Gyanmanjari Innovative University

Course Syllabus
Gyanmanjari Institute of Technology
Semester-4

**Subject:** Intellectual Property Rights (IPR) and Bio-safety-BETXX14212

**Type of course:** Ability Enhancement Courses (AEC)

**Prerequisite:** Basic knowledge of Biotechnology and Biology

**Rationale:**

IPR helps students understand how to protect their innovations and navigate the legal aspects of biotechnology. Bio-safety ensures they follow safe practices and regulations when working with biological materials.

**Teaching and Examination Scheme:**

| Teaching Scheme | | | Credits | Examination Marks | | | | | Total Marks |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Theory Marks | | Practical Marks | | CA | |
| CI | T | P | C | ESE | MSE | V | P | ALA | |
| 02 | 00 | 00 | 02 | 60 | 30 | 10 | 00 | 50 | 150 |

*Legends: CI-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.*

**Course Content:**

| Unit No. | Course content | Hrs | % Weightage |
|---|---|---|---|
| 1 | **Biosafety and Regulatory Framework:** Biosafety and risk assessment issues, Regulatory framework and national biosafety policies, Overview of the Cartagena Protocol on Biosafety, WTO and other international agreements related to biosafety, Cross-border movement of germplasm, Risk management issues and containment strategies | 08 | 25% |
| 2 | **Laboratory and Environmental Biosafety:** Laboratory and environmental biosafety principles, Health aspects: toxicology, allergen city, antibiotic resistance, Impact on the environment: gene flow in natural and artificial ecologies, Sources of gene escape and tolerance of target organisms, Creation of super weeds and super viruses | 08 | 25% |

| | | | |
|---|---|---|---|
| 3 | **Ecological Aspects and Monitoring:** Ecological aspects of GMOs and their impact on biodiversity, Monitoring strategies and methods for detecting transgenic, Radiation safety and non-radio isotopic procedures, Benefits of transgenic to human health, society, and the environment | 07 | 25% |
| 4 | **Intellectual Property Rights:** National biosafety policies and law, The Cartagena protocol on biosafety, WTO and other international agreements related to biosafety, Intellectual properties: copyrights, trademarks, trade secrets, patents, geographical indications, Protection of Plant Variety and Farmers' Rights Act, Indian Patent Act and its amendments; patent filing procedures, Implications of intellectual property rights on the commercialization of biotechnology products | 07 | 25% |

## Continuous Assessment:

| Sr. No. | Active Learning Activities | Marks |
|---|---|---|
| 1. | **Intellectual Property Rights Case Study**: Analyze a case study involving a biotechnology patent. Discuss the implications of IPR on the commercialization of the product and how it relates to the Protection of Plant Variety and Farmers' Rights Act and submit your work at GMIU portal | 10 |
| 2. | **International Agreements Analysis:** Choose two international agreements related to bio-safety (e.g., the Cartagena Protocol and WTO agreements) and analyze their impact on the regulation of GMOs. Summarize your findings in a comparative essay and submit PDF at GMIU portal | 10 |
| 3. | **Bio-safety and Risk Assessment Report:** Write a report analyzing a specific case of bio-safety failure. Discuss the risk assessment issues involved, the regulatory framework applicable, and propose recommendations for improvement, and submit on GMIU portal | 10 |
| Total | | 30 |

## Suggested Specification table with Marks (Theory): 60

| Distribution of Theory Marks (Revised Bloom's Taxonomy) | | | | | | |
|---|---|---|---|---|---|---|
| **Level** | **Remembrance (R)** | **Understanding (U)** | **Application (A)** | **Analyze (N)** | **Evaluate (E)** | **Create (C)** |
| **Weightage** | 30% | 40% | 30% | | | - |

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from the above table.

## Course Outcome:

| After learning the course, the students should be able to: | |
|---|---|
| CO1 | Explain the importance of biosafety and related national and international regulations. |
| CO2 | Implement lab and environmental biosafety protocols to prevent risks like antibiotic resistance. |
| CO3 | Monitor the ecological and societal effects of GMOs and develop containment strategies. |
| CO4 | Understand intellectual property laws to support ethical commercialization of biotech products. |

## Instructional Method:

The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by blackboard, may also use any of the tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.

From the content, 10% of topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done based on the Active Learning Assignment

## Reference Books:

[1] Intellectual Property Rights in Biotechnology, B. D. Singh, Kalyani Publishers, 2015.
[2] Biosafety and Bioethics, R. C. Sobti. IK International Publishing House, 2013.
[3] Biosafety and Bioethics, Rajmohan Joshi, Isha Books
[4] Intellectual Property Rights in Biotechnology, V. Sreenivasulu, SAGE Publications.
[5] Biotechnology and Intellectual Property Rights, Kshitij Kumar Singh, Springer