



GUJARAT TECHNOLOGICAL UNIVERSITY
Master of Science (Integrated-Biotechnology)

Semester: I

Subject Name: Good Laboratory Practices & SOPs

Subject Code: 1310406

Teaching and Examination Scheme:

| Teaching Scheme | | | Credits | Examination Marks | | | | Total Marks |
|-----------------|---|---|---------|-------------------|---------|-----------------|----|-------------|
| L | T | P | | Theory Marks | | Practical Marks | | |
| | | | ESE (E) | PA (M) | ESE (V) | PA (I) | | |
| 0 | 0 | 4 | 2 | 0 | 0 | 0 | 50 | 50 |

Prerequisite:

Students must know about the basic function of the different kinds of laboratory. They must have basic idea about different kind of chemical and reagents use 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 Content:

| Unit No. | Content | No. of Hours | 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. | 6 | 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. | 6 | 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. | 6 | 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. | 6 | 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 | 6 | 20 |
| Total Hours: | | 30 | |



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Reference Books:

Study material will be provided.

Course Outcomes:

| No. | Course Outcomes | RBT Level* |
|-----|--|------------|
| 1 | Students will learn the importance of GLP in the field of Biotechnology | UN,AP,RM |
| 2 | Students will learn the proper handling of instruments and data collection and maintenance | UN,AP,RM |

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

Suggested Course Practical List:

Not Applicable

List of Laboratory/Learning Resources Required

1. <https://www.technologyed.com/courses/good-laboratory-practices-glp-online-course-certificate/>