GUJARAT TECHNOLOGICAL UNIVERSITY

Program Name: Bachelor of Science
Level: Under Graduate
Branch Name: Honors/ Honors With Research (Biotechnology)
Course / Subject Code: BS02001061
Course / Subject Name: GLP and SOP Framework

W.e.f. Academic Year:	2024-25
Semester:	2
Category of the Course:	Ability Enhancement Course (AEC)

Prerequisite: Students must know about the basic function of the different kinds of laboratory. They must have basic ideas about different kinds of chemicals and reagents used in laboratories.
Rationale: This would emphasize the "how, what, where and who" of operations. This will help in understanding the guidelines for proper maintenance, sanitation, operation of equipment, and reporting related activities.

Course Scheme:

Teaching Scheme			Total Credits	Assessment Pattern and Marks				Total Marks
				Theory		Practical		
L	T	PR	C	ESE (E)	PA(M)	ESE (V)	PA (I)	
1	0	2	2	0	50	50	0	100

Course Content:

Sr. No.	Course Content	No. of Hours	% of Weightage
1	Introduction to good Laboratory Practices and need of SOPs in Laboratories Overall idea about good Laboratory Practices, History of GLPs, Fundamental points of GLP, Importance of GLP, Scope of GLPs Various standards guidelines for GLPs, Standard Operating Procedures.	3	20
2	SOP preparation Need of SOPs, regulatory requirements for SOPs, types of SOPs are necessary for GLP studies, How and who should write, review and authorize SOPs, regulatory requirements for reagents and solution.	3	20
3	Data Integrity in Analytical and Biotechnology Laboratories What is data integrity, Various regulatory guidelines for data management IT / Non IT, GLP/ GLP records, Current trends in Data inspection, Data Manipulation and Case studies.	3	20

4	Human Error Investigation and Reduction Strategies Understanding Accuracy, Precision, Reproducibility. Types of the error like systematic error, Random error, Negligent errors, pre analytical errors like observational error, instrumental error. Various Control mechanism to minimise errors.	3	20
5	GLP implementation GLP Lab Set Up, DQ, IQ, OQ and PQ, facilities, instrumentations and software. Personal. selection, Quality control procedures, QA, Documentation and Archiving, Gap analysis	3	20
	Total Hours:	**15**	

Reference Books:

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.

Course Outcome:

After Completion of the Course, Student will able to:

No	Course Outcomes	RBT Level
1	Students will learn the importance of GLP in the field of Biotechnology	UN,AP,RM
2	Apply skills to prepare, review, and authorize Standard Operating Procedures	AP

*RM: Remember, UN: Understand, AP: Apply, AN: Analyse, EL: Evaluate, CR: Create

List of Experiments: (Minimum 6 experiments need to be performed)

1. **Writing SOPs**: Create a laboratory SOP for a process, including all GLP-related sections.
2. **Data Management Simulation**: Use ELN software to enter data in compliance with data integrity principles (ALCOA).
3. **Identifying and Minimizing Errors**: Detect and correct common laboratory errors in a simulated experiment.

4. **Equipment Qualification (OQ)**: Perform an Operational Qualification on a piece of lab equipment.
5. **Gap Analysis & CAPA**: Conduct a GLP audit and develop a CAPA for non-compliance issues.
6. **Data Audit Trails**: Review and document audit trails for data integrity and regulatory compliance.

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