# New Hampshire Community Technical College-Stratham

# SYLLABUS

Course: BTEC 220
CRN: 20037
Department: Biotechnology
Program:
Theory Hours: 2
Credits: 6
Prerequisites: BTEC 210

Course Title: Biotech Experience II Biomanufacturing
Date Prepared: 01-11-07
Prepared By: Deb Audino
Lab Hours: 8

Corequisite: none

**Instructor**

Deb Audino
Office Phone: (603) 559-1525 email address: daudino@nhctc.edu
Please note that I will NOT check voice mail or email on the weekends
**Office Hours:** Mon 11:30-1:30 Weds 11:30-1:30, Thurs 9:30-11:30 or by appointment

**Lab Manager**

Bob O'Brien
Office Phone: (603) 559-1521 email address: robrien@nhctc.edu

**Catalog Description**

Biotech Experience II: Biomanufacturing / Course Number BTEC 220. The second of two experiential, cornerstone courses in Biotechnology. The course begins by introducing the student to the proteins and companies of biotechnology and to cGMP or current good manufacturing practices. In the remainder of the course students use bacteria, mammalian, and yeast cells to produce two human proteins using tools and manufacturing standard operating procedures of biotechnology, including upstream and downstream processing of proteins and quality control of protein production. Lectures provide the knowledge base of biotechnology manufacturing.

**Course Objectives**

1. To understand the role of biomanufacturing in the healthcare industry.
2. To understand the various job opportunities in a biomanufacturing plant.
3. To understand the importance of cGMP, including the history of the development of the FDA and cGMP.
4. To understand and adhere to documentation guidelines of cGMP. This involves writing and following SOPs and filling out batch records and log books.
5. To routinely monitor the environment for particle count and viable microorganisms.
6. To grow bacteria, mammalian cells and yeast cells, monitor their growth and generate growth curves. Growth rates will also be determined.
7. To purify a protein using filtration and chromatography techniques.
8. To evaluate protein production, purity and activity with ELISA, SDS PAGE and activity assays.
9. To evaluate samples for contamination by using Gram stain, LAL and mycoplasma detection assays.
10. To become a subject matter expert in an assigned piece of equipment.
11. To understand the importance of training records and to maintain training records.

**Required Text(s)**
Industrial Biotechnology, Moorpark College
Code of Federal Regulations Part 210 and 211
**Recommended Text(s)**
Reading Material Manual
Lab Manual

**Supplies**
Lab coat
Calculator – must have log and ln functions
Computer with Microsoft office (word, excel, powerpoint) and Internet connection

**Blackboard www.ms.nhctc.edu**
Lectures, reading materials, homework assignments, lab report guidelines, SOPs and a class discussion board are available on the Blackboard site

## Class Expectations:

**THIS IS AN INTENSIVE LAB COURSE. BE PREPARED TO SPEND on average a minimum of 6+ HOURS OUTSIDE OF CLASS READING AND WRITING REPORTS.**

**Plagiarism and Cheating**
Plagiarism: Plagiarism is defined as using or knowingly representing the words or ideas of another as one's own in any academic exercise. Cheating is defined as using or attempting to use unauthorized materials, information, or study aids in any academic exercise or activity without proper reference citations, violations will be referred to the Academic Affairs office for Judicial Review.
All students must sign the policy on plagiarism and cheating, indicating that they understand and agree to abide by this policy.

**Attendance**
This is a skills-based course and therefore absolutely requires your physical presence in class. Your grade will be affected by your attendance (see Grading Section). Additionally, arriving to class late 3 times will be considered an absence and your grade will be affected.

If you miss two consecutive classes and fail to contact me you will be dropped from the course and receive "AF" (Administrative Failure) as a grade. The "AF" grade WILL affect your GPA.

**Withdrawing**
In order to drop the class you must fill out an add/drop form and bring it to the registrar's office. You may drop this course at any point before the first class meeting of the second week of the semester for a full refund. **Simply ceasing to attend class or contacting the instructor does not constitute officially dropping the course.**

Students may initiate withdrawal from the course at any time through the fourteenth week of the semester. Students withdrawing from the course prior to the completion of semester week 10 will be given a grade of "W" that will NOT adversely affect your GPA. Following the tenth week of the semester, students who withdraw will receive either a "WP" (withdraw passing) or "WF" (withdraw failing) grade. "WF" is counted on your GPA as a failing grade.

## Make Up Work

When a student misses a class, it is his/her responsibility to obtain lecture notes and data from another student.
If a quiz, exam, practical, or presentation is missed, the student must contact the instructor prior to the missed class to arrange a makeup date. If a lab report is due, the student must email the report to the instructor on the missed day to avoid a deduction of points.

## School Closings

If the school is closed due to inclement weather or other reasons, the material covered on the missed day will be covered during the next class period. The following radio stations announce school closings

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|---|---|---|
| WOKQ 97.5 FM | WERZ 107 FM and 1450 AM | |
| WHEB 100 FM | WTSN 1270FM | www.wmur.com |

## Student Support

Students may visit the instructor during office hours for additional help. The instructor also encourages questions through email and the blackboard discussion site.

Additional academic support can be obtained through the college's Center for Academic Placement and Support (CAPS). The CAPS office is located in the library at Pease, and on the second floor in room 202 on the Stratham campus. Information about services offered through CAPS can be found on their web site: www.ms.nhctc.edu/caps/.

Disabilities: The college is committed to providing support for students with disabilities. Any student with physical, learning, emotional, or psychological disabilities is encouraged to stop by room 202, the Center for Academic Planning and Support (CAPS) and make an appointment with the Disabilities Coordinator.

## GRADING

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| Lab Reports | 50% |
| Exams | 24% |
| Homework, quizzes, presentations, practical | 26% |

**There is an assignment due every week. It is the responsibility of the student to know when assignments are due.**

**Late Assignments:** Lab reports are due at the **BEGINNING** of the class on their due date. If you are late to class when a report is due, the report is considered one day late.
10% off for each **CALENDAR** day late
Emailed lab reports are only accepted for late lab reports
**All other assignments are not accepted if turned in late**

**Attendance:** **Missed Class:** 1 point deducted from your final grade.
**Late to Class:** 3 times late to class is treated as an absence and 1 point will be deducted from your final grade

## Letter Grades and Numerical Equivalent

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|---|---|---|---|---|---|
| A | 93.33-100 | C+ | 76.67-79.99 | D- | 60.00-63.32 |
| A- | 90.00-93.32 | C | 73.33-76.66 | F | 0-60.00 |
| B+ | 86.67-89.99 | C- | 70.00-73.32 | | |
| B | 83.33-86.66 | D+ | 66.67-69.99 | | |
| B- | 80.00-83.32 | D | 63.33-66.66 | | |

**Dates, Lectures and Labs are subject to change**

Dates highlighted in yellow indicate non-class dates

| DATE | LECTURE | LAB |
|---|---|---|
| (1) 1/16 | Overview of Biomanufacturing<br>Amino acids and Proteins | Lab tour,<br>Computer work: cGMP, Bb, protein/company project |
| 1/18 | Getting a Drug to Market | Movie: Endostatin<br>**Instrument/cGMP Time** |
| (2) 1/23 | History of cGMP<br>**HW 1 due (1)** | CFR Exercise<br>**Instrument/cGMP Time** |
| 1/25 | Documentation 1 | SOP exercise<br>**Instrument/cGMP Time** |
| (3) 1/30 | Documentation 2<br>Safety Procedures<br>**Amino acids/protein Quiz (2)** | cGMP Popcorn Exercise<br>**Autoclave presentation**<br>Validate autoclave |
| 2/1 | Facilities/Environmental Monitoring<br>Gowning | **RCS plus and laser particle counter presentations**<br>**Gowning practical (1)**<br>**Instrument/cGMP Time** |
| (4) 2/6 | Growing Bacteria<br>Normal Flow Filtration/Filter Integrity Testing<br>**HW 2 due (1)** | Make E coli media, pour plates<br>**spectrophotometer and pH meter presentations** |
| 2/8 | No Lecture (long lab) | Grow bacteria 3 shifts (10-2, 2-6, 6-10) |
| (5) 2/13 | Bacteria culture/GFP Production data analysis<br>Mammalian Cell Culture 1 | Count colonies<br>Make CHO media<br>**Biological Safety Cabinet presentation** |
| 2/15 | QC micro: Mycoplasma and Endotoxin Detection<br>**Lab Report: Batch Culture of E. coli (10)** | Mycoplasma PCR<br>LAL Assay |
| (6) 2/20 | Mammalian Cell Culture 2 | Mycoplasma electrophoresis<br>Inoculate CHO cells<br>T0-100ml<br>**Biolyzer presentation** |
| 2/21 | | T1-100ml |
| 2/22 | Bioreactors<br>**HW 3 due (1)** | T2-100ml<br>Assemble and Autoclave Applikon Bioreactor<br>**Applikon Bioreactor presentation** |
| 2/23 | | T3-100ml |
| 2/26 | | T4-100ml |
| (7) 2/27 | Bioreactors<br>**Lab Report: Mycoplasma/LAL (10)** | T5-100ml<br>Scale Up into bioreactor, T0<br>**Instrument/cGMP Time** |
| 2/28 | | T1-bioreactor |
| 3/1 | CIP and SIP<br>Review for Exam | T2-bioreactor<br>Assemble Bioflo 3000 Bioreactor<br>**Bioflo 3000 presentation** |
| 3/2 | | T3-bioreactor |
| (8) 3/6 | Separating Cells from Media and Cryopreservation | T4-bioreactor, harvest<br>Cryopreservation<br>**Instrument/cGMP Time** |
| 3/8 | **QC Micro and Documentation Exam (8)**<br>QC Biochem : ELISA and Activity Assay | ELISA<br>**Plate Reader presentation** |

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| **SPRING BREAK** | | |
| (9) 3/20 | CHO cell culture/tPA Production data analysis<br>Pichia | Make Pichia media<br>Autoclave Bioflo 3000<br>**Instrument/cGMP Time** |
| 3/22 | Hybridomas<br>**Lab Report: Batch Culture of CHO Cells (10)** | Inoculate Bioflo3000<br>T0<br>**Bioreactor practical (2)**<br>**Instrument/cGMP Time** |
| | | T1 |
| | | T2 |
| | | T3 |
| | | T4 |
| (10) 3/27 | | T5<br>**Instrument/cGMP Time** |
| | | T6 |
| 3/29 | Transgenics<br>Competitive ELISA<br>Pichia culture/HSA Production data analysis<br>**HW 4 due (1)** | T7, harvest<br>HSA ELISA |
| 4/1 | **Last day to drop with a W grade. The W will not affect your GPA. After this date, if you withdraw, you will receive a WF or WP which will affect your GPA** | |
| (11) 4/3 | Tangential Flow Filtration<br>**Lab Report: Batch Culture of Pichia (10)** | Make buffers for HSA and tPA purification<br>TFF of HSA-Set up filter |
| 4/5 | Review for Exam | TFF of HSA<br>**Instrument/cGMP Time** |
| (12) 4/10 | **Upstream Exam (8)** | |
| 4/12 | SDS PAGE and Western Blot<br>**Presentations due (3)** | SDS PAGE<br>**SDS PAGE presentation** |
| (13) 4/17 | Chromatography | Purification of HSA: pour and pack columns<br>Determine HETP of Columns<br>**Chromatography presentation** |
| 4/19 | Chromatography<br>**Protein/Company presentations (5)** | Purification of HSA: Run columns<br>**cGMP Time** |
| (14) 4/24 | Chromatography | Purification of tPA: pour, pack columns and run column<br>**cGMP Time** |
| 4/26 | Purification Data Analysis<br>**Protein/Company presentations (5)** | SDS PAGE<br>Activity Assay |
| 4/28 | **Last day to drop with a WP/WF grade. The W will not affect your GPA.** | |
| (15) 5/1 | Fill and Finish<br>Review for exam<br>**Lab Report: Purification of tPA and HSA (10)** | Rerun tPA column (tentative) |
| 5/3 | | **Tour of Genzyme** |
| (16) 5/8 | **QC Chemistry and Downstream EXAM (8)**<br>**cGMP Tutorial Quizzes due (9)** | |

**READING:**

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|---|---|
| Week 1: | Overview of Biotechnology<br>A Short History of Biotechnology<br>Proteins in Biotechnology<br>Biotechnology Companies |
| Week 2: | cGMP: The Regulatory Environment for Biological Pharmaceutical Manufacturing<br>A Brief History of the GMPs The Power of Storytelling<br>Industrial Biotechnology Section 1 |
| Week 3 | Industrial Biotechnology Section 2, 3, 5, 6, 7, 10, 11, 17, |
| Week 4 | Media Buffer and Reagent Preparation<br>Principles of Upstream Processing<br>Cells<br>The Mathematics Behind Growth<br>Industrial Biotechnology Section 13, 19, 20, 22, |
| Week 5 | Introduction to Animal Cell Culture<br>Understanding and Managing Cell Culture Contamination<br>Industrial Biotechnology: Section 18, 30 |
| Week 6 | Endotoxins and Cell Culture |
| Week 7 | Bioreactors<br>Industrial Biotechnology Section 14, 15, 16, 21 |
| Week 8 | General Guide for Cryogenically Storing Animal Cell Cultures<br>Industrial Biotechnology Section 26, 31 |
| Week 9 | High Yield Protein Production from Pichia pastoris<br>Pichia Fermentation Process Guidelines |
| Week 10 | The Future of Transgenics<br>Principles of Downstream Processing |
| Week 11 | Protein Concentration and Diafiltration by TFF<br>Industrial Biotechnology: Section 23, 24 |
| Week 12 | Purification by Liquid Chromatography<br>Industrial Biotechnology: Section 27, 34 |
| Week 13 | |
| Week 14 | Industrial Biotechnology: Section 28 |
| Week 15 | |