

## **BACHELOR WITH BIOTECHNOLOGY AS MAJOR**

### **8<sup>th</sup> SEMESTER**

#### **BTG 822J1:IPR, Bioethics and Biosafety**

**CREDITS: THEORY – 3, PRACTICAL – 1**

- **Course Learning Objective:** This course is intended to acquaint students about various aspects of biosafety regulations, bioethics and Intellectual Property Rights related to different biotechnology products.
- **Course outcome:** A student will be able to;
  - implement biosafety measures in laboratories and evaluate the risks associated with GMOs
  - identify different issues and bioethics related to molecular technology and research.
  - able to file patents(national/international)

#### **Unit -1      15 Hours**

Biosafety: Introduction, guidelines and regulations (National and International). Overview of International agreements - Cartagena Protocol. Role of Institutional Biosafety Committees (IBSC, RCGM, GEAC) for GMO applications in food and agriculture. Biosafety Levels. Recommended biosafety Levels for specific microorganisms, infectious agents and infected animals. GMOs/LMOs- concerns and challenges, environmental release of GMOs, risk analysis, assessment & management and communication. Containment of biohazards.

#### **Unit -2      15 Hours**

Bioethics: Introduction, Principles of ethics, ethical issues related with biotechnological products and techniques (gene cloning, gene editing, stem cell research and human genome project). Ethics involved in use of animals for research. Research ethics: Hypothesis, validation of research, confidentiality in research (collection, recording, usage in research and safe guarding the biological, personal information). Conflict of interest. Publication ethics. Plagiarism, commonly used tools of plagiarism identification. Introduction to Biopiracy and Bioprospecting.

#### **Unit -3      15 Hours**

Intellectual property rights (IPR): Introduction, types-patents, trademark, design, copyrights, traditional knowledge, geographical indication. Implications of intellectual property rights on the commercialization of biotechnology products. Agreements and treaties: GATT, TRIPS, WIPO, Budapest, UPOV convention. Patent: types of patents, patentability criteria and

patentable subject matter, brief procedure for filing a patent (national, international), patent licensing and agreement, patent infringements and revocation, rights of patentee.

**PRACTICALS (1 CREDIT: 30 Hours)**

1. Proxy filing of Indian Product patent to learn the process.
2. Proxy filing of Indian Process patent to learn the process.
3. Planning of establishing a hypothetical biotechnology industry in India
4. A case study on clinical trials of drugs in India with emphasis on ethical issues.
5. Case study on handling and disposal of radioactive waste.

**BOOKS RECOMMENDED**

1. IPR, Biosafety and biotechnology Management. Senthil Kumar Sand Mohammed Jaabir, Jasen Publications
2. IPR, Biosafety and Bioethics, Goel D & Prashar S - Pearson
3. Bioethics and Biosafety in Biotechnology, V Sree Krishna
4. Intellectual Property Law, Lionel Bently & Brad Sherman - OUP.
5. Law of Patent, Elizabeth Verkey - Eastern Book Company, Lucknow.
6. Biosafety and Bioethics, Rajmohan Joshi
7. An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology, Padma Nambisan