GUJARAT TECHNOLOGICAL UNIVERSITY
Integrated Master of Science (Biotechnology)
Semester: 9
Subject Name: Biomanufacturing Principles and Practice
Subject Code: 1390403

Prerequisite: Prerequisites for Biomanufacturing Principles and Practice typically include a foundational understanding of biology, chemistry, and engineering. Key topics you should be familiar with include bioprocessing fundamentals, microbiology, biochemistry, cell culture techniques, molecular biology, and bioreactor operations.

Rationale Biomanufacturing integrates biological systems with engineering principles to produce pharmaceuticals, nutraceuticals, biofuels, and other biomaterials efficiently. Understanding its principles ensures optimized production processes, regulatory compliance, product safety, and scalability. This field emphasizes Good Manufacturing Practices (GMP), bioprocess optimization, quality control, and sustainable resource utilization. Mastering biomanufacturing principles enables innovation, cost-effectiveness, and environmental sustainability in biotechnology industries, ensuring high-quality, reproducible, and safe products for global markets.

Course Scheme:

Teaching Scheme			Total Credits	Assessment Pattern and Marks				Total Marks
				Theory		Practical		
L	T	PR	C	ESE (E)	PA(M)	ESE (V)	PA (I)	
4	0	0	4	70	30	0	0	100

Course Content:

Sr. No.	Course Content	No. of Hours	% of Weightage
1	**Unit 1: Biomanufacturing Principles and Quality Systems** **Content**: 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 Analytical Technology (PAT), tools for data acquisition in fermenters, flow filtration, chromatography, process control tools, continuous improvement, knowledge management, case studies on therapeutic proteins, monoclonal antibodies, and human vaccines. Introduction to quality systems, main elements of a quality system, practical implementation, structure of quality manual, correlation between GMP requirements (WHO) and ISO 9001:2000.	12	20
2	**Unit 2: Personnel, Premises, and Facilities in GMP** Principles of human resource management, duties of senior management, organizational structures, qualification requirements, workplace and job descriptions, health monitoring and occupational health safety, training, function owners subject to public law. Official	12	20

	requirements for premises, material and personnel flow, layout, air cleanliness classes, construction elements, barrier systems, isolators, safety cabinets, HVAC systems, qualification of premises and HVAC systems, pharma monitoring, particle monitoring. Facility planning, hygienic design, system controllers, process control systems, technical documentation, calibration, maintenance, cleaning of facilities, containment in solid handling.		
3	**Unit 3: Pharmaceutical Water, Qualification, and Process Validation** Water quality, generation of pharmaceutical water, distribution and storage of pharmaceutical water, qualification, operation, pure steam systems. Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ), preparation of qualification documentation, qualification of equipment and systems. The role of process validation, official requirements, validation planning and procedures, validation documentation, product lifecycle, process validation documentation.	10	17
4	**Unit 4: Cleaning Validation and Production in GMP** Cleaning validation requirements, cleaning validation master plan, establishing scope, acceptance criteria, limit calculation, sampling procedures, analytical methods, documentation. Sanitation, personnel hygiene, production hygiene, in-process control, prevention of cross-contamination, warehouse and logistics.	8	13
5	**Unit 5: Sterile Production, Packaging, and GMP Regulations** Manufacture of terminally sterilized products, sterilization processes, aseptic processing, freeze-drying, microbiological monitoring, packaging materials, packaging process, qualification of packaging lines, blow-fill-seal technology (BFS). National and international bodies (EU directives, USA CFR, FDA guidelines, ICH guidelines, WHO GMP standards), pharmaceutical associations, GMP regulations across regions.	10	17
6	**Unit 6: Advanced GMP and Documentation Practices** GMP-compliant documentation, batch documentation, standard operating procedures (SOPs), site master file, electronic batch recording and batch release, CAPA, document management systems.	8	13

Reference Books:

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

Course Outcome:

After Completion of the Course, Student will able to:

Sr. No	Course Outcome	RBT Level
1	• Understand basics of biomanufacturing, GMP and GLP requirements. • Discuss quality control measurements taken for biomanufacturing in industries.	UN
2	• Evaluate the quality of products (Biopharmaceuticals, diagnostics and foods) manufactured for human use.	AP
3	• Communicate concepts and ideas effectively.	AN
4	• Transparency, honesty and ethical reasoning in handling biomolecules for product processing.	EV, AP

*RM: Remember, UN: Understand, AP: Apply, AN: Analyze, EL: Evaluate, CR: Create

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