Post Graduate Diploma GXP (GLP/GCP/GMP/CSV/21CFR Part 11)

Objective

This is comprehensive program in GxP for the life sciences industry. Program would provide you end to end understanding of several good practices used in the life sciences industry. The purpose of the GxP quality guidelines is to ensure a product is safe and meets its intended use. GxP guides quality manufacture in regulated industries including food, drugs, medical devices and cosmetics.

The most critical aspects of GxP are:

- Traceability: the ability to reconstruct the development history of a drug or medical device.
- Accountability: the ability to resolve who has contributed what to the development and when.

Following important life sciences good practices would be covered in the program:

GLP/GCLP

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 method discalmanner 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 oastoensure 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/cGMP/ICH-GCP responsibilities

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

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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

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

ICH GCP in Clinical Research

This is a comprehensive GCP Certification program, designed for the Medical Practitioners aspiring to work in the field of clinical research or allied professions like Investigator Site, Ethics Committee & Pharmacovigilance. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Program would help Medical Practitioners in developing career in the field of clinical research.

Program Details The program would cover

- Introduction to Clinical Research & Phases in Clinical Research
- Principles of Good Clinical Practices - ICH GCP
- Ethical Considerations in Clinical Trials
- Regulations in Clinical Research
- Sponsor/Investigator Responsibilities
- Investigator Responsibilities
- Clinical Trial Design
- Protocol Design
- CRF Design
- Essential Documents in Clinical Research
- IND Application
- Clinical Study Report
- NDA Submission
- Informed Consent Process & Documentation
- Site Selection & Pre-study Visits
- Site Initiation
- Subjects Recruitment & Retention Plan
- Site Contracts & Budgeting
- Routine Site Monitoring
- CRF Review & Source Data Verification
- Adverse Event Reporting

- Drug Safety Reporting
- Drug Accountability
- Site Close-out
- Standard Operating Procedures for Clinical Research
- Sponsor Compliance & Audits
- Site Audit

cGMP – Good Manufacturing Practices

The first GMP regulation was issued in 1963, one year after the enactment of the 1962 Kefauver – Harris Drug amendments. Although it took about eight years (1971) to revise them, they are in no way stagnant. Regulation defined the "cGMP as a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product".

This course is designed to provide extensive skills on maintain Quality procedures while manufacturing the drugs and other medicinal products, Validation of clean room, Risk Assessment & Process Control Plans and Documentation of cGMP compliance etc.

Program Details The program would cover

- Introduction to GMP
- Basic elements of a Quality Assurance program
- Roles of personnel working in GMP environments
- Facility design for cGMP compliance
- Concept of Clean Room
- Validation & Qualification Principles
- Risk Assessment & Process Control Plans
- Documentation for cGMP compliance
- Audits: Self Inspection, Vendor Audits
- Procurement
- Utility systems for the Pharmaceutical Industry

Computer System Validation

Validation is the process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages.

Global regulatory bodies (as part of their commitment to expedite & speed-up the treatment approvals) promote

submission of Manufacturing, clinical trials and all other associated data through electronic submissions.

It is a requirement that the submitted data meets ALCOA + so that the decisions are made quicker. (Accurate, Legible, Contemporaneous, Original, Attributable + Complete)

In the pharmaceutical industry, it is very important that in addition to final testing and compliance of products, it is also assured that the process will consistently produce the expected results. The desired results are established in terms of specifications for outcome of the process. Qualification of systems and equipment is therefore a part of the process of validation. Validation is a requirement of food, drug and pharmaceutical regulating agencies such as the US FDA and their good manufacturing practices guidelines.

A wide variety of procedures, processes, and activities need to be validated in this process.

Reasons for Validation

- Process parameters and controls are determined during the validation of any process or system.
- It helps to determine the worst case and risks that may arise during the manufacturing of the quality products.
- Validation helps to investigate the deviations caused during the process
- Deep study and understanding of the system equipment are made possible due to the validation and
- The risk of the regulatory non-compliance is minimized after the validation.

Validation Process

- 21 CFR Part 11 Evaluation
- 21 CFR Part 11 Remediation Plan
- 21 CFR Part 11 Development Activities
- 21 CFR Part 11 Ongoing Compliance

Critical Steps of a CSV

- System criticality Assessment (GxP/Non GxP – GAMP4/GAMP5)
- Assessing and managing the Risks
- Decision on Validation and the extent of Validation
- Selection of SDLC methodology (Water-fall/Agile/hybrid)
- Defining – designing - documenting the Business case & User requirement specification
- End to End CSV Validation Project Management
- Independent Compliance assessment (21 CFR Part 11)
- End to End CSV Documentation
- Adjudication and release
- Change controls

- Training and Operational SOPs
- On-Site Qualification kit (if applicable)
- Ongoing – Life time Regulatory inspection support

Steps in developing and implementing CSV

- Concept business development
- Planning & scoping
- Requirements & design
- Build
- Test
- Deploy
- Risk assessment level
- GAMP5 – CSV Framework for a configured product

21 CFR PART 11

Compliance Training on 21 CFR Part 11

Part 11 Assessment are the first steps to controlling your systems. As the USFDA increases regulatory enforcement of 21 CFR 11, one of the most challenging issue for many companies is to know what technological and procedural controls their computer systems require in order to be in compliance.

Cliniminds has conducted training sessions on several topics, including preparing for USFDA CSV Inspections, Automating CSV Processes, and 21 CFR Part 11 Compliance and Validation for Databases and Spreadsheets. 21 CFR Part 11 training includes:

- The history of 21 CFR Part 11: When and why was this regulation enacted?
- All definitions as part of Part 11
- Detail of requirements of 21 CFR Part 11, the US regulation covering Electronic Records and Electronic Signatures. What each clause of the regulation means and how it can best be complied with.
- What records and signatures does Part 11 apply to and records and signatures which are outside the scope of the regulations
- Part 11 technical, procedural, and documentation requirements for electronic records, electronic signatures, and open systems
- Security of computerized systems
- FDA Guidance on compliance with Part 11

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Mode	Online Distance/Online E learn
Duration	03 Months – Online
Methodology	Optional Online Training Sessions
Examination	Online MCQ exams
Eligibility	All medical, pharmacy, life sciences, nursing graduates & post graduates. Working professionals form the Pharma Industry, Laboratories, Clinical Trials, Pharmacovigilance and other Health Sciences.
Accreditation	Program is accredited by the ACCRE USA
Certificate	Certificate would be awarded upon successful completion of the program. Program to relevant organization and interviews would be arranged for appropriate positions.
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.
Course Objectives	International : Through Debit/Credit cards

- Prover overall understanding of GxP Compliances
- Provide basic understanding of GLP/GCLP
- Provide relevant job skills on GLP/GCLP
- Prepare you to face audits and regulatory inspections
- Better understand the regulations regarding clinical research in human subjects, ethics
- Better understanding of roles and responsibilities in planning and conducting clinical trials
- State the underlying principles of GMP & Quality, their significance in and develop practical strategies to apply those principles in the workplace. Understand how to integrate GMP elements into a Quality System
- Identify areas of GMP non-compliance and propose and implement corrective actions
- Define the current trends in International GMP compliance
- Provide understanding of 21CFR Part 11 and Computer System Validation

Technology & Knowledge Partners

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