Understanding the Regulations: GLP vs GCP vs GMP

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The quality of data or goods resulting from scientific research must be held to high standards. For this reason, the GLP regulations, GCP guidelines, and GMP guidelines must be followed. Good Laboratory Practice (GLP) regulates the processes and conditions under which clinical and non-clinical research is conducted. GLP also governs how these research facilities should be maintained. Good Clinical Practice (GCP) guidelines are dictated by the International Conference on Harmonization (ICH). The ICH GCP governs the ethical and scientific quality of clinical trials. The ICH GCP covers things such as the study design, methodology, and data reporting related to clinical trials. Finally, Good Manufacturing Practice (GMP) regulates the design, monitoring, and control of manufacturing processes and facilities. GMP compliance, for example, ensures the identity, strength, quality, and purity of drug products.

Good Laboratory Practice Regulations

GLP is intended to ensure the trustworthiness of laboratory data. In order for a study to be GLP compliant, it must have

- assigned study directors
- a quality assurance unit (QAU)
- standard operating procedures (SOPs) which researchers have been trained to adhere to
- a written study protocol
- a final study report

The Food and Drug Administration (FDA) has the right to inspect studies that are the basis for products marketed in the United States, irrespective of where the products were developed or manufactured. The FDA should conduct at least one routine inspection to determine if a study is GLP compliant at least once every other year. They may also conduct for-cause inspections if there is a reason to believe that a study site is failing to comply with GLP regulations.

Good Clinical Practice Regulations

GCP, on the other hand, is intended to ensure the safety of trial participants. It is important that there is a system in place to report all adverse events (AE) or severe adverse events (SAE). GCP also governs data collection during clinical trials. It is important that the data generated in the trial is recorded in compliance with GCP regulations to ensure its integrity. Under ICH GCP, the sponsor or sponsor-investigator must ensure that the required standard operating procedures are written and enforced. The sponsor must also set the level of the GCP monitoring process. The monitoring process itself must be documented to show that the study meets GCP standards before, during, and after the clinical trial. The FDA has a bioresearch monitoring program (BIMO) which inspects clinical and non-clinical studies associated with research and marketing submissions made to the FDA.

Good Manufacturing Practice Regulations

GMP regulations, as the name suggests, exist to control the quality of manufactured goods. GMP requirements are flexible to give each manufacturer the ability to choose how they implement the necessary controls. All GMP protocols rely on rigorously tested scientific principles. GMP also requires strict quality management, use of good quality raw materials, identifying deviations in product quality, and using reliable testing laboratories. GMP ensures consistent adherence to the quality standards required if the final product is effectively and reliably used. The FDA inspects pharmaceutical

companies around the world to determine if they are GMP compliant. If a company does not abide by GMP and therefore produces a defective drug, a recall may be issued. The FDA cannot force a recall but it can warn the public of the danger and seize any defective drugs present in the marketplace. The FDA may also acquire a legal injunction to address GMP violations.

GLP, GCP, and GMP regulations all exist to ensure that the processes they govern are held to high scientific and ethical standards. GLP regulations are mostly concerned with good study protocols and record keeping. These safeguard the integrity of the findings. GCP guidelines ensure that the safety of clinical trial participants remains of utmost importance. These guidelines are set by the ICH. Finally, GMP guidelines ensure that the manufacturing process is of a high standard with the appropriate quality control and quality assurance measures in place. In these ways, all three sets of regulations protect consumers, patients, test subjects, and researchers.

Difference Among GLP, GCP, and GLP

Topic	GLP	GCP	G
Responsibility	Study Director appointed by testing facility management.	The Study Sponsor is responsible. In a case where a study is conducted by a team of individuals, the Principal Investigator is responsible.	No Study Director single point of con
Quality Assurance Unit or Quality Control Unit	Quality Assurance Unit inspects critical phases of each study and periodically inspects the facility. Quality control system is not involved.	The Study Sponsor is responsible for implementing and maintaining quality assurance and quality control.	Quality Control Un approve or reject a aspects of testing/
Study Supervision	Testing Facility Management is responsible for designating a Study Director. The Study Director ensures that the facility, personnel, equipment, etc. is available and complies with the GLPs.	Study Sponsors are responsible for ensuring that a GCP study is adequately supervised. Whereas, Principal Investigators ensure that participating Sub-Investigators have adequate training and experience to assist in the study.	Supervisors shoul training. Responsi written procedures
Type of Testing Conducted	Open-ended determination of product performance, often for submission to the EPA or FDA for pre-market approval.	Studies that involve the participation of human subjects where data is intended to be submitted to regulatory authorities.	Determination of w product/sample ha specifications.

Facility	Design and construction must be suitable to the type of testing conducted.	The testing facility must have adequate facilities available for the foreseen duration of the study.	Design constructio the type of testing
Equipment	Equipment must be appropriate, maintained, calibrated, and the state of equipment documented to provide study reconstructability.	Equipment must be appropriate to safely conduct the study.	Equipment must b accuracy, sensitivi reproducibility in m processes.
Standard Operating Procedure (SOP)	SOPs must be drafted by a qualified personnel, approved by Testing Facility Management.	Drafted by a qualified personnel, and may be written by the Study Sponsor, Contract Research Organization, or Testing Site.	Drafted by a qualif approved by Quali
Protocol	Each study requires a study-specific protocol.	Each study requires a study-specific protocol indicating study objectives, methodology, statistical considerations, and organization of a study.	Study-specific prot required. Standard are followed.
Records	Signature or initials of personnel conducting all procedures, preparations, calibrations, etc. are required along with dates completed and must be on all records.	The Investigator maintains essential study documents for at least 2 years after the last approval of a marketing application or at least 2 years have elapsed since the discontinuation of clinical development of the product.	Signature of both t conducting proced verifying steps of p on all records.
CAPA System	Not required.	Not Required.	Required.

Have you ever faced problems while conducting experiment efficiently? Let us know about your experience while conducting experiments in the comments section below!

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