GEORGIA | PEACH STATE PATHWAYS

Career, Technical, & Agricultural Education

HEALTHCARE SCIENCE

PATHWAY: Biotechnology Research & Development

COURSE: Applications of Biotechnology

UNIT 11: Culminating Project

INTRODUCTION

Annotation:

Students will understand the phases of clinical trials, regulatory policies governing healthcare and Biotechnology and the importance of bioethics.

Grade(s):

	9th
	10th
X	11th
X	12th

Time:

20 hours

Author:

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Students with Disabilities:

For students with disabilities, the instructor should refer to the student's IEP to be sure that the accommodations specified are being provided. Instructors should also familiarize themselves with the provisions of Behavior Intervention Plans that may be part of a student's IEP. Frequent consultation with a student's special education instructor will be beneficial in providing appropriate differentiation.

FOCUS STANDARDS

GPS Focus Standards:

HS-ABT-5 **Students will demonstrate an understanding of current trends, ethical, legal, and regulatory issues related to the development of biotechnology products.**

c) Describe the concept of integrity and the ethical use of statistics, controls, and standards.

d) Apply knowledge of bioethical/legal issues to various scenarios, including clinical trials, Institutional Review Boards (IRB) applications, privacy (HIPAA), choice of genetic traits, and use of genetic testing data.

f) Explain the meaning of human dignity and informed consent in biotechnology and healthcare.

h) Explain the phases of clinical trials and requirements for obtaining FDA product approval.

j) Document and keep accurate records according to regulatory requirements.

GPS Academic Standards:

MM1P1 Students will solve problems (using appropriate technology).
MM1P4 Students will make connections among mathematical ideas and to other disciplines.
MM1P5 Students will represent mathematics in multiple ways.

UNDERSTANDINGS & GOALS

Enduring Understandings:

- Intellectual honesty and proper use of statistics, controls and standards are necessary to avoid misrepresentation and misinterpretation of data.
- Bioethical and legal issues must be considered during clinical trials, selection of genetic traits for recombinant DNA, and use of genetic testing data and production of products that will be consumed by humans.
- Specific regulatory policies are in place for the regulation of clinical trials and for requesting FDA approval for commercial use of biotechnology products including the use of animals, construction of recombinant DNA and the role of documentation and record keeping.

Essential Questions:

- How are the lack of intellectual honesty, proper use of statistics, controls, and standards involved in misrepresentation and misinterpretation of data?
- Why must bioethical and legal issues be considered during clinical trials, selection of genetic traits for recombinant DNA, and use of genetic testing data and production of products that will be consumed by humans?
- What are specific regulatory policies that are in place for the regulation of clinical trials and for requesting FDA approval for commercial use of biotechnology products including the use of animals, construction of recombinant DNA and the role of documentation and record keeping?

Knowledge from this Unit:

Students will be able to:

- Explain the phases of clinical trials and requirements for obtaining FDA product approval
- Regulations governing product development
- Research and development involved in manufacturing and marketing biotechnology products

Skills from this Unit:
Students will be able to:

- Evaluate a biotechnology product based on techniques and organisms involved
- Documentation and record keeping methods used in biotechnology companies

ASSESSMENTS

Assessment Method Type:

_____ Pre-test
_____ Objective assessment - multiple-choice, true- false, etc.
__ Quizzes/Tests
__ Unit test
X Group project
_____ Individual project
_____ Self-assessment - May include practice quizzes, games, simulations, checklists, etc.
__ Self-check rubrics
__ Self-check during writing/planning process
__ Journal reflections on concepts, personal experiences and impact on one's life
__ Reflect on evaluations of work from teachers, business partners, and competition judges
__ Academic prompts
__ Practice quizzes/tests
_____ Subjective assessment/Informal observations
__ Essay tests
__ Observe students working with partners
__ Observe students role playing
_____ Peer-assessment
__ Peer editing & commentary of products/projects/presentations using rubrics
__ Peer editing and/or critiquing
_____ Dialogue and Discussion
__ Student/teacher conferences
_X_ Partner and small group discussions
_X_ Whole group discussions
__ Interaction with/feedback from community members/speakers and business partners
_____ Constructed Responses
__ Chart good reading/writing/listening/speaking habits
__ Application of skills to real-life situations/scenarios
_____ Post-test

Assessment Attachments and / or Directions:

Great Debate Rubric

LESSON PLANS

• LESSON 1: GREAT DEBATES

1. Identify the standards. Standards should be posted in the classroom.

HS-ABT-5 **Students will demonstrate an understanding of current trends, ethical, legal, and regulatory issues related to the development of biotechnology products.**

c) Describe the concept of integrity and the ethical use of statistics, controls, and standards.
d) Apply knowledge of bioethical/legal issues to various scenarios, including clinical trials, Institutional Review Boards (IRB) applications, privacy (HIPAA), choice of genetic traits, and use of genetic testing data.
f) Explain the meaning of human dignity and informed consent in biotechnology and healthcare.
h) Explain the phases of clinical trials and requirements for obtaining FDA product approval.
j) Document and keep accurate records according to regulatory requirements.

2. Review Essential Question(s). Post Essential Questions in the classroom.

- Who decides what is right and what is wrong when it comes to scientific advances and new technology used in the biotechnology industry?
- How is the lack of intellectual honesty and proper use of statistics, controls and standards involved in misrepresentation and misinterpretation of data?

3. Identify and review the unit vocabulary. Terms may be posted on word wall.

Bioethics	Recombinant DNA	Regulatory policies

4. Interest approach – Mental set

- Supply students with advertisements that have a strong influence on people's opinions and actions. Discuss which senses the advertisement appeals to.
- Present 5 different scenarios of dishonesty and subsequent harm to individuals such at the Tuskegee Experiment. Allow students to form groups to research the topic. Assign students to debate the pros and cons of the scenario.

5. Allow the students to analyze part of "The Great Debaters" that shows proper technique in debating.

6. Allow the teams practice time to prepare for the debates.

7. Schedule the debates during class time with help from other teachers, community partners, and parents serving as judges.

• LESSON 2: BIOETHICS AND LEGAL ISSUES

1. Review Essential Questions. Post Essential Questions in the classroom.

- Why bioethical and legal issues must be considered during clinical trials, selection of genetic traits for recombinant DNA, and use of genetic testing data and production of products that will be consumed by humans?

2. Display a newsflash of Michael Jackson's death. Ask students their opinion about the doctor that has been blamed for his death. Lead a discussion about the ethics and legalities involved in this case.

3. Assign students the task of identifying other cases in which unethical or illegal actions have been implicated surrounding the production and/or use of biotechnology techniques and products (i. e. the use of stem cells obtain from human embryos)

• LESSON 3: GOVERNMENT REGULATION

1. Review Essential Questions. Post Essential Questions in the classroom.

    - What are specific regulatory policies that are in place for the regulation of clinical trials and for requesting FDA approval for commercial use of biotechnology products including the use of animals, construction of recombinant DNA and the role of documentation and record keeping.

2. Display information about the recent development of an immunization against human papilloma virus named Gardasil®. Over the years there have been many reports of problems.

3. The teacher will invite a speaker from the Food and Drug Administration to explain the process for product development, testing and approval for distribution and sales. Allow students to complete a KWL chart about the process of drug development before and after the FDA speaker's presentation.

4. The speaker will provide an outline of their presentation for students to use to take notes.

5. The student will complete the KWL chart.

• NOTES & REFLECTION:

The student will have a thorough understanding of the role of regulatory agencies in insuring that biotechnology products are produced using the safest procedures.

CULMINATING PERFORMANCE TASK

Culminating Unit Performance Task Title: THE GREAT DEBATES

This culminating project is taken directly from lesson one of this unit. Students will debate the pros and cons of the scenario provided by teacher. Each scenario involves bioethical or legal implications.

Culminating Unit Performance Task Description/Directions/Differentiated Instruction:

Students will debate the pros and cons of the scenario provided to them after they have research the scenario given to them by the teacher. They will point out any bioethical and legal issues involved with the conditions involved in the situation.

Attachments for Culminating Performance Task:

Great Debate

UNIT RESOURCES

Web Resources:

Food and Drug Administration www.fda.gov

21st Century Technology Used:

☐	Slide Show Software	☐	Graphing Software	☐	Audio File(s)
☐	Interactive Whiteboard	☐	Calculator	☐	Graphic Organizer
☐	Student Response System	☐	Desktop Publishing	☐	Image File(s)
☐	Web Design Software	☐	Blog	☐	Video
☐	Animation Software	☐	Wiki	☐	Electronic Game or Puzzle Maker
☐	Email	x	Website		