22BT102 GOOD LABORATORY PRACTICES

Source : https://journalsofindia.com/good-laboratory-practice-glp-working-group-of-oecd/

Hours Per Week :

L	T	P	C
2	2	0	3

PREREQUISITE KNOWLEDGE: Microbiology and Fermentation Technology, Genetic Engineering, Industrial Biotechnology

COURSE DESCRIPTION AND OBJECTIVES:

The course provides insights about regulations and standards associated with GLP and GMP followed in industries. Further, create awareness on safety standards and the fundamental requirements of GLP and consequences of noncompliance for regulated laboratories.

MODULE-1

UNIT-1 **8L+8T+0P=16 Hours**

GOOD LABORATORY PRACTICE

Good laboratory Practices-Fundamentals, WHO guidelines on GLP and GMP, History of Good Laboratory Practices, Quality assurances in GLP.

UNIT-2 **8L+8T+0P=16 Hours**

QUALITY STANDARD AND ASSURANCES

Quality standards- advantages and disadvantages, concept of quality control, Quality assurance- their functions and advantages, Quality assurance and quality management in industry, Customer requirement of quality, Government and trade standards of quality federal food and drug law, FDA action, BSTI: action, activities and other food laws (Legalization).

PRACTICES:

- Indian policies related to GMP and GLP.
- Laws related to FDA.
- Quality standards for manufactured products.
- Report on WHO guidelines pertaining to GLP and GMP.

MODULE-2

UNIT-1 **8L+8T+0P=16 Hours**

QUALITY CONTROL

Introduction to quality control and total quality control in the food industry, Various quality attributes of food such as size, shape, texture, color, viscosity and flavor; Instrumental, chemical and microbial quality control, Sensory evaluation of food and statistical analysis, Food regulation and compliance, Food inspection and food law.

UNIT-2 **8L+8T+0P=16 Hours**

BACKGROUND, BIOSAFETY IN LABORATORY/ INSTITUTION

Laboratory associated infections and other hazards, Assessment of biological hazards and levels of biosafety, Prudent biosafety practices in the laboratory/institution, Introduction to biological safety cabinets, Primary containment of biohazards, Biomedical waste management, biosafety levels, Recommended biosafety levels for infectious agents and infected animals' bio safety guidelines; Government of India guidelines, definition of genetically modified organisms (GMOs).

SKILLS:

- ✓ *Following good laboratory practices*
- ✓ *Assessing the quality of products.*
- ✓ *Handling hazardous chemicals.*

PRACTICES:

- Quality control management in industry considering two industry examples.
- A report on Food inspection laws.
- Examination and preparation of a report on the functioning of biosafety cabinets in the biotechnology lab including the components.
- A report on Biomedical waste management in India.
- Disposal of biological and radio isotope wastes.
- Biosafety levels and related infectious agents handling.

COURSE OUTCOMES:

Upon successful completion of the course, students will have the ability to:

CO No.	Course Outcomes	Blooms Level	Module No.	Mapping with POs
1	Analyze GLP environment.	Analyze	1	6,7,8,9,10
2	Apply the principles of GLP.	Apply	1	4,7,8,5,9,10
3	Evaluate the risks and environmental release of GMO's.	Evaluate	2	6,7,8,9,10
4	Create awareness on biosafety guidelines.	Creating	2	3,6,7,8,9,10

TEXTBOOK:

1. Syed Imtiaz Haider, "Pharmaceutical Master Validation Plan the Ultimate Guide to FDA, GMP, and GLP Compliance", St. Lucie, 2002.
2. Hubbard MR, "Statistical quality control for the food industry", Springer Science & Business Media, 3rd edition, 2012.

REFERENCEBOOK:

1. Richmond JY, McKinney RW, "Biosafety in microbiological and biomedical laboratories", US Government Printing Office, 2009.
2. Nally JD, "Good manufacturing practices for pharmaceuticals", 1st edition, CRC Press, 2016.
3. Sharp J, "Good pharmaceutical manufacturing practice: rationale and compliance", 1st edition, CRC Press, 2004.