

Course Number: BTN1120 Section: 120 Term: 13FA

Credits: 2.000

Room: 9 322 Meeting Days: TTH Meeting Time: 02:00 PM - 02:50 PM

Faculty Information:

| | | | |
|-------------------------|--------------|--------------------------|--|
| Instructor(s): | Luken, Susan | | |
| Department: | Biology | Division: | Science, Mathematics and Engineering |
| Phone Number: | 512-3049 | Alternate Number: | |
| Use Course Mail: | Yes | Alternate Email: | susan.luken@sinclair.edu (for fastest response use this email) |
| Office Location: | 3012B | Office Hours: | MWF 12 - 1PM |

Prerequisites: NONE

Other Prerequisite(s): NONE

Textbook(s):

BASIC LABORATORY METHODS FOR BIOTECHNOLOGY, SEIDMAN

Edition: 2 Copyright: 09
ISBN: 0-321-57014-6 **Req**

Used New
\$72.90 \$97.20

Technical Requirements:

Students will need to have access to the Internet at home or at school in order to complete class assignments.

Course Description:

Introduction to lab safety culture, precautionary labels, Material Safety Data Sheets, using personal protective equipment, handling lab equipment safely, handling, storing and disposing of chemicals safely, using emergency equipment as well as safety planning.

Course Objectives/Competencies:

General Education Outcomes:

- Written Communication Competency
- Critical Thinking/Problem Solving Competency
- Values/Citizenship/Community Competency
- Computer Literacy Competency
- Information Literacy Competency

Course Outcomes:

Chemical Labeling & Safety

Demonstrate safe handling of chemicals and equipment in the laboratory.

Good Lab Practice, Good Manufacturing Practice & Fire Safety

Demonstrate knowledge of Good Laboratory Practices (GLPs), Good Manufacturing Practices (GMPs) and Fire Safety

Regulatory Agencies

Demonstrate familiarity with international and federal regulatory agencies that impact the work of Biotechnology.

Emergency Equipment & Standard Operating Procedures

Recognize and maintain various PPE and emergency equipment in a laboratory setting as well as evaluating Standard Operating Procedures (SOPs) and safety plans.

Course Outline:

Material safety data sheets

Good lab practices
 Good manufacturing practices
 Fire safety
 Regulatory agencies
 Safe use of lab equipment & chemicals
 Using emergency equipment
 Safety planning

Course Requirements:

Students will need access to the Internet at home or on campus for this course.

Class Policies:

Regular attendance and punctuality is highly encouraged in order to succeed in this course. Lectures are **not** intended to replace the reading assignments. Reading the material prior to class will contribute to the learning process and participation.

If you miss a class, it is **your responsibility** to obtain lecture notes or handouts and to stay informed of any changes in assignments or testing dates announced in class. You will be held to the same due dates as the rest of the class.

Please be considerate of others and turn off or mute cell phones during all lectures, activities and exams.

A passing grade in Laboratory Safety is necessary in continuing on to the Reagent Preparation course, for your and your classmates safety.

Evaluation/Grades:

| Exams and Assignments | Points/Percentage | Grading Scale |
|------------------------------|-------------------|-----------------|
| Exam 100 points x 4 | 400 | 100-90% A |
| Open Book Test cGLPs | 40 | 89-80 % B |
| Open Book Test cGMPs | 40 | 79-70% C |
| Homework 10 points x 5 | 50 | 69-60% D |
| Attendance and Participation | 20 | 59% and below F |

Course Schedule:

| Course Schedule for BTN1120 - 120 | | |
|-----------------------------------|--|--|
| Week/Date | Material to be covered | Assignments Due |
| Week 1 | Introduction to the course & Chapter 2: The Business of Biotechnology: The Transformation of Knowledge into Products | |
| Week 2 | Chapter 3: The Lifecycle of Pharmaceutical Products | Aug 26, Last Day to withdraw with a refund without record |
| Week 3 | Tuesday no class - Labor day holiday Chapter 4: Introduction to Product Quality Systems | Exam 1 (Chapters 2, 3 & 4) will be due by Sunday Sept 8th by 11:55 PM |
| Week 4 | Chapter 5: Biotechnology and the Regulation of Medical Food Products Chapter 6: Documentation | Chapter 4 Homework due at the beginning of class on Tuesday Chapter 5 Homework due at the beginning of class on Thursday |
| Week 5 | Chapter 6: Documentation | |
| Week 6 | Chapter 7: Quality Systems in the Production Facility Chapter 8: Quality Systems in the Laboratory | Exam 2 (Chapters 5, 6 & 7) due by 11:55 PM on Sunday Sept. 29th Chapter 6 Homework due at the beginning of class on Tuesday |
| Week 7 | cGMP - Deb Hoffer, Quality Control/Quality Assurance Manager, The Rogosin Institute | cGMP exam do by 11:55 PM Sunday Sept 6th |
| Week 8 | Fire Safety | Class will meet in Building 20 Dress for the weather |
| Week 9 | Chapter 9: Introduction to a Safe Workplace | Chapter 9 Homework due at the beginning of class on Thursday |
| Week 10 | Chapter 10: Working Safely in the Laboratory: General Considerations and Physical Hazards | |

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| Week 11 | Chapter 10: Working Safely in the Laboratory: General Considerations and Physical Hazards Chapter 11: Working Safely with Chemicals | Exam 3 (Chapters 8, 9 & 10) due by 11:55 PM Sunday November 3rd |
| Week 12 | cGLP - Ralph Anderson, president, Anderson Consultants | |
| Week 13 | cGLP - Ralph Anderson, president, Anderson Consultants Chapter 11: Working Safely with Chemicals | November 15 Last day to withdraw cGLP exam due by 11:55 PM Sunday Nov 17th |
| Week 14 | Chapter 11: Working Safely with Chemicals | Chapter 11 Homework due at the beginning of class on Thursday |
| Week 15a | Chapter 12: Working Safely with Biological Materials Thursday - no class Thanksgiving holiday | |
| Week 15b | Chapter 12: Working Safely with Biological Materials | |
| Week 16 : Evaluation Week | Cumulative Final Exam | |

Unit Outcomes:

Practicing safe science is an essential and fundamental responsibility of every laboratory worker. In this course, we will examine some common laboratory procedures, the hazards associated with these procedures, personal protective equipment that can be used to minimize associated with the laboratory accidents and emergency equipment that can be used in the event of specific types of laboratory accidents. In order to assure consumer safety and product quality, the biomedical and pharmaceutical industry is regulated by various government agencies. Compliance with the regulations and guidelines set forth by these agencies is essential for successful product development, licensing and marketing. Therefore, we will examine some of the predominant regulations and the enforcing agencies.

Additional Information:

Guest Lecturers:

We are very fortunate to have the rare opportunity of bringing to you industry experts in specific areas to share their wealth of knowledge. Mr. Ralph Anderson, President, Anderson Consultants, will handle the topic of current Good Laboratory Practices, and Ms. Deborah Hoffer, Quality Control/Quality Assurance Manager, The Rogosin Institute, Xenia, will cover the lectures on current Good Manufacturing Practices.

Testing Information:

Exams must be taken on the date posted. If you are an individual that needs extra time on written tests, please inform the instructor in writing at the beginning of the quarter and we will make arrangements for you to take the tests in the testing center located on the 4th floor of building 10. You are able to change your mind during the quarter if you feel that you need these arrangements or no longer need them.

Sinclair Policies:

Sinclair Academic Policies

Visit the links below to view Sinclair policies regarding adding or dropping a course, withdrawing from college, late registrations, change of schedule, administrative withdrawal, student behavior guidelines, safety and security, and other academic policies. Understanding these policies is the responsibility of every student.

- Policies for Academic Progress, Academically Dismissed Students, FERPA Records, Fresh Start <http://www.sinclair.edu/services/registration/Policies/>
- Add/Drop a Course <http://www.sinclair.edu/services/registration/Registration/AddorDropClasses/>
- Honor Code and Plagiarism Policies: <http://www.sinclair.edu/about/learning/gened/hc/>
- Student Handbook <http://www.sinclair.edu/student/leader/handbook/>
- Policies, Procedures & Services <http://www.sinclair.edu/catalog/pub/2012/policiesandprocedures.pdf>
- Disabilities Policy & Procedure Guidelines for Students <http://www.sinclair.edu/support/disability/policies/>

Attendance

Students are expected to be present at all class sessions. It is the students' responsibility to read and understand the class attendance policy or the SinclairOnline course participation policy that will be defined in the syllabus for each course. It is the faculty member's responsibility to define attendance or participation requirements and to monitor and record the students' fulfillment of these requirements. It is a program's prerogative to have specific policies across multiple sections due to the unique requirements of that program. Attendance for traditional classes or participation for SinclairOnline classes may affect final grades, financial aid eligibility, and V.A. benefits.

Sinclair Semester Dates

Click the link below to view important semester dates such as registration deadlines, payment deadlines, start and end dates for the semester as well as the last day to withdraw with a refund and the last day that withdrawal is allowed. <http://www.sinclair.edu/stservices/rsr/dates/index.cfm>