ASSIGNMENT SHEET B: QUALITY IN THE LAB

Review the following pages in the laboratory text.
1. Unit II. Product Quality and Biotechnology (pgs. 45-50)
2. Quality in the laboratory (Chapter 4, pgs. 51 - 58)
3. Laboratory documentation (Chapter 5, pgs. 59 - 73)
4. Laboratory Quality & Methods (Chapter 6, pgs. 75 - 83)
5. Biological Production (Chapter 7, pgs. 85 - 96)

Note the definitions and meanings of the following terminology.
- Accuracy
- Biological Activity
- Calibrate
- Current Good manufacturing Practices (cGMP)
- Cytotoxic
- Documentation
- Electrophoresis
- Food and Drug Administration, FDA
- Form
- Good Clinical Practices (GCP)
- Good Laboratory Practices (GLP)
- Immunoassays
- International Organization for Standardization (ISO)
- ISO 9000
- Laboratory Notebook
- Limit of Detection
- Limit of Quantization
- Linearity
- Logbook
- Lot Number
- Method
- Precision
- Procedure
- Protocol
- Pyrogen
- Quality Control
- Range
- Raw Data
- Regulatory Agency
- Repeatability
- Report
- Reproducibility
- Sample
- Specifications
- Standard
- Standard Operating Procedure (SOP)
- Validation

Objectives:
1. Describe the product of an academic laboratory.
2. Describe some of the characteristics associated with "doing good science".
3. Explain how quality is monitored in an academic laboratory.
4. Describe the major differences between quality in an academic lab versus other types of labs (See Table 4.3)
5. Explain the importance of documentation in all types of laboratories.
6. Describe the acceptance of change in different types of laboratories. (Read the Example Problem on page 57 and the Case study on page 58)
7. List the functions of documentation.
8. Describe the different types of documentation used in laboratories (See Table 5.2)
9. Be familiar with the differences between a procedure, a protocol, a form, and a report
10. List and/or describe the typical components of a laboratory notebook (See Table 5.3)
11. List and/or describe the guidelines for keeping a laboratory notebook (See Table 5.4)
12. List and/or describe the typical components of an SOP. (See Table 5.4)
13. List and/or describe the typical components of a protocol. (See Table 5.7)
14. List and/or describe the typical components of a label (See Table 5.9)
15. List and/or describe the types of analysis commonly used in a biological laboratory (See Table 6.1)
16. The characteristics of a method that can be evaluated include its (1) accuracy, (2) precision, (3) limit of detection, (4) limit of quantification, (5) selectivity, (6) linearity and range, and (7) robustness. Give a general description of these characteristics.
17. Be able to evaluate the appropriate use of a specific chemical based on the specifications presented on its label or listed in a catalog.