BMAN 1120 Basic Biomanufacturing Skills
1 semester (1 period), 0.5 credit

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Consultation: A Days 2:15- 3:15
B Days 1:45 - 3:15

General Course Information

PREREQUISITE Helpful but not required: Biology 1-2, Algebra I, Exploring Technology or Gateway to Technology, Manufacturing, Chemistry.

PREREQUISITE (may be taken concurrently) BMAN 1110 Introduction to Biomanufacturing.

FEES $20.00 for lab notebook, gloves and lab supplies.

REQUIRED MATERIALS: flash drive, scientific calculator (about $15.00), **permanent marker** (fine point is best), **paper, pens, pencils**

TEXTBOOK NOT REQUIRED but some course work will be taken from High-performance Manufacturing Portable Production Skills, McGraw-Hill, ISBN-10: 0078614872, ISBN-13: 978-0078614873

HIGH SCHOOL GRADUATION CREDIT: This course gives 0.5 credit toward the high school graduation requirement for either Career Technology Education or as a 3rd Science course.

DELIVERY FORMATS: This course will introduce the biomanufacturing skills through relevant hands-on activities and laboratory experiments, lectures, class discussions, assignments, and guest speakers.

SAFETY: Lab safety is of primary importance. Instructions on using the equipment will always be given in the pre-lab activities. Because of the dangerous and expensive nature of the equipment and supplies, any deliberate disobedient behavior is grounds for expulsion.

COURSE DESCRIPTION: Basic Biomanufacturing Skills is a one semester, 70 minute course designed to transform students' awareness of the biomanufacturing industry into an understanding of the regulations and the technical skills that are practiced in the industry. Through lab-based instruction, students will gain a higher level of technical proficiency in managing bio-manufacturing processes. Additionally, students will perform analytical biochemistry and other essential Validation Quality and Assurance tests as they learn the importance of verifying the identity and quality of both starting and finished products. A main focus of the course, as laboratory work progresses, is the vital importance of maintaining proper and thorough documentation.

This course offers students the unique opportunity of working in the same state of the art facility as college students and industry professionals. For this reason, students are expected to behave with maturity and professionalism. Students are expected to show an increased level of maturity, level of discussion and self-management. Safety in the lab and with equipment is extremely important. Disruptive, disrespectful or dangerous behavior is not permitted; you will simply be dropped from the class.

POLICIES:

1) Attendance: Timely attendance is crucial to participation in class activities and discussion, and will be counted toward your grade – let the instructor know before the absence when possible if you will need to miss a class.
2) Homework assignments: Must be submitted in a timely manner. You will receive ONE exemption for a late assignment. After that, you will incur a 10% penalty for every day the assignment is past due.
3) If an exam is missed due to an excused absence, arrangements must be made to take a make-up exam. This will usually be scheduled outside of class time. Students have one week to complete the make-up exam.
4) Electronic devices: To minimize disruptions, all electronic devices (Cell phones, pagers, games, mp3 players or videos, etc) must be turned off during class. Cell phones or pagers may only be used in case of emergency.
5) Classroom conduct: All students are expected to display professional behavior that is conducive to a safe, productive learning environment.
6) Safety Procedures are part of this course. Safety is a priority and the appropriate rules and practices must be followed at all times. No food or drink is allowed in the laboratory, and appropriate personal safety attire is required (no open toe shoes in the lab, long hair must be tied back).
7) Academic dishonesty / plagiarism: Will result in zero credit for the applicable assignment(s) or exam.

LEARNING OUTCOMES:

Upon completion of the Basic Biomanufacturing Skills course, the students are expected to

- Use science process and thinking skills.
- Manifest science interests and attitudes.
- Understand important science concepts and principles.
- Communicate effectively using science language and reasoning.
- Demonstrate awareness of the social and historical aspects of science.
- Understand the nature of science.
- Demonstrate an ability to function on multi-disciplinary teams
- Demonstrate professional and ethical responsibility
- Demonstrate a knowledge of contemporary issues
- Demonstrate the ability to use the techniques, skills, and modern engineering tools necessary for engineering practice.
- Demonstrate knowledge of the Quality Assurance and Validation procedures in the biomanufacturing industry.

GRADING SCALE AND CRITERIA

A = 93-100 %	B- = 80–82%	D+ = 67-69%
A- = 90-93 %	C+ = 77-79%	D = 60-66%

B+ = 86-89 %	C = 73-76%	D- = 55-59%
B = 83-85 %	C- = 70-72%	E = 0-54%

BMAN 1120 Basic Biomanufacturing Skills Outline

Unit 1 : Demonstrate biochemistry and microbiology skills in necessary to biomanufacturing	
Topic	**Activity**
Assays and Antibodies	• Perform an ELISA or other assay using antibodies • Produce a simple assay
Culture and Maintain Microorganisms on a Large Scale.	• Explain the challenges faced by researchers in growing microorganisms on a large scale (media, ph, aeration states) • Select the appropriate apparatus, medium and method of inoculation for each microorganism
Maintain a clean and safe laboratory environment	• Correctly label reagents, specimen samples and reactions • *Demonstrate proper aseptic & sterilizing techniques.* • Explain the appropriate sterilization methods(e.g., steam, chemical UV radiation)
Prepare Agar and broth media	• *Demonstrate the ability to culture and maintain microorganisms* • Explain the different methods of inoculation • Inoculate media using various techniques(i.e., streak, spread) • Select the appropriate media and method of inoculation
Prepare bacterial growth media	• Compare and contrast bacterial growth requirements with other common microorganisms • Select the appropriate bacterial growth requirements for specific protocols (antibiotics, temperatures, selective agents). • Utilize appropriate protocols to prepare several types of bacterial media
Purify a pure protein from a large-scale culture & test for the protein's retention of functional characteristics.	• *Demonstrate proper separation techniques to differentiate molecules based on size and structure (chromatography).* • Describe how various purification protocols might ensure the

	structural and functional integrity of molecule. • Purify whole cell extract, determine molecule concentration • Describe the importance of healthy cultures for extraction • Explain various extraction protocols • Identify the reagents needed
Relate dilution to solution preparation	• Explain spectrophotometry and dilution principles • Prepare serial molar dilutions of specific solutions • Demonstrate proper liquid and solid measuring techniques • *Prepare solutions of defined concentrations*
Relate pH to solution preparation and reaction rates	• Proper assembly and mixing techniques • Explain acid base chemistry, ph scale and buffer properties • Measure and adjust the ph of specific solutions with commonly used acids and bases • Investigate the effect of temperature, particle size and pH on dissolution rate of various solids.
Understand the nature and properties of materials CHANGING RAW MATERIALS INTO FINISHED PRODUCTS	• Describe the characteristics of biological molecules.(i.e., hydrophobic vs. Hydrophilic, acidic vs. Basic, polar vs. Non polar) • Distinguish between covalent, ionic and hydrogen bonds.
Unit 2: Demonstrate scientific principles and reasoning skills necessary in biomanufacturing. **DATA & ANAYLSIS exhibit proper data handling and analysis skills.**	• Perform basic calculations • Demonstrate root cause analysis • Recognize problems and how to effectively correct them • Demonstrate proper data collection • Exhibit & justify basic data interpretation • Calculate the mean and standard deviation of a sample or population • Form logical conclusions based on acquired data • Perform basic statistical methods • Interpret normal distribution data • Present graphs and charts using reasoning, mathematical and spreadsheet software
Unit 3: Exhibit appropriate safety procedures in the laboratory for personal and team safety.	

Demonstrate appropriate use of personal protective devices	• Demonstrate safe removal of protective devices (gloves) • Describe how personal protective devices protect the experiment and the lab worker • Wear the appropriate personal protective devices. •
Exhibit appropriate behavior to protect coworkers and self	• Explain the dangers of microbial & hazardous chemical contamination via food, drink, cosmetics, lotion, eye drops and contact lenses • *Show locations of emergency equipment* • Take appropriate action when observing hazardous conditions(chemicals, broken glass, sharps, microbial waste) • Use resources, tools, materials, and processes safely and efficiently.
Maintain a clean laboratory environment	• Identify precautions to prevent microbial or hazardous chemical contamination of tools, surfaces, self and others
Understand procedures for handling of hazardous materials chemicals.	• Explain the appropriate handling and disposal of hazardous reagents • Use an MSDS sheet to identify the hazardous properties of chemicals used in a laboratory setting and their safe use.
Use laboratory equipment safely	• Turn off equipment when not in use • Identify and demonstrate the proper use of engineering/manufacturing, biotechnology equipment.
Unit 4: Follow laboratory and documentation procedures properly to ensure product quality and public safety.	
Changing raw materials into finished products	• Inspect incoming raw materials • Inspect intermediate and final products • Inspect packaging
Exhibit ability to follow laboratory protocols	• Interpret individual steps within a protocol • Perform the steps of laboratory protocols accurately and in sequence

Comply with policies and requirements for documentation and record keeping	• Follow standard operating procedures. • *Maintain accurate records and documentation by recording all procedures followed, using the proper documentation forms.* • Get all documents signed and verified before leaving class. • Incorporate standards in a lab setting
Exhibit ability to follow work instructions.	• Interpret individual steps within a work instruction • Perform the steps of work instructions accurately and in sequence, documenting all work and deviances
Understand the role of proper documentation in quality assurance	• Understand the functional differences between a standard laboratory notebook and standard operating procedure, a protocol, a work instruction and a batch record. • Maintain accurate batch records and compare recorded procedures with batch results
Follow appropriate labeling procedures and comply with safety signs, symbols and labels	• *Describe the procedures that help companies maintain compliance with regulatory standards.* • During lab work, employ the methods by which companies track their own processes through proper labeling and documentation.
Federal Regulation and Oversight. Understand the need for and practical application of federal regulatory oversight of the biomanufacturing industry.	• Describe and practice OSHA standards
Identify the properly use equipment, machinery and facilities characteristics that are commonly found within BMAN companies	• Identify equipment for a "wet" lab and "dry" lab and discuss whether this distinction is clear. • Calibrate equipment and micrometers using gage standards
Understand and practice Quality Control in manufacturing technologies.	• Demonstrate constant thorough awareness while working • Describe the consequences of quality approvals and failures
Unit 5: Understand the role of biomanufacturing in society.	
Demonstrate civic engagement	• Develop partnerships with local, state, and national chapters and other organizations • Participate in service-learning opportunities • Describe ethical and legal issues in

	biomanufactufing that affect soceity

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