GUJARAT TECHNOLOGICAL UNIVERSITY
Integrated Master of Science (Biotechnology)
Semester: 9
Subject Name: Translational Medicine and Biomarkers
Subject Code: 1390408

Prerequisite: Students should have a fundamental understanding of molecular biology, clinical research, and biostatistics. Familiarity with biomarker discovery, drug development, and personalized medicine is beneficial.

Rationale: This course provides an in-depth understanding of translational medicine and biomarker development. It covers biomarker discovery, validation, clinical applications, and regulatory pathways. Emphasis is placed on bridging basic research with clinical applications to improve patient care.

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: Introduction to Translational Medicine and Biomarkers** • Definition and Scope of Translational Medicine • Role of Biomarkers in Disease Diagnosis and Therapy • Types of Biomarkers: Prognostic, Diagnostic, Predictive, and Pharmacodynamic • Clinical and Regulatory Considerations for Biomarker Development • Ethical and Legal Aspects in Translational Research	**12**	**20**
2	**Unit 2: Biomarker Discovery and Validation** • Techniques for Biomarker Discovery (Genomic, Proteomic, Metabolomic Approaches) • Bioinformatics and Machine Learning in Biomarker Analysis • Validation Methods: ELISA, qPCR, Western Blot, LC-MS • Challenges in Biomarker Reproducibility and Standardization • Case Studies: Cancer, Neurodegenerative Diseases, Cardiovascular Biomarkers	**15**	**30**
3	**Unit 3: Biomarkers in Precision Medicine**	**13**	**20**

	• Role of Biomarkers in Personalized Medicine • Pharmacogenomics and Drug Response Prediction • Liquid Biopsy: Circulating Tumor Cells (CTCs) and Cell-Free DNA (cfDNA) • Biomarker-Based Companion Diagnostics in Oncology • Regulatory Frameworks for Companion Diagnostics (FDA, EMA)		
4	**Unit 4: Translational Research and Clinical Applications** • Preclinical to Clinical Translation of Biomarkers • Design and Conduct of Clinical Trials for Biomarkers • Biomarkers in Infectious Diseases and Autoimmune Disorders • Role of AI and Big Data in Translational Research • Case Studies of FDA-Approved Biomarkers	**10**	**15**
5	**Unit 5: Future Directions in Translational Medicine** • Role of Multi-Omics in Biomarker Discovery • Emerging Technologies: CRISPR-Based Biosensors, AI-Powered Biomarker Discovery • Challenges in Translational Medicine (Regulatory, Ethical, Financial) • Future Prospects: Precision Medicine and Predictive Analytics	**10**	**15**

Reference Books:

1. **Translational Medicine: Tools and Techniques** – Robert A. Meyers
2. **Biomarkers in Medicine** – Robert J. Richards
3. **Translational Medicine: From Bench to Bedside** – Joshua Lederberg
4. **Precision Medicine and Biomarkers** – Klaus Lindpaintner

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