Faculty of Science and Humanities
M.Sc. (Biotechnology/ Microbiology) (Semester -I)
In Effect from Academic Year 2026-27

Branch Name:	M.Sc. Biotechnology / Microbiology
Program Code:	SC201 / SC202
Course Name:	Regulatory Framework in Biosafety
Course Code:	3SC2000101
Pre-requisite Course:	

Course Objectives:

- To learn the social responsibility of researchers and bioethics.
- Students will also be learning biosafety guidelines with special emphasis on individuals, institutions and the society.
- To learn about Intellectual Property Rights and Patenting for all the students of Microbiology and Biotechnology.

Teaching and Examination Scheme:

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)				
				Theory (Marks)		Practical (Marks)		
Lecture (L)	Tutorial (T)	Practical (P)	Credit	University Assessment	Continuous Assessment	University Assessment	Continuous Assessment	Total (Marks)
4	--	--	4	50	50	--	--	100

Subject Contents:

Unit	Content	Lectures	Weightage
1	Biosafety: • Introduction, History • Definitions, Objectives • Risk Assessment Containment • Planned introduction of GMO • Biosafety during Industrial Production using GMO Guideline in India	15	25%
2	**Fundamentals of IPR** • Concept and definition of Intellectual Property • Types of Intellectual Property: Patents, Copyrights, Trademarks, Geographical Indications, Industrial Designs • Need, objectives, and importance of IPR in science and technology • Tangible vs. intangible property • Overview of international organizations: WTO, WIPO • TRIPS Agreement and its implications • Introduction to Indian IPR framework.	15	25%
3	**Patents and Legal Framework** • Concept of patents: novelty, non-obviousness, utility • Patentable and non-patentable inventions • Prior art, anticipation, and novelty search • Patent filing procedure: drafting, filing, publication, examination, opposition, grant • Patent prosecution and maintenance • Indian Patent Act and amendments • Other IPR laws: Copyright Act, Trademark Act, Industrial Design Act, Geographical Indications Act • Plant Breeder's Rights and protection of biotechnological inventions	15	25%
4	**IPR and its Commercialization** • IPR issues in biotechnology and microbiology	15	25%

	• Biosafety and ethical considerations in IPR • Patenting of microorganisms and genetically modified organisms • Licensing, technology transfer, and commercialization of patents • Patent databases and search engines (Google Patents, WIPO, USPTO) • Case studies in IPR (biotechnology/pharmaceutical sector) • Challenges and emerging trends in IPR.		

Textbooks:

- B.D. Singh. Biotechnology expanding horizons.
- H.K.Das. Text book of biotechnology 3rd edition.
- Biotechnology by U Satyanarayana and U. Chakrapani

Reference Books:

- Fleming, D.A., Hunt, D.L., (2000). Biotechnology and Safety Assessment (3rd Ed) Academic press.ISBN-1555811804,9781555811808.
- Thomas, J.A., Fuch, R.L. (1999). Biotechnology and safety assessment (3rd Ed). CRC press, Washington. ISBN: 1560327219, 9781560327219
- Law and Strategy of biotechnological patents by Sibley. Butterworth publication.(2007) ISBN: 075069440, 9780750694445.
- Intellectual property rights- Ganguli-Tat McGrawhill. (2001) ISBN-10: 0074638602,
- Intellectual Property Right- Wattal- Oxford Publicatiopn House.(1997) ISBN:0195905024.
- Biotechnology - A comprehensive treatise (Vol. 12). Legal economic and ethical dimensions VCH. (2nd ed) ISBN-10 3527304320.
- Encyclopedia of Bioethics 5 vol set, (2003) ISBN-10: 0028657748.
- Thomas, J.A., Fuch, R.L. (2002). Biotechnology and safety Assessment (3rd Ed) Academic press.

List of Open-Source Software/learning website:

- https://archive.nptel.ac.in/noc/courses/noc22/SEM1/noc22-hs59/
- https://archive.nptel.ac.in/noc/courses/noc22/SEM1/noc22-hs62/
- https://archive.nptel.ac.in/noc/courses/noc22/SEM1/noc22-hs05/

Course Learning Outcomes (CLO): On completion of this course, the students will be able to:

CLO	Description	Bloom's Taxonomy Level
CLO1	Define and explain the fundamental concepts, history, objectives, and regulatory frameworks of biosafety, including risk assessment and containment strategies.	1 Remember 2 Understand
CLO2	Explain, apply, and analyze biosafety principles in the planned introduction and industrial use of genetically modified organisms (GMOs), with reference to national guidelines in India.	2 Understand 3 Apply 4 Analyze
CLO3	Define, explain, and apply the concepts of intellectual property rights, including various forms of IPR and their role in protecting intellectual creativity and innovation.	1 Remember 2 Understand 3 Apply
CLO4	Explain, apply, analyze, and evaluate international and national IPR frameworks, including WTO, TRIPS, WIPO, and Indian regulations governing biotechnological inventions and plant breeder's rights.	2 Understand 3 Apply 4 Analyze 5 Evaluate
CLO5	Explain, apply, analyze, and evaluate patent-related concepts such as novelty, non-obviousness, utility, prior art, and demonstrate understanding of patent drafting, filing, prosecution, and commercialization processes.	2 Understand 3Apply 4 Analyze 5 Evaluate
CLO6	Apply, analyze, evaluate, and design strategies for intellectual property protection by integrating knowledge of patent laws, trademarks, copyrights, geographical indications, industrial design, and patent search tools in real-world scenarios.	3Apply 4 Analyse 5 Evaluate 6 Create

Mapping of CLO s with POs & PSOs

Course Learning Outcomes	Programme Outcomes (POs)																Programme Specific Outcome (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	PSO1	PSO2	PSO3
CLO1	3	1			1	1													1
CLO2		2			2	1											1	2	1
CLO3		2			2	1													
CLO4		2			2	1													
CLO5	3	2			2	1								1					
CLO6	3	3			2	3								1			1	1	2

3: High, 2: Medium, 1: Low