemistry course requirements and were awarded the A.S. degree in June. • 12 students enrolled in program for 2023-2024 and are on track to complete program requirements in June. • Majority of students who enroll in program complete the program and are awarded a certificate and/or A.S. degree. 	<p>Industry partners were informed of current enrollment and completion data and activities to increase program enrollment.</p>

<p>Eleanor reviewed the four core biotech courses required for both the certificate in biomanufacturing and the A.S. degree in biotechnology.</p> <p>Eleanor reviewed the skills/equipment training for the two lab biotech courses.</p> <p>Eleanor discussed the proposed additional (stackable) certificate of achievement in environmental monitoring which will include a new short 6-week EM lab course to better prepare students for EM technician positions.</p>	<p>Eleanor outlined the four core biotech courses required for both the certificate in biomanufacturing and the A.S. degree in biotechnology and when these courses are offered during the academic year (BIOT 107, Fall and Spring; BIOT 110, Fall; BIOT 150 & 125, Spring).</p> <p>Eleanor provided a summary of the skills training for the two lab courses:</p> <p>BIOT 110:</p> <ul style="list-style-type: none"> • Lab safety • GDP/lab notebook/SOPs • Mass/volume measurements • pH/conductivity measurements • Stock solutions and dilutions • Spectrophotometry/standard curves • Growth media prep/bacterial cultivation • BSC/aseptic technique • Bacterial transformation/GFP-E.coli • Plasmid prep/PCR/agarose gel electrophoresis <p>BIOT 150:</p> <ul style="list-style-type: none"> • Lab safety • GDP/Work instruction documents • Equipment log books (digital/QR codes) • GMP/QMS/Quality by Design • Data integrity/filter integrity testing • Validation • Solution prep/osmolality testing • Scale-up of GFP-E.coli (bioreactors/flasks) • Downstream processing of GFP protein <ul style="list-style-type: none"> ➢ Liquid chromatography ➢ TFF ➢ QC- SDS-PAGE & ELISA • Environmental monitoring (one week) <p>Both courses emphasize the following soft skills:</p> <ul style="list-style-type: none"> • Resume/Interview skills • Teamwork/Communication • Time management • Integrity • Punctuality <p>The certificate of biomanufacturing includes the four core biotech courses (BIOT 107, BIOT 110, BIOT 150, BIOT 125) in addition to a math course (either technical math, MA 144, or statistics MA 165 since</p>	<p>Eleanor provided an overview of the certificate and A.S. degree course requirements noting that the certificate math requirement has changed to include statistics (MA 165) since intermediate algebra can no longer be offered at CA community colleges.</p> <p>Eleanor provided a summary of the skills/equipment training for the two biotech lab courses in preparation for a discussion of the EM course that is being developed by Kathy. Eleanor discussed how this new EM lab course will allow students to earn an additional stackable certificate with a focus on environmental monitoring in biomanufacturing since this certificate will require the four core biotech courses for the existing certificate in addition to the new EM lab course that is under development.</p>
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	<p>intermediate algebra is no longer offered at CA community colleges). Overall, the certificate includes 19-20 units. For the A.S. degree in biotechnology, students will need to complete the four core biotech courses in addition to MATH 165 and one year of chemistry (CHEM 103/104 or CHEM 111/112) and includes 29 units in the major along with the required GE units.</p> <p>Eleanor discussed a stackable certificate with the addition of the new short EM lab course that Kathy is developing. This certificate would include the courses required for the current certificate in biomanufacturing with the addition of the new EM lab course that students would take in the summer following the completion of BIOT 150 in the spring. The course would be 6 weeks in length and would include 15 lecture hours and 45 lab hours, totaling 2 units and would be called Environmental Monitoring and Quality Operations in Biomanufacturing. Thus, students who complete this new EM lab course, in addition to the other core biotech courses, would obtain two certificates including a Certificate of Achievement in Biomanufacturing and a Certificate of Achievement in Biomanufacturing Environmental Monitoring. Thus, having a stackable certificate pathway would generate more employment opportunities for our students and better prepare them for additional roles in the biotech industry.</p>	
<p>Kathy discussed the new BIOT 160 EM/QC microbiology course and proposed curriculum for the stackable certificate.</p>	<p>BIOT 160: Environmental Monitoring and Quality Operations in Biomanufacturing The focus of this course is to train students for environmental monitoring positions in a manufacturing setting and focusing on viable and non-viable contaminants. Trying to cover the relevant topics in BIOT 150 has proven difficult hence the need for a dedicated course for these topics. Currently, the course dedicates 6 hours to topics of viable and non-viable particle testing but there is not enough time to cover gowning and cleaning procedure required for an environmental monitoring plan. Quality currently focuses on the biologic and the tools/equipment used for creating the product in the form of validation processes. The current BIOT 150 curriculum is missing quality topics and practices associated with the physical environment (water, air and personnel) which is another arm of the quality picture. Kathy mentioned pulling some of that curriculum out of BIOT 150 which would allow for more time on downstream processing techniques such as QC tests related to the product.</p> <p>Proposed Course Outline of Record for BIOT 160 Course Description: This course builds on the concepts and laboratory techniques introduced in Biotechnology II: Biomanufacturing and Quality Principles. Students will examine the roles of Environmental Monitoring and Quality Control Microbiology in the context of biomanufacturing to ensuring the safety of biological drug products. Routine facility, personnel, and utilities environmental monitoring plans and procedures will be highlighted in the context of a comprehensive quality system. This course will review detection, analysis, and control of both viable and non-viable contaminants with an emphasis on aseptic technique and interpretation of testing data. This course includes a significant laboratory component which emphasizes the selection of appropriate equipment and procedures for non-viable particle monitoring in air, bioburden assessment of air, water, surfaces, and personnel, microbial identification, endotoxin testing, and aseptic gowning procedures. The course will be in the summer over a 6-week period and students would meet for 3 hours a day, 3 days in a row. Lecture will be online. 15 lecture hours, 45 lab hours</p>	<p>Kathy discussed the course outline of record for the new EM course (BIOT 160). Kathy shared the course description, student learning outcomes and the proposed lecture and lab content. Kathy shared the document with industry advisors to seek feedback regarding the proposed curriculum.</p> <p>Industry partners were supportive of the proposed curriculum and were enthusiastic about its future launch.</p>

Student Learning Outcomes:

1. Explain the microbiological cleanliness standards required for the manufacture of biopharmaceutical drug substances and drug products. Explain why microbiological control is important in a biomanufacturing facility and provide examples of how it is achieved and maintained.
2. Use laboratory and/or monitoring results to identify, characterize, quantify, summarize, and/or evaluate microbial contaminants from diverse samples as part of an environmental monitoring plan. Describe the various sources of microbial contamination within a biomanufacturing facility/process and name specific microbial contaminants and their possible sources.
3. Independently perform aseptic gowning procedures appropriate for work in various levels of cleanroom environments, including ISO class 5, 7 & 8. Demonstrate appropriate behaviors while performing work in a cleanroom environment to protect product integrity.
4. Collect, perform, document and evaluate microbial testing data and propose response procedures in the context of a quality control plan. Explain the importance of information derived from environmental monitoring and describe how this information is used in investigations.
5. Describe the components of an effective environmental monitoring program along with specific environmental monitoring testing methods. Evaluate an environmental monitoring program for its compliance with regulatory agencies.
6. Professionally document sampling and monitoring activities following the guidelines of good documentation practices (GDP).

Scott Eaker (Prolacta) asked if the activities would also include testing for non-viable particles and Kathy answered that this would be included. Scott also pointed out that an EM technician would also be sampling critical systems in the manufacturing area such as the HVAC system, compressed gases or steam.

Kathy confirmed with Maria Berry that Grifols does utilize a Biolog ID platform in their operations with respect to environmental monitoring for identifying microbial contaminants.

Kathy discussed the importance of gowning procedures (SLO3) and Willie Zuniga shared that he has had past workers quit after their first day of work because they did not like the gowning process and staying in a gown. Scott Eaker agreed that some workers do feel claustrophobic while wearing the appropriate protective clothing that is required for working in a cleanroom. Scott suggested that activities include gowning qualifications where gowns are sampled immediately after students have gowned up and after they have performed their work to test for how well they executed the steps of gowning up and to assess their behaviors while operating in the "cleanroom". This demonstrates to students how to collect those samples and who is able to gown up without contaminating their gowns. Although it is not a clean environment, it can demonstrate the importance of behaviors while one works in a cleanroom and that sampling gowns periodically will be expected as part of an environmental monitoring plan. Kathy agreed that it would be helpful for students to sample gowns prior to, during and after they have completed their work to demonstrate this component of environmental monitoring.

Kathy discussed the course content which she developed using the SLOs as a guide. Kathy emphasized that the class is only 6 weeks, so we want to be targeted and intentional with respect to the content that is covered to ensure we are covering topics that are a high priority for EM roles.

Lecture Topics for BIOT 160:

1. Foundational microbiology topics
2. Environmental monitoring program/plan design
3. Types of contamination in a biomanufacturing facility (viable vs nonviable)
4. Strategies for reducing contamination

Lab Content for BIOT 160:

1. Environmental monitoring plan design
2. Aseptic gowning and techniques
3. Testing methodology
 - a. Non-viable air particle monitoring
 - b. Microbial air monitoring
 - c. Surface monitoring of personnel and equipment
 - d. Utility monitoring
 - e. Endotoxin screening
 - f. Microbial identification

Kathy shared the draft of the course outline of record in the chat so committee members can look at it and provide Kathy with feedback in the future.

Willie shared that he believes it is critical for a manufacturing technician to be familiar with the topics of EM that we currently cover in the BIOT 150 course and he would advise that these topics remain in the BIOT 150 curriculum to best prepare those students who do pursue manufacturing technician roles. Kathy agreed that these topics are important and will remain in the BIOT 150 curriculum. The BIOT 160 course will simply allow for Kathy to provide further instruction with respect to EM and augment knowledge acquired in BIOT 150.

Willie inquired if the BIOT 160 course would be a requirement for the current certificate and Eleanor indicated that it would not be required but that students can choose to take the BIOT 160 course and earn an additional certificate with an emphasis on environmental monitoring in biomanufacturing.

Students who earn the additional certificate will still complete their training in 12 months which is ideal.

Both Kathy and Eleanor are hopeful that many of our students will take the summer EM course to ensure their training is targeted for these lab EM roles.

	<p>Industry partners all approved of the course curriculum and were enthusiastic about the skills training the lab EM course will provide to future students.</p> <p>Eric shared that it does take two years to get a course through the approval process. Eric let Kathy know that she should submit the COR to tech review in August.</p>	
Meeting Adjourned at 4:00 PM	Eleanor thanked the members for their invaluable input and willingness to continue supporting the Citrus biotech program. The next advisory meeting will be held in 12 months.	Follow-up advisory meeting will be held at the end of the spring semester next year.

Minutes prepared & submitted by: Eleanor Tsark