



Approved in 44th BoA Meeting (24-11-2021)

Course number	: BE 305
Course Name	: Bioethics and Regulatory Affairs
Credit Distribution	: 1-0-0-1
Intended for	: B. Tech M.Tech Integrated Dual Degree Bioengineering students
Prerequisite	: IC 136 Understanding Biotechnology and its Applications
Distribution	: Core for IDD BE and elective for others
Mutual Exclusion	: None

1. Preamble: This course intended to serve as a broad introduction to the field of bioethics and regulatory affairs. The course will combine lectures with small-group case work that encourages students to explore ethical dilemmas in a faculty-supported, peer-educated environment. The course also provides a discussion on drug and pharmaceutical regulatory affairs.

2. Course Modules with quantitative lecture hours

Module 1. Introduction to Bioethics (4 hours)

Ethics and ethical theory, the nuremberg code, declaration of helsinki, the belmont report, history of ethics, justice and rights, liberty and morality. Deontology, utilitarianism and Principalism, Virtue ethics, Ethics of Care, Human Rights.

Module 2. Ethics of research involving human participants (5 hours)

Biomedical research involving human participants. Guidelines for research on children, Stem cell research, animal research etc. Ethical issues in Genetic research and studies involving Genetic information. Ethics of investigator-participant relationship, problems of randomized clinical trial, constitution of Ethics Committees, informed consent and its theoretical value (respecting autonomy, nonmaleficence, concept of confidentiality etc.), research on vulnerable population.

Module 3. Drug regulatory affairs (5 hours)

Pharmaceutical regulatory affairs, national regulatory affairs, drug approval and international drug regulations, regulatory affairs of controlled drug delivery system, regulatory requirements for product approvals, environmental concerns and regulations. National regulatory affairs and bodies – Central Drugs Standard Control Organization (CDSCO) headed by the Drug Controller General of India (DCGI).

3. Text books:

Text Book:

1. Ronald Munson, "Intervention and Reflection: Basic Issues in Medical Ethics 10th Edition, Cengage Learning, 2018
2. Beauchamp, Tom L and Childress, JamesF. 2019. Principles of Biomedical Ethics. New York and Oxford: Oxford University Press.

References:

1. Rachels, James and Stuart Rachels. 2012. Elements of Moral Philosophy. (5-7th editions), New York: McGraw-Hill.
2. Santoro, Michael A and Thomas M Gorrie. Ethics and the Pharmaceutical Industry, New York, Cambridge University Press.

5. Similarity Content declaration with existing courses: Nil (0%)

S. No.	Course Code	Similarity Content	Approx. % of Content
1.	Nil	Nil	N/A

6. Justification of new course proposal if cumulative similarity content is >30%: Not Applicable



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