

## Career Launch Endorsement Review (CLER) Application



INSTITUTION _	Shoreline	Community College		
PROPOSED PF	OGRAM Biotechr	nology Program		
	EVEL (CHECK ALL ool Diploma	THAT APPLY):		
X College C	ertificate			
_X_College A	ssociate Degree			
College B	achelor Degree			
_X_Industry I	Recognized Certifi	cate(s)		
PROGRAM CIF	41.0101	PROGRA	M NAICS CODE 54171	1
COLLEGES ON	ILY: PROGRAM EPO	C (Legacy)678	PLAN CODE (PeopleS	oft) <u>N/A</u>
CONTACT INFO	ORMATION			
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7.0	5. france	lb-Ph.	$\square$	June, 2, 2021
Chief Acade	mic Officer			Date
Application co	As W Ot		ollege Relations and P ard for Community and 7	-
Ap	olications reviewed	monthly and are d	ue the first business d	ay of the month.

Electronic submissions only to scopeland@sbctc.edu

### P1. Program description including length of program in years and total hours (including split between classroom and worksite).

Shoreline Community College's Biotechnology program is pleased to apply for Career Launch Endorsement. One of the oldest programs in the U.S. and the only AAAS in the state, Shoreline's Biotechnology program prepares students for a fulfilling, life-long career with significant advancement opportunities in a rapidly growing and innovating industry.

As the biopharmaceutical and biomanufacturing industries grow in King and Snohomish counties, and around the state, demand for biotechnicians is also increasing rapidly. To serve these workforce needs, working in partnership with AGC biologics, the Malik Lab at Fred Hutch Institute, and other future partners, Shoreline's program offers students in-class training and instruction paired with on-site, paid work in a lab or biomanufacturing setting. The Career Launch endorsement will help build strong industry relationships, expand Shoreline's Biotechnology program, and meet future workforce demands.

Shoreline Community College's Biotechnology program comprises of the following certificates and degree:

Introduction to Biomanufacturing certificate with a BioPath AGC Internship (9-credits) Students in their junior year of high school can gain knowledge and experience to launch a fulltime career in biotechnology after graduation and completion of the certificate. Students engage in a one-year internship with paid hourly compensation while enrolled in high school. The certificate provides high school credit and college credit at the same time. The internship lasts September 2021 – June 2022 (32 weeks)

#### Biotech Lab Specialist certificate (37-38 credits)

The certificate prepares students for entry-level laboratory work across the biotechnology field. Gain foundational skills and working knowledge of concepts through classroom lecture and extensive hands-on, lab learning experiences.

Associate in Applied Arts and Sciences (AAAS) degree (92.5 - 93.5 credits)

The AAAS prepares students for entry-level laboratory work across the biotechnology field. Students gain foundational skills and working knowledge of concepts through classroom lecture and extensive hands-on, lab learning experiences. The AAAS requires students to complete a 30-credit internship with a participating biotechnology company or lab.

### P2. Estimated number of hours per week at worksite and in classroom (this approach may shift throughout the program).

Credential	Hours per week at worksite	Hours per week in classroom
Introduction to Biomanufacturing Certificate	5 hours of on-site work at AGC	2-3 hours per week of course work, including lectures, readings, assignments, and exams
Biotech Lab Specialist certificate	Varies 10-20	Varies 20-30

Associate in Applied Arts and Sciences (AAAS)	Varies 10-20	Varies 20-30
degree		

#### P3. Demonstration of labor market demand for specified skills/career in local region.

According to the U.S. Bureau of Labor Statistics (BLS), employment for the profession of biological technician is projected to grow nationally at 7% between 2018 to 2028 –significantly faster than other occupations. In terms of job positions, the BLS estimates an increase of 5,700 new positions from a baseline of 85,000 positions in 2018 to a projected 90,700 positions in 2028 (BLS Occupational Outlook Handbook: Biological Technicians, 2020).

In the context of Washington state's growth of biological technicians (SOC: 19-4021.00), the Washington State Employment Security Department (ESD) estimates an annual employment growth rate 1.6% between 2017 and 2027, adding about 930 new positions (WA State Demand: Biological Technicians, 2020). In addition, O-NET, an open-source database that shows occupation demand, projects that the occupation of biological technicians will grow 17% between 2018 and 2028, and by 5% nationally over the same time period. These numbers demonstrate significant growth for the field of biomanufacturing.

### P4. Projected count of student enrollment, student completion, and anticipated employer participation for 5 years, post-pilot.

Year	1	2	3	4	5
Student enrollment	12	12	15	16	16
Student completion	8	8	10	11	11
Employer participation	2	3	4	5	6

## P5. Concise description of development process to create the Career Launch program (e.g. who was involved, when, how was the program piloted, etc.). Include a listing of program advisory committee members and their affiliation to the program.

In 1991, Shoreline Community College started one of the first biotechnology education programs in the nation. Now, despite an increasing demand for entry-level biomanufacturing technicians, Shoreline continues to be the only 2-year biotech program in Washington state. Since its inception, Shoreline's biotech program has worked to not only meet the workforce needs of the biomanufacturing sector, but it has striven to be at the cutting edge of industry trends and innovations. Throughout this time, the program has provided biopharmaceutical and biomanufacturing companies with skilled and motivated workers.

In 2020, Shoreline was awarded a Career Connect Intermediary grant to develop an endorsed Biotechnician program. Over the past year, the project manager has worked to finalize internships and curriculum to endorse the program. With the support of its project partners and the Executive Dean for Workforce and STEM, the program is prepared to apply for Career Launch Endorsement. With increased demand across the region, the program is well-positioned to grow.

P6. Signed letter of endorsement from all relevant partners, stakeholders and regional networks (including employers, labor organizations, academic institutions, community-based organizations, individuals, and other relevant stakeholders in support of the proposed Career Launch program). Regional network endorsement preferred.

Please see letters of endorsement

P7. Description of resources, supports, or other processes to recruit and support students from underserved backgrounds (e.g. including students of color, students from low income families, English language learners, students with disabilities, foster students, students experiencing homelessness, students from single parent homes, and other populations that face barriers to employment); or create an implementation plan to do so.

Shoreline and the Biotech program is committed to serving its students, especially those from diverse and underserved backgrounds. Below is a detailed list of services and supports available to students.

#### **Tutoring services**

Shoreline students are eligible for free individual, one-on-one tutoring for any Shoreline course they're taking for credit. We also offer Free online tutoring, available through the college's partnership in the Western e-Tutoring Consortium. Students can interact with tutors in a live online chatroom, submit e-Questions and submit papers to the online writing lab and expect a response within 48 hours.

The Math Learning Center is located in the Library. The Math Learning Center (MLC) is an extra- help resource for MATH 060 through MATH 264. The MLC provides individual assistance on a drop-in basis from qualified tutors devoted to student's success.

#### **Emergency assistance funding**

The Foundation provides emergency assistance grants when unexpected bills and expenses limits a student's ability to stay in school. Student assistance grants come from 3 sources: recent HERF student aid funds, a United Way grant, and funds come from the Foundation's own charitable fund raising. From these three sources, students can receive help to cover the costs of rent, tuition and fees, books and supplies, parking permits or bus passes, and living expenses. The Foundation has worked to make the application process low-barrier, accessible, and known to all students. Foundation staff coordinate with programs across campus to make sure students who need financial assistance can access these funds.

#### **Food Pantry**

Shoreline's Benefits Hub houses the College's food pantry, which was started in 2013 by the Women's and Gender Equity Center, provides meals, snacks, and toiletries to students facing basic need insecurities.

#### Shoreline Community College Foundation

The Shoreline Community College Foundation has made significant contributions to supporting students facing housing insecurity. In 2019, the Foundation established a fund to provide on campus housing for 5 Shoreline students experiencing housing insecurity for up to 12 months. These grants provide rental assistance as well as supplies to outfit the apartment (e.g., with a shower curtain, sheets, and silverware).

#### The Benefits Hub

Since 2017, located in the center of campus on the main floor of the student union building, the Benefits Hub has enhanced resources offered to students in financial need, but it has also become an important place where students can access knowledge of additional resources on and off campus.

#### Workforce

Shoreline's Workforce program assists students who struggle to pay for college. Shoreline's Workforce program helps qualifying student pay for tuition, fees, books, parking or ORCA bus passes. Through Workforce, students can access Basic Food Employment & Training (BFET) services, and staff can help student see if they're eligible for the Opportunity Grant, Worker Retraining, or WorkFirst Programs.

#### Industry-Related Checklist

I-R1. Address of worksite(s) where Career Launch students will complete supervised training.

#### **AGC Biologics:**

AGC Biologics 21511 23rd Dr. SE Bothell, WA 98021 USA

#### Fred Hutch, Malik Lab:

Fred Hutchinson Cancer Research Center 1100 Fairview Ave N, A2-025 Seattle, WA 98109-1024

#### I-R2. Hourly wage for Career Launch participants.

AGC Biologics: \$13.69 per hour

Fred Hutch, Malik Lab: \$15.00 per hour

### I-R3. List of entry-level positions and associated job descriptions for which a Career Launch student would be eligible for upon completion.

#### Entry-level position: Manufacturing Tech

**SUMMARY:** The **Manufacturing Support Technician I** directly impacts commercial production through routine manufacturing support duties and sanitization activities.

#### **PRINCIPAL RESPONSIBILITIES:**

- Support unit operations described in standard operating procedures (100% of effort)
- Recognize and report deviations from procedures
- Prepare media and buffers
- Document processing steps on batch records and other approved attachments
- Label/organize the area and equipment
- Maintain/inventory and stock supplies and gowns
- Support operations such as filter integrity testing, operation of sterilizers, CIP and COP carts
- Clean, assemble/disassemble, sterilize and operate processing equipment
- Meet GMP regulations (ICH Q7A) as it applies to job function
- Assist in Materials Control shipping and receiving
- General inventory control/movement ensuring accuracy of data and related transactions
- Other duties as assigned

#### **KNOWLEDGE, SKILLS & ABILITIES:**

• Strong verbal and written communication skills

- Ability to work in a fast-paced, dynamic environment, with limited supervision.
- Demonstrated ability to multi-task
- Ability to communicate, read, and write legibly in English
- Strong computer skills sufficient to read and write email, review production schedules, read standard operating procedures
- Detail oriented with the ability to complete written and verbally assigned tasks following specific procedures
- Ability to interact constructively with peers and support groups

#### EDUCATION/EXPERIENCE:

- High School Diploma or equivalent required
- A minimum of 1 year relevant experience desired (GMP operations, Bioprocessing awareness, facility sanitization, cleaning, assembly, sterilization, and operation of primary process equipment)
- Equivalent education and experience may substitute for stated requirements

#### Entry-level position: Manufacturing Associate, level 1

Purpose And Scope Of Position The primary purpose of the Manufacturing Associate role is to complete production assignments with high quality and timely output in a cellular therapeutic manufacturing environment. Duties And Responsibilities

• Works on routine manufacturing assignments per written procedures, where ability to recognize deviation from accepted practice is required.

• Adheres to Good Manufacturing Practices and standard operating procedures.

• Weighs and checks raw materials. Assembles, cleans and sanitizes process equipment, monitors processes.

• Completes work instructions and maintains clean room environment to comply with regulatory requirements. • Trains for proficiency in the operation of primary production equipment within the assigned functional area.

• Trains for proficiency in process systems (i.e. Syncade MES and Oracle interfaces) and some supporting business systems (i.e. Oracle, ETQ, BMRAM etc.).

• Assist with the revision and or creation of process documents, such as SOPs and electronic work instructions. • Assists in maintaining material and components inventory level.

• Supports safe work environment.

• Work in teams and have continual interaction with members of his/her team as well as other manufacturing teams throughout the production process in order to exchange information regarding the batch(s) in process.

• Works on assignments that are routine in nature where judgment is required in resolving problems and making routine recommendations. Required Competencies Knowledge, Skills, and Abilities: Education: Associate's or Bachelor's degree in related field is preferred. Minimum of high school diploma and/or equivalent combination of education and experience is required.

Experience 0-2 years of cGMP manufacturing experience is desired or equivalent in work experience or education.

Proven experience working on teams where combined contribution, collaboration, and results were expected.

Demonstrated proficiency in common computer tools such as word processing, spreadsheet and web-based applications.

Experience where attention to detail and personal accountability were critical to success. Demonstrates good interpersonal skills, is attentive and approachable.

Maintains a professional and productive relationship with area management and co-workers.

- Must be able to work in a cleanroom environment that requires gowning.
- Must be able to stand for extended periods of time.

• Required to carry and/or lift to 30 pounds several times a day while handling production equipment and/or materials.

• Required to push, and/or pull up to 50 pounds several times a day while handling production equipment and/or materials

- Work in areas that may have strong magnets.
- Work in areas where handling human blood products (Biosafety Level 2) may be required.
- May work in areas with exposure to vapor phase liquid nitrogen.

• Must be able to work nights, weekends, mandatory bi-weekly overtime and holidays in a 12-hour shift structure.

# I-R4. List of specific skills and competencies required for completion of Career Launch program, with demonstrated alignment to entry-level positions, job descriptions, and average local salary ranges.

The following entry-level positions come from composite of Manufacturing Tech position and entry-level Manufacturing Associate level-1 position. The job-duty descriptions reflect the typical biomanufacturing entry-level job. Within the corresponding skills and competencies, the course number is provided.

Skills and competencies required for completion of Project Biopath program, Biotech (AAAS), & Lab Specialist Certificate	Demonstrated alignment to entry-level positions
Learn how to identify and report deviations from SOPs (procedures) via lab notebook upkeep. (Classes: BIOL 274; 277; 286)	Recognize and report deviations from procedures
Gain experience using molecular techniques, such as PCR and ELISA	Apply PCR and ELISA in a research lab setting
Apply the following techniques: gene cloning, PCR, DNA and protein electrophoresis, and protein purification (BIOL 274).	Use gene cloning, PCR, DNA and protein electrophoresis, and protein purification techniques in regular research lab setting
Preparation of media and solutions commonly used in biotechnology laboratories (BIOL 265)	Prepare media and buffers
Preparation of media and solutions commonly used in biotechnology laboratories. Use of basic lab tools such as pipettors, pH meters, scales, centrifuges, autoclaves and	Document processing steps on batch records and other approved attachments

spectrophotometers. Use of MDS, GLP procedures and lab safety. (BIOL 266)	
Students learn basic Biotechnology lab manufacturing and production techniques used to isolate and purify recombinant and/or therapeutic proteins in academic and industrial research laboratories. (BIOL 279)	Support operations such as filter integrity testing, operation of sterilizers, CIP (clean-in-place) and COP (clean-out-of-place) carts
Provides hands-on experience with sterilizing, assembling, and running bioreactors. (BIOL 246)	Clean, assemble/disassemble, sterilize and operate processing equipment
Understand the reasons why biological products must be elaborated following standard procedures (cGMP's) and consensus practices (BIOL 111; 112; &113)	Meet GMP regulations as it applies to job function
This course will focus on the skills needed to find internships and jobs in biotechnology. It will include speakers from the biotechnology industry, HR experts, and special topics such as cover letter and resume writing as well as interviewing skills. (BIOL 280)	Ability to interact constructively with peers and support groups
Introduction to theory and concepts of animal cell & tissue culturing. Teaches the fundamentals in tissue culture techniques, subculturing & maintenance of cell lines. Skills also include: cell viability testing. cell counting, feeding of cell lines & quality control. (BIOL 249)	Trains for proficiency in the operation of primary production equipment within the assigned functional area.
Introduces basic principles of bioreactor operation and cleanroom use and maintenance (BIOL 246)	Completes work instructions and maintains clean room environment to comply with regulatory requirements.

### I-R5. Employer attests that Career Launch program is in compliance with required federal, state, and local regulations.

Please see letters of endorsement

#### I-R6. Employers will outline a student supervision and mentorship model.

Please see letters of endorsement

### I-R7. Description of common career pathway(s) beginning with entry-level position specified with demonstration of likely salary growth over specified time period.

In biotechnology, career paths can have many branches. Careers often begin with technical education at two- or four-year colleges. Community colleges such as Shoreline prepare students for working in industry by providing hands-on education through associates and

bachelors degree programs. These colleges also offer certificates that focus on technical skills. As individuals gain experience, they can advance their careers through promotions, new jobs, or additional education and advanced degrees.

Career advancement pathways Manufacturing Tech I (MA I) OR Quality Associate I (QA I) Starting salary: \$22-\$23 per hour / \$42,000 annually; \$48,000 (with average overtime) 1-2 years

Manufacturing Associate (MA II) OR Quality Associate II (QA II) Salary \$70,000 2-3 years

Manufacturing Associate (MA III) OR Quality Associate III (QA III) Salary \$82,000 3-5 years

The most successful workers, those who demonstrate leadership skills on the manufacturing floor, will be on track to make more than \$100,000 in 3-5 years. Example: "David," an AGC manufacturing associate with high school education, has been with AGC Biologics for five years and now earns \$82,000 as his base salary. With overtime, last year, David earned \$120,000.

### I-R8. Demonstrated competency alignment with relevant professional standards for specified entry-level positions when applicable.

Shoreline's Biotechnology program and curriculum is reviewed regularly by its robust Advisory Committee, which comprises of industry leaders. The program has worked to not only meet the workforce needs of the biomanufacturing sector, but it has striven to be at the cutting edge of industry trends and innovations. This is evident particularly in Shoreline's participatory work involving colleges and companies at identifying and developing skills standards for biomanufacturing technician education.

Most recently, with funding from the National Institute for Innovation in Manufacturing (NIIMBL), the program has undertaken several initiatives to ensure that the program outcomes align to entry-level positions and professional standards. The most recent and clearest example of the program's alignment to industry standards is the attached Competencies Rating chart, which was produced in 2018-19 with industry partners to identify the most critical skills and competences for entry-level biotechnicians (please see Appendix 1). These standards are integrated in the Biotechnology program.

I-R9. Signed letter from employers partners attesting that Career Launch completers will be ready for specified entry-level jobs, including an optional, non-binding commitment estimating number of Career Launch completers they plan to interview/hire over the first three years of the program.

Please see letters of endorsement

#### Academic-Related Checklist

A-R1. List of academic institution(s) providing career-aligned instruction for Career Launch program.

Shoreline Community College

## A-R2. Curriculum scope and sequence aligned to skills and competencies provided in employment checklist.

Curriculum scope	Alignment to employment skills and competencies
BIOL 111	
BIOL 112	Meet GMP regulations as it applies to job function
BIOL 113	
BIOL 246 Introduction to clean room dynamics/ bioreactors	<ul> <li>Clean, assemble/disassemble, sterilize and operate processing equipment</li> <li>Trains for proficiency in the operation of primary production equipment within the assigned functional area.</li> <li>Completes work instructions and maintains clean room environment to comply with regulatory requirements</li> </ul>
BIOL 274 Molecular Biology Lab	<ul> <li>Recognize and report deviations from procedures</li> <li>Use gene cloning, PCR, DNA and protein electrophoresis, and protein purification techniques in regular research lab setting</li> </ul>
BIOL 280 Seminar In Biotechnology	Ability to interact constructively with peers and support groups
BIOL 265 Media and Solution Preparation I	Prepare media and buffers
BIOL 266 Media and Solution Preparation II	Document processing steps on batch records and other approved attachments
BIOL 286 Molecular Lab Techniques	Recognize and report deviations from procedures
BIOL 249 Tissue Culture and Staining	Trains for proficiency in the operation of primary production equipment within the assigned functional area.
BIOL 277 Immunology	<ul> <li>Recognize and report deviations from procedures</li> <li>Apply PCR and ELISA in a research lab setting</li> </ul>
BIOL 279 Biotechnology Techniques	Support operations such as filter integrity testing, operation of sterilizers, CIP (clean-in-place) and COP (clean-out-of-place) carts

## A-R3. Demonstration of student supports (e.g. mentoring, advising, financial aid, tutoring) available for Career Launch students enrolled in the course.

**Tutoring services** 

Shoreline students are eligible for free individual, one-on-one tutoring for any Shoreline course they're taking for credit. We also offer Free online tutoring is available through the college's partnership in the Western e-Tutoring Consortium. Students can interact with tutors in a live online chatroom, submit e-Questions and submit papers to the online writing lab and expect a response within 48 hours.

#### Advising

We provide advising for students who need assistance with course selection. Advising is a process based on a close student-advisor relationship intended to help students achieve their educational, career, and personal goals through the use of the college and community resources.

#### **Financial aid**

We help students with financial aid in a number of ways. We help students fill out the FAFSA and WAFSA applications for financial aid. We ensure that students who are eligible for Workforce funding receive assistance. This includes Basic Food Employment & Training (BFET) services, and staff can help student see if they're eligible for the Opportunity Grant, Worker Retraining, or WorkFirst Programs. Shoreline's Workforce program helps qualifying student pay for tuition, fees, books, parking or ORCA bus passes.

Through our emergency assistance funds, we also provide direct financial assistance to students. We currently have at least 3 sources of emergency assistance funding in which students can receive up to \$2,500 to help with expenses associated with school and living. The funding comes from Shoreline Community College Foundation fund, United Way, and Student Emergency Assistance Grant (SEAG), a grant from the SBCTC.

#### Mentoring

Shoreline's Biotechnology students are mentored on-site in the lab or on the manufacturing floor with well-experienced technicians. At Shoreline, we also offer students access to Success coaching, which provides a supportive environment for self-reflection and challenges students to achieve their goals. Success Coaches meet one-one-one or in small groups with students. Coaching is a student-centered approach that introduces students to resources and tools and helps them explore strategies for success in college and in life.

### A-R4. Number of postsecondary credits provided and / or credential earned upon completion of program.

Credential earned	Postsecondary credits
Introduction to Biomanufacturing: BioPath certificate	9 credits
Biotech Lab Specialist certificate	37-38 credits
Associate in Applied Arts and Sciences (AAAS) degree	92.5 - 93.5 credits

### A-R5. Demonstrated curricular alignment with relevant professional and / or academic standards associated with coursework and credential, when applicable.

Please see attached Appendix 1: Core Competencies for Bio-Science Technician and I-R4

# A-R6. Details of potential for current or future partnerships and/or scalability of the program within and across sectors and/or geographic locations (e.g. articulation, degree pathways), when applicable.

Recent breakthroughs in biotechnology have made possible the ability to cure some of society's most deadly diseases and cancers. The manufacturing of these new treatments requires a high number of biomanufacturing technicians at all skill levels. The Puget Sound economy is quickly becoming both major center for cutting-edge clinical research and biomanufacturing. Shoreline has taken notice of recent innovations biopharmaceutical and biomanufacturing industries in the Puget Sound region.

Shoreline has worked to address the growing workforce needs of this expanding field. Most recently, the program was awarded a 3-year NSF grant to establish a Biotechnology Hub that focuses on expanding industry partnerships and increasing the capacity to train additional workers. As a result, the program has been developing relationships with companies such as Seagen Biotechnology, Bristol Myers Squibb, and others. The program will seek to develop Career Launch and work-based learning opportunities with these and other future partners.



AGC Biologics, 21511 23<sup>rd</sup> Dr. SE Bothell, WA 98021

May 21<sup>st</sup>, 2021

Dear Career Launch Endorsement Committee,

AGC Biologics would like to offer its support to Shoreline Community College's application for Career Launch Endorsement of its Biotechnology program. As the only college that provides a 2-year biotechnology associate's degree in Washington, the program produces a critical supply of biomanufacturing technicians to the region's life sciences workforce.

Shoreline Community College and AGC Biologics have partnered to create the BioPath internship program, which provides paid, on-the-job training to students of the program to fulfill Shoreline's credit based internship requirement. While working in the lab, students receive hands-on mentorship with experienced researchers and scientists and college credit to compete their degrees. During their internship, interns receive \$13.69 per hour, critical on-the-job training and experience, and a valuable credential when they complete the internship and program at Shoreline. AGC Biologics maintains compliance with applicable federal, state, and local regulations.

The combined work experience and Biomanufacturing certificate makes students particularly competitive in the job market upon graduation. With the combined Biomanufacturing certificate and the experience gained from AGC Biologics, students will be ready for entry-level positions, such as Manufacturing Associate, in the biotechnology field. We will consider hiring successful graduates of the BioPath program who meet our employment qualifications and labor needs.

AGC Biologics is excited to continue its partnership with Shoreline's Biotechnology program and provide workbased learning opportunities for the BioPath internship program.

Please feel free to contact me if you have questions or would like additional information regarding Shoreline's Biotechnology Career Launch program.

Sincerely,

Rodrigo H. Conzalez PhD. Senior Director, Learning and Performance, Biomanufacturing Operations 21511 23<sup>rd</sup> Dr. SE Bothell, WA 98021 Cell 1: +1.425.236.8614 (US) Email: <u>rgonzalez@agcbio.com</u> Web: <u>www.agcbio.com</u>

#### www.agcbio.com



Harmit S. Malik Member, Basic Sciences & HHMI Investigator Fred Hutchinson Cancer Research Center 1100 Fairview Ave N, A2-025 Seattle, WA 98109-1024 e-mail: hsmalik@fhcrc.org 15 May 2021

Dear Career Launch Endorsement Committee,

The Malik Lab at Fred Hutchinson Cancer Research Center would like to offer its strong endorsement in support of Shoreline Community College's application for Career Launch Endorsement of its Biotechnology program. Shoreline Community College (SCC) is the only college that provides a 2-year biotechnology associate's degree in Washington. As a result, this program produces a critical supply of trained personnel for a variety of careers essential for the vibrancy of the region's life sciences workforce.

The Malik Lab has partnered and will continue to partner with SCC's Biotech program to provide paid, on-the-job training to students of the program to fulfill Shoreline's credit based internship requirement. While working in the lab, students receive hands-on mentorship with experienced researchers and scientists and college credit to compete their degrees. In most cases, they actively participate in research projects and have even earned authorships on scientific publications by virtue of their contributions, which also greatly increases their job prospects, During their internship, paid interns receive \$15 per hour, critical on-the-job training and experience, and a valuable credential when they complete the internship and program at Shoreline. The Malik Lab and Fred Hutch maintain compliance with required federal, state, and local regulations.

The combined work experience and biotechnology degree makes students particularly competitive in the job market upon graduation. With the combined Biotechnology degree and the experience gained from the Malik Lab, students will be ready for research technician I and II positions in the biotechnology field. This has allowed graduates of the program who have trained with us to successfully obtain desired position in both academic and biotech settings. Our lab has hired three of these successful graduates of Shoreline's Career Launch Biotechnology program who meet our employment qualifications and labor needs, and we will continue to seek candidates for our lab positions from this pool of graduates in the future.

The Malik Lab and Fred Hutch are excited to continue the partnership with Shoreline's Biotechnology program and provide high-quality, paid, work-based learning opportunities for students of the Biotechnology program.

Please feel free to contact me if you have questions or would like additional information regarding Shoreline's Biotechnology Career Launch program.

With best wishes,

Harmit Malik

### **APPENDIX 1**

		and from findings of the National Center for Therapeutics Manufacturing (NCTM) on 18 July 2 KEY	
		1 = critical	
		2 = important 3 = desirable	
		4 = unimportant	
			-
		<b>Competency Concentration Areas</b> (Competencies begin"Ability to")	
(	СОММ		Industry Importance
A	Dem	onstrate Effective Communication Skills	Rating
	a1	Use e-mail and other electronic means of communication effectively	2
	a2	Appropriately construct written letters and non-technical communication	3
	a3	Write legibly	1
	a4	Demonstrate ability to read and comprehend instructions	1
	a5	Demonstrate ability to listen and comprehend instructions	1
	a6	Demonstrate good observation skills	1
	a7	Recall and apply key job-related information (processes, references, terminology, acronyms)	1
	a8	Understand and apply specific instructions per procedures	1
	a9	Comply with company communication policies	2
В	Man	age and Communicate information	
	b1	Demonstrate ability to write technical documents such as instructions, reports and technical communications	3
	b2	Communicate information in an appropriate manner	1
	b3	Assist in reviewing and revising technical documents	3
	b4	Suggest continuous improvements to procedures, processes	2
С	Dem	oonstrate Appropriate Computer Skills and Uses	
	c1	Demonstrate adherence to computer security practices	1
	c2	Utilize computer systems and programs to record information (Trackwise, LIMs, control worksheets, process monitoring spreadsheets, etc.)	1
	c3	Create documents using word processing, spreadsheets, analytical and presentation	3
	c4	software Use the internet/intranet appropriately to research and acquire technical information	3

2	v	VORK	PLACE COMPETENCIES	Industry Importance	
	A	Dem	onstrate Expected Workplace Performance	Rating	
		a1	Demonstrate flexibility, willingness to learn	1	
		a2	Identify and document problems; escalate, verbalize per company policy	1	

	a3	Understand their range of responsibility and accept responsibility for decisions	1	
	a4	Apply problem solving methods and continuous improvement techniques	3	
в	Dem	onstrate Effective Work With Teams		-
	a1	Work productively in a team environment	1	
	a2	Demonstrate understanding of the behavior of successful teams	2	
	a3	Manage conflict effectively and with sensitivity to the needs and perceptions of others	2	
	a4	Demonstrate self-awareness	3	
с	Dem	onstrate Personal Professionalism		
	c1	Manage time efficiently	2	
	c2	Adhere to the human resource policies of the employer	1	
	c3	Practice proper personal hygiene	1	
	c4	Demonstrate, implement skills and knowledge acquired during training	1	
	c5	Display the personal and ethical characteristics of a professional	1	
	c6	Observe and adhere to the principles of intellectual property rights, patient data protection and confidentiality agreements	1	
	c7	Demonstrate life-long learning and plan and track professional growth	3	
	c8	Demonstrate good presentation skills for small groups and larger audiences	3	
D	Dem	onstrate Cultural Awareness in the Workplace		
	d1	Demonstrate awareness of cultural differences to facilitate effective communication	2	
	d2	Demonstrate emotional intelligence in dealing with workplace issues	2	
E	Dem	onstrate Technician Career Readiness		
	e1	Understand and describe the impact of bio-science on the lives of others	3	
	e2	Describe the roles and functions of the various departments most commonly found in bio-science and bio-technology companies	2	
	e3	Define common employment opportunities in bio-science and bio-technology	3	
	e4	Demonstrate awareness of and preparation for common employment interview methods, scenarios	3	

SAF	ETY AND REGULATORY COMPETENCIES	Industry Importance	
A De	monstrate Exemplary Workplace Safety Methods	Rating	
а	Describe and demonstrate safe and accepted behavior in a lab environment	1	
а	2 Demonstrate the application of ergonomic principles in the workplace	2	
а	Understand and interpret safety data sheets (sds/msds)	1	
	Understand and follow established biological handling procedures	1	
а	Identify hazardous materials and by-products and their proper handling	1	
а	Identify and use appropriate personal protection equipment (PPE)	1	
а	Follow established procedures for disposal of hazardous waste and by-products	1	
а	Demonstrate understanding and compliance with clean room behavior, processes and regulations	1	

a	Demonstrate effective aseptic and sterilization techniques	1
в Со	mply with Applicable Regulations and Standards	
b	Follow established policies and procedures	1
b	Record information according to established procedures	1
b	Exercise proper document control	1
b	Participate in required training	1
b	5 Demonstrate audit readiness	1
b	Demonstrate understanding and adherence to control principles in accordance with the established quality system	1
b	Demonstrate understanding and exercise adherence to traceability principles	1
b	Participate in validation activities	3
b	Recognize and address nonconformances	1
C Ma	intain a Safe and Productive Work Environment	
c	Recognize unsafe conditions and take corrective and/or preventative action(s)	1
c	Follow relevant safety policies, guidelines, and regulations (company, OSHA, EPA, CDC)	1
c	Access and use safety data sheets (SDS) and other safety information sources	1
Cé	Maintain a safe, clean, contamination-free, and clutter-free environment	1

4 TECHNICIAN COMPETENCIES		Industry Importance			
Α	A Perform Measurements, Tests, Assays				
	a1	Collect samples according to established procedures and applicable sampling plans	1		
	a2	Prepare samples according to established procedures	1		
	a3	Follow appropriate test procedures/instructions	1		
	a4	Document data and results according to established procedures	1		
	a5	Interpret and/or analyze data and results within range of responsibility	1		
В	Perf	orm Mathematical Manipulations			
	b1	Demonstrate mastery of fundamental mathematics	2		
	b2	Perform calculations related to work function	1		
	b3	Manipulate, convert and accurately report units for all calculations	2		
	b4	Interpret statistical graphs (bar graph, histograph, etc.)	2		
	b5	Perform data analysis	3		
	b6	Show that data, calculations and results are reasonable	2		
с	C Provide Routine Facility Support				
	c1	Operate and maintain equipment according to company SOP or manufacturer's instructions	1		
	c2	Prepare materials, supplies, and/or equipment for use	1		
	c3	Maintain inventory of raw materials, parts, components and/or equipment	1		
		Research and understand new equipment	2		
		Understand the basic functionality of equipment frequently found in the lab	1		

5	CLEAN	VING/STERILIZATION COMPETENCIES (Participant Additions)	Industry Importance Rating	
	1	Disinfection vs sanitization vs cleaning vs sterilization (Uses of IPA, spor klenz, viracidals, etc	1	
	2	Understanding of contamination control and how a clean room operates.	1	
	3	Awareness of environmental monitoring (EM), bioburden	2	
	4	Sources of contamination (bacteria vs mold) - how introduced and how controlled.	1	
	5	Operation of BSC and laminer flow hoods.	1	
	6	Awareness of pest control.	3	

6	6 ADDITIONAL COMPETENCIES (from NCTM)			Industry Importance	
	A	Prin	Rating		
		1	Product development cycle, scientific principles	2	
		2	Biopharmaceutical facility operations/safety	2	
		3	Proper documentation purpose and protocols	1	
		4	Document control/pathway, process documentation	1	
		5	Understanding deviations and CAPA response	2	
	в	Qua	lity Systems and Analytical Techniques		
		1	Prep/proper labeling of reagents/media	1	
		2	Aseptic technique, sterile environment operations/behavior	1	
		3	Gowning, environmental monitoring	1	
		5	Equipment calibration, validation	3	
		6	Bacterial endotoxin testing, SDS-PAGE assay, total protein assay, HPLC, TOC analysis	3	