ASSIGNMENT SHEET A: INTRODUCTION

Review the following pages in the laboratory text.

1. Unit 1: Introduction to the Biotechnology Workplace (Pgs. 1-5)
2. Biotechnology and the Workplace (Chapter 1, pgs. 7-17)
3. Introduction to a Safe Workplace (Chapter 2, pgs. 19-31)
4. Biotechnology and the Regulation of Medical and Food Products (Chapter 3, pgs. 33-43)

Note the definitions and meanings of the following terminology.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Cell Culture</td>
<td>Good Laboratory Practices, GLP</td>
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<td>Cell Line</td>
<td>Good Manufacturing Practices, GMPs</td>
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<td>Expression (in genetics)</td>
<td>Hybridoma</td>
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<td>Environmental Protection Agency, EPA</td>
<td>Monoclonal Antibodies</td>
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<td>Fermentation (in Biotechnology)</td>
<td>Plasmid</td>
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<td>Fermenter</td>
<td>Pyrogen</td>
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<td>Gene Therapy</td>
<td>Quality Assurance (QA)</td>
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<td>Genetic Engineering</td>
<td>Quality Control (QC)</td>
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<td>Genetically Modified Organism</td>
<td>Recombinant DNA</td>
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Objectives:
1. Define biotechnology. Clarify what is meant by “modern biotechnology”.
2. Describe the steps to genetically modify bacteria as outlined in Fig 1.1.
3. Describe why it is more costly to produce a protein in mammalian cell culture than with a bacterial culture.
4. What was the first transgenic animal produced? What was the unusual phenotype of this animal?
5. What are monoclonal antibodies and how can they be used in biotechnology?
6. Describe the production of vaccines in transgenic plants.
7. Describe an example of Gene therapy.
8. Briefly describe the differences in the responsibilities of an employee working in the following units of biotechnology company. Include an example of a job title for each type of position.
   a. research and development
   b. Production unit
   c. Quality Control/ Quality Assurance
10. After reading Chapter 2, discuss the problems presented on page 31. Write a short summary of the discussion.
11. Summarize the life cycle of a pharmaceutical product.
12. Differentiate between Phase I, Phase II and Phase III clinical trials.
13. Describe the functions of the three primary federal agencies involved in the regulation of food and agriculture in the United States.