



**Course Title: Regulatory Affairs, Biosafety Regulations, IPR and Technology Transfer**

**Course Code: BIOT701**

**Credit Units: 3**

**Level: PG**

| L | T | P/S | SW/FW | No. of PSDA | TOTAL CREDIT UNITS |
|---|---|-----|-------|-------------|--------------------|
| 3 | 0 | 0   | -     | 3           | 3                  |

| #                                  |   |  |
|------------------------------------|---|--|
| 1                                  | <p><b>Course Objectives:</b><br/>The course is designed, keeping in mind that the students learn and explore emerging trends and technology in IPR and Biosafety Regulations and Technology Transfer</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> The course will develop the understanding of relevance, Commercial impact and protection of Intellectual property Rights</li> <li><input type="checkbox"/> The course will disseminate the information on different types of Intellectual Property Rights; Patents, Copyrights, Trademarks, Industrial Designs, Geographical Indications and International Conventions, Biosafety and Bioethics.</li> <li><input type="checkbox"/> The course will sensitize the learners with the emerging issues in IPR and the rationale for the protection of IPR issues in the national and international Level.</li> </ul> |  |
| 2                                  | <p><b>Prerequisites:</b><br/>Basic knowledge of Biotechnology and Business Laws</p>   |  |
| 3                                  | <p><b>Student Learning Outcomes:</b></p> <ol style="list-style-type: none"> <li>1. Student will be able to demonstrate knowledge of different forms of Intellectual Property Rights, their Relevance to Biotechnology Industry &amp; Academia.</li> <li>2. Student will be able to identify the International conventions &amp; Trade agreements: WTO, TRIPS, WIPO, Implication for developing countries; Process involved in Patenting, Patent Search</li> <li>3. Student will be able to analyse need of bioethics on different issues of biotech industry and research.</li> <li>4. Student will be able to apply knowledge of technology transfer</li> </ol>  |  |
| <b>Course Contents / Syllabus:</b> |   |  |

|  |   |                  |
|--|---|------------------|
| 4  | <b>Module I General Overview of Intellectual Property Rights</b>  | <b>Weightage</b> |
|  | <ul style="list-style-type: none"> <li>• Concept, classification and Applications of Intellectual property and IP Rights Protection.</li> <li>• UPOV</li> <li>• WIPO – Mission and Activities, WTO Objective and WTO Agreements: General Agreement on Trade and Tariff (GATT), TRIPS Agreement.</li> <li>• IPR Informatics, patent landscaping</li> </ul>               | <b>20</b>        |
| 5  | <b>Module II Patent, Copyrights, Trademarks and Industrial Designs</b>  | <b>Weightage</b> |
|  | <ul style="list-style-type: none"> <li>• PCT (National and International)</li> <li>• Patent infringement and Related case studies.</li> <li>• Copyright, Infringement of copyright and related Case Studies.</li> <li>• Trademark, Infringement of Trademark and Related case studies.</li> <li>• Industrial Designs</li> </ul>   | <b>25</b>        |
| 6  | <b>Module III Geographical Indicators and Preservation of Biodiversity</b>  | <b>Weightage</b> |
|  | <ul style="list-style-type: none"> <li>• Geographical Indications</li> <li>• Bio prospecting and Bio piracy</li> <li>• National Biodiversity Authority</li> <li>• TKDL</li> </ul>   | <b>15</b>        |
| 7  | <b>Module IV Biosafety Regulations</b>  | <b>Weightage</b> |
|  | <ul style="list-style-type: none"> <li>• Biosafety Levels, Recombinant DNA Guidelines ,Different Biosafety committees,</li> <li>• ICMR Ethical Guidelines for Biomedical Research on Human Subjects. Guidelines for Stem cell research and gene editing</li> <li>• Cartagena Protocol on Biosafety</li> <li>• Biosafety guidelines in GM foods and organisms</li> </ul> | <b>20</b>        |
| 8  | <b>Module V Technology Transfer</b>   | <b>Weightage</b> |
|  | <ul style="list-style-type: none"> <li>• Managing and marketing of intellectual property,</li> <li>• Transfer of technology, Licensing agreements and assignments,</li> <li>• Issues of ownership,</li> <li>• Collaborative research.</li> <li>• Trade secrets</li> </ul>   | <b>20</b>        |
| 9  | <b>Pedagogy for Course Delivery:</b><br>Lectures: 36<br>Presentation/ Seminar: 4<br>Group Discussions: 3<br>Class Test: 2<br>Total: 45  |                  |
| <b>List of Professional Skill Development Activities (PSDA):</b> |   |                  |

- i. Interaction with IPR expert from Industry/Research**
- ii. Patent analysis exercise**
- iii. Discussion on case studies related to IPR issues in the area of biotechnology**

**Assessment/ Examination Scheme:**

| <b>Theory L/T (%)</b> | <b>Lab/Practical/Studio (%)</b> | <b>End Term Examination</b> |
|-----------------------|---------------------------------|-----------------------------|
| 100%                  | NA                              | 70%                         |

**Theory Assessment (L&T):**

| <b>Continuous Assessment/Internal Assessment</b>                  |                   |                                      |                        |                   | <b>End Term Examination</b> |
|---|-------------------|--------------------------------------|------------------------|-------------------|-----------------------------|
| <b>(30 %)</b>   |                   |                                      |                        |                   | <b>(70 %)</b>               |
| <b>Components (Drop down)</b>                                     | <b>Class Test</b> | <b>Home Assignment</b>               | <b>Quiz</b>            | <b>Attendance</b> |                             |
| <b>Linkage of PSDA with Internal Assessment Component, if any</b> |                   | <b>Case study / group discussion</b> | <b>Patent analysis</b> |                   |                             |
| <b>Weightage (%)</b>  | 10                | 10                                   | 5                      | 5                 |                             |

**Text and References:**

- Sasson A, Biotechnologies and Development ,UNESCO Publications ,1988.
- Kilner, John, et.al, eds., Cutting-Edge Bioethics. Eerdmans 2002.
- Intellectual Property Rights by Brigitte Anderson, Edward Elgar Publishing, 2011

- Intellectual Property Rights and the Life Sciences Industries by Graham Dutfield, Ashgate Publishing , 2009