GUJARAT TECHNOLOGICAL UNIVERSITY

Syllabus for M.Sc. in Industrial Biotechnology, Semester - 3
Subject Name: Elective -Fundamentals of Technology Transfer
Subject Code: 1330109 W.E.F 2021-22

1. Learning Outcomes

Learning Outcome Component	Learning Outcome (Learner will be able to)
Theoretical and practical understanding of Fundamentals of Technology Transfer	● Have a basic understanding of principles of technology transfer. ● Be aware of processes involved in transfer of technology during all stages of drug development.
Value applications of Fundamentals of Technology Transfer in biological research as well as in biotech-industries	● 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.
Effective Communication	● Communicate concepts and ideas effectively.
Professional & Ethical Behaviour	● Transparency, honesty and ethical reasoning in handling formulations 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 Fundamentals of Technology Transfer	2	3	2	3	3	3	2
LO2:Value applications of Fundamentals of Technology Transfer in biological research as well as in biotech-industries	3	3	3	2	2	3	2
LO3: Effective communication	2	2	2	2	2	3	2
LO4: Professional & Ethical Behaviour	3	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	**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.	5	7

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.	6	7
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.	5	7
4	**Training as essential element** Learning from Technology Transfer, Developing a Training Strategy, Scope of Training, Prioritization and Context of 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.	6	7
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.	5	9
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	6	10

	requirement, Qualification of equipment, validation plan: process, cleaning, computer.		
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.	5	9
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.	3	7
9	**Case studies** Case studies and examples.	4	7

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 Gibson	Technology Transfer: an International Good Practice Guide for Pharmaceuticals and Allied Industries	DHI Publishing	Latest Edition

2	International society of Pharmaceutical Engineers	ISPE good practice guide: technology transfer	Tampa, Fla.: ISPE	2nd 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://www.who.int/docs/default-source/medicines/norms-and-standards/guidelines/production/trs961-annex7-transfer-technology-pharmaceutical-manufacturing.pdf?sfvrsn=2e302838_0

Course Outcomes:

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

- Have basic understanding of principles of technology transfer;
- Be aware of process involved in transfer of technology during all stages of drug development.