

**BTC DSC 454(B)T**  
**BIOETHICS AND BIOSAFETY**

**Contact Hours: 45**

**Full Marks = 100 [ESE (70) CCA (30)]**

**Course Objective:** *This course in bioethics and biosafety aims to provide students with a comprehensive understanding of the legal, economic, ethical, and safety aspects related to the biotechnology industry. Students will delve into intellectual property rights and the patenting process in biotechnology. Additionally, the course will explore the intricacies of entrepreneurship in biotechnology, covering product selection, design, development, economic considerations, and cost-benefit analysis. Students will also become well-versed in the regulatory aspects of biotechnology, including excise regulations and biosafety practices. Furthermore, the course will address critical bioethical issues in biotechnology and introduce students to the principles of bioethics and biosafety.*

**UNIT 1** (10 Lectures)

**Intellectual Property Rights:** Introduction to Indian Patent Law; World Trade Organization and its related intellectual property provisions; Intellectual/Industrial property; Legal protection of intellectual property in research, Patenting in Biotechnology; Design and development; Economic, ethical and depository considerations.

**UNIT 2** (8 Lectures)

**Entrepreneurship:** Selection of a product line; Designing of product; Development processes for quality products, Economics on material and energy requirement; Cost benefit analysis; Stocking of product; Release of product.

**UNIT 3** (8 Lectures)

**Basic regulations of excise:** Demand for a given product; Feasibility of its production under given constraints of raw material; Energy input; Financial situations; Export potential.

**UNIT 4** (10 Lectures)

**Bioethics:** Necessity of Bioethics; Ethical regulations; Different paradigms of Bioethics – National & International; GEAC; Ethical issues against the molecular technologies; Ethical issues relating to HGP; Ethical issues in connection with NGS.

**UNIT 5** (9 Lectures)

**Biosafety:** Introduction to biosafety; Health hazards concerning biotechnology. Introduction to the concept of containment level; Good Laboratory Practices (GLP); Good Manufacturing Practices (GMP).

**Course Outcomes:** Upon successful completion of this course, students will have a comprehensive understanding of intellectual property rights and their application in biotechnology, enabling them to navigate the patenting process effectively. They will be equipped with entrepreneurial skills to select, design, and develop biotechnology products, considering economic factors and conducting cost-benefit analyses. Furthermore, students will gain insights into the regulatory framework governing the biotechnology industry, including excise regulations. They will also develop a strong ethical foundation, allowing them to address bioethical dilemmas and make informed decisions regarding biotechnological advancements. Additionally, students will grasp the importance of biosafety in biotechnology, ensuring they can work safely and responsibly in laboratory settings. Overall, this course will prepare students for roles that involve entrepreneurship, regulation, and ethical decision-making in the biotechnology sector.

### **SUGGESTED READING**

1. Nambisan, P. (2017). An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology. United Kingdom: Elsevier Science.
2. Joshi, R. (2006). Biosafety and Bioethics. India: Isha Books.
3. Goel, D., Parashar, S. (2013). IPR, Biosafety and Bioethics. India: Pearson Education India.
4. Sateesh, M. K. (2013). Bioethics and Biosafety. India: I.K. International Publishing House Pvt. Limited.
5. Singh, A., Singh, A. K. (2012). Intellectual Property Rights and Bio-technology: Biosafety and Bioethics. India: Narendra Publishing House.
6. Biological Safety: Principles and Practices. (2017). United Kingdom: Wiley.
7. Veatch, R. M. (2016). The Basics of Bioethics. United Kingdom: Taylor & Francis.