



# LEGAL AND REGULATORY ISSUES IN BIOTECHNOLOGY

**PROF. NIHARIKA SAHOO BHATTACHARYA**

Rajiv Gandhi School of Intellectual Property Law  
IITKGP

**PRE-REQUISITES :** Bachelor degree students; anyone who is interested to know the legal aspects of biotechnology industry

**INTENDED AUDIENCE :** Students, researchers, industry professionals from Law or biotechnology/life science/pharmaceutical science discipline (B.Tech, M.Tech, LLB, LLM, PhD scholars)

**INDUSTRIES APPLICABLE TO :** Pharmaceutical / agro-biotech / environmental biotech companies

**COURSE OUTLINE :**

This course describes the convergence of scientific, regulatory, and commercial factors that drive the biotechnology industry; Equips students to understand the development cycle of a biotechnology derived product from legal and regulatory perspective; This course will introduce students to the interrelated fields of patent law, regulatory law, and contract law that are vital to the biotech and biopharmaceutical sectors; The course will present core concepts in a way that permits students to use them throughout their corporate, academic, and government careers; Create human resource with basic understanding of biotechnology and law which will contribute towards greater protection and commercialization of inventions.

**ABOUT INSTRUCTOR :**

Prof. Niharika Sahoo Bhattacharya is currently working as an Assistant Professor in Rajiv Gandhi School of Intellectual Property Law. She has done her doctoral studies in the interdisciplinary area of IPR and biomedicines from IIT Kharagpur. Her broad research interest is to analyze and understand the complexities between scientific innovations, their protection and commercialization. Her other research interest are IP issues in pharmaceuticals, IP and competition law, Geographical Indications and Plant variety Protection. She is actively involved in the research and teaching of various IP subjects and published in many peer reviewed international journals of repute

**COURSE PLAN :**

**Week 1:** Regulation of Biotechnology Research

**Week 2:** Intellectual Property Rights and Life sciences (Agriculture, Pharma, Biotech)

**Week 3:** Biotech Product commercialization: Regulatory Approval Process

**Week 4:** Understanding technology transfer in biotech sector