COURSE COLOUR CODE: CLOVER

MBIOTECH

MASTER OF BIOTECHNOLOGY PROGRAM

Compulsory Course Component

BTC1810H

BIOTECHNOLOGY & DRUG MANUFACTURING

Tim Lee, Ph.D.

Summer Term, 2022

MASTER OF BIOTECHNOLOGY

UNIVERSITY OF TORONTO MISSISSAUGA

BTC1810H – Biotechnology & Drug Manufacturing

Course Outline (Summer, 2022)

Class Location:	Instructional Building, Room 270 (IB-270)
Class Times:	Classes will start on 30-May (6:30-9:00PM) and occur every Monday until 8-Aug. Please refer to the *Schedule* herein.
Instructor:	**Tim Lee, Ph.D.**
Office Location:	Online
Office Hours:	By appointment
Contact:	timsw.lee@utoronto.ca

Course Description & Objectives

In **Biotechnology & Drug Manufacturing** we seek to explore some of the myriad aspects that feed into the highly interdisciplinary process surrounding the commercialization of biotechnology in its many forms. This course is delivered via lectures, case studies and a set a variety of team exercises. The primary aim of this course is to expose the students to a wide range of interdisciplinary elements that contribute to the start-up and functioning of a biotech corporation and the approval of drug products and medical devices. The secondary aims are to introduce the students to individuals currently working in the industry, and give them the opportunity to learn lessons based on real-life workplace experiences.

A number of recommended readings or electronic materials will be provided.

In addition to the press presentation by each team, there will be quizzes, mid-term and a final examination.

Course Synopsis

Biotechnology & Drug Manufacturing is a half-credit course that introduces students to some of the key aspects of the biopharmaceutical process, with special emphasis on the biotech sector. The course focuses on the fundamental role played by corporate entities in the development of new therapeutic drugs in a highly regulated business environment. Topics covered include biopharmaceutical manufacturing, regulatory approval for drug products and medical devices, setting regulatory standards, quality-by-design, cGMP compliance, risk management and root cause analysis. A high level of preparation is **expected** of students in order to accommodate the diverse subject matter.

Marking Scheme

Individual Assessment—

1.	Examination	25%
2.	Participation	15%

Team Assessment—

3.	Press Report Presentation	25%
4.	Executive Report or Team Presentation	35%
	TOTAL:	**100%**

QUIZZES: Students will have the whole week to complete the quizzes.

Quick-Writes: Students will respond to certain case-studies questions in the lecture material to promote understanding of challenges within the biopharmaceutical company.

Press Report Presentation: These presentations will occur in the beginning of each class prior to the lectures (each of the 7 teams will present).

TEAMS: (1) Press Report Presentations (Team Performance, 25%)

A **fifteen-to-twenty-minute** presentation by the team on a recent (within last 3 months) press release on a relevant biotechnology topic. Topic can be company, product, technology or industry related. ***Please send Ortensia Quendro your top two preferred presentation times.*** Her email is ortensia.qendro@utoronto.ca

You will be evaluated on:

- Presentation (*i.e.*, clear, concise, flows smoothly);
- Your choice of the topic;
- Your Evaluation of topic with regards to the technology or product(s) based on data and analysis; and
- Significance of the topic to the public (*i.e.*, why should I care?).

EXAMPLES OF PREVIOUS TOPICS:

1) Rare Genetic Diseases;
2) Therapeutic Vaccines;
3) Antibody-Drug Conjugates;
4) Biosimilars;
5) Personalized Medicine: Companion Diagnostic/Therapy;
6) Biodefence;
7) Regenerative Medicine;
8) Gene Therapy;
9) Immuno-oncology.

Consider the following in your presentation:

- Disseminate the underlying scientific principles of the technology in a way that is accessible to a non-specialist but scientifically educated audience.
- Discuss the intended application(s) and potential use(s) of the technology, and the novelty thereof.
- **Product Development:** How is the product(s) manufactured and scaled? What clinical stage is the product in? What does the clinical data show? (size and type of trial; primary and secondary endpoints) Safety data? Any adverse reactions? What kind of Intellectual Property (IP) for the product and/or technology?
- **Competitor Analysis:** Identify the competitors for your technology and analyse them with respect to their ability to compete with your product idea. You might include SWOT (Strength, Weakness, Opportunity, Threats) analyses.
- **Business & Marketing Strategy:** Address the potential market niche you are targeting. Do you have a clearly defined market? Relative price-point? How will you sell your product? Who do you sell your product to? Type of customers? Type of distribution
- Estimate the associated costs of your product/project. A budget summary listing the key expenses is more than sufficient: **do not** go into excessive detail.

Other Resources

IMI Health & Wellness Resources: IMI graduate students have access to a variety of health and wellness resources which we encourage you to use at any time. The IMI Embedded Counsellor is a dedicated counsellor, through the HCC, available to meet with IMI students directly. Call 905-828-5255, share that you are an IMI graduate student, and ask for an appointment. You may also access MySSP (open 24 hours), the Mental Health Wayfinder Tool, Good2Talk and the UTM Health and Counselling Centre at any time.

SCHEDULE OF ACTIVITIES

#	DATE	LECTURE TITLE/TOPIC
1	30-May	Introduction to the course **LECTURE 1:** Welcome & introduction
2	6-Jun	**LECTURE 2:** Introduction to biotechnology – host systems, products (bacteria, yeast, mammalian, plant) QUIZ 1 & *Quick-Write 1* (due 12-Jun) & **Press Presentation, Group A**
3	13-Jun	**LECTURE 3:** Biopharmaceutical Manufacturing I – Biologics development, scale-up, commercialization and cost of goods **Press Presentation Group B** *Quick-Write 2* (due 19-Jun)
4	20-Jun	**LECTURE 4:** Biopharmaceutical Manufacturing II – Purification development, commercialization and Biosimiliars QUIZ 2 & *Quick-Write 3* (due 26-Jun) & **Press Presentation, Group C**
5	27-Jun	Mid-Term Exam from 6:30-9:00PM
6	4-Jul	**LECTURE 5:** Regulatory approval of Drug Product and Medical Devices **Press Presentation, Group D**
7	11-Jul	**LECTURE 6:** Setting Regulatory standards – ICH 8,9,10 pertaining to pharmaceutical development, Quality by Design, Risk Management, Quality systems *Quick-Write 4* (due 17-Jul) **Press Presentation, Group E**
8	18-Jul	**LECTURE 7:** GMP compliance and Cleanrooms for drug manufacturing QUIZ 3 & *Quick-Write 5* (due 24-Jul) **Press Presentation, Group F**
9	25-Jul	**LECTURE 8:** GMP gowning, disinfection procedures & CAPAs QUIZ 4 (due 31-Jul) **Press Presentation, Group G**
10	1-Aug	**LECTURE 9:** Q&A session (if required) https://utoronto.zoom.us/j/81732149201 ID: 817 3214 9201 (no passcode)
11	8-Aug	***Final Exam*** GOOD-BYE