# Biotechnology Standards and Skills

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## Health & Safety Standards

### Standard 1: Safety and Health in a Biotechnology Environment

Students will demonstrate the skills necessary to maintain a safe and healthy working environment in biotechnology settings, understanding regulatory requirements, recognizing potential hazards, and implementing appropriate safety protocols and health practices.

* Aligned Industry Recognized Credentials: OSHA, First Aid/CPR/AED

#### Skills:

1. Identify, describe, and demonstrate the effective use of Safety Data Sheets (SDS) to meet documentation requirements.
2. Locate emergency equipment, including the first aid kit, emergency action and response plan, and essential items such as eyewash stations, shower facilities, sinks, fire extinguishers, fire blankets, telephones, master power switches, and emergency exits, ensuring that all labels and signage comply with the OSHA Hazard Communication Program (HAZCOM).
3. Develop an emergency contact list, identifying appropriate health and safety agencies and resources.
4. Describe procedures used to manage emergency situations, defensive measures, and accidents, including identification, reporting, response, evacuation plans, and follow-up procedures.
5. Read and interpret chemical, product, and equipment labels to determine appropriate health and safety considerations.
6. Identify and describe fire protection precautions and response procedures.
7. Demonstrate safety practices and procedures to be followed when working with and around electricity, e.g., ground fault circuit interrupter (GFCI) and frayed wiring.
8. Demonstrate safe handling, storing, disposing of, and recycling hazardous, flammable, and combustible materials, according to Environmental Protection Agency (EPA), OSHA, and product specifications.
9. Identify, describe, and apply EPA and other environmental protection regulations that apply to specific tasks and jobs in the specific occupational area.
10. Demonstrate proper use of personal protective equipment (PPE) and ergonomic practices, including gloves, safety goggles, masks, ear plugs, eye protection, breathing apparatus, appropriate footwear, wrist rests, and adjustable workstations depending on the tasks and hazards present.
11. Demonstrate the safe use, storage, and maintenance of equipment in the lab, shop, and classroom, e.g., the OSHA Lockout/Tagout Program (LOTO).
12. Demonstrate appropriate safe body mechanics, including appropriate lifting techniques and ergonomics.
13. Demonstrate the ability to perform first aid, utilize an Automated External Defibrillator (AED), and administer Cardiopulmonary Resuscitation (CPR) according to current guidelines and best practices.
14. Identify and describe potential consequences for non-compliance with appropriate health and safety regulations.

## Technical & Integrated Academic Standards

### Standard 2: Role of Biotechnology Professionals in Society

Students will examine the role of biotechnology professionals in society, analyze the evolution of biotechnology and its technological advances, and evaluate the impact of biotechnology on environmental awareness and sustainability.

#### Skills:

1. Describe the contributions of biotechnology professionals in various sectors such as healthcare, agriculture, environmental science, and industry.
2. Trace the historical development of biotechnology, including significant milestones and breakthroughs, e.g., discovery of DNA, the first recombinant DNA molecule, and the development of the Polymerase Chain Reaction (PCR).
3. Explore the role of biotechnology in promoting environmental sustainability and addressing environmental challenges through bioremediation, biofuels, waste management, conservation efforts, and environmental monitoring.

### Standard 3: Fundamentals of Biotechnology

Students will apply fundamental biotechnology concepts, explore key techniques and principles, and assess their practical applications and ethical implications.

* Aligned Industry Recognized Credentials: Pathmaker Credential

#### Skills:

1. Identify and explain the main fields of biotechnology and their products, including medical applications, e.g., gene therapies, biopharmaceuticals, mRNA technologies, vaccines, agricultural biotechnology, e.g., GMOs, biopesticides, environmental biotechnology, e.g., bioremediation, and industrial biotechnology, e.g., biofuels, bioplastics.
2. Describe the life cycle of products from research and development to production and commercialization.
3. Explain how new discoveries in biotechnology, such as breakthroughs in gene editing, influence decision-making in scientific research, product development, and ethical considerations.
4. Demonstrate the use of scientific methods and techniques, such as PCR, genetic engineering, and cell culture, to solve problems and explain their application in real-world biotechnology contexts.
5. Understand the concepts of molecular cloning, bioinformatics, and protein engineering and explore how these techniques are used in biotechnology research and development.
6. Describe procedures for ensuring product safety in biotechnology, including basic risk assessment methods and mitigation strategies to prevent contamination or failure.
7. Explain the processes and criteria for evaluating the efficacy of biotechnology products, including methods for testing, validation, and ensuring the quality of biomanufactured products.
8. Examine the social, legal, and ethical challenges that impact the use and development of biotechnological applications.
9. Evaluate broader ethical concerns, such as patient consent and data privacy in the clinical setting.
10. Examine the basics of scientific research, including how to ask research questions, develop hypotheses, and design experiments to test them in the context of biotechnology.

### Standard 4: Fundamentals of Biomanufacturing

Students will be able to proficiently manage and execute biomanufacturing processes by applying advanced manufacturing techniques and standard operating procedures (SOPs).

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Explain manufacturing process management techniques such as process optimization, quality control, and resource management.
2. Identify, create, and use standard operating procedures (SOPs) to ensure consistency, quality, and regulatory compliance in biomanufacturing.
3. Explain biomanufacturing lean techniques as they pertain to improved efficiency, reduction of waste, and increased productivity.
4. Explain the operation of biomanufacturing systems, including how changes in conditions, processes, and environmental factors influence outcomes.
5. Analyze the industrial applications and significance of biotechnological processes such as fermentation, mixing and aeration, bioreactor operations, and downstream processing used to produce and purify biotechnology products.
6. Explain how process control data is used to monitor and adjust processes to ensure product quality and compliance with specifications and regulations.
7. Evaluate a product to verify that it meets specifications and regulations.
8. Utilize principles of total quality management to ensure continuous improvement and quality assurance.
9. **Implement validation procedures** to ensure processes and products meet industry standards and regulatory requirements.
10. Describe the role of feedback and control loop systems in maintaining process stability and product quality in biomanufacturing.
11. Develop a comprehensive product development plan for a biotechnology product, including feedback mechanisms and control loops.

### Standard 5: Regulatory Affairs and Agencies

Students will demonstrate knowledge of navigating the regulatory environment in biotechnology, including regulations and oversight agencies, their roles, functions, and essential policies affecting everyday work and innovation.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Explain the history of pharmaceutical regulations and the Food and Drug Administration (FDA).
2. Explain the organization of the FDA, e.g., the roles of Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).
3. Explain the life cycle of medical products, e.g., discovery through clinical trials, New Drug Application (NDAs), Investigational New Drug (INDs).
4. Explain current Good Manufacturing Practice (cGMP) and Good Laboratory Practice (GLP) regulations, including their purpose, key components, and requirement in biomanufacturing and laboratory settings.
5. Explain good documentation practices used in biomanufacturing, such as the use of signatures, dating, indelible ink, and witnessing requirements, and how these practices help ensure the accuracy, reliability, and traceability of manufacturing records in compliance with cGMP standards.
6. Describe how environmental monitoring helps ensure the safety of products, focusing on controlling contaminants and maintaining regulatory standards in production.
7. Identify and explain the concept of Critical Quality Attributes (CQAs) and their role in determining the quality and effectiveness of biotechnology products.
8. Explain how Critical Process Parameters (CPPs) are identified, monitored, and controlled to ensure consistent product quality.
9. Identify and describe the regulatory agencies at the local, state, and federal levels.
10. Identify and explain the regulatory agencies at local, state, and federal levels, such as the FDA, EPA, and OSHA, and their roles in overseeing biomanufacturing processes.
11. Explain the roles of the Institutional Biosafety Committee (IBC) and the Institutional Animal Care and Use Committee (IACUC).
12. Explain United States Department of Agriculture (USDA) and Public Health Service (PHS) Policy on the humane care and use of laboratory animals and the roles of the American Association for Laboratory Animal Science (AALAS) and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).
13. **Evaluate** the regulatory challenges posed by emerging technologies like CRISPR and synthetic biology.

### Standard 6: Laboratory Management

Students will demonstrate safe laboratory work habits that ensure personal and others' safety and employ effective laboratory management techniques that meet industry standards.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. **Apply 5S components** (Sort, Set in Order, Shine, Standardize, Sustain) in laboratory settings to enhance organization, safety, and productivity.
2. Demonstrate basic lab management skills, including inventorying supplies, ordering required materials, and scheduling work functions.
3. Maintain accurate laboratory records of experiments, equipment usage, and safety inspections.
4. Utilize various documentation methods, including logbooks, computer systems, and forms, to document lab support functions and equipment operations, such as those for autoclaves, pH meters, incubators, and freezers.
5. Apply regulatory standards from relevant agencies, e.g., OSHA, EPA, Center for Disease Control and Prevention (CDC).
6. Analyze the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and interpret Safety Data Sheets (SDS) for chemical substances.
7. Understand biosafety levels (BSL) and their requirements.
8. Demonstrate aseptic techniques and proper handling of biological materials using a biological safety cabinet and explain the principles of maintaining sterility in laboratory environments.
9. Describe procedures for dealing with biological spills and contamination.
10. Explain the concept and importance of sterile welding in maintaining clean room environments and its role in biomanufacturing and laboratory settings.
11. Identify various methods used in clean room sterilization and their applications.
12. Demonstrate the operation of an autoclave and explain its role in maintaining sterile technique.
13. Demonstrate sterilizing reagents, solutions, and media properly according to established procedures.
14. Demonstrate cleaning and sterilizing glassware and counters to meet laboratory procedures.
15. Demonstrate cleaning and maintenance of equipment according to manufacturer’s specifications.
16. Identify, use, and store laboratory equipment, e.g., pipettes, centrifuges, autoclaves.

### Standard 7: Solution Preparation, Instrumentation, and Lab Assays

Students will accurately prepare and analyze solutions, perform precise calculations related to measurements, reagent formulation, and data analysis, and effectively use instrumentation for lab assays.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Accurately calculate measurements, including unit conversions and molarity, and prepare various types of solutions.
2. Determine correct amounts of reagents and media for formulations and dilutions.
3. Formulate solutions with precise percent, molar, and molal concentrations.
4. Conduct dilutions and calculate the concentrations of the resulting solutions.
5. Execute serial dilutions and determine the final concentrations.
6. Use filtration or autoclaving methods to prepare agar plates and broths.
7. Label and store reagents, solutions, and media according to established procedures.
8. Calculate dosage levels based on mg/kg or ml/kg, or other appropriate units for lab and biomanufacturing applications.
9. Calculate quantities and parameters for product processing and quality control.
10. Perform accurate and precise measurements of volume, pH levels, and temperature.
11. Achieve accurate and precise weight measurements.
12. Calibrate and maintain instruments such as balances, pH meters, thermometers, pipettes, and spectrophotometers.
13. Conduct spectrophotometric measurements with acceptable accuracy and precision.
14. Record, compute, and interpret experimental data, including determining growth rates and performing related calculations for cell cultures.
15. Create graphs and analyze data using spreadsheet software.

### Standard 8: Basics of Microscopes

Students will demonstrate the use and care of various types of microscopes and perform laboratory procedures related to microscopy.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Identify, describe, and use the components of a microscope.
2. Differentiate between the different types of microscopes and describe their uses, including compound, inverted, scanning electron, fluorescent, and stereo.
3. Demonstrate proper cleaning technique for the microscope and lenses to maintain functionality and prevent damage.
4. Create and prepare wet mount slides and slides with cross-sections for microscopic examination.
5. Apply staining techniques to observe and analyze cell morphology.
6. Utilize a hemocytometer for accurate cell counting.
7. Identify and describe functions of cellular organelles.

### Standard 9: Standard Lab Assays and Techniques

Students will demonstrate a variety of standard laboratory assays and techniques, including proper documentation, aseptic techniques, protein purification methods, and techniques for the separation, detection, and quantification of proteins.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Document assay procedures and results, analyze the data, and interpret findings, such as determining the amount of analyte in a quantitative assay.
2. Implement aseptic techniques to prevent contamination, including decontamination and proper disposal of waste.
3. Operate an autoclave and explain its use in sterile technique.
4. Sterilize reagents, solutions, and media properly according to established procedures.
5. Demonstrate the ability to isolate DNA from a variety of samples, including bacterial, plant, and animal, using appropriate protocols.
6. Apply spectrophotometric methods, e.g., Nanodrop, or fluorometric methods to measure DNA concentration and purity.
7. Conduct enzyme-linked immunosorbent assays (ELISA) to detect and quantify proteins or antibodies.
8. Execute Western blotting to detect specific proteins in a sample.
9. Conduct DNA fingerprinting for genetic analysis and comparison.
10. Execute polymerase chain reaction (PCR) to amplify DNA segments.
11. Measure enzyme activity using assays appropriate for the enzyme in question.
12. Use microscopy techniques to visualize protein structures and cellular components.
13. Conduct UV-Vis Spectroscopy to measure protein concentration and monitor purity.
14. Perform centrifugation to separate proteins based on density.
15. Apply filtration methods to separate particles from liquids or gases.
16. Measure pH levels to ensure optimal conditions for protein purification.
17. Apply techniques such as Bradford or BCA assays to quantify protein levels.
18. Perform SDS-PAGE to separate proteins by size.
19. Use electrophoresis systems, such as SDS-PAGE for protein separation and agarose gel electrophoresis for nucleic acid (DNA/RNA) separation.
20. Employ various chromatography techniques (size exclusion, affinity, HIC, ion exchange) for separation and analysis of biomolecules.
21. Analyze and differentiate between various chromatography methods based on their principles and applications.
22. Culture and isolate bacterial colonies, perform Gram staining and basic biochemical tests, and use DNA analysis methods, e.g., PCR or 16S rRNA sequencing, to identify bacterial species.
23. Perform bacterial transformation with plasmids and explain transformation protocols for plant and mammalian cells, including key differences between prokaryotic and eukaryotic transformation methods.
24. Maintain and preserve animal cell cultures through techniques such as cryopreservation.
25. Prepare and sterilize plant explants, monitor growth stages, and transfer plantlets to appropriate media.
26. Observe and document cell cultures using inverted microscopes.
27. Assess the viability of cells in culture using appropriate assays.
28. Explain the applications of cells in various biotechnological fields, including cancer research and regenerative medicine.

### Standard 10: Clinical Laboratory Techniques

Students will acquire foundational clinical laboratory skills essential for biotechnology, including aseptic techniques, cell culture, and media preparation, while understanding their application in the development of biotechnological products such as biopharmaceuticals and vaccines.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Apply aseptic techniques to prevent contamination during cell culture work, including the use of sterile tools, laminar flow hoods, and disinfectants, ensuring accuracy and reliability in diagnostic and research outcomes.
2. Prepare and sterilize media for bacterial, yeast, and mammalian cell cultures, ensuring the growth and maintenance of cell lines for diagnostic and therapeutic applications.
3. Demonstrate proper handling and disposal of contaminated materials to maintain a sterile working environment and comply with safety protocols.
4. Cultivate and maintain bacterial cells using appropriate media and aseptic techniques, and explain how bacterial cultures are used in clinical and research labs.
5. Cultivate and maintain yeast cultures, including preparing media, inoculating cultures, and monitoring growth, and explain how yeast is used in both research and production of biotechnological products.
6. Establish and maintain mammalian cell cultures, including subculturing (passaging) and monitoring cell growth under sterile conditions.
7. Perform freeze/thaw processes to preserve and revive cultured cells and explain the importance of these processes in clinical and research settings.
8. Use molecular diagnostic techniques, such as PCR, to detect genetic markers and pathogens, and explain their applications in clinical diagnostics and personalized medicine.
9. Describe the role of cell and gene therapies in clinical medicine, including how they are used to treat genetic diseases, and explain the steps involved in their development.
10. Explain the production process for biopharmaceuticals, such as monoclonal antibodies or therapeutic proteins, including the use of cultured cells for biomanufacturing.
11. Understand and explain the basics of mRNA technology, including how mRNA vaccines work and the role of mRNA in treating diseases.
12. Understand the general steps in vaccine production, including the use of cell cultures or bacterial systems to produce antigens for vaccine development.

### Standard 11: Advanced Lab Techniques

Students will gain an understanding of advanced techniques used in biotechnology and biomanufacturing, including their principles, applications, and significance in research and industry.

* Aligned Industry Recognized Credentials: Pathmaker Credential

**Skills:**

1. Describe how High-Performance Liquid Chromatography (HPLC) works, its applications in protein separation and purification, and its importance in biotechnology.
2. Explain the principles behind Mass Spectrometry (MALDI-TOF MS) and its role in identifying and determining the mass of proteins.
3. Prepare and analyze cell lysates for protein content and purification.
4. Discuss the functionality of AKTA systems in automated protein chromatography and their role in biomanufacturing.
5. Explain how Tangential Flow Filtration (TFF) is used for protein concentration and purification, including its principles and role in biomanufacturing applications.
6. Describe and compare various protein separation techniques, such as HPLC, ion-exchange chromatography, and TFF, and explain how they are applied in biotechnology.
7. Explain how biotechnology techniques like HPLC, MALDI-TOF MS, and TFF are used to separate, analyze, and purify proteins in the production of medicines and vaccines.
8. Use online resources like Google Scholar to research biotechnology topics, such as chromatography and mass spectrometry, and summarize how these techniques are applied in the development of biopharmaceuticals.
9. Formulate a hypothesis about protein purification methods, e.g., comparing HPLC and TFF, design an experiment to test it, and analyze the results.
10. Discuss ethical issues in biotechnology research, such as concerns about animal testing, genetic modification, and data integrity, and evaluate the responsibility of scientists in ensuring accurate and ethical outcomes.

## Employability Standards

### Standard 12: Employability Skills

Students will understand and demonstrate the roles of professional communication, critical thinking, problem-solving, professionalism, teamwork, and collaboration within the context of the biotechnology industry.

**Skills:**

1. Demonstrate effective communication (both oral and written) and collaboration skills in interacting with stakeholders such as customers, suppliers, and regulatory bodies, ensuring clarity, professionalism, and adherence to industry standards.
2. Demonstrate communicating effectively in writing as appropriate for the needs of the audience.
3. Collaborate effectively with team members to navigate organizational changes, technological advancements, or process improvements.
4. Demonstrate the ability to effectively identify, address, and resolve conflicts in a manner that promotes both team progress and positive team dynamics.
5. Identify different career paths in biotechnology, including associated job roles, sample company information, and wage data.

## Entrepreneurship Standards

### Standard 13: Entrepreneurship

Students will be able to describe opportunities for entrepreneurship in the biotechnology field and evaluate the value proposition of business ownership.

**Skills:**

1. Evaluate the licensing, regulatory, and tax implications of self-employment and business ownership compared to W-2 employment.
2. Analyze market demands and trends to identify opportunities for innovation.
3. Describe the purpose, general responsibilities, and value proposition of an owner in the biotechnology industry.

## Digital Literacy Standards

### Standard 14: Digital Literacy

Students will demonstrate the ability to plan, implement, and use technologies that support the day-to-day operations in the biotechnology field.

**Skills:**

1. Demonstrate the ability to collaborate effectively through digital channels, including email, video conferencing, file-sharing platforms, and other messaging applications.
2. Demonstrate the use of software for data management and analysis of large datasets.
3. Utilize specialized software for molecular modeling, simulation, and other biotechnology applications.
4. Create charts, graphs, and other visual representations of data using tools like Excel or Tableau.
5. Identify essential software tools used in biotechnology for tasks such as analyzing genetic sequences, managing laboratory data, visualizing molecular structures, and conducting statistical analyses.
6. Understand how to locate online resources that support effective biotechnology functions and how to be a safe and ethical consumer and creator of digital content.