Good Clinical Laboratory Practice (GCLP) - Some Facts, Some Productive Thinking & Some Exploratory Thinking - What is your Take!?

**Introduction:** There are a trio of terms we need to define first –GCP and GLP, and the integration sort in GCLP**:**

* + 1. **Good Clinical (Research) Practice** (GCP) - is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected. It is consistent with the principles that have their origin in the Declaration of Helsinki (ICH-GCP Guideline).

Neither the ICH-GCP Guidelines nor the EU Clinical Trial Directive have defined detailed principles or guidelines/standards to be followed in the processing of clinical trials specimens. The EU Directive states that guidance documents may be issued to define the requirements for various aspects of trials. It is not clear whether these will include the analyses of clinical trial specimens and no integrative, internationally accepted guidelines are written for GCP related GLP. Within the ICH-GCP Guidelines, an inference can be drawn from a number of sections, including section 2.13, *“Systems with procedures that assure the quality of every aspect of the trial should be implemented”*, and also in section 8, “Essential Documents” parts 8.2.12, requirement of “*MEDICAL/LABORATORY/ TECHNICAL PROCEDURES /TESTS - To document competence of facility to perform required test(s)*, *and support reliability of results”,* and 8.3.7, requirement for *“UPDATES OF MEDICAL/ LABORATORY/ TECHNICAL PROCEDURES/TESTS, - To document that tests remain adequate throughout the trial period”*. There are no defined boundaries of performance (standards) in the ICH-GCP inference on clinical research laboratory systems. No unified, generic standard is proposed for clinical research laboratories to follow in the processing of specimens from a clinical trial. Ethics Committees/Institutional Review Boards, Investigators and Sponsors have clear requirements/guidelines under ICH-GCP. There are ICH-GCP guidelines of Investigational Product.

* + 1. **Good Laboratory Practice** (GLP) - is a quality system that deals with the organisational process and conditions, under which laboratory studies are planned, performed, monitored, recorded and reported (Organization for Economic Co-operation and Development (OECD) GLP Guideline). GLP practices are intended to promote the quality and validity of test data. You may still feel that, if GLP principles are followed, Good Clinical Research Practice requirements are met. Note that what clinical trials follow is not just Good Clinical Practice, which all medical professionals are taught when they train. What they are not trained on is Good Clinical ***Research*** Practices. These principles form a mandatory requirement training base for key personnel in a clinical trial; this is exactly the same with GLP which lacks the clinical research component. So an integration of GC(R) P and GLP gives GCLP.
    2. **Good Clinical Laboratory Practice** (GCLP) - applies those principles established under GLP for data generation used in regulatory submissions relevant to the analysis of samples from a clinical trial (WHO - GCLP/08). As we will presented in this discussion, demonstration is made of how the principles apply to the requirements of GCP and those principles established under GLP for data generation. This ensures the reliability and integrity of data generated by analytical laboratories for clinical trials. Note that there is a history to GC(R) P which resulted from scientific misconducts, leading to meetings, codes, reports, principles, directives, declarations and regulations. A clinical research laboratory deals with specimens in which the Investigational Product is not yet licensed for the management of a particular indication in subjects and the stakes are quite high should specimen processing systems fail or compromise the subject rights, safety and well-being.

**Why GCLP is Important -** It is recognized by site staff that clinical laboratories processing specimens from studies require Good Clinical Laboratory Practice training appropriate to studies and clinical trials to ensure that a critical mass of properly trained laboratory personnel is GCLP competent. The training is a handy set of consolidated standards to guide sites in good practices in the processing of specimens. We wish to identify generic systems required to compliance with principles of Good Clinical (Research) Practice (GCP). When trained personnel implement GCLP body of knowledge, they are assured of a framework for a quality system surrounding the analysis of samples. It ensures the integrity of analytical assays and results as required by ICH-GCP. Compliance with standards of GCLP meets the regulatory framework requirements. It offers Regulatory agents, Ethics Committees/Institutional Review Boards, auditors, monitors and the public, assurance that rights, safety and well-being of trial participants are safeguarded; that data integrity is maintained and that regulatory requirements are followed as per IGH-GCP principles. In implementing GCLP, laboratory personnel have a practical way of demonstrating fulfilment of the ICH-GCP Fundamental Principles of human research ethics.

If research is not conducted in a methodologically rigorous manner, the results will be scientifically unreliable or invalid, even where the research seeks to test socially valuable questions. The development and approval of a well-founded method is of little use if the research is conducted carelessly without regard to accuracy in data collection. It results in data that cannot be interpreted, and is a waste of time and scarce resources. Hence, poor science can be equated with poor ethics because**:**

* + 1. Subjects may be exploited and exposed to unnecessary risks during clinical trials; and,
    2. Limited resources may be wasted on research that produces results that are questionable.
    3. There will have been a miscarriage of the three basic principles considered the foundation of all regulations and guidelines governing research ethics. These principles, Respect for persons, Beneficence, and Justice are considered universal, transcending geographic, cultural, economic, legal and political boundaries.

GCLP compliance will ensure that consistent, reproducible, auditable, and reliable laboratory results that support clinical trials will be produced in an environment conducive to study reconstruction, and ensure the safety of research Subjects.

In clinical trials, biological assays are critical for the development of biologics and biopharmaceuticals. The stakes for inaccurate assays in clinical research are high compared to outcomes in a normal patient management and diagnostic medical laboratory. Many companies find themselves on clinical hold because of poorly-developed and inadequately validated potency assays.

It is recognized that there are no government standards that specifically apply to clinical research laboratories and the development of a GCLP Training focusing primarily on clinical research specimen processing laboratories is critical to the achievement research outcomes.

Improving laboratory capacity is more than supplying new equipment and reagents; that staff training, quality control, and biosafety as they relate to site laboratories are critical in the overall goal for research outcomes. Each research site should endeavour to contribute to the development of these required competences and strive for excellence specimen analysis under GCLP.