

FINAL

Life Science Workforce Gap Analysis and Recommendations

Prepared for

State of Washington – Cascadia College

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Prepared by



This report is CONFIDENTIAL and is intended only for the sponsors of the study and their designated counterparts.

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EXECUTIVE SUMMARY

In April 2018, Life Science Washington, Cascadia College, and the University of Washington – Bothell, hosted a Life Science Workforce Development Summit at Cascadia College. Following the summit, a decision was made to retain a consulting firm to complete a gap analysis and to provide a report of findings and recommendations by August 31, 2018. The gap analysis will consider what the actual performance is, compared to what the desirable performance is. The analysis addresses several questions posed by the study’s steering group, (Dr. Eric Murray, Cascadia College, Ms. Kelly Snyder, University of Washington-Bothell, and Dr. Leslie Alexandre, Life Science Washington):

What workforce needs, skills and competencies exist amongst the life science industry, particularly biotech/pharm and medical device manufacturing firms.

Are the life science workforce needs within the Bothell-Seattle area being addressed in a successful manner?

Which programs at the higher education institutes require further scale-up or development to meet industry needs.

The Seattle-Bothell area is the focus of this study and is known for its high-density of educational institutions in a relatively “tight” geographic space, and the substantial presence of life science firms (which includes medical device manufacturers). The goal of the study is to establish if the workforce training capacity and curriculum offerings by two-year institutions and a public university are meeting the needs of industry. As with most states, Washington’s four-year public institutions have a more traditional academic focus. Emphasis is placed on students enrolling for four-years and the transfer of students from two year institutions, to complete Bachelor-degreed programs, and/or to continue to higher degreed programs such as professional schools (medical school) or masters and doctorates.

The community colleges in the Seattle-Bothell (east-side crescent) are primarily focused on a transfer pathway to a 4-year institution (University of Washington - Bothell), with a few schools strictly focused on technical or workforce training. Community colleges are supported locally, regionally and by state government. Associates degrees typically enable students to complete their general education requirements before transferring to a four-year institution; while technical degrees at 2-year institutions often prepare students to directly enter the workforce.

The two-year institutions reviewed for this study are: Bellevue Community College, Cascadia College, Edmonds Community College, Everett Community College, Lake Washington Institute of Technology and Shoreline Community College. These institutions have articulation agreements (DTA’s, or direct transfer agreements) which allow coursework completed at the

community college to count as credit towards a four-year program at participating institutions. Direct Transfer Agreements (DTA) are a Washington state-wide policy for transfer credit and are NOT an admissions agreement. Students must meet the minimum admission requirements to transfer their associate degree to complete a bachelor's degree of study. For example, an associate degree in biology from a community college aligns with the first two years of a bachelors-of-science degree in biology from a four-year school.

The University of Washington is a multi-campus, public research institution. The primary or central campus is located in Seattle. University of Washington has a southern presence in Tacoma and a northern presence in Bothell. University of Washington Bothell (UW-Bothell) is the four-year public university which has articulation and Direct Transfer Agreements (DTA's) with the listed community colleges and other institutions throughout the state.

The jobs or positions included in the life science industry encompass a broad spectrum of skills, educational background and training. Many positions require a strong background in STEM – science, technology, engineering and mathematics. However, there are positions that entail transferable proficiencies, business acumen, basic manufacturing abilities, and the capacity to be open to learning new skills. Job categories vary between administrative support, logistics, medical and regulatory affairs, information technology, research, technical operations, research and development, engineering (process, electrical, validation, software, component assembly and testing), project management, environmental health, supply chain, scientist (microbiology, molecular biology, chemistry, CAR-T cell therapy viral vector production, protein and small molecule purification, data analytics, and others. Samples of job titles/positions include manufacturing associate research associate, warehouse specialist, sales representative, clinical applications specialist, service technician, program manager, supply chain planner, software engineer, data analyst, machine learning and artificial intelligence expert, mechanical engineer, product manager, manufacturing and process validation, and more.

Facility Logix met with the Cascadia Steering Committee (Dr. Eric Murray, Cascadia College, Ms. Kelly Snyder, University of Washington-Bothell, and Dr. Leslie Alexandre, Life Science Washington), the designated contacts for this study, sixteen life science companies in the area, and with all institutes of higher education (IHEs) administrators and faculty participating in the study.

The sixteen life science companies include biotech/pharma and medical device firms. The focus of these meetings was to identify areas of strengths and weaknesses in education and training offered in the east-side region. Gaps between what industry requires and what the area institutes of higher education offer in response to hiring and training needs in the industry have been identified.

Gaps exist in three areas:

1. **Awareness:** Lack of awareness among life science companies of available programs and support from the IHEs and other support entities;
2. **Workforce experience:** Recruiting STEM students to create a pipeline of employees due to lack of, or appreciation for, “hands-on” or “real world” experience. The gap is exaggerated by the perceived lack of career advancement which has a matching impact on the retention of existing employees.
3. **Curriculum:** Education and training disconnect between academia and industry. Coursework and programs are not relevant to the needs of the local industry.

The state of Washington (and the east-region IHEs) must consider moving towards a more non-traditional curriculum in order to meet the needs of industry.

The life science industry is an equal employer for a broad spectrum of roles and capabilities (e.g., hands-on transferrable skills and regulatory training and awareness apply whether the company is a therapeutic company, a contract manufacturer, or a medical device company). An understanding and an appreciation for how a company’s product/devices improve the lives of others is essential and must be a core objective of the courses offered.

The following page displays an abridged matrix of definitive course offerings versus what the industry requires. Some curriculum content within existing classes is unclear, and therefore, needs to be re-visited and potentially re-branded by the Institutes of Higher Education (IHEs). The complete charts can be viewed on pages 30, 31 and 32.

October 11, 2018

The IHEs that offer these skills/competencies are noted as "Y" (Yes). Those categories with "N" (No) are indicators of the gaps to be addressed, either individually by the school, or collectively.

BIOLOGICS	Present in Curricula as Indicated in Course Description in College Catalog or Syllabus						
Skill / Competency	Bellevue	Cascadia	Everett	Edmunds	LWIT	Shoreline	UW-B
GENERAL LAB SKILLS							
Single Channel Micropipette	Y	Y	Y	Y	Y	Y	Y
Multichannel Micropipette	?	N	N	N	N	?	N
Buffer Prep	?	N	N	N	Y	Y	?
BIOLOGICS & MEDICAL DEVICES	Present in Curricula as Indicated in Course Description in College Catalog or Syllabus						
Skill / Competency	Bellevue	Cascadia	Everett	Edmunds	LWIT	Shoreline	UW-B
QUALITY & REGULATORY							
MS Word MS Excel	Y	Y	Y	Y	Y	Y	Y
GXP Overview	N	N	N	N	N	N	N
BIOLOGICS	Present in Curricula as Indicated in Course Description in College Catalog or Syllabus						
Skill / Competency	Bellevue	Cascadia	Everett	Edmunds	LWIT	Shoreline	UW-B
CELL CULTURE							
Cell Biology	Y	Y	Y	Y	Y	Y	Y
Cell Culture (animal cells)	?	N	N	N	N	Y	? special Research Projects
Aseptic Technique BSC Use	Y	N	N	N	N	Y	? special Research Projects

Regarding medical device skills, much of the applicable coursework is distributed throughout several disciplines: engineering (mechanical, electrical), precision machining (also found in automotive/aerospace, machining, and so forth). The companies interviewed prefer certified or credentialed employees in machining, soldering, 3-D design, blueprint reading, and familiarity with computer numerically controlled (CNC) equipment. Surprising was the fact that the few

medical device companies with whom we spoke, primarily need employees with regulatory experience. The older firms recruit, “unapologetically,” from neighboring aerospace companies. The larger, more established firms have the capacity to do hands-on training within their facilities, more so than the smaller firms.

In our experience, a potential indirect effect of a general lack of workforce training in the quality and, regulatory, is that non-profit research institutes and research faculty from the University of Washington and other institutes, may make discoveries that have commercialization potential that may not be realized without real awareness of the path from bench to bedside and the importance of building quality into the product development process in order to satisfy regulatory requirements.

Taking into consideration the state’s current educational and business climate, findings from interviews with industry and IHEs, and follow-up discussions with both industry leaders and subject matter experts, Facility Logix developed the following recommendations for the consortium to consider and to implement.

A “short-term time line” is defined as immediate action steps, such as within three to eight (3-8) months; a “mid-term time line” is approximately twelve to thirty-six (12-36) months; and a “long term time line” implies anything over three (3) years.

The **RECOMMENDATIONS** listed address the following disparities or **gaps**:

1. **AWARENESS:** Industry lack of awareness among life science industry companies of available programs and support;
2. **WORKFORCE EXPERIENCE:** Recruiting STEM students to create a pipeline of employees due to lack of, or appreciation for, “hands-on” or “real world” experience. This gap is exaggerated by the perceived lack of career advancement which has a corresponding impact on the retention of existing employees.
3. **CURRICULUM:** Education and training disconnect between academia and industry. Coursework and programs are not relevant to the needs of the local industry.

RECOMMENDATIONS

Recommendation ONE: Re-convene the participants from the April 2018 Life Science Academic & Industry Workforce Summit

Actions

- Discuss the findings and recommendations of the workforce gap analysis.
- Prioritize and formulate an action plan according to the recommendations.
- Obtain commitments from both industry and academia to help guide the process.
- Identify an industry champion and an academic champion, who will serve as points of contact and spokespersons, and will promote the agreed to agenda internally and externally.
- Convene the summit participants quarterly – shepherded by the industry and academic “champions” to encourage progress and to sustain momentum.
- Develop and potentially provide some financial support to a primary contact or entity, perhaps from the IHESs or another similar group, to serve as the lead repository of information and action items in a project management capacity. The schools may wish to consider forming a Response to Industry Task Force made of representatives from the various school, who interact directly with industry.

Suggested Timeline & Budget

- Immediate – Short Term: Commence October 2018.
- Minimal budget (utilize existing partners’ meeting space, catering, AV equipment, time and travel).
- May require additional “manpower” of staff to assist with implementation, planning, communications.

Desired Outcome

Reaffirm interest and commitment of ALL parties.
Identify select group of “champions” to speak with one voice.
Inclusive of new participants.
Identification of new opportunities for partnering and collaborating.
Establish vision and priorities that help form alliances.
Distribute responsibilities among participants.

Begin formation of (or enhancements to existing) at each IHE and consider an even broader group to advise these industry advisory groups.

Measuring Success

- Development of consistent message and mission.
- Industry and academic champions speak with one voice on efforts.
- Recurring meetings and discussions with action items that are tracked and implemented.
- Recognition of the group's efforts and goals amongst peers and community.
- Increased interest from possible contributors/investors, and various grant opportunities to support efforts. Funding opportunities may be found with Department of Education, Office of Educational Education, Community Schools Infrastructure Funding, National Education Association, National Science Foundation's Office of International Science & Engineering, and others.

Recommendation TWO: Establish working groups or committees to redesign and/or update curricula with ALL IHEs participating.

*With the exception of Shoreline Community College, Bellevue College and Lake Washington Institute of Technology, **colleges in the Bothell region do not offer a curriculum that truly addresses the needs of the Life Science and Medical Device industries.***

It will be critical to get a true gauge of faculty support in providing instruction within the context of life science as a career path for their students. If so, there are direct financial implication for staffing and infrastructure support from IHEs and the decision is made to move forward, there will be financial implications for the hiring of instructors, ramping up equipment and facilities.

Actions

- All of the participating IHEs (or as many that are interested and able), need to develop and to offer identical or a similar Survey of Life Science course designed for all students including non-science students that meets DTA (Direct Transfer Agreements) requirements.
- Convene IHEs to discuss curriculum and other recommendations of this report.
- Invite industry representatives, at the appropriate time, to discuss specific course criteria.
- Create a working group made of IHEs faculty and industry representatives. Task this group with designing curriculum and presenting to appropriate IHEs administrators.
- Courses do not need to have a laboratory component, therefore traditional classroom space could be utilized, and the courses should be transferable (DTA).
- Consider the following characteristics in redesigning/refreshing curriculum:
 - **Survey of Life Science** – Basic content that includes a broad overview of Life Science sectors with an emphasis on the local industry. The content should be friendly to beginning science students and even non-science students. The course could include a business element that covers start-up to mature business models, finances, project management. Additional topics may include introduction to quality and regulatory affairs. Human Resource representatives from various life science companies may present employment opportunities and list the required skills and competencies.

Suggested Timeline & Budget

- *Short-term (immediate) - Ongoing.*
- *Implementation methodical over 2019-2021.*
- Minimal costs to IHEs.

Desired Outcome

Faculty and administrators engaging with industry.
Collaboration and collegiality firmly established amongst IHEs and industry partners.
Increased enrollment.
Positive feedback from both industry and student/workers.
Community building.

Measures of Success

- *Proposed courses must be reviewed and enthusiastically approved by IHEs' industry advisory boards.*
- *Sets pattern for ongoing dialog and curriculum/industry review participation.*
- *Recognition of quality of workforce from industry.*
- *Recognition of quality of programs from workforce.*
- *Referrals and return enrollment for additional programs.*

Recommendation THREE: Develop, update or refresh curriculum at all locations, as Life Science companies require very distinct skill sets when it comes to R&D, Process Development and Manufacturing.

A “one size fits all” curriculum is not realistic or practical. Ideally industry specific curricula for Biological Molecule Manufacturing, Cell Based Therapies, Molecular Diagnostics and Medical Devices (e.g. imaging systems based on different technologies such as MRI vs ultrasound) would be taught as a dedicated specialty at a specific institution. At the October 2018 Summit, the topic of which institution will teach what should be only introduced, and a separate event led by the IHESs be hosted at the earliest possible date. See Recommendations FOUR (4) and FIVE (5).

Actions

- All IHEs - Applications of Life Science (which includes medical devices) should be incorporated into the content of Biology, Biochemistry and Chemistry courses and clearly identified as a Life Science application. When possible, as part of the mention of Life Science, references to local biotechnology and medical device companies and their products should also be included. For example, when teaching an Anatomy and Physiology course and the cardiovascular system is covered, EKOS’ BTG blood clot ultrasound dissolution instrument could be mentioned and explained as could Philips’ or Sonosites’ ultrasound diagnostic tools. In Biology classes, Nanostring’s DNA diagnostic platform for cancer could be mentioned.
- Offering life science specific curriculum (leading to an AS, AAS, BS or BAS degree) may be most effective if it is delivered by 2-3 lead institutions with the other institutions serving as feeders for students interested in a life science career but who do not want to continue to professional school or grad school. Given the high concentration of education institutions, the high cost of equipment, supplies, facilities and a strong need for faculty with industry expertise, it will be necessary to pool resources to achieve the common goal of meeting the needs of the life science industry. *See Recommendations FOUR (4) and FIVE (5).*
- Improve marketing and awareness efforts as they are instrumental to boosting enrollment.
 - ALL institutions in the Bothell cluster should partner and share resources to market Life Science degrees and opportunities in the Life Science and Medical Device Industry. STEM student enrollment in the Life Sciences is not sufficient to meet industry demand and, for some institutions is declining.
 - Improve websites and print materials across all schools by adding an obvious or easily identifiable “tab” for industry to select. Information needs to be geared

- towards industry needs: opportunities for partnerships and providing instruction, training programs for new and existing employees.
- Have catalogs with course descriptions available online for both prospective students and industry to review. Include a sample syllabus.
 - Identify specific areas of career opportunities and advancement within the Life Sciences.
- Continue to share the advisory board roles among IHEs and include economic development leaders so they are aware of the initiative and may be in a position to identify financial and political efforts to address needs. For specific curricula such as cell based therapies or specific types of medical device manufacturing, separate advisory boards may be created which are composed of individuals who are more familiar with the actual scope of work (e.g. lab managers, research and manufacturing associates).
 - Because of the shortage of qualified employees, companies are hiring individuals with few or no skills and little or no relevant education. Eventually this practice will have a negative impact on both the company and the employee as they will “hit the wall” with respect to advancement both in terms of salary and promotions and the ability to adjust to new technologies.
 - Academic institutions should consider offering classes to incumbent workers at times convenient to the worker (e.g. evenings, weekends, online). Employers should encourage this by providing tuition assistance.
 - Across all academic institutions some basic lab skills common to all biology and chemistry labs, such as volumetric measurements, pipetting, micro-pipetting, and weighing, should be well documented as competencies agreed upon by all institutions and the industry advisory board.
 - Document competencies as stackable credentials which can be included on student resumes and which, through the work of the advisory board, will have value to the industry.
 - Similarly, in the medical device field, competencies such as using a voltmeter, soldering, and the ability to read circuit diagrams could be credentialed.

Suggested Timeline & Budget

- *Short term (immediate) to long term (ongoing)*
- *Substantial timeline*
- *Costs will be based on faculty recruitment packages at various institutions, equipment and materials, infrastructure improvement.*
 - *Will require legislative funding, federal grants, foundation grants, public-private donations.*

Desired Outcome

Hiring of “featured” faculty members at several institutions.

Develop and approve budgetary amounts for:

Necessary infrastructure improvements (air handling, electrical upgrades);

Equipment additions, based on course – multiple units of same equipment for instructional purposes, and possible service contracts (see Recommendation SIX);

Faculty compensation package(s).

Measure of Success

- Funding to create, maintain, and to support longer term/big-vision activities identified by the IHEs for a specialized training facility, improved or new facility at a campus(es) to house specialty programs and equipment.

Recommendation FOUR: IHEs agree to create and to upgrade curricula that are industry relevant. Shoreline, Lake Washington and Bellevue take lead to upgrade their existing curricula with an emphasis on regulatory compliance.

Actions

- Shoreline creates a Biotechnology focused curriculum in the areas of upstream (cell culture and bioreactors) and downstream (protein purification processes).
- Bellevue creates a Biotechnology focused curriculum emphasizing nucleic acid (DNA and RNA methodology) and assay applications.
- Lake Washington creates a medical device focused curriculum, focused on manufacturing and quality control of device components.

Suggested Timeline and Budget

- Initiate mid October 2018 - completed March 2019.
- Budget “release time” for faculty to collaborate with one another and industry partners.

Desired Outcome

Revised curricula prepared for submission to Curricula Approval Committees by the end of the spring 2019 semester.

Measure of Success

- Curricula is endorsed, in writing, by industry, submitted and approved by the respective educational institutions.

Recommendation FIVE: IHEs which do not currently have an existing Biotechnology or Medical Device curriculum agree to implement one or the other.

Actions

- University of Washington Bothell and Cascadia have the potential to develop both Life Science and Medical Device programs if careful planning is observed with the construction of the new building.
- IHEs agreeing to implement a Biotechnology or Medical Device curricula implement the industry approved curricula of Shoreline, Bellevue and Lake Washington and DTAs are created between all participating institutions.
- Faculty responsible for implementation of “new” Biotechnology or Medical Device curricula receive instruction / training at the relevant institution (Shoreline, Bellevue or Lake Washington).

Suggested Timeline and Budget

- Initiate June 2019 – December 2019 or May 2020. Ongoing to long term effort.
- Budget “release time” for faculty to provide and obtain instruction.
- Cost of materials for instruction.

Desired Outcome

IHEs not currently offering a program in Biotechnology or Medical Devices are willing and able to implement an industry relevant curriculum.
All institutions collaborate to maintain standards.

Measure of Success

- Curricula is implemented, significantly increasing the pipeline of well-prepared workers able to meet industry employment needs.

Recommendation SIX: Establish a Life Science Training Center to address the training and skills needs of industry, specifically focusing on Biotechnology and Medical Device manufacturing and biotech/pharma manufacturing.

Actions

- Tour and meet with existing training centers in the state of Washington, such as the Washington Aerospace Training and Research Center (WATR).
 - Edmonds Community College manages WATR and may be a good resource, point of reference, and/or location for establishing a training center for medical device manufacturing, bio/pharma regulations, et cetera. Explore potential overlap of instruction, materials and equipment for training purposes.
- Tour and meet with administrators and faculty at the Earl E. Bakken Medical Devices Center in Minnesota, and Montgomery College, Maryland to learn about best practices and lessons learned.
- Plan, design, and construct a special-use facility potentially located adjacent to both University of Washington-Bothell and Cascadia Community College. This program could be co-located with the programmatic components from prior recommendations.
 - Structure will support the STEM and Engineering programs at both institutions – complementing life science and medical device manufacturing.
 - Facility is centrally located (figuratively and geographically) for industry partners and their employees.
 - Facility to be a showcase for industry partners and training center.

Suggested Timeline & Budget

- *Begin discussions in 2019 once vision for consortium is set.*
- *Planning activities to identify highest and best uses of facility will be ongoing for one to two years.*
- *Identify options for funding and operating (private public partnership, private donations, etc.), will take one to two years, or until funding is secured.*
- *Substantial timeline and cost. May require legislative funding, grants, donations.*

Desired Outcome

IHEs, industry groups, community and political stakeholders engaged with industry.

Collaboration and collegiality across industries and communities.

Purpose-built space that is specific and flexible enough to meet workforce needs.

Measures of Success

- Re-purpose of existing facility or space at University of Washington – Bothell and Cascadia College campuses; or, identify new site/repurpose existing building at another location.
- Funding secured, and design team retained.

Recommendation SEVEN: Create a Life Science-aware community, by enhancing marketing outreach for the life science and medical device industry in Bothell-Seattle area.

Actions

- Identify target audience which should include the general public, state and local elected officials, and the academic community (to include high schools and career counselors in both high school and higher education fields).
- Establish a partnership with Career Connected Learning Program.
 - Establish additional industry and IHE linkages and support by further facilitating job shadowing, guest speakers, internship opportunities, registered apprenticeships.
- Develop informational presentations, ads, events and announcements that address:
 - Why should people care about the biotech industry?
 - Why is biotech important (diverse industry, good jobs, contributes to well-being, environmentally friendly).
 - Define biotech, medical device, health care so people understand diversity of industry.
 - Emphasize importance of the industry contributing to diversifying and expanding Washington State's economy.
 - Inform community stakeholders about jobs and careers that are available at ALL educational levels.
- Target career counselors, informational booths at science fairs, etc.
- Have industry champion(s) partner with IHEs.
- Develop a "road map" marketing piece that outlines IHEs' educational options.
- Identify courses that are career/workforce/skills-related.
- Identify courses/programs focused on transfers to 4-year .
- Identify high priority messaging pathways, pooling resources among schools to create informational brochures, ads (on buses), radio ads, etc.
- Create identifiable and specific page on schools' websites for industry and community.
- One-stop shop to gather information on industry specific programs, training, skills, etc. necessary to enter into the medical device field or the biotech field.

Suggested Timeline & Budget

- Commence ASAP and continue to work with high schools and industry to develop relevant materials and programs.
- Ensure energy, support and enthusiasm for current discussions with Career Connect Washington regarding partnering, support, and expansion of mutually beneficial efforts (marketing materials, resources) continues.
 - o Potentially share findings of this report to provide context and additional conversations.
- Budget will depend upon activities selected and marketing materials developed.
- May potentially defray costs by pooling resources between academic institutions and industry, fund raising, grants.

Desired Outcome

Life Science Washington, IHEs and Industry Champions promote efforts.
Academic Institutions lead efforts on partnering with high schools, counselors and market curriculum as appropriate.
Industry representatives lead efforts on educating community on medical devices, biotech, life science, pharma, etc.
Strong partnership with Career Connect Washington and other entities that support STEM-based career connected learning.

Measures of Success

- A consistent message integrated into all marketing channels and among all partners and participants.
- Increased interest from possible contributors/investor locally, statewide and nationally.
- Joint meetings/discussions with Career Connect Washington and (effective) entities that support career connected learning.

The graphic below summarizes our suggested roadmap to address the gaps identified in this study:



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BACKGROUND

Cascadia College and Life Science Washington hosted a biotech summit on April 13, 2018. The purpose of the summit was to facilitate discussion among six community colleges and the University of Washington-Bothell, and to introduce their relevant programs and curriculum to life science industry partners within their service areas. Summit organizers encouraged an active discussion between industry and the presenting schools on workforce needs. The Summit served to generate awareness among life science employers (industry) for existing programs and to highlight potential gaps between existing programs and industry needs.

As a result of the summit, the Institutes of Higher Education (IHEs) had a subsequent discussion to discuss how best to work together to facilitate a growing and sustainable pipeline of qualified workers. The IHEs recognize that the state is at a tipping point regarding a critical life science workforce shortage.

Numerous industry representatives at the April summit expressed that they were experiencing difficulty in hiring and retaining qualified workers. The industry's job market is flooded with unfilled positions, wages are inflated, and turnover rates are high. Although Washington has the potential to foster a fairly diverse economy, the consensus is that there has been a greater emphasis (political and financial) on the needs of the aerospace (i.e. Boeing) and software (i.e. Microsoft) companies in the state, resulting in a one-dimensional economy at risk of being a boon or bust.

Washington has a history of innovation in the Life Sciences and Medical Device sectors providing an opportunity to expand and to diversify the local economy beyond the dominance of aerospace and information technology. A diversified economy serves to insulate a region against possible future economic downturns (especially in the aerospace industry) and provide additional job opportunities. The Life Science industry has proven to be fairly recession proof, performing as a strong economic engine for its community and stakeholders; however, ***Washington's life science industry and IHEs recognize that there is the risk of life science companies relocating outside of the region or out of the state; several companies have already opened second locations in the San Francisco Bay Area, San Diego or Boston to secure certain types of talent in limited supply locally.*** The TEconomy 2017 study for the "Governor's Life Science and Global Health Advisory Council" cites that the life science industry in Washington state faces a:

"Future at Risk" with recent stagnations in terms of job gains, patent activity, and industrial R&D relative to the U.S. and peer states. While industry leaders cite challenges such as affordability of office and wet lab space, as well as the availability of investment capital, the most common recurring theme and concern raised by Washington's C-suite executives is the availability of skilled talent, both now and into the future.

The Life Science (biotech/pharma, medical device) industry has been shown to be a job multiplier – for every Life Science job, roughly three additional non-science jobs are typically

created (some regional differences apply). If the available workforce is not able to keep pace with industry needs, the potential for losing Life Science firms to another region or state grows.

As some of the region's larger Life Science firms began to express concern in their recruitment efforts, the participating IHEs, with support from Life Science Washington, recognized an opportunity for the region and the state to strengthen its national (if not global) foothold and reputation in the Life Sciences. By being responsive to the workforce needs of industry partners and collaborating with one another, these stakeholders have an opportunity to take the leadership role to develop and to sustain a 21st century Life Science workforce.

GAP ANALYSIS OBJECTIVES

The study objectives, as stated RFP 201805 18 BGA, page 3, section 1.2 are:

1. Meet with the seven regional higher education institutions to fully understand current program offerings in biotechnology, medical device and life science industry.
2. Meet with industry partners identified by Life Science Washington and the seven institutions of higher education.
3. Meet with applicable/regional workforce development councils and/or agencies to determine their role in fulfilling industry workforce needs.
4. With the steering committee, determine the exact needs/design for a gap analysis report.
5. Draft the report and receive feedback from the steering committee before final submission (August 31, 2018).
6. Convey to a larger group as determined by the steering committee the results from the analysis. (Meeting set for September 18, 2018).

The above objectives have been met and the findings with recommendations are included in this gap analysis.

METHODOLOGY

A project kick-off call was held July 7, 2018 with the study's steering committee: Dr. Eric Murray, President of Cascadia College; Ms. Kelly Snyder, University of Washington-Bothell; and Dr. Leslie Alexandre, CEO of Life Science Washington. Project background and objectives were reviewed and a list of contacts to be interviewed was provided. **For the purposes of the report, the term "life science" includes biotechnology, pharmaceutical and medical device companies.**

Facility Logix conducted a site visit to the Seattle-Bothell area in late July 2018. Dr. Collins Jones, Montgomery College and Subject Matter Expert, Pat Larrabee, President of Facility Logix and Nancy Conwell, Senior Consultant, attended meetings and tours of the consortium community college members, University of Washington-Bothell, and both life science and medical device firms. A project scope discussion was held with Dr. Eric Murray and Ms. Kelly Snyder; and, a de-brief of the site visit was done with Dr. Leslie Alexandre and Ms. Meg O'Connor of Life Science Washington. The work plans included follow-up interviews with life science industry representatives, desk research, outreach to Best Practice institutions in other parts of the country, and reviews of reports and documentation provided by the IHEs and Life Science Washington. The steering committee was updated regularly throughout the engagement.

Due to the fast-track nature of this project and as directed by the steering committee, primary considerations in this gap analysis were:

- The presence of supporting institutions of higher learning;
- Quality and content of curriculum focused on the life science industry;
- The expressed needs of area life science companies;
- The presence of a **sector-trained workforce**; and,
- Engaged stakeholders willing to sustain efforts.

This workforce gap analysis is to be viewed as a “road map” for the creation and implementation of realistic and measurable strategic efforts to help guide IHEs and industry in partnering to produce and prepare students, and to elevate the skills of the existing workforce.

CONCLUSIONS

A significant gap exists between what the Seattle-Bothell life science industry requires and what the institutes of higher education (IHEs) in the region offer to life science students. This is not an unusual occurrence across the nation. The Seattle-Bothell IHEs are to be commended for sensing a disconnect and the desire to implement changes to reduce or to eliminate the gaps.

As in previous studies conducted for the state, “life science firms are ‘disconnected’ from the states post-secondary institutions and students, as well as its existing education and workforce training programs” (*Assessing Washington’s Life Science and Global Health Workforce Dynamics...*, p. IV). The lack of industry awareness, the lack of community awareness of the life sciences as a career option, the disconnect between state education and workforce programs to support the life science industry, and the limited opportunities for programs such as internships to connect industry with the IHEs, present an opportunity for the IHEs to take a leadership role to overcome these challenges. Fortunately, Washington state is more nimble than other higher education institutions in other states. The curriculum development and approval process are well designed, responsive and streamlined to meet needs. The IHEs must seize the opportunity lead efforts in closing this gap between industry and academics. With this context, the steering committee identified questions to be answered with this analysis:

1. *What workforce needs, skills and competencies exist amongst the life science industry, particularly biotech/pharm and medical device companies;*
2. *Are the life science workforce needs within the Bothell-Seattle area being addressed in a successful manner?*
3. *Which programs at the higher education institutes require further scale-up or development to meet industry needs; and,*

Through the industry and IHE interviews and research, the following gaps do exist:

1. **Awareness Gap:** Industry lack of awareness of available programs and support;
2. **Workforce Experience Gap:** Recruiting STEM students to create a pipeline of employees due to lack of, or appreciation for, “hands-on” or “real world” experience. This gap is exaggerated by the perceived lack of career advancement which has a corresponding impact on the retention of existing employees.
3. **Curriculum Gap:** Education and training disconnect between academia and industry. Coursework and programs are not relevant to the needs of the local industry.

Both the state of Washington and the regional IHEs in this study, need to consider moving towards a more non-traditional curriculum in order to the meet the needs of its growing life science industry. Also, the state and participating IHEs must pay more attention to and develop stronger business relationships with this industry. The IHEs do not have time to wait and must therefore address those items in their control which include developing stronger industry

relations (and vice versa), informing and including their industry partners in their efforts to help educate and to sustain their workforce.

THE GAPS: ACADEMIA COURSEWORK VS INDUSTRY NEEDS

Dr. Collins Jones, Montgomery College and subject matter expert, analyzed the coursework offered by the IHEs and created this matrix that identifies some of the skills and competencies required by the life science industry. The IHEs that offer these programs are noted as Y or N (Yes or No). Categories with “N” are indicators of gaps to be addressed.

BIOLOGICS	Present in Curricula as Indicated in Course Description in College Catalog or Syllabus						
Skill / Competency	Bellevue	Cascadia	Everett	Edmunds	LWIT	Shoreline	UW -B
GENERAL LAB SKILLS							
Single Channel Micropipette	Y	Y	Y	Y	Y	Y	Y
Multichannel Micropipette	?	N	N	N	N	?	N
Buffer Prep	?	N	N	N	Y	Y	?
pH Meter	Y	N	N	N	Y	Y	?
Conductivity Meter	?	N	N	N	Y	?	?
PAGE Gels	Y	?	?	?	?	Y	?
Agarose Gels	Y	Y	Y	Y	Y	Y	Y
DNA / RNA Isolation	Y	?	?	?	Y	Y	?
DNA Quantitation	Y	?	?	?	?	Y	?
PCR	Y	N	N	N	N	Y	?
qPCR	N	N	N	N	N	?	?
NGS	N	N	N	N	N	N	N
Protein Determination	Y	N	N	N	N	Y	?
Western Blot	?	N	N	N	?	Y	?
ELISA	?	N	N	N	N	?	?

In the general “Biologics” category, the only hands-on general lab skills offered at all of the IHEs are single-channel micro-pipetting and agarose gels. The question marks denote skill areas that we were unable to determine whether they were offered based on available course and program information.

BIOLOGICS & MEDICAL DEVICES	Present in Curricula as Indicated in Course Description in College Catalog or Syllabus						
Skill / Competency	Bellevue	Cascadia	Everett	Edmunds	LWIT	Shoreline	UW-B
QUALITY & REGULATORY							
MS Word MS Excel	Y	Y	Y	Y	Y	Y	Y
Overview	N	N	N	N	N	N	N
Knowledge of Quality Systems	N	N	N	N	N	N	N
GDP	N	N	N	N	N	N	N
Electronic Notebook	N	N	N	N	N	N	N
SOPs	N	N	N	N	N	N	N
Batch Records	N	N	N	N	N	N	N
Document Review / Audits	N	N	N	N	N	N	N

GxP - Good Practice, x= FDA compliance for clinical, manufacturing, pharma, etc.

GLP – Good Laboratory Practice

GCP – Good Clinical Practice

cGMP – Current Good Manufacturing Practice

GDP = Good Documentation Practices (according to FDA or ICH)

For Biologics and Medical Device company requirements, the only common skill offered by all of the IHEs is Microsoft Word and Excel. The feedback we received from the majority of companies was that knowledge of the regulatory environment and quality systems was a big workforce issue and that none of the IHEs were addressing this gap presently.

October 11, 2018

BIOLOGICS	Present in Curricula as Indicated in Course Description in College Catalog or Syllabus						
Skill / Competency	Bellevue	Cascadia	Everett	Edmunds	LWIT	Shoreline	UW-B
CELL CULTURE							
Cell Biology	Y	Y	Y	Y	Y	Y	Y
Cell Culture (animal cells)	?	N	N	N	N	Y	? special Research Projects
Aseptic Technique BSC Use	Y	N	N	N	N	Y	? special Research Projects
Media Prep	?	N	N	N	N	Y	N
Cell Banking / Cryopreservation	?	N	N	N	N	Y	
Cell Counting Manual or automated	?	N	N	N	N	Y	N
Cell Authentication	N	N	N	N	N	?	N
Bioreactor (single use)	N	N	N	N	N	?	N
Cell Based Assays	N	N	N	N	N	N	N
FACS	N	N	N	N	N	Y	N

In the area of cell culture for biologic therapeutics, the only skillset/course available across all of the IHEs is Cell Biology. This makes sense as Cell Biology is part of traditional curricula pointing toward basic research and the attainment of 4-year degrees. With a few exceptions, the hands-on skillsets listed above are mainly absent in current course curricula. Such skills are “table stakes” if one wishes to work at companies in the Contract Development and Manufacturing Organization (CDMO) space such as at AGC Biologics and or in the CAR-T space such as at Juno Therapeutics.

Medical device manufacturing skills has applicable coursework distributed throughout several disciplines: engineering (mechanical, electrical), precision machining (also found in

automotive/aerospace, and machining. The companies interviewed prefer certified or credentialed employees in machining, soldering, 3-D design, blueprint reading, and familiarity with computer numerically controlled (CNC) equipment. The few medical device companies with whom we spoke, primarily need employees with regulatory experience.

All three matrices illustrate the curriculum/skills **GAPS** that exist between industry requirements and academic offerings. Hands-on skills and techniques must be incorporated and focused on course and lab work; otherwise, the content lacks meaning and applicability to the “real world.” Students are put at a competitive skills and workforce disadvantage due to lack of exposure and content for these “basic” life science skills. *An email exchange between a student and their professor regarding employment in the life sciences, located in Appendix E, is an excellent example of this disconnect.*

OPPORTUNITIES FOR DIRECT IMPACT TO INDUSTRY

A recommendation is that the six participating community colleges, the University of Washington-Bothell, and industry, re-design the curriculum to be broader to provide “real world” experience to students. The redesign will facilitate students’ understanding and appreciation for working within regulatory environments, the extreme importance of following protocols and procedures, appreciation for regulations, and build confidence in working within collaborative groups and individually.

Medical Device and Life Science companies require very distinct skill sets when it comes to research and development (R&D), process development (PD), and manufacturing. A robust co-op program could help address the companies’ desire for curricula that provide real-world experience, along with intensive course work. A one-size fits-all curriculum will not be practical. Ideally industry specific curricula for Biological Molecule manufacturing, Cell Based Therapies, Molecular Diagnostics and Medical Devices (e.g. imaging systems based on different technologies, e.g., MRI vs ultrasound) would be taught as dedicated specialties at a specific institution. We recommend the creation of several new courses which could be offered at all interested schools:

These courses would not have a laboratory component and should be transferable (DTA):

- **Survey of Life Science** - Content would be very basic and include a broad overview of Life Science sectors with an emphasis on the local industry. The content would be descriptive and *very light on hardcore science* – it should be friendly to beginning science students perhaps even non-science students. Specific companies and their technologies in the region would be mentioned.

The course could include a business element – overview of a company from start-up to maturation, finances, project management, HR, facilities and would discuss various job functions / employment opportunities and list the required skills / competencies. The survey would also include an introduction to quality and regulatory affairs – the basic

elements of GXP and ISO. If the course stimulated an interest in Life Science, interested students can be directed toward a suitable institution for Life Science specific courses.

- **Coding / programming courses with a life science / medical device emphasis** – this may start with a survey course describing various languages and the use / application of each in life science. Specific courses in each language could be offered. These offerings could be face to face, online or hybrid. Taking several languages might lead to a certificate in coding for Life Science. Several industry interviews, and various industry articles stipulate that preferred programming language for data analysis (especially in the field of bioinformatics) include: Python C++, Perl, Java, and Linux. Area life science firms should be polled to determine the most popular.
- **Quality and Regulatory** - This could be built as a certificate or degree program. An alternative format could be to break the courses / topics up into multi-week short courses. An overview course could be offered at multiple institutions. This course series could potentially be offered online on demand. A series of courses could be constructed to specifically address different requirements. Examples of courses could include Quality Management and TQM Tools, ISO vs cGMP, cGMP for biological therapeutics, cGMP for cell based therapeutics, cGMP for medical devices. There could also be some overlap with other industries such as the aerospace industry.

Everett might be the strategic distribution agent, but different specialized courses could be created by different colleges according to their specialties.

- **Quality management:** a generic quality course designed to be applicable across industries pharma, device, aerospace, software;
- **Quality Management tools:** an overview of proper documentation and reporting including document and data review process mapping, lean Six Sigma, FMEA, Pareto charts, RCA, 5S; and,
- **Quality Management** for supervisors /managers
- **ISO (9001)** standards are required by medical device manufacturing companies. These firms use regulatory compliance software to maintain compliance with FDA regulations. (www.fda.gov/medicaldeviceregulationsandguidance , September 10, 2018).
- **Six Sigma** – with an emphasis on applicability to life science/biotech/medical devices (best practices, lean manufacturing and reducing probability of errors, compliance).
- **FDA Regulatory** – Therapeutics, Diagnostics and Medical Devices, GXP with emphasis on GLP and cGMP. Including both life science molecular therapeutics and diagnostics and device diagnostics and therapeutics.
- **CLIA Regulations** for Diagnostics and Medical Lab Tech.

- **Capstone Course** where students who are earning a certificate or degree actually help a local company. All the quality courses should include examples for the students to work through and should include real life examples supplied by the local industry. Retirees from local industries can create quality scenarios for some or all of these courses. Eventually this particular curriculum might be offered nationally.
- **Statistics and Software Platforms** - Statistics courses should include content specific to life science and medical devices, using life science/device specific examples in both research and testing (e.g. Department of Energy principles for the design of experiments), analyzing genetic information or toxicology data and statistical methods related to quality measurements.

A good example regarding content development is occurring at UW-Bothell where a cross-disciplinary faculty team is considering the development of curriculum in data analytics – covering health and bioinformatics.

- Statistic packages emphasizing life sciences include Minitab, “R” and / or SPSS. We suggest surveying employers to determine their preference.
- Materials Lab (MATLAB)
- CAD (e.g. AutoCAD and Solidworks), GD&T emphasizing biotechnology and medical devices

DEFINING THE INDUSTRY

Life science, bioscience and **biotechnology** are broadly used terms. Consistency in defining and usage of these terms is critical for educating and informing the public, industry stakeholders, and community leaders.

Facility Logix utilizes the federal government's North American Industry Classification System (NAICS). Initially the Standard Industrial Classification (SIC) was developed in the 1930's. In the 1990's the system was updated to NAICS, and is a classification system shared amongst Mexico, Canada and the United States.

For the purposes of this engagement the following terms are used and are defined:

- **Life science** is a term used to define, and to be *inclusive* of all firms involved in ***biotechnology research and development, pharmaceutical and medicine manufacturing, and medical device manufacturing.***

A listing of applicable NAIC life science codes are located under Appendix B.

NATIONAL HIGHLIGHTS OF LIFE SCIENCE INDUSTRY

Life science is a global, transformative and technologically complex industry. Manufacturing of chemical and biological drugs and pharmaceuticals, and medical devices/equipment are major contributors to the country's economy. The life science industry is research intensive, requires highly skilled workers, and provides above average annual earnings. Available jobs in the industry range from research and development, testing, quality assurance and regulatory, assembly, manufacturing, logistics, sales and marketing, project management, customer support and more. The United States is an international leader in the life sciences; however, as the industry continues its breakneck speed of technological advances and industrialization, competition for workforce is a reality as people are recruited to fill positions globally. The United States is experiencing a tightening of this labor force and challenges in recruiting workers globally.

The Information Technology and Innovation Foundation published a report focused on the importance of technology and the life sciences. The report was released in March 2018 with the following data:

- In 2013, U.S. life science companies performed \$96.5 billion in research and development; of this \$74.5 billion was self-funded;
- 22% of domestic pharmaceutical employees work in research and development;
- In 2015, the combined pharma and medical-instrument sub-sectors' output was \$675 billion, about 4% of the U.S.'s total gross domestic product.

- Biotechnology Innovation Organization reported that there are 1.66 million people employed in U.S. bioscience firms. BIO also reports that the “broader employment impact of the 1.66 million U.S. bioscience jobs is an additional 7.53 million jobs throughout the rest of the economy” (www.bio.org/press-release/national-bioscience-report, September 15, 2018).

The United States is one of the largest medical device markets in the world. The U.S. Department of Commerce states that U.S. exports of medical devices exceeded \$41 billion in 2017. This life science subsector employs about 2 million people (directly and indirectly). Eighty percent (80%) of medical device firms consist of fewer than 50 employees. According to Battelle’s Technology Partnership and the Advanced Medical Technology Association’s 2012 medical device technology industry report, the national job multiplier is 1.79.

The medical device industry works with microelectronics, telecommunications, instrumentation, biotechnology, and software development. With so many medical device companies in the Seattle-Bothell area, it is surprising that the region does not have specific training programs or centers like some of the top medical device manufacturing states: Florida (training and simulation centers), Wisconsin, Minnesota, Indiana, Pennsylvania (medical device accelerator program), Arizona, Tennessee (training center focused on producing skilled machinists), California, and New York (info.siteseelectiongroup.com, September 2, 2018). The University of Michigan has a Medical Device Sandbox that promotes interdisciplinary learning for medical student and students from other disciplines to explore design, development, use, regulations, and commercialization of medical devices.

Numerous 2016-2018 life science industry reports authored by commercial real estate firms, think-tanks, associations, and universities note that the Boston and San Francisco markets have retained their “gold standard” leadership in life science cluster rankings. [JLL’s 2018 Life Sciences Cluster Ranking](#) (a report that considers the industry from a real estate perspective), states that Greater Boston is number one. The Seattle Metro area is ranked number seven. This report and others all stipulate that ***the biggest concern for the industry is finding and retaining the skilled workforce necessary to keep the industry strong and competitive.***

According to the Bureau of Labor Statistics, between 2016 and 2020, employment in *life, physical, and social sciences* is projected to increase by 10%; and, the biotechnology research and development industry category is projected to grow 19%. (BLS data updated April 13, 2018). The nature of federal reporting looks back on data; however, with the historical growth of the life science and medical device sector, it is reasonable to project sustained growth for years ahead, particularly with aging demographics.

“The state is not alone in this life science and global health workforce challenge. In a recent survey of pharmaceutical executives by Pricewaterhouse Coopers (PwC), talent tops the list of innovation challenges, ahead of other critical areas such as speed to market of innovative ideas,

establishing an innovative culture, and finding the right partners for collaboration. Nearly three in five biopharmaceutical executives report that “finding and retaining the best talent to make innovation happen” is a challenge for their company, higher than the average for respondents across all industries” (TEconomy *Life Science and Global Health...* report, p. 1).

WASHINGTON STATE’S LIFE SCIENCE INDUSTRY

Washington has a history of innovation exemplified by its life science industry base. The intersection of Washington’s information technology/software development and the life sciences contributed to the creation of the first portable heart defibrillator, ultrasound kidney dialysis machine, ultrasound technology and other devices. Treatments for health issues were developed and include the Scribner shunt for the treatment of kidney disease, and the first unrelated donor bone marrow transplant – which took place at the Fred Hutchinson Center. *A history of innovation in all industry sectors exists in Washington state, but is especially visible in the life science firms that call Washington home.*

The 2015 Washington State Life Sciences Economic Impact Report states that life science is the 5th largest industry employer, directly employing 36,000 people, with an average annual salary of \$86,400. Clear and specific definition(s) for life science, biotech, bio-pharma, medical devices, and global health, are absent from various Washington state and economic development websites. A consistent and cohesive defining of the industry and its sub-categories must be implemented to help guide and inform businesses, the community, and political stakeholders. Life Science Washington, as the industry representative, has been encouraging these efforts with numerous entities across the state.

As Facility Logix conducted interviews with industry and other groups, confirmation of the definition of “bioscience” or life science, and, whether or not this included medical devices, was addressed and reiterated at the onset of any discussion. The community of stakeholders, that range from politicians to members of the community, need a clear understanding of how life science is being defined within the state.

Almost all industry firms interviewed for this project, volunteered their opinion that **Washington state and its economic development entities are focused on aerospace and software development giants, versus even trying to understand the needs of the life science industry.** “Advancing life sciences innovation and successfully delivering it to a highly competitive market requires the right blend of talented, educated, and skilled individuals working together with a common purpose. As the most R&D-intensive industry in the nation, the life sciences are characterized by a unique set of workforce and talent requirements as well as a highly regulated operating environment that adds additional and unique complexity” (*Assessing Washington’s Life Science and Global Health Workforce Dynamics* report, p.7). It must be noted that the stakeholders of this gap analysis are focused and implementing significant ways to address and to support the workforce needs of the life science industry.

The identification of sustainable initiatives responsive to the needs of industry will help the IHEs implement improved workforce skill development programs, therefore creating stronger professional and impactful relationships between industry and the community.

THE SEATTLE-BOTHELL LIFE SCIENCE COMMUNITY

A sampling of companies was interviewed for this study as seen in the chart below. Based on company size and product focus, impactful information has been gathered to develop a “profile” of the workforce, including areas where there are gaps to be addressed. Of the fifteen firms interviewed, six (6) are in medical devices, with three (3) firms located in Bothell; two (2) firms located in Redmond; and the remaining firm in Seattle. Four (4) of the eight (8) therapeutics firms are in Seattle, with the remaining four firms in Bothell and Lynwood. We did not interview any of the non-profit research institutes that represent a significant part of the regional life science cluster from a workforce perspective.

Company	Type / Product	Total Employees	HQ Location
Adaptive Biotechnologies	Bioinformatics Diagnostics	200	Seattle
AGC Biologics	Biotech/Pharma Contract Mfg. – Therapeutics	850	Bothell
Alder Biopharmaceuticals	Biopharma	193	Bothell
Aptevo Therapeutics	Biotech/Pharma - Therapeutics	120	Seattle
Cellnetix Labs, Inc.	Biotech/Pharma		
Ekos	Medical Device		Bothell
Juno Therapeutics (Celgene)	Biotech/Pharma – Therapeutics	660	Seattle and Bothell
Just Biotherapeutics	Biotech/Pharma - Therapeutics		Seattle
NanoString Technologies	Medical Device – Diagnostics	425	Seattle
Partner Therapeutics	Biotech/Pharma – Therapeutics		Lynwood
Physio-Control Inc.	Medical Device	840	Redmond
PharmaIN	Biopharma	18	Bothell
Phillips – Ultrasound	Medical Device		Bothell
FujiFilm – SonoSite	Medical Device	858	Bothell
Spiration	Medical Device		Redmond

THE LIFE SCIENCE WORKFORCE IN WASHINGTON

For any life science ecosystem, workforce is the driving factor for economic development, innovation, and industry success. Life science based economic development is active across the country and around the world; as a result, education and workforce development (and sustainability) has become increasingly critical and competitive. **A new paradigm is that high technology industries are competing for the same talented STEM (science technology engineering and math) graduates. Given the size, scope and rapid growth of the state's tech industry, Washington life science companies face even greater competition for STEM talent than their peers in other states.**

The 2017 report: The Life Science and Global Health Development in Washington State: Future at Risk, reminds industry and higher education institutions in the Seattle-Bothell region to recognize that a skilled workforce is THE critical issue. Most curriculum offered at these institutions including UW-Bothell, emphasize discovery and to a limited extent, commercialization (i.e. engineering and business). As a result, **a gap between the “traditional science courses” and the non-traditional courses (as required by industry), does exist.** Within the context of competing industries in the state (and around the country), developing and sustaining an educated workforce is a priority in order to ensure that the life science industry remains and grows in Washington.

Life science firms interviewed for this study expressed the following when asked about hiring and retention experience:

- Companies experienced early success in hiring because of low-turnover rates after a merger or acquisition; however, they foresee challenges in hiring in the near future.
- Being in start-up mode means they hire more scientists and fewer entry-level positions.
- As a medical device firm, they are able to recruit employees from aerospace and software firms without issue; however, they experience poaching from these firms as well.
- The high cost of housing limits a company from recruiting from lower cost areas – therefore, they tend to focus recruitment efforts on Boston and the San Francisco Bay area.
- Wage inflation within the industry and across industries makes retention difficult.
- Companies do not provide career advancement.
- Larger companies have their own training programs or provide on the job training.
- Finding employees that speak, read and write English in order to perform tasks can be challenging. They may have great credentials, but the inability to communicate is a major roadblock.
- Stricter enforcement/limitations of the US H-1B visa for specialty workers limits recruitment.

- Difficult to find accredited and certified machinists and those with capabilities of interpreting and adjusting blueprints.
- Finding employees who can work effectively in team situations.
- New or entry level employees are afraid to point out errors, communicate questions and concerns, or to solve problems.
- New employees get “bored” and treat jobs like video games – always looking to get to the next level without understanding the importance of learning their jobs.
- Would like to hire more veterans but they are hard to find with the appropriate skills. Train veterans.

Despite where they are in their business success and growth, all of the companies interviewed recognize that the labor market is tight due to increasing competition. For medical device firms, they are competing for some of the same employees that the aerospace and software firms seek. All of the medical device firms expressed that their best recruitment efforts are from the engineering program at University of Washington (Seattle) or out of state engineering programs. Very rarely are they able to recruit two-year degreed/certified students due to lack of hands-on training. Overall, life science firms prefer employees with industry experience, or at a minimum, a background in manufacturing, engineering, or specialized training in biology, genetics, and more.

A local Seattle-based firm complained that University of Washington and the rest of the state does not offer accredited Pathology Assistant programs, and therefore, must go out of state to recruit. Only ten such programs have been accredited in the U.S. by the National Accrediting Agency for Clinical Laboratory Sciences. Nine schools offer two-year programs that typically culminate with a master’s degree. One school requires a bachelor’s in science. Pre-requisite undergraduate courses required for a Pathology Assistant degree may include microbiology, general pathology, forensic photography, human anatomy, genetics and immunology. Creating new degrees - such as a Pathology Assistant degree - requires additional discussions with industries to determine true capacity need, an understanding of competing programs, student interest. The creation of a new program/degree will be a substantial investment to undertake and must be carefully evaluated.

SKILLS FOR THE LIFE SCIENCE INDUSTRY

Biotechnology firms typically require a broad range of hands on competencies such as pipetting, buffer and media preparation, the ability to use pH and conductivity meters, aseptic technique and the ability to work in a Biological Safety Cabinet and cleanroom, microbiology and environmental monitoring, cell culture (the growth and maintenance of animal cells such as CHO cells), the ability to conduct assays (e.g. protein assays, ELISAs, cell based assays), protein purification using chromatographic systems, DNA and RNA isolation, PCR (Polymerase Chain Reaction), qPCR (quantitative PCR), ddPCR (digital droplet PCR) and NGS (Next Generation

Sequencing). Additionally, non-laboratory knowledge of the regulatory environment is also essential for Biotech/Biopharma/Medical Device companies producing FDA regulated products.

Regulatory knowledge includes a familiarity with Quality Systems (e.g. Six Sigma), GXP (Good Laboratory Practices, Good Clinical Practices, current Good Manufacturing Practices), good documentation practices (traceability, Standard Operating Procedures, Batch Records) and the principles of validation. Individuals having a working knowledge of basic data analysis and statistics as they apply to the biotech/biopharma medical device is also preferred. Several companies surveyed indicated they would like potential employees to be familiar with statistical software ranging from Prism/INSTAT to R to SPSS.

In general, these competencies are not a part of the traditional STEM curriculum, including Biology and Biochemistry courses. A few of the topics above are sometimes covered (e.g. microbiology, PCR, protein assays) in a traditional STEM course but not with the rigor of industry (e.g. conducting the method using SOPs and using good documentation practices including traceability) or with the amount of repetition required for true competency (i.e. the ability to successfully complete the method independently or unsupervised). More often than not the method or topic is presented as a part of a survey of techniques in the context of basic research or to illustrate a theoretical point as opposed to a real world application.

That said, however, dedicated Life Science programs do exist in a number of community and technical colleges throughout the United States. These programs were created with the support of state and local government, and considerable help from industry, to serve the workforce needs of the local life science companies. Life science specific programs vary greatly in their depth with respect to curricula and enrollment depending on the resources available to them.

Two examples of successful life science programs which address the competencies required for the biotechnology/biopharma industry are Solano Community College in California and Montgomery College in Maryland. (It should be noted that Shoreline Community College also has a nationally recognized Biotechnology Program). The curricula for the two programs were created, and are regularly updated, with **direct feedback from the local industry partners who hire their students**. Specific courses in Life Science Programs include Cell Culture, Protein Purification, Fermentation, Upstream Processing, Downstream Processing, Introduction to the regulatory environment, Nucleic Acid Methods, Bioprocess Control, Supply Chain and Enterprise Resource Planning, Six Sigma for the Biopharmaceutical Industry, Immunology and Immunological Methods. A key feature of these programs includes extensive hands on laboratory work utilizing state of the art, industry relevant equipment.

Important to note is that most of these specialized Life Science Programs struggle to recruit students and maintain enrollment. Shoreline Community College typically enrolls 16 students per semester, Solano enrolls 10-20 per semester and Montgomery College in Maryland has an

enrollment of 140-180 students per semester. The enrollment figure for Montgomery College took over 15 years to build.

The Biotechnology (Life Science) program at Montgomery College in Maryland offers an AAS degree or certificates in biotechnology and in biomanufacturing. Students enrolled in the program vary greatly in their educational level with approximately 50% enrolling directly from secondary schools and 50% enrolling already having completed a bachelor's or master's degree in a life science. Approximately 30% of the students are currently employed in the local life science industry. All of the lab courses in the Biotech program at Montgomery College with the exception of Nucleic Acid Methods are written as SOPs or, in the case of biomanufacturing, as a batch record to familiarize students with working in a regulatory environment. The material has been reviewed and approved by the local industry partners. Life Science students are given hands on instruction using state of the art equipment such as AKTA Explorer FPLCs and Bio-Rad NGCs for protein purification, BioFlo 310 bioreactors using single use reactors, Bio-Rad qPCRs, Bio-Rad Fluorescent activated cell sorter, Shimadzu gradient HPLCs with and Illumina MiSeq DNA. The cost of the lab equipment alone was valued at approximately \$7 million. The laboratory projects simulate real world biotechnology activities and the lecture content teaches theory as an application relevant to the industry. The Biomanufacturing course has a unit on quality systems and introduces to students to quality concepts such as 5S, Kaizen and lean Six Sigma. The college offers short courses (1-5 days) through workforce development in Quality (these classes are more in depth than the credit courses), Project Management, Protein Purification, Cell Culture, Cleanroom basics, FACS, R, CRISPR, and multiple DNA and RNA sequencing short courses.

A sample abridged syllabus is below with an additional, abridged examples in Appendix D.

II. General Course Information

Course Title: Introduction to Biotechnology

Credit Hours: 2

Course Number, Meeting Times and Location: CRN 22737* MW 5:00-6:10 PM G Bioscience Education Center 148

* Late start 10 September 2018

Course Format: Lecture only

Prerequisites: None (prefer high school Biology and Chemistry or BIOL 101 and CHEM 099 or higher level)

III. Specific Outcomes

On completion of BIOT 110 students should be able to:

- Describe the different sectors of biotechnology
- Describe basic cell function and cellular molecules such as DNA, RNA and proteins
- Describe the central dogma of biology (flow of genetic information)

- Describe the scientific principles of modern biotechnology such as DNA isolation and sequencing, PCR, DNA microarrays, genetic engineering and cloning and protein purification
- Describe the basic steps in a biomanufacturing process
- Describe development of a biotech product and related business principles
- Describe the role of the FDA and basic principles of GLP and cGMP
- Complete a resume and sample cover letter for biotech job interviews

VIII. Course Schedule / Syllabus

Please Note: The course syllabus is a tentative schedule of lecture topics and exam dates. The exact schedule may be subject to change. One major factor affecting the pace at which the syllabus is covered is the student. Topics are arranged sequentially and thus it is often necessary to be sure that one concept is covered and understood before continuing to the next topic. Please keep your in class questions focused and brief. I will be happy to answer specialized, tangential or interest questions after class or during my office hours

A. Tentative Lecture Syllabus

10 September	Introduction/Course Policies What is Biotechnology
17 September	Cells and Biotechnology
24 September	Cells and Biotechnology Mini Exam 01
01 October	Biotech Sectors Broad Overview Biotech Sectors Healthcare
08 October	Biotech Sectors Healthcare Mini Exam 02
15 October	Biotech Sectors Healthcare Mid Term Exam
22 October	Biotech Sectors Healthcare Biotech Sectors Agriculture
29 October	Biotech Sectors Agriculture
05 November	Biotech Sectors Environmental and Biomaterials

Mini Exam 03

12 November	The Business of Biotech - Idea to Market for Biologics Biotechnology Corporate Structure
19 November	Finding and Keeping a Job in Biotechnology
21 November	NO CLASS - Thanksgiving Break 21-25 November
26 November	Finding and Keeping a Job in Biotechnology The Importance of the FDA and GXP's Mini Exam 04 - Resume Due
3 December	Documentation Basics and Intro to Lab Math
10 December	FINAL EXAM - cumulative for semester - all students must take the final exam

SKILLS AND COMPETENCIES FOR MEDICAL DEVICE FIRMS

Medical device industry employers seek a workforce with a combination of skills and experience that range from chemistry, mathematics, design control, basic manufacturing skills, engineering, FDA regulations and policy, software development, and marketing. Applicable coursework is distributed throughout several disciplines: engineering (mechanical, electrical), precision machining (also found in automotive/aerospace, machining, and so forth. Companies interviewed prefer recruiting certified or credentialed employees in machining, soldering, 3-D design, blueprint reading, and familiarity with computer numerically controlled (CNC) equipment. Also critical is the need for employees with regulatory experience.

Certificate programs may provide exposure to equipment maintenance, computer-aided design, quality assurance and so forth. For a medical device firm, on the job training is very common. Hands on experience is important; yet, the most widely expressed important requirement is that the employee is able to read, understand, speak and write English. The medical device firms interviewed for this study were the most vocal about having entry level employees fairly fluent in English language skills. Technical skills were, of course, critical as well.

Some best practice examples include:

Salt Lake Community College offers a Medical Device Manufacturing: Processes and Practices certificate program. The certificate addresses competencies required by the medical device industry, core knowledge and skills for entry-level positions (www.slcc.edu/continuinged, 9/4/2018). Courses include:

- **CEMD 0910 Intro Medical Device Industry** – focus on medical device industry in Utah. Addresses diversity of products, size and scope of industry, product life cycles.
- **CEMD 0920 Basic Manufacturing Skills** - measurement, performing measurements, data management and analysis. Mastery of these skills are key to successful careers in medical device and bioscience industry.
- **CEMD 0930 Intro to FDA Regulations** - Overview of FDA regulations and an overview of equivalent international regulations.
- **CEMD 0940 Intro to Quality Systems** (review of 21 CFR 820 ISO134, FDA-GMP, compliance and non-compliance) – master competencies related to the regulation and medical device quality system, understand the consequences of non-compliance, introduces concept of quality system, system structure, FDA – GMP.
- **CEMD 0950 Intro to Quality Control Online** – introduce tools used by quality control technicians in the life sciences (medical devices, pharmaceuticals, and nutritional supplements). Overview of cGMP. Hands-on approach with class discussion. Students will utilize Microsoft Word and Microsoft Excel to effectively use quality tools and descriptive writing skills.
- **CEMD 0960 QA Auditing Concepts** – Introduction to the field of auditing concepts. Standards and regulations from auditors’ perspective. Audit program structure, planning, performance, reporting and action plans.

UCLA Extension offers a Medical Device Engineering certificate online. This program is designed to provide basic knowledge and skills in medical device engineering, design, quality and regulatory requirements. Students must complete all courses in this stream (www.uclaextension.edu/bioengineering/certificate, 9/4/2018).

- Process Development and Quality Systems for Medical Devices
- Biomaterials and Biocompatibility
- Medical Device Manufacturing: Processes, Equipment, and Techniques
- Fundamentals of Medical Device Engineering
- Regulatory Affairs for Medical Devices

UCLA Extension also offers an online course in **Biotechnology Engineering** which is promoted to those who wish to understand the engineering processes in drug development using genes, DNA, etc., the manufacturing process for biotech, quality management and European and FDA rules, regulations and guidelines:

- Fundamentals of Biotechnology Engineering

- Manufacturing Processes in Biotechnology
- Process Development and Quality Systems for Biotechnology
- Regulatory Affairs for Biotechnology

WHAT WASHINGTON'S LIFE SCIENCE INDUSTRY NEEDS

Approximately 85% of the two dozen Industry representatives interviewed emphasized the need for the following:

1. Experience (hands-on) or expertise in the latest technology (genetics, oncology, regenerative medicine, biomarkers, cell-based therapies and cell-based assays, single use technologies, continuous manufacturing, liquid handling systems, advanced engineering including robotics and 3-D printing);
2. Ability to work with massive amounts of data, followed by the ability to analyze the data (statistics, algorithms, machine learning and artificial intelligence);
3. Understanding biology, chemistry and health science;
4. Appreciation for product development coupled with an understanding of quality control, regulatory, and good practices;
5. Understanding the importance and basics of working in an FDA regulated environment and the role of quality systems in maintaining compliance;
6. Business acumen/understanding coupled with decision making, collaboration, team work, problem solving, and communication skills; and,
7. Solid English reading, writing and verbal skills.

Throughout discussions, almost all companies expressed the desire to have employees that “get the big picture” - understand the overall picture of what they and the company do. ***If an employee does not understand or appreciate that what they are doing contributes to the well-being of humanity, then they may not understand or appreciate the need for accuracy, attention to detail, trouble-shooting, and process and documentation within a regulatory environment.*** The ability to identify and to verbalize problems, think creatively, and suggest solutions is a critical skill set. Most companies interviewed confirmed that a college degree is not always necessary to perform the jobs assigned. However, if an employee does not have the capacity or aptitude to anticipate and to problem-solve, pay attention to details, think creatively, communicate with team members (verbally or written), then training them to learn the tasks required of them in the field is a waste of company resources and time.

Many employers relayed that new employee recruits (particularly those out of two or even four-year schools) are unprepared for the hands-on work required. Some students graduate with degrees but have never worked in a commercial or clinical lab (versus a research lab), operated key pieces of equipment (such as a PLC or flow cytometer), know how to gown-up in a clean room setting, execute aseptic technique, or understand the importance of accurate documentation and working within an FDA-regulated environment. A factor may be that these new employees do not appreciate or understand the “big picture” as to what they are doing

and why it is so critical to follow procedures. Such scenarios drive employers to hire individuals with “more experience.”

A goal to be considered is that “grooming the next generation” is tantamount to the success of the industry. A recommendation within this report is create a “bio-aware” community. The Career Connect Washington initiative directly aligns with this goal. Awareness of the industry must be delivered to students (at an early age), their parents, teachers and high school career counselors. The email exchange (Appendix E) between a student and faculty member regarding finding a life science job, illustrates the fact that book knowledge and four year degrees must include hands on experience. This community must understand what life science has to offer, the various career paths available, and the straight-forward soft skill requirements that go well beyond a STEM education. Fortunately, Life Science Washington has been part of the business steering committee leading the way in creating the Career Connect Washington’s strategic plan that will be presented to Governor Inslee on October 25, 2018. Through the leadership of Dr. Alexandre and Dr. Hans Bishop, former CEO of Juno Therapeutics, nearly 20 Washington state life science companies, representing all sectors, have been engaged in the initial planning of this statewide initiative.

Exposing students, the counselors these students may interact, and the students’ families and peers, to the driving force in this industry (saving and/or improving lives), the culture and opportunities the industry has to offer can begin now! More can and should be done to facilitate partnerships and collaboration between academic institutions (kindergarten through college) and industry. Such activities include:

1. Identify where there are misalignments between industry and academic institutions;
2. Create and encourage opportunities for industry and academia to professionally interact such as participation in advisory boards, roundtable discussions on curriculum and on areas where industry and education can work together to expose students to the sciences *within a commercial setting*;
3. Design curriculum that is meaningful and apropos to industry and a culture of innovation;
4. Continue to build, and to enhance *hands-on learning opportunities* to students at all levels; and,
5. Build awareness of the above by including parents and career counselors and elementary/high school STEM instructors in the discussions. These stakeholders also need to understand and appreciate the promise of the life science industry to encourage their students to pursue this field.

All industry representatives expressed their desire to partner with academia. Many offered their own suggestions:

1. Design research projects requiring critical thinking, communicating, problem solving and team work;
2. Have an industry representative teach a course, host a lunch and learn for students (and parents if appropriate);
3. Provide internships and/or facilitate co-op programs;
4. Encourage involvement in trade associations' educational events; and,
5. Participate in industry-academic advisory teams.

While the Career Connect Washington initiative may already be focused on the above areas, it is important—and encouraging—to note that this feedback from industry was consistent during our interviews as well.

We evaluated current entry-level Life Science job openings as an indicator of demand and to examine how the postings stack up against what we were hearing from the industry interviews regarding a) jobs needed; and b) skills required. Life Science Washington has a Career Center that posts jobs online. The positions listed range from administrative to executive level. Most of the firms interviewed post their openings on their company website, company LinkedIn page, or INDEED. Some firms use recruiting firms, especially when recruiting PhD's, and executives. As of September 13, 2018, the job search site, Indeed.com featured over 900 full time jobs in the life science field for the state of Washington. The types of entry level jobs advertised are as follows:

1. Pathology Assistant
2. Cytotechnician
3. Materials Handling
4. Soldering
5. Electronic Components
6. Manufacturing Associates
7. Quality Control Analyst
8. Quality Assurance
9. Validation Engineers
10. Robotics
11. Customer Service
12. Software (including data analytics broadly defined, such as machine learning and artificial intelligence)
13. Biotech Engineering (mechanical, electrical, computer engineering)

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Below is a summary of some of the positions and skills/requirements drawn from the job postings and from input provided during interviews with industry. The IHEs should review these postings regularly and work directly with industry on how best to address the skills and knowledge gap to help produce a stronger and more work-ready labor pool.

Job Category	Occupation/Job Title	Skills	Degree/Certification/ Experience
Entry Level - Medical Device Manufacturing	Manufacturing Associate	Work w/blueprints, drawings, circuit boards, welding, soldering, adjust blueprints, computer skills, basic math, conversational and written English; provide training and guidance to other associations	High School or Equivalent
Midlevel – Medical Device Manufacturing	Service Operations Specialist	PCB Assemblies, Soldering certification, ESD standards, Datasweep and quality system Agile, ISO and FDA training, PCB fab repair	3 years surface soldering experience, soldering certifications, computer, conversational and written English
Entry-Mid Level – Bio/Pharma	Lab Assistant 1	Help technologist/technicians and pathologist; HIPAA standards, PPE, and strict SOPs for hazards including formalin, disease, human tissue, etc.	High School, Associates or BA w/emphasis on bio, chem, anatomy. Prior clinical med or lab experience preferred, computer skills, customer service
Entry-Mid Level – Bio/Pharma	Cytotechnologist	Screen slides identify abnormal or cancerous cells. Must complete CAP Proficiency Test annual with score of 90% or higher.	Bachelor's degree in related field, Cytotechnologist certification by ASCP. Basic computer skills, self-directed, ability to analyze and confidently make decisions

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APPENDIX A – INTERVIEWS WITH INDUSTRY CONTACTS

NAME	TITLE	COMPANY
Lori Stewart	Human Resources	Adaptive
Daisy Szabo	Human Resources	AGC Biologics
Heather Malcolm	Human Resources	Alder Bio
Heather Malcolm	VP Human Resources	Alder Biotechnologies
Susan Gillespie	VP Human Resources	Cellnetix Labs, Inc.
Lori Melkerson	VP Operations	Ekos
Tracy Matthews	Sr. HR Partner	EKOS/BTG
Pam Englund	HR Business Partner	Juno Therapeutics
Snehal Patel	Vice President - JuMP Site Head	Juno Therapeutics
Caroline Chan	Human Resources	Just Biotherapeutics
Debbie Krogman	VP - Human Resources	NanoString
Diana Craig	Human Resources	Omeros
Fio Gaia	Talent Recruitment	Omeros
David Carlson	Sr. Director of Manufacturing	Partner Therapeutics
Elijah Bolotin	CEO	PharmaIN
Matt Holttum	Dir. Ultrasound Supply Chain	Phillips Healthcare
Brandon Sofie	Manager, Service Operations	Phillips Healthcare
Jim Low	Manufacturing Supervisor	Phillips Healthcare
Matt Smith	Dir. Industry & Resource Development	Snohomish Economic Alliance
Meredyth Wanink	Senior Manager - Human Resources	SonoSite
Tom Davidson	Director of Manufacturing	SonoSite
Mark Nicholson	VP Global Operations	SonoSite
Christine Garrison	Director, Human Resources	Spiration

APPENDIX B – NAICS DEFINITIONS

NAICS - North American Industry Codes (www.census.gov)

The following are brief definitions and examples of typical NAICS codes used to identify firms in the life sciences, and was kept in the back of the team's minds in conducting their research for this document:

5417 – *Scientific Research & Development Services – research and experimental development in physical engineering and life sciences.*

- 541711: Research and development in microorganisms, and cellular and biomolecular processes.
- 541712: Research and development in physical, engineering, and life sciences (does NOT include biotechnology), such as agriculture, electronics, environmental, biology, botany, computers, chemistry, food, fisheries, forests, geology, health, math, medicine, oceanography, pharmacy, physics, veterinary and other allied subjects.

3254 – *Pharmaceutical & Medicine Manufacturing – medicinal and botanical manufacturing of uncompounded medicinal chemicals and their derivatives.*

- 325411: medicinal and botanical manufacturing for use by pharmaceutical preparation manufacturers. Includes grading, grinding, and milling uncompounded botanicals. Product examples include antibiotics, anesthetics, fish liver oils (medicinal), cortisone, herbal supplements, insulin, nicotine, salicylic acid, vitamins.
- 325412: in-vivo diagnostic substances and pharmaceutical preparations (except biological) intended for internal and external consumption in dose forms - ampoules, tablets, capsules, vials, ointments, powders, solutions, and suspensions. Product types include birth control pills, antacids, analgesic, botanical extract preparations, eye and ear preparations, hormone preparations, thyroid preparations, sedatives.
- 325413: in-vitro diagnostic substances, such as chemical, biological, or radioactive substances. Uses include diagnostic tests performed in test tubes, petri dishes, machines, and other diagnostic test-type devices. Products include blood glucose, HIV, hormone diagnostic, and pregnancy tests.
- 325414: These companies manufacture vaccines and culture media of plant or animal origin (except diagnostic). Examples include antigens, antiserums, vaccines (bacterial, virus), blood derivatives, plasma.

3345 – Navigational, Measuring, Electro medical, and Control Instruments Mfg.

- 334510: manufacture apparatus such as magnetic resonance imaging equipment, medical ultrasound equipment, pacemakers, hearing aids, electrocardiographs, and electro medical endoscopic equipment. Additional examples include defibrillators, MRI's, dialysis equipment, pacemakers, hearing aids, laser equipment.
- 334517: irradiation apparatus and tubes for applications, such as medical diagnostic, medical therapeutic, industrial, research and scientific evaluation.

3391 - Medical Equipment & Supplies Manufacturing

- 339112: surgical and medical instruments for human and veterinary surgical and ophthalmic use. Does not include electrotherapeutic, electro medical and irradiation apparatus. Products in the 3391 category include: syringes, hypodermic needles, anesthesia apparatus, blood transfusion equipment, catheters, surgical clamps, and medical thermometers.
- 339113: surgical appliances and supplies such as orthopedic devices, artificial limbs, biohazard clothing, surgical dressing, sutures, cotton and cotton balls, depressors, operating room tables, and wheelchairs.

APPENDIX C – BIOMANUFACTURING BROCHURE SAMPLE

Solano College Upper Division Courses for Biomanufacturing Majors.

This table gives brief descriptions for the core courses for the baccalaureate biomanufacturing degree that will be offered in the new Biotechnology building at the Solano College Vacaville Center.

Biomanufacturing Courses	
Biomanufacturing Process Sciences and Engineering Principles (Lecture/Lab) BIOT 401 (5 Units) - Physical and chemical principles of biochemical engineering that enable large cell culture - Thermodynamics and the properties of fluids; mass and heat transfer, fluid flow, and the energy relationships in fluid systems - Biomanufacturing technologies enabling large	Supply Chain and Enterprise Resource Planning (Lecture) BIOT 406 (3 Units) - Manage flow of materials in a supply chain - Understand the design, planning and execution of raw material procurement and use - Eligibility for certification test
Design of Experiments for Biomanufacturing (Lecture/Lab) BIOT 402 (4 Units) Established methods to systematically vary process parameters to improve and optimize a biomanufacturing process	Advanced Topics in Quality Assurance and Regulatory Affairs (Lecture) BIOT 407 (4 Units) Study of the harmonized quality system approaches of ICH Q8, 9, 10, and 11, including quality risk management, qualification, and validation
Design of Biomanufacturing Facilities, Critical Utilities, Processes, and Equipment (Lecture) BIOT 403 (4 Units) - An examination of how the robust design of all aspects of a biomanufacturing facility minimizes errors - The role of Quality by Design (ICH Q8) in facility design - Processes and equipment in biological production, recovery, and purification. - Aseptic process design. - Clean utility and support systems	Six Sigma and Lean Manufacturing (Lecture/Discussion) BIOT 408 (4 Units) - Study of key six sigma concepts and tools; the DMAIC phases: design, measure, analyze, improve, and control - Use and implementation of lean tools to reduce waste - Completion of this course prepares students to earn a certification in six sigma.
Bioprocess Monitoring and Control (Lecture/Lab) BIOT 404 (5 Units) The measurement, monitoring, modeling, and control of biomanufacturing processes.	Methods in Quality Improvements, Investigations, and Audits (Lecture) BIOT 409 (4 Units) The study of continuous quality improvement techniques, including investigational methods into process deviations
Emerging Biomanufacturing Technologies (Seminar) BIOT 405 (3 Units) An examination of new technologies in biological production and purification operations.	Emerging Trends in Biomanufacturing Quality (Seminar) BIOT 410 (3 Units) An examination of new regulatory requirements and changes to current practices in biomanufacturing quality

SOLANO COLLEGE BIOMANUFACTURING BACCALAUREATE

Solano College is now a four-year college. In 2015 the California State legislature voted to allow some community colleges in California the opportunity to grant a bachelor's degrees for the first time in the history of the state. After an extensive and competitive application process, Solano Community College was approved in May 2015 as one of the 15 colleges chosen to pilot this program. Solano College's degree is in biomanufacturing.

What is Biomanufacturing? Biomanufacturing uses genetically engineered living cells (bacterial, yeast, or animal cells) grown in large tanks called bioreactors and to produce a protein that serves as a medicine. That protein then must be separated from other cellular components and purified by using techniques that exploit its properties to isolate it away from other cellular proteins. Then technicians use analytical techniques to prove the purity of the isolated protein. In the future Biomanufacturing will be expanded to include the industrial production of biofuels, biomaterials, stem cells, and other products currently manufactured using chemical rather than biological techniques. Solano Community College is exploring the addition of these elements to its program.

When can students apply? The upper division courses (Junior and Senior level) started to be offered in Fall 2017. The first class will graduate with a Bachelor of Science in Biomanufacturing in Spring 2019. Applications are now being accepted for Fall 2018.

Can I take the program part time? Yes. The part time option for the program has begun. With this option, working students can complete the program in three years.

This table represents the sequence of course offerings. The start of the program in August 2017 was coincident with the opening of the new \$ 34 million biotechnology/science building on the Vacaville campus of Solano County.

Lower Division	Biotechnology associate degree or equivalent preparation	
Upper Division, Year One	Fall Term • Biomanufacturing Process Sciences and Engineering Principles-BIOT401 (5 Units) • Advanced Topics in Quality Assurance and Regulatory Affairs BIOT407 (4 Units) • Upper division GE: Technical Writing ENG 400 (3 Units) • Elective (3 Units)	Spring Term • Design of Biomanufacturing Facilities, Critical Utilities, Processes and Equipment BIOT403 (4 Units) • Bioprocess Monitoring and Control BIOT404 (5 Units) • Design of Experiments for Biomanufacturing BIOT402 (4 Units) • Elective (3 Units)
Upper Division, Year Two	Fall Term • Supply Chain and Enterprise Resource Planning BIOT 406 (3 Units) • Emerging Biomanufacturing Technologies BIOT405 (3 Units) • Six Sigma and Lean Manufacturing BIOT408 (4 Units) • Upper division GE: Bioethics PHIL 400 (3 Units) • Electives (3 Units)	Spring Term • Methods in Quality Improvements, Investigations and Audits BIOT409 (4 Units) • Emerging Trends in Biomanufacturing Quality BIOT410 (3 Units) • Upper division GE: Project Management BUS400 (3 Units) • Elective (3 Units)

APPENDIX D – SYLLABUS SAMPLE

Abridged Syllabus from Montgomery College Biotechnology Program

BIOT 200 Dr. Collins Jones

CRN 22744 Lecture: Monday 9:00 AM to 11:40 AM Room BE 148 BIOT 200L

CRN 22745 Laboratory: Wednesday 9:00 PM to 11:40 AM Room BE 025

NOTE: Some labs may run late up to 45 minutes

Course Format: Lecture and Laboratory Exercises

Prerequisites: CHEM 131, BIOL150 (prefer CHEM 150 or CHEM 203)

Co-requisites: none

III. Specific Outcomes

On completion of BIOT 200 Protein Biotechnology students should have a basic understanding of the following.

1. Basic Protein structure - amino acids, peptide bonds and the four levels of protein structure
2. Important post-translational modifications and their importance
3. Methods to characterize proteins
4. Principles of protein assays – quantitative
5. Basic principles of protein purification
6. Principles of protein assays - functional
7. Protein stability and formulation

Students should have completed hands on

- Buffer and solution preparation - stock and working solutions
- Spectrophotometric Protein Assays including construction of standard curves
- Simple bench scale protein chromatography packing and running a gravity column
- Purifying a protein from a mixture using the Bio-Rad NGC system
- SDS and IEF PAGE
- A simple enzyme assay

IV. Text and Supplies

Textbook: Handouts will be supplied as needed. There is no suitable text for this course at this level. The student is encouraged to use basic biotechnology, biochemistry and molecular biology texts as supplementary references.

Lab Manual: Lab Handouts will be posted on MyMC and will have to be printed at your expense.

Additional Required Lab Materials :

- *Eye Protection (e.g. Safety Glasses or Goggles (must be department approved)
- *Lab Coat
- *Scientific Calculator
- *Lab Notebook (department approved MC Biotech Scientific Notebook)
- *Pen (Blue ink only)
- * Items to be obtained before second laboratory

Laboratory Evaluation

Each student taking a Biotechnology Laboratory will be evaluated by his or her instructor during the course of the semester. The specifics of the evaluation will be kept confidential. Evaluation criteria will include:

Time management: Starts lab on time; Completes lab on time

Organizes and plans work time during the lab?

Attentiveness: Listens to pre-lab and in-class directions or does he or she repeatedly ask questions on items already covered

Pays attention to protocols and carries out directions properly. Is able to follow written and oral directions

Asks for clarification when confused (a good thing!)

Come to class on time and focused on classroom activity

Preparation: Does the student come to class prepared with lab notebook, lab coat, safety goggles and black ink pen, has a knowledge of the protocol (e.g. what is the title, what reagents and equipment will be needed?)

Participation - Does fair share of work - does not watch but actually does work

Behavior / Attitude: Participates with enthusiasm and does fair share of work; Treats instructor, other students and lab environment (equipment and reagents etc.) with courtesy and respect; Able to work as a team member collectively and individually ? Asks for and gives assistance as needed? Obeys rules of laboratory safety, reagent handling, ...

“Laboratory Hands”: Demonstrates proper dexterity, eye-hand coordination, to successfully perform basic laboratory tasks.

Able to competently use and understand basic laboratory equipment such as BSC, pipette man, pipette aid, balance, electrophoresis apparatus, spectrophotometer.

Evaluation: at the end of each period you may be asked to evaluate yourself and your lab partner on a short form to be explained the first lab period.

Sample Lecture Topics

- Introduction / Course Policies
- Central Dogma of Biology Protein Structure - the fast version
- Classes of Proteins and their function - enzymes, receptors
- Sources of proteins
- Cells are the source
- Research - microbes, plants, animals
- Manufacturing - large scale cell culture
- Sample protein products
- Industrial enzymes for food, modification of chemicals
- Healthcare Diagnostic and therapeutic - insulin, Mabs,
- Regulatory Issues (Lab Documentation)
- What do GXP's stand for
- Why GXP's SOPs and Documentation Basics

Sample Laboratory Topics

- Introduction to the Protein Biotechnology Laboratory
- Safety PowerPoint Key Points
- Documentation for the Biotechnology Lab Key Points
- Highlight Measurement and Sig Figures Key Points
- Buffer Preparation
- What is a buffer and other key chemical (e.g. EDTA)
- Stock Solution, Working Solution
- Dilution of Solutions
- Labeling

- Read: All GBT SOPs in the student folders
- Lab Safety PowerPoint
- How to keep a lab notebook PowerPoint

Print: GBT.020A Protocol for Validation of Ranin Pipetman Pages 4-14 and mount in your notebook

APPENDIX E – STUDENT-FACULTY CORRESPONDENCE

Student Email to Professor Seeking Employment Assistance

Good afternoon Dr. XXXXX,

This is Samantha from your Tuesday 6pm - 10:25pm BIOT 120 class. It was a pleasure meeting you last class and if I had known I would have talked to you last class about this but, I understand that you help students find jobs in the biotech field.

I have a friend who would be perfect for such a job. She recently graduated from XXXXX College with her bachelor's in biology and minored in French. She is also a well-rounded individual. She has been looking for a job in the biotechnology field ever since she graduated and is still currently looking. She has plenty of experience, but she needs someone to give her a chance to grow as an individual. She's a good person and very smart as well and able to work in a team because she has plenty of experience working in situations which requested teamwork.

Her name is ##### and I would appreciate it if you could get in contact with her and help her find a job just right for her. I will list her contact information below. Or if you wish to meet her in person let me know so that I can introduce you to her. [Contact info deleted](#)

Thank you for taking your time to read this email. If you have further questions about her or anything else, please email me back any time.

*Sincerely,
xxxx*

Response Letter to student from Professor

Hi Samantha –

It is really nice of you to reach out for your friend!

I am surprised XXXXX College was not able to help her?

I hope you will understand what I am about to say.

As I mentioned in the intro lecture we cannot promise anyone a job. The assistance we do offer is only for students who are in the Biotech Program at XXXX and who have taken classes with Dr. XXXX or me. Otherwise we would be overwhelmed with this type of request and become a de facto job placement agency. Your friend's difficulty in finding a job is very common for life science graduates of 4-year institutions. Those institutions do a great job of preparing life science students to apply to med school or grad school but not for a job in the biotech industry.

Industry hires our XXXX College Biotech students because 1) they have been taught information that is directly applicable to industry needs and 2) the laboratory classes closely resemble what a student will

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encounter in industry. Biotech students are industry ready (and grad school ready but not so much med school ready).

For those reasons job placement assistance is something we do for our XXX College biotech students only. And, as I stated in class, to be considered for placement assistance the student has to meet our standards of attendance, behavior and lab skills – things we have to personally observe.

This is what differentiates the Biotechnology Program at XXXX College from traditional Biology, Biochemistry, Microbiology degrees at 2-year or 4-year schools. Therefore, we are not able to recommend anyone who has not completed at least two XXXX College biotechnology laboratory classes for a job or internship. These criteria also apply to XXXX College students in Biology classes. Unless you have completed two or more Biotech lab courses we will not recommend anyone for a job.

What I can suggest is that you friend reach out to Aerotek or TechUSA. Both of those companies are employment agencies that specialize in placing people at Biotech companies and they are often able to help folks with 2 or 4 year biology degrees find a job. They will also help with resume writing and interview skills.

If you friend would like to talk me I am happy to do so. Please have her email me and/or make an appointment to speak with me.

I hope this helps.

Student Thank You Response

Dr. XXXX,

Thank you for taking your time to read my email. I know you did say you only helped out the students within the program but, it was worth still asking. I will let her know about what you said, and I will give her your contact information so that she may reach out to speak with you. **Surprisingly, many students who come out with their 4-year degree are unable to get jobs!** which is crazy because many students are coming out with passion and have studied and have had experience with lab work since many courses include laboratories now. But I appreciate your response.

Thank you! :)

APPENDIX F – REFERENCES

- Association, M. D. (2017). *2017 Annual Report - Shaping a New Direction*. Washington, DC: MDMA.
- Battelle. (2014). *Battell/BIO State Bioscience Jobs, Investments and Innovation 2014*. Columbus: Battelle.
- Bays, J. (2016, September 26). Top States for Medical Device Manufacturing. *Site Selection Group*, p. 1.
- Choose Washington - Our Key Industries*. (2018, August 5). Retrieved from Choose Washington: <http://choosewashingtonstate.com/why-washington/our-key-sectors/life-sciencesglobal-health>
- Community Attributes (CAI). (2015). *Washington Global Health Landscape Study 2015*. Seattle: Washington Global Health Alliance.
- International Trade Administration. (2017). *Medical Technology Spotlight - Medical Technology Industry in the United States*. Washington, DC: SelectUSA.
- Kennedy, J. (2018). *ow to Ensure that America's Life Sciences Sector Remains Globally Competitive*. Washington, DC: Information Technology and Innovation Foundation.
- Simon Tripp, M. G. (2012). *The Economic Impact of the U.S. Advanced Medical Technology Industry*. Battelle Technology Partnership Practice.
- Simon Tripp, M. G. (2012). *The Economic Impact of the U.S. Advanced Medical Technology Industry*. Battelle.
- Standardization, I. O. (2016, August). *Medical Device Regulations and Guidance*. Retrieved from ISO 9001-2000: ISO 13485-2016(en): <https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en>
- Statistics, B. o. (2018). *Life, Physical, and Social Science Occupations*. Washington, DC: Bureau of Labor Statistcs.
- Summary, L. S. (2018). *Biotech / Life Science Programs & Degree Pathways*. Bothell: Cascadia College.
- TEconomy Partners LLC. (2017). *Assessing Washington's Life Science and Global Health Health Workforce Dynamics: Enhancing Connections and Address the Skills Gaps to Ensure Future Growth*. Cincinnati: TEconomy Partners LLC.
- TEconomy Partners, LLC. (2017). *Life Science and Global Health Development in Washington State*. Columbus: TEconomy.
- TEconomy/BIO. (2016). *The Value of Bioscience Innovaton in Growing Jobs and Improving Quality of Life 2016*. Columbus: TEconomy.
- U.S. Bureau of Labor Statistics. (2011). *The Pharmaceuitcal Industry: An Overview of CPI, PPI, and IPP Methodology*. Washington, DC: Office of Prices and Living Conditions.
- Washington Department of Commerce Office of Economic Development & Competitiveness. (2016). *Sector Leads - Life Science Strategy*. Olympia: WA Department of Commerce.

October 11, 2018

Workforce, N. C. (2011, September 2). *www.biotechworkforce.org/skills development*. Retrieved from NCBW.org: <http://www.biotechworkforce.org/AMSDL.html>