

BTEC 1300: Introduction to Regulations and Quality

This course introduces concepts and processes used in the manufacture of biotechnology products. Emphasis is placed on the role of documentation, quality, and good manufacturing practices in complying with federal regulations.

INSTRUCTOR: Mary L. Nelson, PhD

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801-957-6327

JHS 240 (please feel free to come by and talk!)

PREREQUISITES: Students are required to have completed BTEC 1000, BTEC 1100, and BTEC 1200, all with a B or better.

COURSE MATERIALS: Students need access to the Canvas online course management system (slcc.instructure.com). Instructional material can only be accessed through Canvas. A lab coat and lab notebook will be provided.

COURSE FORMAT and OBJECTIVES: The course uses a hybrid, competency-based format in which online instruction and activities are reinforced by select laboratory experiences. Students may conduct experiments during the open lab hours whenever it suits their own schedule.

This course has four primary learning objectives (referred to as competencies):

1. The student explains how federal regulations affect the manufacturing process.
2. The student demonstrates good documentation practices using a document management system.
3. The student explains good manufacturing practices and how they relate to federal regulations and documentation.
4. The student applies quality principles to the manufacturing process.

LEARNING LAB: The standard hours for the learning lab are Tuesday – Saturday, 8:00 am – 8:00 pm. Semester breaks and college holidays are observed. Unless otherwise noted, there will always be a faculty member in the learning lab during open lab hours. All students who work in the lab must clean up after themselves, participate in community chores, and maintain an environment conducive to experimentation and learning for all who use the learning lab.

GRADING: Because this course is competency-based, grades are given solely on the four performance assessments associated with this course. Each performance assessment is worth 25% of a student's total grade. Grades will be assigned based on the percentage scale below. **Students must achieve a B or better on all aspects of each assignment to proceed to the next biotechnology course.**

Performance Assessments	
FDA Regulations	25%
Documentation	25%
Manufacturing	25%
Quality	25%
TOTAL	100%

Final %	Grade
93–100	A
90–92	A-
87–89	B+
83–86	B
80–82	B-
77–79	C+
73–76	C
70–72	C-
67–69	D+
63–66	D

Danielle Mills 10/17/2017 11:32 AM

Comment [1]: Danielle Mills 11:30 AM
If going to a CBE model and a B is a minimum grade requirement to prove proficiency, I recommend putting that in the syllabus. Especially if it is a pre-req to another class.

POLICIES:

1. Plagiarism/cheating will result in zero credit for the applicable assignment.
2. Students are expected to follow the SLCC Code of Conduct found at http://www.slcc.edu/policies/docs/Student_Code_of_Conduct.pdf
3. As outlined in the SLCC Policy and Procedures Manual, the instructor will “monitor and promote safe, effective and supportive learning environments and exercise defined prerogative when dealing with student behavior that distracts students from learning.” <http://www.slcc.edu/policies/docs/c4s01-03 .pdf>
4. SLCC values inclusive learning environments and strives to make all aspects of the College accessible to our students. If you have a disability and believe you need accommodations to improve access to learning materials or the learning environment, please contact the Disability Resource Center: (phone) 801-957-4659; (email) drc@slcc.edu; (website) www.slcc.edu/drc.
5. SLCC is committed to fostering and assessing the following student learning outcomes in its courses:
 - *Acquiring substantive knowledge in the field of their choice
 - *Developing quantitative literacies
 - *Developing the knowledge and skills to be civically engaged
 - *Thinking critically
 - *Communicating effectively
6. Title IX of the Educational Amendments of 1972 prohibits discrimination based on sex in any educational institution that receives federal funding. Salt Lake Community College does not tolerate sex discrimination of any kind including: sexual misconduct; sexual harassment; relationship/sexual violence and stalking. These incidents may interfere with or limit an individual’s ability to benefit from or participate in the College’s educational programs or activities. If you have questions or concerns regarding your rights or responsibilities, or if you would like to file a Title IX complaint please contact: Kenneth Stonebrook, J.D.

Dean of Students and Assistant Vice President, Title IX Coordinator
Salt Lake Community College Taylorsville Redwood Campus – STC 276A
(801) 957-5027 ken.stonebrook@slcc.edu

Online Reporting Form: https://cm.maxient.com/reportingform.php?SaltLakeCC&layout_id=20

Students may also report incidents to an SLCC faculty or staff member, who are required by law to notify the Title IX Coordinator. If a student wishes to keep the information confidential, the student may speak with staff members of the Center for Health and Counseling, (801) 957- 4268. For more information about Title IX, go to: <http://www.slcc.edu/title-ix/index.aspx>

7. The syllabus is not a binding legal contract. It may be modified by the instructor when the student is given reasonable notice of the modification.

Syllabus Statement—Important Information for Students

General Education Regardless of your major, General Education courses build a foundation of broad knowledge and skills that help you in your further career and life. <http://www.slcc.edu/gened>

General Learning Support & Tutoring Services provide support for SLCC students enrolled in any class at the College. All resources are provided free-of-charge. Ask your instructor about discipline-specific learning support and tutoring services.

The **Tutoring and Learning Centers** provide free assistance in Math, Science, Accounting, CSIS and Allied Health Classes at 6 campus locations. <https://www.slcc.edu/tutoring>

The **Student Writing Center** provides in-person and online feedback on all writing assignments. <http://www.slcc.edu/swc>

The **Academic Literacy Center** provides tutoring in reading and conversation. <https://www.slcc.edu/english/academic-literacy-center.aspx>

Library Services provides research help, print and online resources, computers and study space. <libweb.slcc.edu>

The **ePortfolio Lab** provides drop-in assistance for all ePortfolio questions. <http://eportresource.weebly.com/>

eLearning Support provides support for navigating online and hybrid classes. <https://slcc.instructure.com/courses/297606>

The **Business Resource and Innovation Center** provides tutors and a study space for students in Business and CSIS courses. Located in BB 226 on Taylorsville-Redwood Campus.

Advising and Counseling Support Services provide support for students enrolled in any class as the college.

The **Center for Health and Counseling** provides health care, mental health counseling, massage therapy services and healthy lifestyle programs. <http://www.slcc.edu/chc/index.aspx>

Veterans' Services assists hundreds of students in using their VA education benefits each semester. <http://www.slcc.edu/veterans>

Academic and Career Advising helps students plan, explore, make decisions, access resources and evaluate their academic and career goals. And the Academic Achievement Center helps students achieve GPA requirements for graduation.

<https://www.slcc.edu/academicadvising>

<https://www.slcc.edu/academic-achievement-center/index.aspx>

Student Code of Conduct: http://www.slcc.edu/policies/docs/Student_Code_of_Conduct.pdf

David Hess 10/17/2017 3:35 PM

Comment [2]: Reviewed 10/17/2017