

BTY196:BIOSAFETY AND BIOETHICS

L:2 T:0 P:0 Credits:2

Course Outcomes: Through this course students should be able to

- CO1 :: learn the concept of biosafety levels and biological safety cabinets
- CO2 :: understand the role of regulatory bodies for successful implementation of biosafety
- CO3 :: interpret risk analysis, assessment, and management
- CO4 :: analyze good laboratory practice, clinical practice, and manufacturing practice
- CO5 :: evaluate ethical issues in biotechnology
- CO6 :: generalize research ethics and ethical issues in cloning and stem cell research

Unit I

Biosafety : Introduction, Historical Background, Biological Safety Cabinets, Containment for Biohazards, Biosafety Levels, Biosafety Levels of Specific Microorganisms, Recommended Biosafety Levels for Infectious Agents and Infected Animals

Unit II

Biosafety regulatory framework : Regulatory framework in India governing GMOs-recombinant DNA advisory committee and (RDAC), Institutional biosafety committee (IBC), Genetic engineering approval committee (GEAC), State biosafety coordination committee and district level committee, Recombinant DNA guidelines (1990), Revised guidelines for research in transgenic plants (1998), Farmers right and plant breeders right

Unit III

Biosafety Risk : Risk analysis, Risk Assessment, Risk management and communication, Overview of national regulations and relevant international Agreements, Cartagena Protocol, Roles of institutional biosafety committee

Unit IV

GLP, GCP and GMP : Introduction: History, definition, Principles, Good Laboratory Practices (GLP) and its application, GLP: training, resources, rules, characterization, documentation, quality assurance, facilities: building and equipment, GLP and FDA, Stepwise implementation of GLP and compliance monitoring, Good manufacturing practices (GMP), Good clinical practices (GCP), Standard operating procedure (SOP): Introduction, preparation, validation and revision

Unit V

Ethical issues in Biotechnology : Basics of ethical issues in Biology and its relation with biotechnology and other branches, Application of bioethics and socioeconomic impacts of biotechnology, Public education and ethical concerns of biotechnology research and innovation, Bioethics in health care, Bioethics in biodiversity and resource management

Unit VI

Research ethics : Institutional Review Board (IRB) and its functions, Ethical issues in clinical research, Vulnerable populations, Risks and benefits, Authorship, Human protectionism, Issues in research ethics, Ethical issues in human cloning reproduction and stem cells research, Social and ethical implications of biological weapons, Euthanasia

Text Books:

1. BIOETHICS AND BIOSAFETY by M K SATEESH, I. K. INTERNATIONAL PUBLISHING HOUSE

References:

1. BIOETHICS AND BIOSAFETY IN BIOTECHNOLOGY by V. SREE KRISHNA, NEW AGE INTERNATIONAL

