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Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

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ACCRE
Assuring and Advancing Quality in Clinical Research Education since 1965

CERTIFICATE PROGRAM IN GOOD LABORATORY PRACTICE / GOOD CLINICAL LABORATORY PRACTICE (GLP & GCLP)

Objective

A comprehensive training on fundamentals of GLP & GCLP and advanced understanding in an industrial setup. This training will help the trainees to develop the concept in a very methodical manner with real time examples.

GLP/GCLP guidelines are used in the evaluation of safety & efficacy of the several therapeutic drugs/ chemicals & devices in animal and human. GCLP is applicable to data generated through clinical experiments and studies conducted in humans for market authorization.

GCLP is a quality system of management controls that has been developed for research laboratories and similar bodies so as to ensure the regularity, homogeneity, dependability, reproducibility, quality, and integrity of clinical safety tests.

Why it is important to learn GLP/GCLP?

Some of the important reasons are:

1. Most of the error happens due to incomplete information; the basic objective is to build on the quality standards, before we learn the actual work.
2. Learning and applying principles of GLP would ensure that laboratory testing and results are of a good quality and are traceable.
3. It will help you develop very good understanding of the subject and getting absorbed in industry.
4. It will be easier to understand the work in industry, and deliver quality if one knows the fundamentals.
5. It will provide an edge to the students who opt for the program and through an interactive session, questions can be asked and answered.

GLP/GCLP training certification is important and need for trained and certified professionals is increasing. There is an immense need in the industry for people who are trained and certified in Good Clinical Laboratory Practices

Who Can Undertake the Course?

All the aspirants who want to enter into clinical research industry or Pharma industry in general shall attend it. It will help them to build their detailed understanding on the subject and eventually help them getting absorbed into industry.

This course is also suitable for all professionals working within industry, government, academia and/or contract testing facilities especially:

- Scientists at Pharmaceutical and development companies, CROs, BA BE facilities
- Regulatory/Compliance Personnel
- Quality Assurance Staff
- Professionals assigned with GLP/GCLP responsibilities

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India | Canada | US | UK | Saudi Arabia | Philippines |

Topics to be covered:

Module 1 – Introduction to GLP

- Introduction to GLP
- Fundamentals of GLP
- OECD GLP principal
- WHO GLP in brief

Module 2 GLP Lab Set Up

- SOP
- DQ, IQ, OQ and PQ, facilities, instrumentation's and software.
- Personal selection
- Staffing and training
- Quality control procedures
- QA
- Documentation and Archiving
- Gap analysis

Module 3 Analysis of Samples and QA

- Chromatography review
- Integration parameters
- Quality assurance

Module 4 Reporting and Investigation of Experiments

- Complete experimental work from start till end
- Study objective
- Description of test system
- Results and discussion
- References
- GLP complaint statement
- QA statement
- Investigations - Study based, Facility based and process based

Module 5 - Data Storage and Retrieval and Maintenance of Archive

- Records to be archived
- Indexing
- Placing the records
- Document transfer
- Retention period
- Disposal
- Dedicated electronic archiving system and maintenance

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Module 6 - Introduction to GDP

- Standards of GDP and its purpose
- Typical element of documentation
- Common documentation error

Module 7 - GCLP audit and Inspection

- Element of GCLP inspection
- Inspection objective
- Types of inspection and its application to 21 CFR part 320 and method validation
- Conducting a GCLP inspection of a BE study
- Inspection of analytical data
- Problem areas of GCLP inspection

Mode	Online Distance Learning	Eligibility	All medical, pharmacy, life sciences, nursing graduates & post graduates. Working professionals form the Pharma Industry, Laboratories, Clinical Trials, Pharmacovigilance and other Health Sciences.
Duration	03 Months – Online	Accreditation	Accreditation would be awarded upon successful completion of the program.
Methodology	Optional Online Training Sessions	Certificate	Certificate would be awarded upon successful completion of the program. Program to relevant organization and interviews would be arranged for appropriate positions.
Examination	Online MCQ exams	Fee Payment	Fee Payable by Cash, Cheque/Bank draft in the name of "TENET HEALTH EDUTECH PVT LTD." payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards. International : Through Debit/Credit cards using Paypal or wire payment through banks

Course Objectives:

- Provide basic understanding of GLP/GCLP
- Provide relevant job skills on GLP/GCLP
- Prepare you to face audits and regulatory inspections

Technology & Knowledge Partners

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Cliniminds, Unit of Tenet Health Edutech Pvt. Ltd.

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