



First Semester 2023-2024
Course Handout

11-08-2023

Course No. : BITS F467
Course Title : Bioethics & Biosafety
Instructor : RUCHI JAIN DEY, Supratim Ghosh
Instructor-in-charge : RUCHI JAIN DEY

1. Course Description: This course will address biosafety regulation, biosafety guidelines and ethical considerations related to the responsible practice of modern biotechnology and genetic engineering. The first half of the course will address the concepts underlying various biotech applications and the relevant biosafety guidelines and regulations and will be taken together with bioethical issues surrounding the implementation of each of these biotech applications.

2. Scope and Objective: Introduction to the need and issues governing biosafety, legal, ethical and social implications of human gene manipulation, guidelines for research involving transgenic organisms, socio-economic impacts of biotechnological experiments, ethics in stem cell research, organ transplants, animal experimentation and CPCSEA guidelines, environmental pollution-hazards and control, GLP & GMP guidelines, public education and participation in biosafety, IPR and patent processing.

3. Text Book (T1): *Bioethics and Biosafety in Biotechnology*, by V. Sreekrishna, new age international publishers, New Delhi,

4. Reference Book (R1): *Bioethics* by Ben Mepham; 2nd Edn., Oxford University Press, Hampshire, Great Britain, 2008; *Bioethics and Biosafety* by M. Sathish.

5. Course Plan:

Lec.No	Topics to be covered	Ref. to Chapters (Unit)
1-4	Introduction to the need and issues governing biosafety (arising from applications of biotechnology in health and agriculture); Need, definition and application of bioethics	Unit-1 T1
5-7	Biosafety guidelines and regulations; biosafety containment levels; chemical and biological hazardous materials and their safe disposal; public participation in biosafety, Workplace Hazardous Materials Information and handling (WHMIS)	Unit-1, Unit-2; T1; Research articles and reviews
8-10	Genetically Modified Organisms (GMOs) and GM products, ethical issues and concerns	Unit 2 T1, Research articles and reviews
11-13	Cloning technology pros and cons; animal and human cloning; therapeutic and reproductive cloning; sources and types of organ	Unit-3, T1, Research articles and reviews

	transplantation	
14-16	Ethical issues related to animal and human cloning, why cloning Humans is ethically unacceptable?	Unit 5 T1, Research articles and reviews
17-19	Animal research and testing; GM-animals and animal models; CPCSEA guidelines	Unit 4 T1
20-21	Animal rights and laboratory animal management, CCAC guidelines on transgenic animals, need for ethical review.	Unit 3, 4 and Unit 5 T1
22-25	Stem cell research; stem cell therapy and biosafety aspects, Ethics involved in Stem cell research	Unit 4, T1, Research articles and reviews
26-28	Assisted reproduction techniques (ART); genetic disorders; human gene testing and manipulation; gene therapy	Unit 3, Unit 4; T1
29-30	Ethical issues related to ART, genetic testing & genetic therapy	Unit 4 and 5 T1
31-32	Introduction to environmental pollution and environmental ethics, public health, Sanitization, Medicine and Bioethics	R1:12.3.3, Unit-2, Unit-3, Research articles and reviews
33-35	Good Laboratory & Manufacturing Practices (GLP & GMP): guidelines & implementation	Unit 5 T1
36-38	Intellectual property, forms of IPR; international organizations, WTO, WIPO; patents and the process involved in patenting	Unit 2 T1
39-40	Socio-economic impacts of biotechnology: legal, ethical, social and economic impact related to human reproduction, gene manipulation and genetic testing	Unit 5 T1

*Supplemented with class notes, research and review articles, case studies.

6. Evaluation Scheme:

EC No.	Evaluation Component	Duration	Weightage %	Date, Time & Venue	Remarks
1	2 Announced Quizzes	Variable	20 (40M)	To be announced	CB
2	Mid-Sem	90 Min.	20 (40M)	13/10 - 4.00 - 5.30PM	CB
3	Presentation	-----	20 (40M)	To be announced	OB
4	Comprehensive	3 Hrs.	40 (80M)	19/12 AN	CB

OB- Open Book; CB- Closed Book

7. Chamber consultation hour: To be announced in the class.

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8. Notices: All notices concerning this course will be displayed on CMS or via emails.

9. Make-up policy: Make-up will be granted for Mid-semester and Comprehensive exam only in case of medical emergency requiring submission of proof in form of doctors' note/prescription. No makeup for quizzes.

10. Academic Honesty and Integrity Policy: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor-in-charge
BITS F467