GUJARAT TECHNOLOGICAL UNIVERSITY
Integrated Master of Science (Biotechnology)
Semester: 9
Subject Name: Fundamental of Technology Transfer
Subject Code: 1390405

Prerequisite: Candidates enrolling in the Integrated MSc in Industrial Biotechnology program with an allied compulsory in Fundamentals of Technology Transfer are expected to have a solid foundation in core biotechnological principles such as molecular biology, microbiology, and bioprocess engineering.

Rationale: Integrating a course on Fundamentals of Technology Transfer into the MSc Industrial Biotechnology curriculum is critical for bridging the gap between innovative research and commercial success. This course equips students with the strategic, legal, and managerial skills necessary to navigate the complex process of moving biotechnological innovations from the lab to the marketplace.

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)	
0	0	4	2	0	0	0	50	50

Course Content:

Module No:	Module Content	No. of Sessions	% of weightage
1	**Introduction to tech transfer** Purpose, Life cycle of product development: Technology Transfer, Drug Discovery and Development Process, Importance of Technology Transfer; Scope and Glossary in Biomanufacturing.	**7**	12
2	**Regulatory and business perspective** Regulatory Requirements for Technology Transfer, Safety, Health and Environmental (SHE) Regulations, Waste Disposal, Potential Impact of notification of new substances (NONS) regulations, economic factor, Social Aspects and impact, culture and team building.	8	13
3	**Organisation strategy, planning and management** Stages of the Technology Transfer Process, Management of Change, Organization, Teams Supporting the TT Process, Global Technology Transfer Management Team (GTTMT), Documentation Required to Support TT, Planning, Timings.	**7**	12
4	**Training as essential element** Learning from Technology Transfer, Developing a Training Strategy, Scope of Training, Prioritization and Context of	8	13

	Training Needs, Detailed Contents of Training Programmes, Methods and Tools for Delivering Training, Management of Training Programmes, Trainers, Templates and Style Guidelines, Training Documentation, Measuring Success and Auditing of Training.		
5	**Quality control: analytical method transfer** Analytical T T: Principles, What, when and How? (Objective, Scope, Responsibilities), procedure including Pre-transfer activities, Transfer protocol and Report, Experimental design and Acceptance criteria, Alternate approaches.	**7**	12
6	**Active pharmaceutical/ product ingredients** Introduction, Synthesis/preparation, route/process and final forms, Developmental data, Stability Data, Raw material, Process information: Process Research and Development, Role of Process R&D, Good Process Design, equipment description, specifications, packaging specifications, facility requirement, Qualification of equipment, validation plan: process, cleaning, computer.	8	13
7	**Production: Dosage form (Processing, packaging and cleaning)** Introduction, Stability Data, API, Excipients and Raw material, Process information, equipment description, packaging specification, facility requirement, Qualification and validation.	**7**	12
8	**Documentation** Batch manufacturing records (BMR), SOPs for analytical procedure, format COA, format stability data, format for testing of raw material, Validation Plan, Validation report.	4	7
9	**Case studies** Case studies and examples.	4	6

Reference Books:

No	Author	Name of the Book	Publisher	Year of Publication / Edition
1	Mark Gibson	Technology Transfer: an International Good Practice Guide for	DHI Publishing	Latest Edition

		Pharmaceuticals and Allied Industries		
2	International society of Pharmaceutical Engineers	ISPE good practice guide: technology transfer	Tampa, Fla.: ISPE	2nd Edition

Course Outcome:

After Completion of the Course, Student will able to:

No	Course Outcomes	RBT Level
1	Have a basic understanding of principles of technology transfer. Be aware of processes involved in transfer of technology during all stages of drug development.	UN
2	Explain and Process R&D, scaleup, manufacturing, production to launch and approval phase. Strengthen in additional domains such as project management, Clinical, Regulatory affairs, Quality Control and Quality Assurance.	AN
3	Communicate concepts and ideas effectively.	EL
4	Transparency, honesty and ethical reasoning in handling formulations for product processing.	RM

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

List of Assignments (Minimum 5 to be completed):

1. Preparation of Technology Transfer Plan (TTP)
2. Drafting of Standard Operating Procedure (SOP)
3. Development of Process Validation Plan
4. Case study analysis: Scale-up failure
5. Designing training module for TT team
6. Preparation of Validation Report
7. Equipment qualification documentation (IQ/OQ/PQ)
8. Risk assessment (FMEA approach)
9. Mini Project: Complete TT dossier for a biotech product

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