Career & Technical Education
Curriculum Framework

Washington Office of Superintendent of
PUBLIC INSTRUCTION

Required Form

Course Information		
Course: BIOMANUFACTURING		**Total Framework Actual Hours:** 180 HOURS
CIP Code: 140501	☐ **Exploratory** ☒ **Preparatory** *Preparatory courses are best built with a min. of 140 hours.*	**Date Last Modified:** 4/13/2023
Career Cluster: Science, Technology, Engineering & Mathematics		**Cluster Pathway:** HEALTH SCIENCES
Course Summary: This course is a second-year biotechnology course which focuses on biomanufacturing lab knowledge and skills.		

Industry-Recognized Certificates: Biotechnology Assistant Certificate

Work-Based Learning: Field trips, guest speaker, internship

Unit Information	
Unit: Introduction to Biomanufacturing	**Total Learning Hours for Unit:** 15 hours
Unit Summary: In this unit, students will learn the biomanufacturing process including the evolution of pharmaceuticals, bioethics case studies, key stakeholders, and the importance of SOPs within the biomanufacturing lab.	
Components and Assessments	
Performance Assessments: Students will:	

- Explain why biological products must be produced following standard procedures cGMP (Current Good Manufacturing Practices) and consensus practices.
- Summarize the history and the original events that triggered the creation of cGMP in biomanufacturing
- Describe the basic quality structure necessary to manufacture biological products and the steps that must be followed for approved by regulatory authorities such as the FDA
- Compare and contrast the purposes and impacts of Current Good Manufacturing Practices (cGMP), Current Good Clinical Practices (cGCP), and Current Distribution Practices (cGDP).
- Design a Standard Operating Procedure (SOP) and investigate how different outcomes could be obtained by the same procedure.
- Summarize the Clinical Phases of New Drug Development and Biologic License Application.
- Cite evidence of Quality Assurance systems observed during a Biomanufacturing facility tour.
- Pass Compliance Unit Assessment

Leadership Alignment:

- Students will think creatively and collaborate with others to design a SOP based on cGMP.
- Students will reason effectively and use systems thinking to analyze problems with a SOP that results in inconsistent product outcomes.
- Students will collaborate with others to apply OSHA and CDC safety regulations, and in the proper use of Personal Protective Equipment.

Industry Standards and/or Competencies

Name of standards:	**Website:**
1. Biotechnology Research and Development Pathway Standards 2. National Health Science Standards 3. Common Core State Standards for English Language Arts 4. Common Core State Standards for Mathematics 5. Next Generation Science Standards	1. https://www.nchste.org/pageimages/ACFC9.pdf 2. https://resources.youscience.com/hubfs/Partners/NCHSE/National_Health_Science_Standards.pdf 3. https://learning.ccsso.org/wp-content/uploads/2022/11/ELA_Standards1.pdf 4. https://learning.ccsso.org/wp-content/uploads/2022/11/Math_Standards1.pdf 5. https://www.nextgenscience.org/

Biotechnology Research and Development Pathway Standards
Standard 05: Product Design and Development
5.1 Development 5.11 Diagram the process involved in making one biotech product in an industrial setting.
5.12 Analyze the role of pre-clinical and clinical trials in biotechnology product development.
5.2 Regulation
5.21 Examine the role of a Quality Assurance person in this process.
5.22 Define cGMP and why it is important in biotech production.
Standard 06: Bioethics
6.1 Societal
6.11 Differentiate between morality and ethics and the relationship of each to biotechnology health care product development.
6.12 Discuss bioethical issues related to recombinant products.
6.13 Contrast personal, professional and organizational ethics.
6.2 Institutional 6.21 Comply with policies and requirements for documentation and record keeping.
6.22 Comply with institutional ethical policies and procedures.

National Health Science Foundation Standards Foundation
Standard 03: Systems
3.1 Healthcare Delivery Systems
3.1.1 Differentiate healthcare delivery systems and healthcare related agencies. Government Biomanufacturing Centers for Disease Control and Prevention (CDC) - Food and Drug Administration (FDA) - Occupational Safety and Health Administration (OSHA) - Public Health Service (PHS)

Aligned Washington State Learning Standards	
English Language Arts	Reading for Literacy in Science and Technical Subjects GRADES 11-12 RST.11-12.2 Determine the central ideas or conclusions of a text; summarize complex concepts, processes, or information presented in a text by paraphrasing them in simpler but still accurate terms. RST.11-12.3 Follow precisely a complex multistep procedure when carrying out experiments, taking measurements, or performing technical tasks; analyze the specific results based on explanations in the text. RST.11-12.4 Determine the meaning of symbols, key terms, and other domain-specific words and phrases as they are used in a specific scientific or technical context relevant to grades 11–12 texts and topics. RST.11-12.5 Analyze how the text structures information or ideas into categories or hierarchies, demonstrating understanding of the information or ideas.

	RST.11-12.6 Analyze the author's purpose in providing an explanation, describing a procedure, or discussing an experiment in a text, identifying important issues that remain unresolved. RST.11-12.8 Evaluate the hypotheses, data, analysis, and conclusions in a science or technical text, verifying the data when possible and corroborating or challenging conclusions with other sources of information. RST.11-12.9 Synthesize information from a range of sources (e.g., texts, experiments, simulations) into a coherent understanding of a process, phenomenon, or concept, resolving conflicting information when possible. Speaking and Listening GRADES 11-12 SL.11-12.1 Initiate and participate effectively in a range of collaborative discussions (one-on-one, in groups, and teacher-led) with diverse partners on grades 11–12 topics, texts, and issues, building on others' ideas and expressing their own clearly and persuasively. SL.11-12.1a Come to discussions prepared, having read and researched material under study; explicitly draw on that preparation by referring to evidence from texts and other research on the topic or issue to stimulate a thoughtful, well-reasoned exchange of ideas. SL.11-12.4 Present information, findings, and supporting evidence, conveying a clear and distinct perspective, such that listeners can follow the line of reasoning, alternative or opposing perspectives are addressed, and the organization, development, substance, and style are appropriate to purpose, audience, and a range of formal and informal tasks. SL.11-12.5 Make strategic use of digital media (e.g., textual, graphical, audio, visual, and interactive elements) in presentations to enhance understanding of findings, reasoning, and evidence and to add interest. SL.11-12.6 Adapt speech to a variety of contexts and tasks, demonstrating a command of formal English when indicated or appropriate. (See grades 11–12 Language standards 1 and 3 here for specific expectations.) Writing for Literacy in History/Social Studies, Science, and Technical Subjects GRADES 11-12 WHST.11-12.1 Write arguments focused on discipline-specific content. WHST.11-12.1c Use words, phrases, and clauses as well as varied syntax to link the major sections of the text, create cohesion, and clarify the relationships
Science	Disciplinary Core Ideas Engineering, Technology, and Applications of Science ETS1.A Defining and Delimiting Engineering Problems ETS1.B Developing Possible Solutions ETS1.C Optimizing the Design Solution Life Sciences LS1.A Structure and function LS1.D Information Processing LS3.A Inheritance of traits Engineering, Technology, and Applications of Science Engineering, Technology, and Applications of Science HS-ETS1 Engineering Design

	HS-ETS1-1. Analyze a major global challenge to specify qualitative and quantitative criteria and constraints for solutions that account for societal needs and wants. HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering. HS-ETS1-3. Evaluate a solution to a complex real-world problem based on prioritized criteria and trade-offs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts. Life Sciences HS-LS1 From Molecules to Organisms: Structures and Processes HS-LS1-1. Construct an explanation based on evidence for how the structure of DNA determines the structure of proteins which carry out the essential functions of life through systems of specialized cells. HS-LS1-2. Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms. HS-LS3 Heredity: Inheritance and Variation of Traits HS-LS3-1. Ask questions to clarify relationships about the role of DNA and chromosomes in coding the instructions for characteristic traits passed from parents to offspring. Science and Engineering Practices • Asking questions and defining problems • Developing and using models • Analyzing and interpreting data • Engaging in argument from evidence • Obtaining, evaluating, and communicating information Science Crosscutting Concepts • Patterns • Cause and effect: • Mechanism and explanation • Systems and system models • Structure and function

Unit Information	
Unit: Analytical Methods	**Total Learning Hours for Unit:** 15 hours
Unit Summary: In this unit, students will become familiar with equipment and procedures necessary to run a biomanufacturing lab and act as a biotechnician focusing on lab safety, units of measurement, graphing data using spectroscopy, calibration of equipment, and gel electrophoresis.	

Components and Assessments
Performance Assessments: Students will • Explain the role of ELISA and spectrometry in biotech labs. • Perform total quantification by ultraviolet spectroscopy and dye-binding procedures. • Describe how electrophoresis is used in labs. • Compare and contrast 1-D and 2-D electrophoresis. • Analyze and interpret ELISA plate results to make a standard curve and graph the distribution of data. • Determine the Quality Control measures used in Bioassays to identify specific biologic active proteins. • Calibrate and use micropipettes and analytical balances. • Pass Analytical Methods Unit Assessment
Leadership Alignment: • Students will adapt to change in response to product outcomes that arise unexpectedly. • Students will work effectively in diverse teams to build positive team relationships in the workplace.

Industry Standards and/or Competencies	
Name of standards: 6. Biotechnology Research and Development Pathway Standards 7. National Health Science Standards 8. Common Core State Standards for English Language Arts 9. Common Core State Standards for Mathematics 10. Next Generation Science Standards	**Website:** 6. https://www.nchste.org/pageimages/ACFC9.pdf 7. https://resources.youscience.com/hubfs/Partners/NCHSE/National_Health_Science_Standards.pdf 8. https://learning.ccsso.org/wp-content/uploads/2022/11/ELA_Standards1.pdf 9. https://learning.ccsso.org/wp-content/uploads/2022/11/Math_Standards1.pdf 10. https://www.nextgenscience.org/

Biotechnology Research and Development Pathway Standards

Standard 02: Academic Foundations

2.1 Mathematical concepts

2.11 Illustrate the concepts of percentages and ratios using a biotechnology application.

2.12 Contract weight-to-weight and weight-to-volume calculations for solutions.

2.13 Explain scientific notation.

2.2 Statistics

2.21 Compare the standard deviation and the mean of efficacy testing data of two biotechnology products.

2.22 Graphically illustrate a set of biotech data such that a layman would understand it.

2.4 Organic Chemistry

2.42 Create an equation of two organic substrates leading to a product.

2.44 Contrast covalent, ionic and hydrogen bonding.

2.5 Biochemistry

2.51 Diagram six chemical side groups that could be in a biotechnology product.

2.52 Categorize all amino acids into essential and non-essential.

2.53 Describe the relationship between biochemistry and biotechnology product development.

2.54 Compare the underlying reasons why some molecules are hydrophilic and some are hydrophobic.

Standard 03: Introduction to Biotechnology Knowledge Areas and Techniques

3.1 Techniques

3.11 Describe the following techniques; recombinant DNA, genetic engineering, monoclonal antibody production, separation and purification of biotechnology products and bioprocessing.

Standard 04: Laboratory Protocols and Procedures

4.2 Protocols

4.21 Distinguish the requirements of sterile techniques.

4.22 Respond to a hypothetical laboratory accident appropriately as a member of a laboratory team.

Standard 05: Product Design and Development

5.1 Development

5.11 Diagram the process involved in making one biotech product in an industrial setting.

5.12 Analyze the role of pre-clinical and clinical trials in biotechnology product development.

5.2 Regulation

5.21 Examine the role of a Quality Assurance person in this process.

5.22 Define cGMP and why it is important in biotech production.

National Health Science Foundation Standards Foundation

Standard 01: Academic Foundation 1.3 Medical Mathematics

1.3.1 Demonstrate competency using basic math skills and mathematical conversions as they relate to healthcare. a. Metric system - Kilo- - Centi- - Deci- - Milli- - Microb. Mathematical - Average - Ratios - Fractions - Percentages - Addition / Subtraction - Multiplication / Division c. Conversions - Volume (ml/cc) - Temperature (F/C)

Foundation Standard 07: Safety Practices

7.2 Personal Safety

7.2.1 Apply personal safety procedures based on Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) regulations.

7.2.3 Demonstrate and apply the use of personal protective equipment (PPE).

7.3 Environmental Safety

.3.1 Apply safety techniques in the work environment. - Ergonomics - Safe operation of equipment - Patient/client/employee safety measures

7.4 Common Safety Hazards

7.4.1 Observe all safety standards related to the occupational exposure to hazardous chemicals standard (safety data sheets [SDS]).

7.4.2 Comply with safety signs, symbols, and labels.

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Mathematics	Algebra Creating Equations (A-CED) 1 - Create equations and inequalities in one variable and use them to solve problems. Include equations arising from linear and quadratic functions, and simple rational and exponential functions.* 2 - Create equations in two or more variables to represent relationships between quantities; graph equations on coordinate axes with labels and scales.* 3 - Represent constraints by equations or inequalities, and by systems of equations and/or inequalities, and interpret solutions as viable or non-viable options in a modeling context. For example, represent inequalities describing nutritional and cost constraints on combinations of different foods.*

	4 - Rearrange formulas to highlight a quantity of interest, using the same reasoning as in solving equations. For example, rearrange Ohm's law V = IR to highlight resistance R.* Mathematical Practices CC: Mathematical Practices (MP) • Make sense of problems and persevere in solving them. • Reason abstractly and quantitatively. • Construct viable arguments and critique the reasoning of others. • Model with mathematics. • Use appropriate tools strategically. • Attend to precision. • Look for and make use of structure. • Look for and express regularity in repeated reasoning. Statistics and Probability Interpreting Categorical and Quantitative Data (S-ID) 1 - Represent data with plots on the real number line (dot plots, histograms, and box plots).* 2 - Use statistics appropriate to the shape of the data distribution to compare center (median, mean) and spread (interquartile range, standard deviation) of two or more different data sets.*
Science	Disciplinary Core Ideas Engineering, Technology, and Applications of Science ETS1.A Defining and Delimiting Engineering Problems ETS1.B Developing Possible Solutions ETS1.C Optimizing the Design Solution Life Sciences LS1.A Structure and function LS1.D Information Processing LS3.A Inheritance of traits Engineering, Technology, and Applications of Science Engineering, Technology, and Applications of Science HS-ETS1 Engineering Design HS-ETS1-1. Analyze a major global challenge to specify qualitative and quantitative criteria and constraints for solutions that account for societal needs and wants. HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering. HS-ETS1-3. Evaluate a solution to a complex real-world problem based on prioritized criteria and trade-offs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts. Life Sciences

	HS-LS1 From Molecules to Organisms: Structures and Processes HS-LS1-1. Construct an explanation based on evidence for how the structure of DNA determines the structure of proteins which carry out the essential functions of life through systems of specialized cells. HS-LS1-2. Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms. HS-LS3 Heredity: Inheritance and Variation of Traits HS-LS3-1. Ask questions to clarify relationships about the role of DNA and chromosomes in coding the instructions for characteristic traits passed from parents to offspring. Science and Engineering Practices • Asking questions and defining problems • Developing and using models • Analyzing and interpreting data • Engaging in argument from evidence • Obtaining, evaluating, and communicating information Science Crosscutting Concepts • Patterns • Cause and effect: • Mechanism and explanation • Systems and system models • Structure and function

Unit: Introduction to Bioreactors	**Total Learning Hours for Unit:** 15 hours
Unit Summary: In this unit, using the engineering process to make bioreactors for the purpose of growing cells to identify process occurring within cells and the byproducts made.	
Components and Assessments	
Performance Assessments: Students will • Summarize the basic physiological principles underlying growth and culture of cells and microorganisms • Perform microscopic investigations to identify and differentiate bacteria, yeast, and mammalian cells • Design and operate prototype bioreactors according to their final use	

- Control microbial growth and product biosynthesis reproducibly during lab investigations
- Apply mathematical models to predict microbial and cellular behavior Interpret the meaning of "fermentation" under a variety of circumstance
- Assemble a laboratory scale bioreactor
- Calibrate pH, dissolved oxygen, temperature using sensors
- Formulate media for cell culture -- Explain the purpose of the components of culture media
- Explain microbial and cellular growth models -- Use computational mathematics models to predict bacterial growth
- Pass Intro to Bioreactors Unit Assessment

Leadership Alignment:

- Students will solve problems to determine the environmental requirements and growth patterns of microbial and cellular growth.
- Students will use systems thinking to formulate proper timing and conditions for cell harvest in downstream processing of biologics.

Industry Standards and/or Competencies

Name of standards:	**Website:**
11. Biotechnology Research and Development Pathway Standards 12. National Health Science Standards 13. Common Core State Standards for English Language Arts 14. Common Core State Standards for Mathematics 15. Next Generation Science Standards	11. https://www.nchste.org/pageimages/ACFC9.pdf 12. https://resources.youscience.com/hubfs/Partners/NCHSE/National_Health_Science_Standards.pdf 13. https://learning.ccsso.org/wp-content/uploads/2022/11/ELA_Standards1.pdf 14. https://learning.ccsso.org/wp-content/uploads/2022/11/Math_Standards1.pdf 15. https://www.nextgenscience.org/

Biotechnology Research and Development Pathway Standards

Standards Standard 02: Academic Foundations

2.1 Mathematical concepts

2.11 Illustrate the concepts of percentages and ratios using a biotechnology application.

2.12 Contract weight-to-weight and weight-to-volume calculations for solutions.

2.13 Explain scientific notation.
2.2 Statistics
2.22 Graphically illustrate a set of biotech data such that a layman would understand it.
2.5 Biochemistry
2.53 Describe the relationship between biochemistry and biotechnology product development.
2.6 Cell Biology
2.61 Describe the basic structures and functions of cells and how this knowledge is used in biotechnology.
2.62 Select cellular barriers to be overcome for a biotechnology product to work inside a cell.
2.7 Molecular biology
2.72 Demonstrate DNA replication graphically and its' importance to biotechnology product development.
2.73 Describe the central dogma of molecular biology and how understanding this process impacts biotechnology research and development.
2.8 Microbiology
2.81 Analyze how microorganisms are used in mass producing recombinant proteins.
2.82 Compare and contrast bacterial, fungal, and animal cells and how these similarities and differences affect biotechnology product development and production decisions.
Standard 04: Laboratory Protocols and Procedures
4.1 Procedures 4.11 Describe how molarity relates to solution preparation.
4.12 Calculate the molarity of a given solution and measure the pH of this solution.
4.2 Protocols
4.21 Distinguish the requirements of sterile techniques.
4.22 Respond to a hypothetical laboratory accident appropriately as a member of a laboratory team. Standard 05: Product Design and Development
5.1 Development
5.11 Diagram the process involved in making one biotech product in an industrial setting.
5.2 Regulation
5.21 Examine the role of a Quality Assurance person in this process.
5.22 Define cGMP and why it is important in biotech production.

National Health Science Foundation Standards Foundation
Standard 01: Academic Foundation
1.1 Human Anatomy and Physiology

1.1.1 Describe the organization of the human body and directional terms. a. Identify Levels of Organization - Chemical - Cellular - Tissue - Organ - System - Organism
1.3 Medical Mathematics
1.3.1 Demonstrate competency using basic math skills and mathematical conversions as they relate to healthcare. a. Metric system - Kilo- - Centi- - Deci- - Milli- - Mathematical - Average - Ratios - Fractions - Percentages - Addition / Subtraction - Multiplication / Division c. Conversions - Volume (ml/cc) Biomanufacturing Temperature (F/C)
1.3.2 Demonstrate the ability to analyze diagrams, charts, graphs, and tables to interpret healthcare results.
Foundation Standard
07: Safety Practices 7.1 Infection Control
7.1.1 Explain principles of infection transmission. a. Identify classifications of pathogens - Bacteria Fungi - Parasites - Viruses b. Describe characteristics of microorganisms - Aerobic - Anaerobic - Non-pathogenic - Pathogenic c. Recognize chain of infection d. Describe mode of transmission - Common vehicle (air, food, water) - Direct - Healthcare-associated infections (nosocomial) - Indirect - Opportunistic - Vectors
7.1.2 Differentiate methods of controlling the spread and growth of pathogens. a. Asepsis - Sanitization - Antisepsis - Disinfection - Sterile technique - Sterilization b. Standard precautions - Handwashing - Gloving - Personal Protective Equipment (PPE) - Environmental cleaning d. Bloodborne pathogen precautions
7.2 Personal Safety
7.2.1 Apply personal safety procedures based on Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) regulations.
7.2.3 Demonstrate and apply the use of personal protective equipment (PPE)

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	represent inequalities describing nutritional and cost constraints on combinations of different foods.* 4 - Rearrange formulas to highlight a quantity of interest, using the same reasoning as in solving equations. For example, rearrange Ohm's law V = IR to highlight resistance R.* Mathematical Practices CC: Mathematical Practices (MP) Make sense of problems and persevere in solving them. Reason abstractly and quantitatively. Construct viable arguments and critique the reasoning of others. Model with mathematics. Statistics and Probability Interpreting Categorical and Quantitative Data (S-ID) 1 - Represent data with plots on the real number line (dot plots, histograms, and box plots).* 3 - Interpret differences in shape, center, and spread in the context of the data sets, accounting for possible effects of extreme data points (outliers).*
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Unit: Cell Cultures	**Total Learning Hours for Unit:** 15 hours
Unit Summary: In this unit, students will culture different cell types to compare the growth requirements while utilizing sterile technique.	
Components and Assessments	
Performance Assessments: Students will • Cite evidence of the special requirements for culturing mammalian cell lines to be used in developing biologicals. • Critique stress demonstration in cell suspensions using extreme heat and damage. • Describe the assembly sequence, principles, and advantages of Single Use Bioreactors (SUB's) • Assess the advantages of SUB's. • Investigate SUB assembly principles. • Explain why cell lines are a source of complex biological active products.	

- List the requirements of mammalian cell media.
- Perform differential cell staining and quantification using a Neubauer chamber.
- Describe the importance of posttranslational modifications of proteins in human health.
- Formulate proper timing and conditions for cell harvest procedures with Downstream Processing considerations.
- Describe the relevance of maintaining research, master, and working cell banks.
- Investigate environmental microbial burden using nutrient broth agar in petri dishes and in sterile growth medium.
- Pass Cell Culture Unit Assessment

Leadership Alignment:

- Students will reason effectively when determining the requirements for culturing mammalian cell lines used in the development of protein-based therapeutics.
- Students will solve problems that arise when growing mammalian cell lines in a lab.

Industry Standards and/or Competencies

Name of standards:	**Website:**
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Standard 02: Academic Foundations

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2.12 Contract weight-to-weight and weight-to-volume calculations for solutions.

2.13 Explain scientific notation.

2.2 Statistics

2.22 Graphically illustrate a set of biotech data such that a layman would understand it.

2.3 Genetics

2.31 Describe the basic structure of a chromosome.

2.33 Differentiate the genetic inheritance of a lethal dominant homozygous trait (e.g. dwarfism) from a heterozygous disease (e.g., sickle cell anemia).

2.5 Biochemistry

2.52 Categorize all amino acids into essential and non-essential.

2.53 Describe the relationship between biochemistry and biotechnology product development.

2.6 Cell Biology 2.61 Describe the basic structures and functions of cells and how this knowledge is used in biotechnology.

2.62 Select cellular barriers to be overcome for a biotechnology product to work inside a cell.

2.8 Microbiology

2.81 Analyze how microorganisms are used in mass producing recombinant proteins.

2.82 Compare and contrast bacterial, fungal, and animal cells and how these similarities and differences affect biotechnology product development and production decisions.

Standard 04: Laboratory Protocols and Procedures

4.1 Procedures

4.11 Describe how molarity relates to solution preparation.

4.2 Protocols

4.21 Distinguish the requirements of sterile techniques.

4.22 Respond to a hypothetical laboratory accident appropriately as a member of a laboratory team. Standard 05: Product Design and Development

5.1 Development

5.11 Diagram the process involved in making one biotech product in an industrial setting.

5.2 Regulation

5.21 Examine the role of a Quality Assurance person in this process. 5.22 Define cGMP and why it is important in biotech production.

National Health Science Foundation Standards Foundation

Standard 01: Academic Foundation

1.1 Human Anatomy and Physiology

1.1.1 Describe the organization of the human body and directional terms. a. Identify Levels of Organization - Chemical - Cellular

1.3 Medical Mathematics

1.3.1 Demonstrate competency using basic math skills and mathematical conversions as they relate to healthcare. a. Metric system - Kilo- - Centi- - Deci- - Milli- - Mathematical - Average - Ratios - Fractions - Percentages - Addition / Subtraction - Multiplication / Division c. Conversions - Volume (ml/cc) - Temperature (F/C) Foundation Standard 07:

Safety Practices 7 .1 Infection Control

7.1.1 Explain principles of infection transmission. a. Identify classifications of pathogens - Bacteria Fungi - Parasites - Protozoa - Viruses b. Describe characteristics of microorganisms - Aerobic - Anaerobic - Non-pathogenic - Pathogenic c. Recognize chain of infection d. Describe mode of transmission - Common vehicle (air, food, water) - Direct - Healthcare-associated infections (nosocomial) - Indirect - Opportunistic - Vectors

7.1.2 Differentiate methods of controlling the spread and growth of pathogens. a. Asepsis - Sanitization - Antisepsis - Disinfection - Sterile technique - Sterilization b. Standard precautions - Handwashing - Gloving - Personal Protective Equipment (PPE) - Environmental cleaning d. Bloodborne pathogen precautions

7.2 Personal Safety

7.2.1 Apply personal safety procedures based on Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) regulations.

7.2.3 Demonstrate and apply the use of personal protective equipment (PPE).

Aligned Washington State Learning Standards	
English Language Arts	Reading for Literacy in Science and Technical Subjects GRADES 11-12 RST.11-12.2 Determine the central ideas or conclusions of a text; summarize complex concepts, processes, or information presented in a text by paraphrasing them in simpler but still accurate terms. RST.11-12.3 Follow precisely a complex multistep procedure when carrying out experiments, taking measurements, or performing technical tasks; analyze the specific results based on explanations in the text. RST.11-12.4 Determine the meaning of symbols, key terms, and other domain-specific words and phrases as they are used in a specific scientific or technical context relevant to grades 11–12 texts and topics. RST.11-12.5 Analyze how the text structures information or ideas into categories or hierarchies, demonstrating understanding of the information or ideas.

	RST.11-12.6 Analyze the author's purpose in providing an explanation, describing a procedure, or discussing an experiment in a text, identifying important issues that remain unresolved. RST.11-12.8 Evaluate the hypotheses, data, analysis, and conclusions in a science or technical text, verifying the data when possible and corroborating or challenging conclusions with other sources of information. RST.11-12.9 Synthesize information from a range of sources (e.g., texts, experiments, simulations) into a coherent understanding of a process, phenomenon, or concept, resolving conflicting information when possible. Speaking and Listening GRADES 11-12 SL.11-12.1 Initiate and participate effectively in a range of collaborative discussions (one-on-one, in groups, and teacher-led) with diverse partners on grades 11–12 topics, texts, and issues, building on others' ideas and expressing their own clearly and persuasively. SL.11-12.1a Come to discussions prepared, having read and researched material under study; explicitly draw on that preparation by referring to evidence from texts and other research on the topic or issue to stimulate a thoughtful, well-reasoned exchange of ideas. SL.11-12.4 Present information, findings, and supporting evidence, conveying a clear and distinct perspective, such that listeners can follow the line of reasoning, alternative or opposing perspectives are addressed, and the organization, development, substance, and style are appropriate to purpose, audience, and a range of formal and informal tasks. SL.11-12.5 Make strategic use of digital media (e.g., textual, graphical, audio, visual, and interactive elements) in presentations to enhance understanding of findings, reasoning, and evidence and to add interest. SL.11-12.6 Adapt speech to a variety of contexts and tasks, demonstrating a command of formal English when indicated or appropriate. (See grades 11–12 Language standards 1 and 3 here for specific expectations.) Writing for Literacy in History/Social Studies, Science, and Technical Subjects GRADES 11-12 WHST.11-12.1 Write arguments focused on discipline-specific content. WHST.11-12.1c Use words, phrases, and clauses as well as varied syntax to link the major sections of the text, create cohesion, and clarify the relationships
Mathematics	Algebra Creating Equations (A-CED) 1 - Create equations and inequalities in one variable and use them to solve problems. Include equations arising from linear and quadratic functions, and simple rational and exponential functions.* 2 - Create equations in two or more variables to represent relationships between quantities; graph equations on coordinate axes with labels and scales.* 3 - Represent constraints by equations or inequalities, and by systems of equations and/or inequalities, and interpret solutions as viable or non-viable options in a modeling context. For example,

	represent inequalities describing nutritional and cost constraints on combinations of different foods.* 4-Rearrange formulas to highlight a quantity of interest, using the same reasoning as in solving equations. For example, rearrange Ohm's law V = IR to highlight resistance R.* Mathematical Practices CC: Mathematical Practices (MP) • Make sense of problems and persevere in solving them. • Reason abstractly and quantitatively. • Construct viable arguments and critique the reasoning of others. • Model with mathematics. • Use appropriate tools strategically. • Attend to precision. • Look for and make use of structure. • Look for and express regularity in repeated reasoning. Statistics and Probability Interpreting Categorical and Quantitative Data (S-ID) 1 - Represent data with plots on the real number line (dot plots, histograms, and box plots).* 2 - Use statistics appropriate to the shape of the data distribution to compare center (median, mean) and spread (interquartile range, standard deviation) of two or more different data sets.*
Science	Disciplinary Core Ideas Engineering, Technology, and Applications of Science ETS1.A Defining and Delimiting Engineering Problems ETS1.B Developing Possible Solutions ETS1.C Optimizing the Design Solution Life Sciences LS1.A Structure and function LS1.D Information Processing LS3.A Inheritance of traits Engineering, Technology, and Applications of Science Engineering, Technology, and Applications of Science HS-ETS1 Engineering Design HS-ETS1-1. Analyze a major global challenge to specify qualitative and quantitative criteria and constraints for solutions that account for societal needs and wants. HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering.

	HS-ETS1-3. Evaluate a solution to a complex real-world problem based on prioritized criteria and trade-offs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts. Life Sciences HS-LS1 From Molecules to Organisms: Structures and Processes HS-LS1-1. Construct an explanation based on evidence for how the structure of DNA determines the structure of proteins which carry out the essential functions of life through systems of specialized cells. HS-LS1-2. Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms. HS-LS3 Heredity: Inheritance and Variation of Traits HS-LS3-1. Ask questions to clarify relationships about the role of DNA and chromosomes in coding the instructions for characteristic traits passed from parents to offspring. Science and Engineering Practices • Asking questions and defining problems • Developing and using models • Analyzing and interpreting data • Engaging in argument from evidence • Obtaining, evaluating, and communicating information Science Crosscutting Concepts • Patterns • Cause and effect: • Mechanism and explanation • Systems and system models • Structure and function

Unit: Protein Purification	**Total Learning Hours for Unit:** 30 hours
Unit Summary: In this unit, students will express and purify proteins through bacterial transformation.	
Components and Assessments	
Performance Assessments: Students will • Describe the molecular properties that serve as the basis for protein separation --	

- Perform protein purification principles based on differential molecular properties --
- Use computer models to simulate different protein purification strategies --
- Precipitate proteins by altering pH, ionic strength, organic solvents, and temperature --
- Summarize filtration principles -- Compare and contrast Tangential Flow Filtration and Normal Flow Filtration --
- Perform an investigation assess flow filtration, buffer exchange and concentration --
- Explain the principles of Size Exclusion Chromatography, Ion Exchange Chromatography, Hydrophobic Interaction Chromatography, Affinity Chromatography, and Metal Chelate Chromatography --
- Perform protein purification using simulation software, including problem solving and discussion --
- Summarize bacterial and yeast expression systems and induction strategies
- Summarize how cells produce proteins
- Pass Protein Purification Unit Assessment

Leadership Alignment:

- Students will apply technology effectively in protein purification procedures.
- Students will make judgements and decisions involved in making biotech products in an industrial setting.
- Students will apply technology effectively to analyze the products obtained for identification, quality, quantity, and purity.

Industry Standards and/or Competencies

Name of standards:	**Website:**
21. Biotechnology Research and Development Pathway Standards	21. https://www.nchste.org/pageimages/ACFC9.pdf
22. National Health Science Standards	22. https://resources.youscience.com/hubfs/Partners/NCHSE/National_Health_Science_Standards.pdf
23. Common Core State Standards for English Language Arts	23. https://learning.ccsso.org/wp-content/uploads/2022/11/ELA_Standards1.pdf
24. Common Core State Standards for Mathematics	24. https://learning.ccsso.org/wp-content/uploads/2022/11/Math_Standards1.pdf
25. Next Generation Science Standards	25. https://www.nextgenscience.org/

Biotechnology Research and Development Pathway Standards

Standard 01: Contributions of Biotechnology to health and the human condition

1.1 Contributions to quality of life

1.11 Propose an industrial enzyme that could contribute to the quality of life.

1.12 Generate a list of environmental diseases or chronic conditions that have been or could be treated with biotechnology products. Standard 02: Academic Foundations

2.1 Mathematical concepts

2.11 Illustrate the concepts of percentages and ratios using a biotechnology application.

2.12 Contract weight-to-weight and weight-to-volume calculations for solutions.

2.13 Explain scientific notation.

2.2 Statistics

2.22 Graphically illustrate a set of biotech data such that a layman would understand it.

2.4 Organic Chemistry

2.42 Create an equation of two organic substrates leading to a product.

2.44 Contrast covalent, ionic and hydrogen bonding.

2.5 Biochemistry

2.51 Diagram six chemical side groups that could be in a biotechnology product.

2.52 Categorize all amino acids into essential and non-essential.

2.53 Describe the relationship between biochemistry and biotechnology product development.

2.54 Compare the underlying reasons why some molecules are hydrophilic and some are hydrophobic.

2.7 Molecular biology

2.73 Describe the central dogma of molecular biology and how understanding this process impacts biotechnology research and development.

2.8 Microbiology

2.81 Analyze how microorganisms are used in mass producing recombinant proteins.

Standard 03: Introduction to Biotechnology Knowledge Areas and Techniques

3.1 Techniques

3.11 Describe the following techniques; recombinant DNA, genetic engineering, monoclonal antibody production, separation and purification of biotechnology products and bioprocessing.

Standard 04: Laboratory Protocols and Procedures

4.2 Protocols

4.21 Distinguish the requirements of sterile techniques.

4.22 Respond to a hypothetical laboratory accident appropriately as a member of a laboratory team.
Standard 05: Product Design and Development
5.1 Development
5.11 Diagram the process involved in making one biotech product in an industrial setting.
5.12 Analyze the role of pre-clinical and clinical trials in biotechnology product development. 5.2 Regulation 5.21 Examine the role of a Quality Assurance person in this process.
5.22 Define cGMP and why it is important in biotech production.

National Health Science Foundation Standards
Foundation Standard 01: Academic Foundation
1.3 Medical Mathematics
1.3.1 Demonstrate competency using basic math skills and mathematical conversions as they relate to healthcare. a. Metric system - Kilo- - Centi- - Deci- - Milli- - Mathematical - Average - Ratios - Fractions - Percentages - Addition / Subtraction - Multiplication / Division c. Conversions - Volume (ml/cc) - Temperature (F/C)
1.3.2 Demonstrate the ability to analyze diagrams, charts, graphs, and tables to interpret healthcare results.
Foundation Standard 07: Safety Practices
7.2 Personal Safety
7.2.1 Apply personal safety procedures based on Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) regulations.
7.2.3 Demonstrate and apply the use of personal protective equipment (PPE).
7.3 Environmental Safety
7.3.1 Apply safety techniques in the work environment. - Ergonomics - Safe operation of equipment - Patient/client/employee safety measures
7.4 Common Safety Hazards
7.4.1 Observe all safety standards related to the occupational exposure to hazardous chemicals standard (safety data sheets [SDS]).
7.4.2 Comply with safety signs, symbols, and labels.

Aligned Washington State Learning Standards	
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Science	Disciplinary Core Ideas Engineering, Technology, and Applications of Science ETS1.A Defining and Delimiting Engineering Problems

	ETS1.B Developing Possible Solutions ETS1.C Optimizing the Design Solution Life Sciences LS1.A Structure and function LS1.D Information Processing LS3.A Inheritance of traits Engineering, Technology, and Applications of Science Engineering, Technology, and Applications of Science HS-ETS1 Engineering Design HS-ETS1-1. Analyze a major global challenge to specify qualitative and quantitative criteria and constraints for solutions that account for societal needs and wants. HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering. HS-ETS1-3. Evaluate a solution to a complex real-world problem based on prioritized criteria and trade-offs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts. Life Sciences HS-LS1 From Molecules to Organisms: Structures and Processes HS-LS1-1. Construct an explanation based on evidence for how the structure of DNA determines the structure of proteins which carry out the essential functions of life through systems of specialized cells. HS-LS1-2. Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms. HS-LS3 Heredity: Inheritance and Variation of Traits HS-LS3-1. Ask questions to clarify relationships about the role of DNA and chromosomes in coding the instructions for characteristic traits passed from parents to offspring. Science and Engineering Practices • Asking questions and defining problems • Developing and using models • Analyzing and interpreting data • Engaging in argument from evidence • Obtaining, evaluating, and communicating information Science Crosscutting Concepts • Patterns • Cause and effect: • Mechanism and explanation • Systems and system models • Structure and function

Unit: Case Studies	**Total Learning Hours for Unit:** 15 hours
Unit Summary: In this unit, students will discover the development, manufacturing and launch of the biopharmaceutical, including pre-clinical phase, preclinic phase and test phase.	

Components and Assessments

Performance Assessments:

Students will

- Analyze and discuss selected articles from technical literature on case studies in Biomanufacturing, related to: diseases and disorders and/or related biopharmaceuticals
- Pass Case Studies Unit Assessment

Leadership Alignment:

- Students will think creatively in proposing proteins that could be purified for use in improving the quality of life.
- Students will work creatively with others investigate current biotechnology-related ethical issues, and the impact of quality of life as well as biomanufacturing industry.
- Students will communicate clearly to present their findings on the molecular biology of disease and the role of biomanufacturing in improving the quality of life.
- Students will access and evaluate information on compliance policies, bioethical issues, and the impact of the industry of biologics production.

Industry Standards and/or Competencies

Name of standards:	**Website:**
26. Biotechnology Research and Development Pathway Standards	26. https://www.nchste.org/pageimages/ACFC9.pdf
27. National Health Science Standards	27. https://resources.youscience.com/hubfs/Partners/NCHSE/National_Health_Science_Standards.pdf
28. Common Core State Standards for English Language Arts	28. https://learning.ccsso.org/wp-content/uploads/2022/11/ELA_Standards1.pdf
29. Commone Core State Standards for Mathematics	29. https://learning.ccsso.org/wp-content/uploads/2022/11/Math_Standards1.pdf
30. Next Generation Science Standards	30. https://www.nextgenscience.org/

Biotechnology Research and Development Pathway Standards Standard 01: Contributions of Biotechnology to health and the human condition 1.1 Contributions to quality of life 1.11 Propose an industrial enzyme that could contribute to the quality of life. 1.12 Generate a list of environmental diseases or chronic conditions that have been or could be treated with biotechnology products. 1.2 Legal and Ethical Considerations 1.21 Assess a current biotechnology-related ethical issue in the news and how it may affect the quality of life. Standard 03: Introduction to Biotechnology Knowledge Areas and Techniques 3.2 Knowledge Areas 3.21 Predict how nanotechnology, bioinformatics, proteomics, genomics and transcriptomics will create new career opportunities. Standard 05: Product Design and Development 5.1 Development 5.11 Diagram the process involved in making one biotech product in an industrial setting. 5.12 Analyze the role of pre-clinical and clinical trials in biotechnology product development. 5.2 Regulation 5.21 Examine the role of a Quality Assurance person in this process. 5.22 Define cGMP and why it is important in biotech production. Standard 06: Bioethics 6.1 Societal 6.11 Differentiate between morality and ethics and the relationship of each to biotechnology health care product development. 6.12 Discuss bioethical issues related to recombinant products. 6.13 Contrast personal, professional and organizational ethics. 6.2 Institutional 6.21 Comply with policies and requirements for documentation and record keeping. 6.22 Comply with institutional ethical policies and procedures. **National Health Science Foundation Standards** Foundation Standard 01: Academic Foundation 1.2 Diseases and Disorders 1.2.1 Describe etiology, pathology, diagnosis, treatment, and prevention of common diseases and disorders, including, but not limited to the following: - Arthritis - Asthma - Cancer - Cystic fibrosis - Dementia - Hepatitis - Hypertension - Melanoma - Muscular Dystrophy - Myocardial Infarction - Tuberculosis	

1.2.2 Describe biomedical therapies as they relate to the prevention, pathology, and treatment of disease. - Gene testing - Gene therapy - Stem cell research
Foundation Standard 02: Communications
2.1 Concepts of Effective Communication
2.1.1 Model verbal and nonverbal therapeutic communication. - Active listening - Silence - Summarizing - Reflecting
2.1.3 Distinguish between subjective and objective information.
2.1.4 Interpret elements of communication using sender-message-receiver feedback model.
2.3 Written Communication Skills
2.3.1 Use proper elements of written and electronic communication (spelling, grammar, and formatting).
2.3.2 Prepare examples of technical and informative writing.
2.3.3 Demonstrate appropriate use of digital communication in a work environment, such as email, text, and social media

Aligned Washington State Learning Standards	
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	SL.11-12.1a Come to discussions prepared, having read and researched material under study; explicitly draw on that preparation by referring to evidence from texts and other research on the topic or issue to stimulate a thoughtful, well-reasoned exchange of ideas. SL.11-12.4 Present information, findings, and supporting evidence, conveying a clear and distinct perspective, such that listeners can follow the line of reasoning, alternative or opposing perspectives are addressed, and the organization, development, substance, and style are appropriate to purpose, audience, and a range of formal and informal tasks. SL.11-12.5 Make strategic use of digital media (e.g., textual, graphical, audio, visual, and interactive elements) in presentations to enhance understanding of findings, reasoning, and evidence and to add interest. SL.11-12.6 Adapt speech to a variety of contexts and tasks, demonstrating a command of formal English when indicated or appropriate. (See grades 11–12 Language standards 1 and 3 here for specific expectations.) Writing for Literacy in History/Social Studies, Science, and Technical Subjects GRADES 11-12 WHST.11-12.1 Write arguments focused on discipline-specific content. WHST.11-12.1c Use words, phrases, and clauses as well as varied syntax to link the major sections of the text, create cohesion, and clarify the relationships Writing for Literacy in History/Social Studies, Science, and Technical Subjects GRADES 11-12 WHST.11-12.1 Write arguments focused on discipline-specific content. WHST.11-12.1c Use words, phrases, and clauses as well as varied syntax to link the major sections of the text, create cohesion, and clarify the relationships between claim(s) and reasons, between reasons and evidence, and between claim(s) and counterclaims. WHST.11-12.1d Establish and maintain a formal style and objective tone while attending to the norms and conventions of the discipline in which they are writing. WHST.11-12.1e Provide a concluding statement or section that follows from or supports the argument presented. WHST.11-12.2 Write informative/explanatory texts, including the narration of historical events, scientific procedures/ experiments, or technical processes. WHST.11-12.2d Use precise language, domain-specific vocabulary and techniques such as metaphor, simile, and analogy to manage the complexity of the topic; convey a knowledgeable stance in a style that responds to the discipline and context as well as to the expertise of likely readers.

	WHST.11-12.2e Provide a concluding statement or section that follows from and supports the information or explanation provided (e.g., articulating implications or the significance of the topic). WHST.11-12.4 Produce clear and coherent writing in which the development, organization, and style are appropriate to task, purpose, and audience. WHST.11-12.6 Use technology, including the Internet, to produce, publish, and update individual or shared writing products in response to ongoing feedback, including new arguments or information. WHST.11-12.8 Gather relevant information from multiple authoritative print and digital sources, using advanced searches effectively; assess the strengths and limitations of each source in terms of the specific task, purpose, and audience; integrate information into the text selectively to maintain the flow of ideas, avoiding plagiarism and overreliance on any one source and following a standard format for citation. WHST.11-12.9 Draw evidence from informational texts to support analysis, reflection, and research WHST.11-12.10 Write routinely over extended time frames (time for reflection and revision) and shorter time frames (a single sitting or a day or two) for a range of discipline specific tasks, purposes, and audiences.
Science	Disciplinary Core Ideas Engineering, Technology, and Applications of Science ETS1.A Defining and Delimiting Engineering Problems ETS1.B Developing Possible Solutions ETS1.C Optimizing the Design Solution Life Sciences LS1.A Structure and function LS1.D Information Processing LS3.A Inheritance of traits Engineering, Technology, and Applications of Science Engineering, Technology, and Applications of Science HS-ETS1 Engineering Design HS-ETS1-1. Analyze a major global challenge to specify qualitative and quantitative criteria and constraints for solutions that account for societal needs and wants. HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering.

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Unit: Product Development & Manufacturing	**Total Learning Hours for Unit:** 75 hours
Unit Summary: In this unit, students will	
Components and Assessments	
Performance Assessments: Students will:	

- Implement all expected laboratory practices, under guided supervision leading toward independent performance, in industry site-based departments of Biomanufacturing, Process Development, and/or Quality Control Maintain a safe and productive work environment --
- Recognize unsafe conditions and take corrective and/or preventive action --
- Follow relevant safety policies, guidelines, and regulation --
- Access and use SDS and other safety information sources --
- Maintain a safe, clean, contamination-free, and clutter-free environment, as appropriate --
- Select appropriate PPE to use to protect self from biological, chemical, and/or physical hazards Provide routine facility support --
- Monitor, maintain, and troubleshoot/repair equipment --
- Use equipment correctly according to manufacturer's guidelines --
- Maintain inventory of raw materials, parts, components and/or equipment --
- Prepare materials/supplies/equipment for use Perform measurements / tests / assays --
- Collect samples according to established procedures and applicable sampling plans -- Prepare samples according to established procedures
- Follow appropriate test procedures/instructions --
- Document data & results according to established procedures --
- Interpret and/or analyze data & results as appropriate Comply with applicable regulations and standards --
- Follow established policies and procedures --
- Record information according to established procedures --
- Exercise proper document control --
- Participate in required training –
- Respond to audit-related activities -- Adhere to control principles in accordance with the established quality system --
- Adhere to traceability principles -- Participate in validation activities --
- Recognize and address nonconformances Manage and communicate information -- Comply with company communication policies --
- Communicate information in an appropriate manner --
- Assist in reviewing/commenting, revising, and writing technical documents --
- Suggest continuous improvements --
- Use computer tools effectively Perform mathematical manipulations –

- Perform calculations relating to work function --
- Perform data analysis

Unit 7: Performance Assessments: Perform site-based biomanufacturing employee expectations including --

- Work in compliance with established environmental health and safety regulations --
- Work in compliance with cGMPs --
- Clean and maintain production areas --
- Maintain effective communication --
- Prepare process materials --
- Prepare equipment --
- Perform basic manufacturing operations --
- Perform upstream manufacturing operations, downstream manufacturing operations --
- Perform laboratory work --
- Provide technical and/or validation support -- Perform sampling Explore careers specific to the Biomanufacturing field --
- Utilize Bio-Link.org to identify biomanufacturing fields --
- Identify pathways to biomanufacturing careers of interest –
- Incorporate biomanufacturing work-site experience in resume and letter of interest

Leadership Alignment:

- Students will use and manage information to comply with institutional ethical policies and procedures in site-based biomanufacturing protocols.
- Students will be flexible and make use of peer and supervisor critique to optimize the lab skill development required for biologic production.
- Students will manage goals and time while developing a timeline for skills development, lab hours, goals and site supervisor mentoring.
- Students will work independently upon site supervisor's approval of mastery of lab protocols used in biomanufacturing.
- Students will be self-directed learners in seeking out context and application of lab protocols.
- Students will interact effectively with diverse teams in seeking feedback on self-understanding of the foundational biotechnology concepts used on site, and evaluation of lab work.

- Students will collaborate with others to build positive team relationships in the workplace.
- Students will manage projects and produce results using scientific thinking and decision-making criteria.
- Students will communicate clearly with others in maintaining safe work environments and following all biosafety protocols.
- Students will access and evaluate information to comply with institutional ethical policies and procedures

Industry Standards and/or Competencies

Name of standards:	**Website:**
31. Biotechnology Research and Development Pathway Standards 32. National Health Science Standards 33. Common Core State Standards for English Language Arts 34. Common Core State Standards for Mathematics 35. Next Generation Science Standards	31. https://www.nchste.org/pageimages/ACFC9.pdf 32. https://resources.youscience.com/hubfs/Partners/NCHSE/National_Health_Science_Standards.pdf 33. https://learning.ccsso.org/wp-content/uploads/2022/11/ELA_Standards1.pdf 34. https://learning.ccsso.org/wp-content/uploads/2022/11/Math_Standards1.pdf 35. https://www.nextgenscience.org/

Biotechnology Research and Development Pathway Standards

Standard 01: Contributions of Biotechnology to health and the human condition

1.1 Contributions to quality of life

1.11 Propose an industrial enzyme that could contribute to the quality of life.

1.12 Generate a list of environmental diseases or chronic conditions that have been or could be treated with biotechnology products.

1.2 Legal and Ethical Considerations

1.21 Assess a current biotechnology-related ethical issue in the news and how it may affect the quality of life.

Standard 02: Academic Foundations

2.1 Mathematical concepts

2.11 Illustrate the concepts of percentages and ratios using a biotechnology application.

2.12 Contract weight-to-weight and weight-to-volume calculations for solutions.

2.13 Explain scientific notation.

2.2 Statistics

2.22 Graphically illustrate a set of biotech data such that a layman would understand it.

2.3 Genetics
2.33 Differentiate the genetic inheritance of a lethal dominant homozygous trait (e.g. dwarfism) from a heterozygous disease (e.g., sickle cell anemia).
2.4 Organic Chemistry
2.42 Create an equation of two organic substrates leading to a product.
2.44 Contrast covalent, ionic and hydrogen bonding.
2.5 Biochemistry
2.52 Categorize all amino acids into essential and non-essential.
2.53 Describe the relationship between biochemistry and biotechnology product development.
2.54 Compare the underlying reasons why some molecules are hydrophilic and some are hydrophobic.
2.6 Cell Biology
2.61 Describe the basic structures and functions of cells and how this knowledge is used in biotechnology.
2.62 Select cellular barriers to be overcome for a biotechnology product to work inside a cell.
.7 Molecular biology
2.73 Describe the central dogma of molecular biology and how understanding this process impacts biotechnology research and development.
2.8 Microbiology
2.81 Analyze how microorganisms are used in mass producing recombinant proteins.
2.82 Compare and contrast bacterial, fungal, and animal cells and how these similarities and differences affect biotechnology product development and production decisions.
2.83 Compare and contrast the use of plasmids in bacterial transformation and the process of plasmid DNA isolation.
Standard 03: Introduction to Biotechnology Knowledge Areas and Techniques
3.1 Techniques
3.11 Describe the following techniques; recombinant DNA, genetic engineering, monoclonal antibody production, separation and purification of biotechnology products and bioprocessing.
3.2 Knowledge Areas
3.21 Predict how nanotechnology, bioinformatics, proteomics, genomics and transcriptomics will create new career opportunities.
Standard 04: Laboratory Protocols and Procedures
4.1 Procedures
4.11 Describe how molarity relates to solution preparation.
4.12 Calculate the molarity of a given solution and measure the pH of this solution.
4.13 Prepare a serial dilution of a microbial culture starting with 10-3 going to 10-8 and plate on to nutrient agar petri dishes. Determine the original concentration of the microbial culture.

4.21 Distinguish the requirements of sterile techniques.
4.22 Respond to a hypothetical laboratory accident appropriately as a member of a laboratory team.
Standard 05: Product Design and Development
5.1 Development
5.11 Diagram the process involved in making one biotech product in an industrial setting.
5.12 Analyze the role of pre-clinical and clinical trials in biotechnology product development.
5.2 Regulation
5.21 Examine the role of a Quality Assurance person in this process.
5.22 Define cGMP and why it is important in biotech production.
Standard 06: Bioethics
6.1 Societal
6.11 Differentiate between morality and ethics and the relationship of each to biotechnology health care product development. 6.12 Discuss bioethical issues related to recombinant products.
6.13 Contrast personal, professional and organizational ethics.
6.2 Institutional
6.21 Comply with policies and requirements for documentation and record keeping.
6.22 Comply with institutional ethical policies and procedures.

N**ational Health Science Foundation Standards Foundation**
Standard 01: Academic Foundation
1.1 Human Anatomy and Physiology
1.1.1 Describe the organization of the human body and directional terms. a. Identify Levels of Organization
1.2 Diseases and Disorders
1.2.1 Describe etiology, pathology, diagnosis, treatment, and prevention of common diseases and disorders, including, but not limited to the following:
1.2.2 Describe biomedical therapies as they relate to the prevention, pathology, and treatment of disease. 1.3 Medical Mathematics
1.3.1 Demonstrate competency using basic math skills and mathematical conversions as they relate to healthcare. a. Metric system b. Mathematical c. Conversions
1.3.2 Demonstrate the ability to analyze diagrams, charts, graphs, and tables to interpret healthcare results.
Foundation Standard 02: Communications
2.1 Concepts of Effective Communication
2.1.1 Model verbal and nonverbal therapeutic communication.
2.1.3 Distinguish between subjective and objective information.

2.1.4 Interpret elements of communication using sender-message-receiver feedback model.
2.3 Written Communication Skills 2.3.1 Use proper elements of written and electronic communication (spelling, grammar, and formatting).
2.3.2 Prepare examples of technical and informative writing.
2.3.3 Demonstrate appropriate use of digital communication in a work environment, such as email, text, and social media.
Foundation Standard 03: Systems
3.1 Healthcare Delivery Systems
3.1.1 Differentiate healthcare delivery systems and healthcare related agencies.
Foundation Standard 04: Employability Skills
4.1 Personal Traits of the Health Professional
4.1.1 Identify personal traits and attitudes desirable in a career ready member of a health team.
4.1.2 Summarize professional standards as they apply to hygiene, dress, language, confidentiality and behavior.
4.2 Employability Skills
4.2.1 Apply employability skills in healthcare.
4.3 Career Decision-making
4.3.1 Research levels of education, credentialing requirements, and employment trends in health professions.
4.3.2 Distinguish differences among careers within a health science pathway.
4.4 Employability Preparation
4.4.1 Develop components of a personal portfolio.
Foundation Standard 07: Safety Practices
7.1 Infection Control
7.1.1 Explain principles of infection transmission. a. Identify classifications of pathogens b. Describe characteristics of microorganisms c. Recognize chain of infection d. Describe mode of transmission
7.1.2 Differentiate methods of controlling the spread and growth of pathogens. a. Asepsis b. Standard precautions c. Isolation precautions d. Bloodborne pathogen precautions
7.2 Personal Safety
7.2.1 Apply personal safety procedures based on Occupational Safety and Health Administration (OSHA) and Centers for Disease Control (CDC) regulations.
7.2.3 Demonstrate and apply the use of personal protective equipment (PPE).
7.3 Environmental Safety
7.3.1 Apply safety techniques in the work environment.
7.4 Common Safety Hazards

7.4.1 Observe all safety standards related to the occupational exposure to hazardous chemicals standard (safety data sheets [SDS]).
7.4.2 Comply with safety signs, symbols, and labels.
7.5 Emergency Procedures and Protocols
7.5.1 Practice fire safety in a healthcare setting.
7.5.2 Apply principles of basic emergency response in natural disasters and other emergencies (safe location, contact emergency personnel, follow facility protocols). Foundation Standard 08: Teamwork
8.2 Team Member Participation
8.2.1 Recognize methods for building positive team relationships.
8.2.2 Analyze attributes and attitudes of an effective leader. a. Characteristics b. Types c. Roles
8.2.3 Apply effective techniques for managing team conflict.

Aligned Washington State Learning Standards	
English Language Arts	Reading for Literacy in Science and Technical Subjects GRADES 11-12 RST.11-12.2 Determine the central ideas or conclusions of a text; summarize complex concepts, processes, or information presented in a text by paraphrasing them in simpler but still accurate terms. RST.11-12.3 Follow precisely a complex multistep procedure when carrying out experiments, taking measurements, or performing technical tasks; analyze the specific results based on explanations in the text. RST.11-12.4 Determine the meaning of symbols, key terms, and other domain-specific words and phrases as they are used in a specific scientific or technical context relevant to grades 11–12 texts and topics. RST.11-12.5 Analyze how the text structures information or ideas into categories or hierarchies, demonstrating understanding of the information or ideas. RST.11-12.6 Analyze the author's purpose in providing an explanation, describing a procedure, or discussing an experiment in a text, identifying important issues that remain unresolved. RST.11-12.8 Evaluate the hypotheses, data, analysis, and conclusions in a science or technical text, verifying the data when possible and corroborating or challenging conclusions with other sources of information. RST.11-12.9 Synthesize information from a range of sources (e.g., texts, experiments, simulations) into a coherent understanding of a process, phenomenon, or concept, resolving conflicting information when possible. Speaking and Listening GRADES 11-12 SL.11-12.1 Initiate and participate effectively in a range of collaborative discussions (one-on-one, in groups, and teacher-led) with diverse partners on grades 11–12 topics, texts, and issues, building on others' ideas and expressing their own clearly and persuasively.

	SL.11-12.1a Come to discussions prepared, having read and researched material under study; explicitly draw on that preparation by referring to evidence from texts and other research on the topic or issue to stimulate a thoughtful, well-reasoned exchange of ideas. SL.11-12.4 Present information, findings, and supporting evidence, conveying a clear and distinct perspective, such that listeners can follow the line of reasoning, alternative or opposing perspectives are addressed, and the organization, development, substance, and style are appropriate to purpose, audience, and a range of formal and informal tasks. SL.11-12.5 Make strategic use of digital media (e.g., textual, graphical, audio, visual, and interactive elements) in presentations to enhance understanding of findings, reasoning, and evidence and to add interest. SL.11-12.6 Adapt speech to a variety of contexts and tasks, demonstrating a command of formal English when indicated or appropriate. (See grades 11–12 Language standards 1 and 3 here for specific expectations.) Writing for Literacy in History/Social Studies, Science, and Technical Subjects GRADES 11-12 WHST.11-12.1 Write arguments focused on discipline-specific content. WHST.11-12.1c Use words, phrases, and clauses as well as varied syntax to link the major sections of the text, create cohesion, and clarify the relationships Writing for Literacy in History/Social Studies, Science, and Technical Subjects GRADES 11-12 WHST.11-12.1 Write arguments focused on discipline-specific content. WHST.11-12.1c Use words, phrases, and clauses as well as varied syntax to link the major sections of the text, create cohesion, and clarify the relationships between claim(s) and reasons, between reasons and evidence, and between claim(s) and counterclaims. WHST.11-12.1d Establish and maintain a formal style and objective tone while attending to the norms and conventions of the discipline in which they are writing. WHST.11-12.1e Provide a concluding statement or section that follows from or supports the argument presented. WHST.11-12.2 Write informative/explanatory texts, including the narration of historical events, scientific procedures/ experiments, or technical processes. WHST.11-12.2d Use precise language, domain-specific vocabulary and techniques such as metaphor, simile, and analogy to manage the complexity of the topic; convey a knowledgeable stance in a style that responds to the discipline and context as well as to the expertise of likely readers.

	WHST.11-12.2e Provide a concluding statement or section that follows from and supports the information or explanation provided (e.g., articulating implications or the significance of the topic). WHST.11-12.4 Produce clear and coherent writing in which the development, organization, and style are appropriate to task, purpose, and audience. WHST.11-12.6 Use technology, including the Internet, to produce, publish, and update individual or shared writing products in response to ongoing feedback, including new arguments or information. WHST.11-12.8 Gather relevant information from multiple authoritative print and digital sources, using advanced searches effectively; assess the strengths and limitations of each source in terms of the specific task, purpose, and audience; integrate information into the text selectively to maintain the flow of ideas, avoiding plagiarism and overreliance on any one source and following a standard format for citation. WHST.11-12.9 Draw evidence from informational texts to support analysis, reflection, and research. WHST.11-12.10 Write routinely over extended time frames (time for reflection and revision) and shorter time frames (a single sitting or a day or two) for a range of disciplinespecific tasks, purposes, and audiences.
Mathematics	Algebra Creating Equations (A-CED) 1 - Create equations and inequalities in one variable and use them to solve problems. Include equations arising from linear and quadratic functions, and simple rational and exponential functions.* 2 - Create equations in two or more variables to represent relationships between quantities; graph equations on coordinate axes with labels and scales.* Biomanufacturing Page 38 of 42 Edmonds School District 3 - Represent constraints by equations or inequalities, and by systems of equations and/or inequalities, and interpret solutions as viable or non-viable options in a modeling context. For example, represent inequalities describing nutritional and cost constraints on combinations of different foods.*

	4 - Rearrange formulas to highlight a quantity of interest, using the same reasoning as in solving equations. For example, rearrange Ohm's law V = IR to highlight resistance R.* Mathematical Practices CC: Mathematical Practices (MP) Make sense of problems and persevere in solving them. • Reason abstractly and quantitatively. • Construct viable arguments and critique the reasoning of others. • Model with mathematics. • Use appropriate tools strategically. • Attend to precision. Look for and make use of structure. • Look for and express regularity in repeated reasoning. Statistics and Probability Interpreting Categorical and Quantitative Data (S-ID) 1 - Represent data with plots on the real number line (dot plots, histograms, and box plots).* 2 - Use statistics appropriate to the shape of the data distribution to compare center (median, mean) and spread (interquartile range, standard deviation) of two or more different data sets.*
Science	Disciplinary Core Ideas Engineering, Technology, and Applications of Science ETS1.A Defining and Delimiting Engineering Problems ETS1.B Developing Possible Solutions ETS1.C Optimizing the Design Solution Life Sciences LS1.A Structure and function LS1.D Information Processing LS3.A Inheritance of traits LS3.B Variation of traits Physical Sciences PS1.A Structure of matter PS1.B Chemical reactions PS2.A Forces and motions PS2.B Types of interactions PS2.C Stability and instability in physical systems Engineering, Technology, and Applications of Science Engineering, Technology, and Applications of Science

	HS-ETS1 Engineering Design HS-ETS1-1. Analyze a major global challenge to specify qualitative and quantitative criteria and constraints for solutions that account for societal needs and wants. HS-ETS1-2. Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering. HS-ETS1-3. Evaluate a solution to a complex real-world problem based on prioritized criteria and trade-offs that account for a range of constraints, including cost, safety, reliability, and aesthetics, as well as possible social, cultural, and environmental impacts. Life Sciences HS-LS1 From Molecules to Organisms: Structures and Processes HS-LS1-1. Construct an explanation based on evidence for how the structure of DNA determines the structure of proteins which carry out the essential functions of life through systems of specialized cells. HS-LS1-2. Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms. HS-LS1-3. Plan and conduct an investigation to provide evidence that feedback mechanisms maintain homeostasis. HS-LS1-4. Use a model to illustrate the role of cellular division (mitosis) and differentiation in producing and maintaining complex organisms. HS-LS1-7. Use a model to illustrate that cellular respiration is a chemical process whereby the bonds of food molecules and oxygen molecules are broken and the bonds in new compounds are formed resulting in a net transfer of energy. HS-LS3 Heredity: Inheritance and Variation of Traits HS-LS3-1. Ask questions to clarify relationships about the role of DNA and chromosomes in coding the instructions for characteristic traits passed from parents to offspring. Physical Sciences HS-PS1 Matter and Its Interactions HS-PS1-1. Use the periodic table as a model to predict the relative properties of elements based on the patterns of electrons in the outermost energy level of atoms. HS-PS1-2. Construct and revise an explanation for the outcome of a simple chemical reaction based on the outermost electron states of atoms, trends in the periodic table, and knowledge of the patterns of chemical properties.

	HS-PS1-3. Plan and conduct an investigation to gather evidence to compare the structure of substances at the bulk scale to infer the strength of electrical forces between particles. HS-PS1-5. Apply scientific principles and evidence to provide an explanation about the effects of changing the temperature or concentration of the reacting particles on the rate at which a reaction occurs. HS-PS1-6. Refine the design of a chemical system by specifying a change in conditions that would produce increased amounts of products at equilibrium. Science and Engineering Practices • Asking questions and defining problems • Developing and using models • Planning and carrying out investigations • Analyzing and interpreting data • Using mathematics and computational thinking • Constructing explanations and designing solutions • Engaging in argument from evidence • Obtaining, evaluating, and communicating information Science Crosscutting Concepts • Patterns • Cause and effect: Mechanism and explanation • Scale, proportion, and quantity • Systems and system models • Energy and matter: Flows, cycles, and conservation • Structure and function • Stability and change

The 21st Century Skills should be taught and assessed throughout the course.This table should be included at the end of this document.

21st Century Skills		
Check those that students will demonstrate in this course:		
LEARNING & INNOVATION **Creativity and Innovation** ☑ Think Creatively ☑ Work Creatively with Others Implement Innovations **Critical Thinking and Problem Solving** ☑ Reason Effectively ☑ Use Systems Thinking ☑ Make Judgments and Decisions ☑ Solve Problems **Communication and Collaboration** ☑ Communicate Clearly ☑ Collaborate with Others	**INFORMATION, MEDIA & TECHNOLOGY SKILLS** **Information Literacy** ☑ Access and Evaluate Information ☑ Use and Manage Information **Media Literacy** Analyze Media Create Media Products **Information, Communications and Technology (ICT Literacy)** ☑ Apply Technology Effectively	**LIFE & CAREER SKILLS** **Flexibility and Adaptability** ☑ Adapt to Change ☑ Be Flexible **Initiative and Self-Direction** ☑ Manage Goals and Time Work Independently ☑ Be Self-Directed Learners **Social and Cross-Cultural** ☑ Interact Effectively with Others ☑ Work Effectively in Diverse Teams **Productivity and Accountability** ☑ Manage Projects ☑ Produce Results **Leadership and Responsibility** Guide and Lead Others Be Responsible to Others