GUJARAT TECHNOLOGICAL UNIVERSITY

Syllabus for M.Sc. in Industrial Biotechnology, Semester - 3
Subject Name: Biomanufacturing Principles and Practice
Subject Code: 1330103 W.E.F 2021-22

1. Learning Outcomes

Learning Outcome Component	Learning Outcome (Learner will be able to)
Theoretical and practical understanding of biomanufacturing principles and practice	● Understand basics of biomanufacturing, GMP and GLP requirements. ● Discuss quality control measurements taken for biomanufacturing in industries.
Value applications of biomanufacturing principles and practice in biological research as well as in biotech-industries	● Evaluate the quality of products (Biopharmaceuticals, diagnostics and foods) manufactured for human use.
Effective Communication	● Communicate concepts and ideas effectively.
Professional & Ethical Behaviour	● Transparency, honesty and ethical reasoning in handling biomolecules for product processing .

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

Sub Code: 1330103	PO1	PO2	PO3	PO4	PO5	PO6	PO7
LO1:Theoretical and practical understanding of biomanufacturing principles and practice	3	3	2	2	2	3	2
LO2:Value applications of biomanufacturing principles and practice in biological research as well as in biotech-industries	3	2	3	2	2	2	2
LO3: Effective communication	3	2	2	2	3	3	2
LO4: Professional & Ethical Behaviour	2	2	2	2	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	**Biomanufacturing principles** Overview and design of biomanufacturing, quality by design approach, technical considerations, phases and scale up: life cycle of manufacturing, raw material considerations, compliance and quality in biomanufacturing, lean biomanufacturing; Process	15	20

	analytical technology (PAT) during biomanufacturing: background and need tools for data acquisitions (software in fermenters, flow filtrations, chromatography, analysis and design process analysers, process control tools and continuous improvement and knowledge management; Standard manufacturing operating procedures of biotechnology, including upstream and downstream processing of proteins, and quality control of protein production, and final fill and finish of product; Case studies to be included at least: therapeutic proteins, monoclonal antibodies, human vaccines.		
2	**Quality system** Introduction to quality system, main elements of a quality system; Essential of quality system; Practical implementation of a quality system; Structure of quality manual, correlation between GMP requirements (WHO) and ISO 9001:2000.	5	10
3	**Principles and practice of GMP** Personnel: Principles of human resource management, duties of senior management, organizational structures, qualification and profiles requirement, workplace and job descriptions, health monitoring and occupational health safety, training, function owners subject to public law; Premises: Official requirements, material & personnel flow and layout, air cleanliness classes and grades, construction elements, barrier systems, isolators and safety cabinets, building services, heating ventilation air conditioning (HVAC), process gases, qualification of premises and HVAC systems, pharma monitoring of HVAC systems, particle monitoring.; Facilities and Equipment: Facility planning, materials, hygienic design in solid handling, system controllers and process control	20	30

	systems, technical documentation, calibration, maintenance, cleaning of facilities, containment (personnel protection) in solid handling; Pharmaceutical water: Water qualitiy, generation of pharmaceutical water, distribution and storage of pharmaceutical water, qualification of water supplies, operation of water supplies, pure steam systems; Qualification: Official requirements, preparation of qualification, qualification documentation, design qualification (DQ), Installation qualification (IQ), operational qualification (OQ), Performance qualification (PQ), special cases of qualification; Process Validation: Official requirements, Validation - a key element of quality management, validation planning and procedure, validation documentation, process validation and product lifecycle; Cleaning Validation: Official requirements, how to validate cleaning procedures, cleaning validation master plan, establishing scope of validation, acceptance criteria and limit calculation, sampling procedures, analytical procedure, documentation, maintenance of validated status, cleaning validation documentation; Production: Sanitation, personnel hygiene, production hygiene, sanitation programme, environmental monitoring, GMP in production process, weigh-in, identification, in-process control prevention of cross-contamination, empty chapter, reworking, warehouse and logistics; Sterile Production and Packaging: Introduction, Air lock concepts, manufacture of terminally sterilised products, sterilisation processes, aseptic processing, freeze-drying, testing for sterility, testing for endotoxins, testing for leakage and for particles, microbiological monitoring, packaging materials, packaging process, qualification of a servo-controlled blister packaging line, blow-fill-seal technology (BFS technology); Documentation: Official requirements, GMP-compliant documentation, batch documentation, standard		

	operating procedures (SOPs), site master file, electronic batch recording and batch release, CAPA, document management systems.		
4	**GMP regulation** Information, national bodies and pharmaceutical associations; Pharmacopeia; EU directives and guidelines, USA: CFR and FDA guidelines, ICH-guidelines, PIC/S guidelines, GMP of other regions, WHO guidelines.	5	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	Mark Witcher	Introduction to Biomanufacturing	John Wiley & Blackwell	Latest Edition
2	John M. Centanni, Michael J. Roy	Biotechnology Operations: Principles and Practices	CRC press	Latest Edition
3	Nigel Smart	Learn Biomanufacturing	Woodhead Publishing	1st Edition
4	Maas & Peither	GMP Manual	GMP Publishing	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

- http://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;jsessionid=5AD6C35F80A479E22A2230706F3393ED?sequence=1
- https://archive.nptel.ac.in/courses/102/105/102105058/

Course Outcomes:

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

- Understand basics of biomanufacturing, GMP and GLP requirements;
- Understanding quality control measurements taken for biomanufacturing in industries.