GUJARAT TECHNOLOGICAL UNIVERSITY

Syllabus for M.Sc. in Industrial Biotechnology, Semester - 3

Subject Name: Elective -Advanced Biomanufacturing

Subject Code: 1330106 W.E.F 2021-22

1. Learning Outcomes

Learning Outcome Component	Learning Outcome (Learner will be able to)
Theoretical and practical understanding of Advanced Biomanufacturing	● Hands-on training on microbiological methods, cell biological methods, bioprocess development with industrial oriented approach. ● Become an entry-level biomanufacturing scientist, who can produce new drug discoveries, biologicals, biomedical devices used in surgeries, and food products in a very clean environment.
Value applications of Advanced Biomanufacturing in biological research as well as in biotech-industries	● Describe standard operating procedures for biotechnology research and assign Biosafety levels. ● Perform activities in compliance with the cGMP's (Current Good Manufacturing Practices) that are mandated by the FDA (Food & Drug Administration).
Effective Communication	● Communicate concepts and ideas effectively.
Professional & Ethical Behaviour	● Transparency, honesty and ethical reasoning in handling microbes for product processing.

LO – PO Mapping: Correlation Levels:
1 = Slight (Low); 2 = Moderate (Medium); 3 = Substantial (High), "-"= no correlation

Sub Code: _____	PO1	PO2	PO3	PO4	PO5	PO6	PO7
LO1:Theoretical and practical understanding of Advanced Biomanufacturing	2	3	2	2	3	3	2
LO2:Value applications of Advanced Biomanufacturing in biological research as well as in biotech-industries	3	1	3	2	2	2	3
LO3: Effective communication	3	2	2	2	2	3	2
LO4: Professional & Ethical Behaviour	3	3	2	3	3	2	3

2. Course Duration: The course duration is 45 sessions of 60 minutes each.

3. Course Contents:

Module No:	Module Content	No. of Sessions	70 Marks (External Evaluation)
1	**Survey of various microscopic agents of particular importance to humans**	5	10

	Emphasis on those involved in infectious disease, host defenses against disease, and elements of infection chains and means utilized for breaking chains, monoclonal antibodies etc.		
2	**Clean rooms and biosafety levels** Clean Room classification, gowning, Introduction to clean room gowning, proper sanitation techniques, regulations and recommendations for biosafety, ascending levels of containment, Defining microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling a particular agent. Introduction to Safe Laboratory Practices: Guidelines for safe laboratory practices, role of institution's safety committee and local rules and regulations pertaining to laboratory safety	8	10
3	**Scientific communication in biomanufacturing** Analysis and preparation of protocols and standard operating procedures (SOPs), report and present data and experimental conclusion, analysis of articles about scientific research and developments in biotechnology.	8	10
4	**Biomanufacturing production** Emphasis on growth and monitoring of fermenters and bioreactors, including cleaning, media preparation, aseptic inoculation, cell harvesting, lysis, protein recovery and purification of proteins using centrifugation, ultrafiltration and chromatography techniques.	8	15
5	**Development, production, recovery and analysis of biotechnology products** Case studies of Vaccine manufacturing process that briefly involves generation of antigen/virus/bacteria/recombinant product, purification, testing product, evaluating efficacy of product, stability of product, formulating product and its stability etc., (Tracing the path of a drug or biologic	10	15

	from cell through production facility, final processing, and in human body), growth characteristics of organisms used to produce pharmaceutical proteins, and techniques used. Fundamentals in biotechnology laboratory techniques: Emphasis on developing skillful use of applicable instruments; protein purification and assays; recombinant DNA work; isolation and tracking techniques; laboratory notebook, spreadsheet data analysis; written protocols and familiarity with standard operating procedures.		
6	**Business and regulatory practices** Sound manufacturing procedures and basic business principles: Key concepts for product quality and safety as it moves through a biomanufacturing production pipeline, roles of governmental oversight and regulation during discovery, development and manufacturing of new products for biopharmaceutical industry.	6	10

4. Pedagogy:

- ICT enabled Classroom teaching
- Practical / live assignment
- Interactive classroom discussions

5. Evaluation:

Students shall be evaluated on the following components:

A	**Mid-Semester Examination**	**(Internal assessment-30 Marks)**
B	**End-Semester Examination**	**(External assessment-70 Marks)**

6. Reference Books:

No	Author	Name of the Book	Publisher	Year of Publication / Edition
1	Zhong, Jian-Jiang	Biomanufacturing	Springer	Latest Edition
2	Michael C. Flickinger, Stephen W. Drew	The Encyclopedia of Bioprocess Technology: Fermentation, Biocatalysis, and Bioseparation	Wiley-Blackwell	Latest Edition

3	James E. Bailey , David F. Ollis	Biochemical Engineering Fundamentals	McGraw-Hill	Latest Edition
4	Nathan S. Mosier, Michael R. Ladisch	Modern Biotechnology: Connecting Innovations in Microbiology and Biochemistry to Engineering Fundamentals	Wiley-AIChE.	Latest Edition

Note: Wherever the standard books are not available for the topic appropriate print and online resources, journals and books published by different authors may be prescribed.

7. List of Journals/Periodicals/Magazines/Newspapers / Web resources, etc

- https://nptel.ac.in/courses/102106053
- https://nptel.ac.in/courses/102106057
- https://atecentral.net/downloads/1974/295331987337921343-biomanufacturing-lab-manual-restricted.pdf

Course Outcomes:

On completion of this course, Students should be able to:

- Understand how a product can be developed;
- Knowledge on regulatory and Quality aspects of product development;
- Demonstrate good laboratory procedures and practices;
- Describe standard operating procedures for biotechnology research and assign Biosafety levels;
- Perform activities in compliance with the cGMP's (Current Good Manufacturing Practices) that are mandated by the FDA (Food & Drug Administration);
- Hands-on training on microbiological methods, cell biological methods, bioprocess development with industrial oriented approach;
- Become an entry-level biomanufacturing scientist, who can produce new drug discoveries, biologicals, biomedical devices used in surgeries, and food products in a very clean environment

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