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BEC 591: cGMP Course Syllabus

Biomanufacturing Operations

Instructor Information

Name	Email	Office Location
Danny Monroe, Ph.D. **Course Admin**	**dsmonroe@ncsu.edu**	**BTEC rm 195**
Kurt Selle, Ph.D. Upstream instructor	kmselle@ncsu.edu	BTEC rm 119
Jennifer Pancorbo, Ph.D. Upstream Instructor	jruiz2@ncsu.edu	BTEC rm 186
Gary Gilleskie, Ph.D. Downstream Instructor	glgilles@ncsu.edu	BTEC rm 192
John van Zanten, Ph.D. Downstream Instructor	jhvanzan@ncsu.edu	BTEC rm 184

Office Hours

Danny Monroe - Virtual office hours by appointment via Zoom

Course Information

Course Website: NC State WolfWare

Course Credit Hours: 3

Catalog Description

This online lecture-based course introduces students to upstream and downstream biomanufacturing for the production of biopharmaceuticals. The course will provide students with key upstream fermentation and cell culture concepts used by biomanufacturing industries including microbial growth, bioreactors,

process controls, etc. Downstream concepts include separations, homogenization, chromatography, and ultrafiltration. There will be a specific focus on scale-up and cGMP operations for both upstream and downstream unit areas. This is a full-semester course offered in the fall only.

Structure

☑ This course is completely **asynchronous**, which means that students have no real-time class meeting requirements. Learning materials, activities, assignments, and assessments are delivered through **Moodle**, a secure and easy-to-use online learning platform.

☐ This course is delivered in a **hybrid** format, meaning it has asynchronous and synchronous components. Asynchronous components are delivered through **Moodle**, a secure and easy-to-use online learning platform.

☐ The majority of this course is **synchronous**, delivered through real-time, face-to-face class sessions. Additional materials and activities are delivered through **Moodle**, a secure and easy-to-use online learning platform.

Learning activities in this course will include recorded video lectures, quizzes, and exams.

This course consists of 15 learning modules. Most modules last one week with each module beginning on Sunday and ends the following Sunday. Assignments are due by midnight on Sunday.

Meeting Time and Tool Used

No in-person/synchronous meetings are required for this course. Weeks will be unlocked a few at a time. This course is NOT self-paced and must be attended on a weekly basis.

Prerequisites/Corequisites

BIO 183 and CH 221 or 225

Minimum Technical and Digital Information Literacy Skills

Required technical Skills
- Navigate and use Moodle, NC State's Learning Management System.
- Use Gmail, including attaching files to email messages
- Create and submit files in commonly used word processing program formats (MS Word, text editors, Google Docs).
- Download and upload attachments
- Use web conferencing tools including Zoom
- Post to discussion boards and forums

General Education Program (GEP) Information

GEP Category Fulfilled

None

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GEP Corequisites

None

Learning Outcomes

Upon completion of this course, students will be able to:

1. Define the term biopharmaceutical and describe different biopharmaceutical products
2. Describe aerobic fermentation processes and the use of bioreactors for mass cultivation of microbes for biomanufacturing
3. Determine key fermentation process indicators including growth kinetics and yield coefficients through basic analytical assays
4. Describe typical downstream unit operations, including their purpose and parameters likely to impact their performance
5. Describe basic concepts involved in developing and scaling up downstream processing steps
6. Prepare cGMP compliant documentation and understand SOPs as they pertain to upstream and downstream manufacturing

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Course Materials

Required textbook

None

Other required materials

Optional materials

None

Technology Requirements

NC State University Libraries offers [Technology Lending](#), where many devices are available to borrow for a 7-day period. [Computer labs](#) are available in various locations around campus for student use.

Computer

A laptop computer is recommended for students taking this course. NC State's Online and Distance Education provides [technology requirements and recommendations](#) for computer hardware, and NC State's Office of Information Technology provides recommendations for [your computer at NC State](#).]

Other devices

None

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Other Student Expenses

None

Communication Guidelines

Respecting our learning community

The [NC State Code of Student Conduct](#) outlines expectations for behavior in the classroom (whether virtual or physical) and the consequences for students who violate these expectations. Any behavior that impacts other students' ability to learn and succeed will be addressed, but expressing diverse viewpoints and interpretations of course content is welcome.

Community guidelines for this course include:

- Use a respectful tone in all forms of communication (email, written, oral, visual)
- Maintain professionalism (avoid slang, poor grammar, etc.) in your written communication.
- Respect regional dialects and culturally embedded ways of oral communication.
- Stay home or in your dorm room if you are exhibiting symptoms of a contagious illness (fever, chills, etc.).
- Enter our virtual and/or physical classroom community respectfully by refraining from lewd or indecent speech or behavior, helping to maintain a safe physical environment, not using your cell phone for voice or text communication except when explicitly given leave to do so, and not attending class under the influence of any substance.
- Treat each community member with respect by not recording others without their consent or engaging in any form of hazing, harassment, intimidation, or abuse.
- Respect cultural differences that may influence communication styles and needs.]

Grading and Feedback

Grading criteria, details, and timing of feedback

Percentage of grade	Component	Details and timing of feedback
10 %	Discussion Forum	• One post or response per week is required
40 %	Weekly quizzes	• There will be 15 quizzes throughout the course, one per week. Each quiz will feature 10-20 questions on that week's topics.
25 %	Midterm	• The midterm will cover all Upstream topics (weeks 1-8)
25 %	Final	• The final will cover all Downstream topics (weeks 9-15)

Grading scale

This course uses this grading scale:

Low	Letter	High
97 ≤	A+	≤ 100
93 ≤	A	< 97
90 ≤	A-	< 93
87 ≤	B+	< 90
83 ≤	B	< 87
80 ≤	B-	< 83
77 ≤	C+	< 80
73 ≤	C	< 77
70 ≤	C-	< 73
67 ≤	D+	< 70
63 ≤	D	< 67
60 ≤	D-	< 63
0 ≤	F	< 60

Course Schedule

Please note: the course schedule is subject to change.

Week	Date Range	Topic	Activities	Due Date
Week 1	Jan 7-14	Introduction to Biomanufacturing and Biomolecules	Weekly videos, post, and quiz	Jan 14
Week 2	Jan 14-21	Cell Growth	"	Jan 21
Week 3	Jan 21-28	Expression Systems	"	Jan 28
Week 4	Jan 28-Feb 4	Introduction to Bioreactors	"	Feb 4
Week 5	Feb 4-11	Oxygen Transfer	"	Feb 11

Week 6	Feb 11-18	Sterilization Methods and Basics of Sensing and Measurement	"	Feb 18
Week 7	Feb 18-25	cGMP Fermentation Operations	" **Midterm opens**	Feb 25
Week 8	Feb 25-Mar 3	Downstream Introduction and Cell Lysis	Weekly videos, post, and quiz; **Midterm closes**	Mar 3
Week 9	Mar 3-10	Spring Break	No Class	
Week 10	Mar 10-17	Centrifugation	Weekly videos, post, and quiz	Mar 17
Week 11	Mar 17-24	Filtration	"	Mar 24
Week 12	Mar 24-31	Downstream Measurements and Intro to Chromatography	"	Mar 31
Week 13	Mar 31-Apr 7	Chromatography continued	"	Apr 7
Week 14	Apr 7-14	Ultrafiltration	"	Apr 14
Week 15	Apr 14-21	Ultrafiltration Design and Filling	" **Final opens**	Apr 21
Week 16	Apr 21-28	Exam Week	**Final closes**	Apr 29

Course Policies

Late assignments

Late assignments will not be accepted. Most assignments are quizzes and tests and need to be completed by the due date since answers will be released. If extenuating circumstances arise, please contact Dr. Monroe immediately for rescheduling.

Incomplete grades, withdrawals

Information on incomplete grades can be found at REG 02.50.03 – Grades and Grade Point Average. If you encounter a serious disruption to your work not caused by you and you would have otherwise successfully completed the course, contact your instructor as soon as you can to discuss the possibility of earning an incomplete in the course for the semester, including an agreement on when the remaining work must be done in order to change the grade to the appropriate letter grade.

Attendance

- Students must log in the Moodle page weekly. Weekly assignments include watching videos, post to the forum, and completing quizzes/tests.

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- This course is an asynchronous but NOT self-paced online course. For timing flexibility, students may work up to one week in advance of the current week to accommodate work, travel, life issues, etc.

Related NC State Policy: REG 02.20.03 – Attendance Regulations

University Policies

Academic integrity and honesty

Students are required to comply with the university policy on academic integrity found in the Code of Student Conduct 11.35.01 sections 8 and 9. Therefore, students are required to uphold the Pack Pledge: "I have neither given nor received unauthorized aid on this test or assignment." Violations of academic integrity will be handled in accordance with the Student Discipline Procedures.

Please refer to the Academic Integrity web page for a detailed explanation of the University's policies on academic integrity and some of the common understandings related to those policies.

Student privacy

Originality Checking Software

- ☐ Software is being used in this course to detect the originality of student submissions.
- ☑ Software is not used in this course to detect the originality of student submissions.

Class privacy statement:

- ☑ This course requires online exchanges among students and the instructor, but NOT with persons outside the course. Students may be required to disclose personally identifiable information to other students in the course, via electronic tools like email or web postings, where relevant to the course. Examples include online discussions of class topics and posting of student coursework. All students are expected to respect the privacy of each other by not sharing or using such information outside the course.
- ☐ Student information in this course may be accessible to persons beyond the instructor and students in the course. This course may involve electronic sharing or posting of personally identifiable student work or other information with persons not taking or administering the course. Students will be asked to sign a consent form allowing disclosure of their personally identifiable work. No student must sign the consent form as a condition of taking the course. If a student wants to avoid signing the consent form, he or she has the right to ask the instructor for an alternative, private means of completing the coursework.

Other Policies

Students are responsible for reviewing the NC State University PRR's which pertain to their course rights and responsibilities:

- Equal Opportunity and Non-Discrimination Policy Statement and additional references
- Code of Student Conduct

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- [Grades and Grade Point Average](#)
- [Credit-Only Courses](#)
- [Audits](#)

Student Resources

Academic and Student Affairs maintains a website with links for student support on campus, including academic support, community support, health and wellness, financial hardship or insecurity, and more. [Find Help on Campus.](#)

Disability resources

Reasonable accommodations will be made for students with verifiable disabilities. In order to take advantage of available accommodations, students must register with the [Disability Resource Office (DRO)](#). For more information on NC State's policy on working with students with disabilities, please see the [Policies, Rules and Regulations page maintained by the DRO](#) and [REG 02.20.01 Academic Accommodations for Students with Disabilities](#).

Safe at NC State

At NC State, we take the health and safety of students, faculty and staff seriously. The [Office for Institutional Equity and Diversity](#) supports the university community by providing services and resources to support and guide individuals in obtaining the help they need. See the [Safe at NC State webpage](#) for resources.

Supporting Fellow Students in Distress

[Example: As members of the NC State Wolfpack community, we each share a personal responsibility to express concern for one another and to ensure that this classroom and the campus as a whole remain a healthy and safe environment for learning. Occasionally, you may come across a fellow classmate whose personal behavior concerns or worries you, either for the classmate's well-being or yours. If you feel this way, I would encourage you to report this behavior to the [NC State CARES website](#). Although you can report anonymously, it is preferred that you share your contact information so they can follow up with you personally.]

Course Evaluations

ClassEval is the end-of-semester survey for students to evaluate the instruction of all university classes. The current survey is administered online and includes 12 closed-ended questions and 3 open-ended questions. Deans, department heads, and instructors may add a limited number of their own questions to these 15 common-core questions.

Each semester students' responses are compiled into a ClassEval report for every instructor and class. Instructors use the evaluations to improve instruction and include them in their promotion and tenure

dossiers, while department heads use them in annual reviews. The reports are included in instructors' personnel files and are considered confidential.

Online class evaluations will be available for students to complete during the last two weeks of the semester for full-semester courses and the last week of shorter sessions. Students will receive an email directing them to a website to complete class evaluations. These become unavailable at 8 am on the first day of finals.

- Contact ClassEval Help Desk: classeval@ncsu.edu
- ClassEval website
- More information about ClassEval