National Consortium on Health Science ad Technology Education
National Health Science Career Cluster Model

Biotechnology Research and Development (R & D) Pathway
Standards & Accountability Criteria

These standards apply to occupations and functions primarily involved in bioscience research and development that applies to human health. The standards specify the knowledge and skills common to occupations in the biotechnology research and development pathway.

Biotechnology R & D Pathway Standard 1: Contributions of Biotechnology to health and the human condition
Biotechnology R & D professionals will understand that biotechnology products are based on molecular biology of disease and health; the quality of life through finding a cure for genetic, environmental and behavioral diseases, chronic conditions, industrial enzymes and new diagnostic tools; and legal and ethical issues to protect and preserve the quality of life, with emphasis on social and diversity issues.

Accountability Criteria

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.

Biotechnology R & D Pathway Standard 2: Academic Foundations
Biotechnology R & D professionals will be knowledgeable in the fundamentals of mathematical concepts, statistics, genetics, organic chemistry, biochemistry, cell biology, molecular biology and microbiology.

Accountability Criteria

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.

2.3 Genetics

2.31 Describe the basic structure of a chromosome.
2.32 Construct a karyotype with human chromosomes.
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

2.41 Construct a molecule of a compound with 3 or more carbon atoms.
2.42 Create an equation of two organic substrates leading to a product.
2.43 Describe atomic number, atomic mass and orbitals.
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.

2.6 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

2.71 Diagram the structure of the nucleic acid DNA.
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.
2.83 Compare and contrast the use of plasmids in bacterial transformation and the process of plasmid DNA isolation.

Biotechnology R & D Standard 3: Introduction to Biotechnology Knowledge Areas and Techniques

Biotechnology R & D professionals will be introduced to the following recombinant DNA and genetic engineering, bioprocessing (producing recombinant DNA products on a large scale for profit), monoclonal antibody production, separation and purification of biotechnology products, nanotechnology, bioinformatics, genomics, proteomics and transcriptomics.

Accountability Criteria

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.

Biotechnology R & D Standard 4: Laboratory Protocols and Procedures

Biotechnology R & D professionals will understand the principles of solution preparation such as molarity, pH, and dilution; sterile techniques such as inoculum development and transfer; knowledge of contamination control; and measurement and calibration of instruments such as micropipettors and pH meters. They will maintain a sanitary, safe and hazard free laboratory environment. Employees will be adept at teamwork, oral and written communication skills, problem solving, emergency lab response and biosafety protocols.

Accountability Criteria

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.

4.2 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.

Biotechnology R & D Standard 5: Product Design and Development

Biotechnology R & D professionals will have the knowledge of how the product is designed, and what is involved in its development and subsequent production, including the laboratory procedures and regulatory requirements. The employee will have a general understanding of the entire process in order to know how their scope of work contributes to the result including; R & D at the lab bench level, both pre-clinical trials, clinical trials (3 phases), product license application, regulatory process for clinical trials (current Good Manufacturing Practices [cGMPs], and Good Laboratory Practices [GLPs]), for production (cGMPs, GLPs).

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.

Biotechnology R & D Standard 6: Bioethics
Biotechnology R & D professionals are not isolated from the social effect of their products in our society. Science, technology and society are intertwined. Biotechnology R & D employees will be conversant with the larger ethical, moral and legal issues related to biotech research, product development and use in society.

Accountability Criteria
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.