Legal and Regulatory Issues in Life Sciences

Course Rationale

The research in the broad field of life sciences includes the exploitation of plants, animals, micro-organisms, biological processes, cells or cellular components and leads to the development of new products, processes and efficient tools which are useful in many sectors including research, environment, agriculture and health. Though the field of Life Sciences and Biotechnology are prospering in all possible directions, the interdisciplinary approach has not gained much prominence. Many a times the researchers are not informed about the legal and regulatory aspect associated with of biotechnologically derived products which is critical for the commercialization aspects. The role and possibilities arising out of biotechnological research, their protection and exploitation through patents and other forms of intellectual property rights are mostly unexplored by the researchers from the field.

To fill all those gaps this course aims to provide the students with an understanding of the legal and regulatory strategies that surround the development decision making process, towards the goals of product development and approval in the field of biotechnology . A simpler understanding of operational, strategic and commercial aspects of the development and regulatory approval process for new drug, biologic and biotechnology products will provide the students with better insight into the real commercial world of biotechnological products. The topics are designed to provide a chronological review of the requirements needed to develop a product starting from research and development, clinical trials and marketing approval. We will examine and analyze the regulatory process as product candidates are advanced from research and development, through pre-clinical and clinical testing, to marketing approval, product launch and the post-marketing phase. The goal of this course is to introduce and familiarize students with the terminology, timelines and actual steps followed by the professionals during various stages of product development and also to introduce the legal and ethical aspects associated with biotechnology industry.

Legal and Regulatory Issues in Life Sciences

Autumn Semester

Subject Teachers:

Dr Niharika Sahoo Bhattacharya, Assistant Professor, RGSOIPL

Dr M. Padmavati, Professor, RGSOIPL

Subject Name: Legal and Regulatory Issues in Life Sciences

Subject Code:

Credit: 2-1-0 **Prerequisite: None**

Legal and Regulatory Issues in Life Sciences

A total number of 30 lecture hours and 10 Tutorials will cover for the entire syllabus

Objective of the Course:

a) This course describes the convergence of scientific, regulatory, and commercial factors that drive the biotechnology industry.
b) Equip students to understand the development cycle of a biotechnology derived product from legal and regulatory perspective.
c) 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.
d) The course will present core concepts in a way that permits students to use them throughout their corporate, academic, and government careers.
e) Create human resource with basic understanding of biotechnology and law which will contribute towards greater protection and commercialization of inventions.

Teaching- Learning Methodology:

The method of teaching-learning in the course on **Legal and Regulatory Issues in Life Sciences** will provide an interdisciplinary perspective bringing together concepts from the field of biotechnology, law, ethics, regulatory frameworks and management to develop a critical appreciation of the this rapidly developing field. A combination of lectures, interactive exercises and case studies will form the method of teaching-learning. Student will learn about the different international standards and procedures applicable to different groups of biotechnological products and can understand the legal/ regulatory hurdles associated with the commercialization of biotech products

Course Contents:

Module-1: Research and Industry Ethics……6CHS

- Biotechnology product development cycle and critical issues
- Research and development: the ethical aspects
- Bioethics, Ethics in Animal Research
- International Ethical Codes
- Clinical trial regulations

Module-2: Regulation of Biotechnology Research……4CHS

- Biosafety rules and guidelines
- Role of IBSC, RCGM, GEAC
- Industrial safety and hazard management in biotech industry
- Regulation on stem cell and cloning research

Module-3: Biopharmaceutical Regulatory Approval Process…….10 CHS

- Drug development and regulatory approval process for biopharmaceuticals
    - Regulatory Authority : nature and function
    - Laws on drug :Drugs and Cosmetics Act of 1940,
    - GMP, GLP guidelines and Guidelines for clinical Trial
- Regulatory approval process for Biologics ,Blood products, rDNA products, Stem cell and cell based products and Vaccines
- International harmonization, ICH guideline

Module-4: Intellectual Property Rights and Biotechnology……..5CHS

- Different Forms of IPR
- Patentability in Biotechnology: Nature and scope
- Patenting life forms: critical issues
- International treaties applicable to biotechnological research

Module 5- Access to Natural Resources and Resource sharing……3 CHS

- Convention on Biodiversity, UPOV
- Issues of Bio piracy, TKDL
- Plant variety Protection and Patenting
- Resource sharing mechanisms, Material Transfer Agreements

Module 6- Understanding technology transfer in biotech sector……..2 CHS

- Biotech contracts, Licensing negotiation

Detailed Class Schedule: Legal and Regulatory Issues in Life Sciences

Each Lecture is of 1 hour duration

Lecture no	Subject of lecture
1	Biotechnology product development cycle and critical issues
2	Bioethics, Ethics in animal research
3	Ethics in embryonic research
4	International Ethical Codes
5	Clinical trial regulations
6	Biosafety rules and guidelines
7	Role of IBSC, RCGM, GEAC
8	Industrial safety and hazard management in biotech industry
9	Regulation on stem cell and cloning research
10	Drug development and regulatory approval process for biopharmaceuticals
11	Laws on drug :Drugs and Cosmetics Act of 1940, Food, Drugs and Cosmetics Act, 1940 of US, EU Directive on Biological products
12	Drug regulatory Authorities and Function: CDSCO, USFDA, EMA
13	Type of Drug applications and requirements- NDA, ANDA
14	Biopharmaceuticals, Biologics and Biosimilars
15	GMP, GLP guidelines and Guidelines for clinical Trial
16	Regulatory approval process for Biologics ,Blood products, rDNA products,
17	Regulatory approval process Stem cell and cell based products and Vaccines
18	Medical Device regulation
19	Post-market monitoring of biopharmaceuticals and devices
20	International harmonization, ICH guideline
21	Different Forms of IPR
22	Patentability in Biotechnology: Nature and scope
23	Patenting life forms: critical issues
24	International treaties applicable to biotechnological research-TRIPS, Budapest Treaty
25	Convention on Biodiversity, UPOV
26	Issues of Bio piracy, TKDL
27	Plant variety Protection and Patenting
28	Resource sharing mechanisms, Material Transfer Agreements
29	Biotech contracts
30	Licensing negotiation

Applicability:

Undergraduate

Postgraduate

MS/PhD Scholars

Evaluation system:

Continuous Assessment and Attendance: 20%
Mid Semester Examination: 30%
End Semester Examination: 50%

Suggested Books

1. Bucknell Duncan (ed.), I *Pharmaceutical,Biotechnology and Chemical Inventions* (Oxford University Press, 2011).
2. Cook M.Trevor, *Pharmaceutical Biotechnology and the Law* (Lexis Nexis , 2d ed. 2009).
3. Cook M.Trevor,*The Protection Of Regulatory Data In Pharmaceutical And Other Sectors* (Sweet and Maxwell, 2000).
4. Hardcastel Rohan, *Law and The Human Body; Property Rights, Ownership and Control* (Hart Publishing, 2007).
5. Valverde J.L. (ed.), *Key Issues in Pharmaceutical Law* (IOS Press, Vol. 9 2009).
6. Drexl Josef, Nari Lee (ed.), *Pharmaceutical Innovation, Competition and Patent Law; A Trilateral Perspective* (Edward Elgar, 2013),
7. Verkey Elizabeth, *Law of Plant Varieties Protection, 30-32* (Eastern Book Company, 1st ed. 2007).
8. Herring Jonathan, *Medical Law & Ethics* (Oxford University Press, 5th Ed., 2014).
9. Ventose Eddy, *Medical Patent law- The Challenges of Medical Treatment* (Edward Elgar, 2011).

10. Krattiger Anatole, Mahoney T. Richard, *et.al.,* II *Intellectual Property Management in Health and Agricultural Innovation; A handbook of best practices* (MIHR, Oxford Center for Innovation, 2007).

11. Emily Jackson, Medical Law, text, cases and Materials , (Oxford University Press, 4th ed. 2013)

12. Holy F Lynch, Effy Vayena and Urs Gasser, Big data, Health Law and Bioethics, Edited by I. G. Cohen, (Cambridge University Press, 2018)

13. Patents for Chemicals, Pharmaceuticals, and Biotechnology: Fundamentals of Global Law, Practice, and Strategy, Philip W. Grubb, Peter R. Thomsen, Peter Thomsen (Oxford University Press, 2010)

References:

1. G.Q. Daley, I. Hyun, J.F. Apperley, R.A. Barker, N. Benvenisty, A.L. Bredenoord, C.K. Breuer, T. Caulfield, M.I. Cedars, J. Frey-Vasconcells, *et al.* Setting global standards for stem cell research and clinical translation: the 2016 ISSCR guidelines, Stem Cell Reports, 6 (2016), pp. 787-797

2. Roger A. Barker, Melissa K. Carpenter, Stuart Forbes, Steven A. Goldman, Catriona Jamieson, Charles E. Murry, Jun Takahashi, Gordon Weir, The Challenges of First-in-Human Stem Cell Clinical Trials: What Does This Mean for Ethics and Institutional Review Boards?, Stem Cell Reports, 10 (2018), pp 1429-1431

3. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials in medicinal products for human use and repealing Directive 2001/20/EC, Off. J. L 158 (27.05.2014) (2014) 1.

4. M. Gehring, R.S. Taylor, M. Mellody, B. Casteels, A. Piazzi, et al., Factors influencing clinical trial site selection in Europe: the Survey of Attitudes towards Trial sites in Europe (the SAT-EU Study), BMJ 3 (11) (2013).

5. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the application of good clinical practice in the conduct of clinical trials with medicinal products for human use, Off. J. (34) (2001) EC No L 121.

6. Kirsteen A. Jones, Michael Semple, Ethics in clinical trials, Anaesthesia & Intensive Care Medicine, Volume 18, Issue 11,(2017) pp 586-589,

7. Onora O'Neill, Stem cells: ethics, legislation and regulation, Comptes Rendus Biologies, Volume 326, 7 (2003),pp 673-676,

8. Suman Jangid, Laura Beth Kupsch, EU Rules for Cell-Based Therapies: Regulations and Strategies for Approval, Editor(s): Rui L. Reis,Encyclopedia of Tissue Engineering and Regenerative Medicine,Academic Press,2019,Pages 147-158.

9. Gail A. Van Norman, Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, JACC: Basic to Translational Science, 1(2016),pp 170-179

10. Michael Mendicino, Yong Fan, Deborah Griffin, Kurt C. Gunter, Karen Nichols, Current state of U.S. Food and Drug Administration regulation for cellular and gene therapy products: potential cures on the horizon, Cytotherapy, Volume 21, Issue 7,(2019) pp 699-724.

11. Donna M. Gitter, Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law, 19 Berkeley Journal of International Law 1 (2001).

12. Abigail Perkins, Gene[ie] in a Bottle: Regulating the Future of Man, 21 Tulane Journal of Technology and Intellectual Property 91 (2019).

13. Miyako Okada-Takagi, Intellectual Property Law in Biotechnology, 16 Medicine and Law. 9 (1997).

14. Gerd Winter, Patent Law Policy in Biotechnology, Journal of environmental Law 167 (1992).

15. Pharmaceutical Medicine, Biotechnology and European Law, Journal of legal Medicine 159 (2002).

16. Andrew J. Allen, Biotechnology, Research and Intellectual Property Law, 8 Canterbury Law Review. 365 (2002).

(Note: The journal articles are of indicative nature)