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EDITORIAL

Good Clinical Laboratory Practice: Eminence Challenge in Clinical Laboratory

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INTRODUCTION

In a clinical trial, good clinical laboratory practice (GCLP) is a standard system that provides guidance which applies in good laboratory practice (GLP) and good clinical practice (GCP) ethics for the investigation of samples.

GLP is one of the quality systems which overcomes the organizational process and different situations through it non-clinical laboratory studies are made, planned observed, verified, archived and reported. Quality and validity of non-clinical test data are planned and promoted by GLP (OECD GLP Guideline).

GCP is clinical trials which have to be planned, directed, watched, recorded, investigated and reported as per worldwide moral and precise quality that encompass the involvement of human individuals. On behalf of agreement with this standard, it provides community guarantee. According to GCP, welfare or maintenance of trial subjects become secure and constant by various ethics which have on basis of Declaration of Helsinki.

Considering combined guidelines of GLP and GCP, GCLP confirms the quality and reliability of the clinical trial data generated by laboratories. In 2003, the British Association of Research Quality Assurance (BARQA), first described Good Clinical Laboratory Practice guidelines, which were created to bridge the gap between guidelines for GCP and GLP. In other words, GCLP is one type of agenda through which organizations can do to develop systems and trials which give a guarantee of laboratory work and results.

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GCLP encompass all aspects related to clinical trial laboratory operations. These are mainly a system of laboratory, facilities, and equipment used in the laboratory. Materials and reagents also considered. GCLP embrace other features of a laboratory like standard operating procedures, work planning, trial materials, ways of work, reporting, quality control & audits along with storage and retention of study records as well as reports with its confidentiality.

For compliance with the GCLP standards, the laboratory should monitor annually by external audits, which helps to maintain clinical trial data integrity and produce reliable, auditable and repeatable results. Equipment available in the clinical research must be verified and "fit for purpose" as per GCLP guidelines. Documentation of proper installation, operation, maintenance, inspection, and calibration should be maintained for high quality.

For clinical sample analysis, the guidance of GCLP might be applied universally consequently enable patient assurance and security. Thus, it is significant for understanding GCLP guidance which must be interpreted and followed by work organizations. Laboratory administration might confirm that the rules of GCLP as assumed as per guidelines are compiled by the laboratory with the agreement of guidelines of GCP.

Suitable facilities, equipment, and materials accessibility must available in laboratory individual's skill also improve. Various records should maintain like educations, training, applicable experience and job responsibilities of every one individual employed in the laboratory. Personnel might understand the roles and responsibility. Health and safety precautions should take within the laboratory. Appropriate standard operating procedures (SOPS) must establish and follow in the laboratory.

Essential commands for procedure and maintenance of equipment might be followed by laboratories and also history record of all SOPS. Existing quality audit programme with a designated person must be planned and applied. Programme of QC is also operated through suitable, association of external expertise systems.

The investigative plan should be present which explains the investigation to be done in the laboratory. Sufficient personnel is appointed for suitable work done

efficiently. Before the starting work in the laboratory for every pilot, it must under the supervision of analytical project manager with the suitable qualifications, training, and experience. All laboratory employees have yearly defined job description including employee's whole presentation of job responsibilities, liabilities, and tasks. Individual or organization must be identified as their responsibility regarding the retention of trial and laboratory records.

Consequently, complete GCLP compliance is very critical. Such compliance by laboratories will support in their correct, precise and reproducible data. Implementation of GCLP guidelines in laboratories of all places like research bodies private and community sector will be a valuable stage in the improvement of health research and care services centers. Thus, unique quality possesses throughGCLP concepts, as these concepts embrace the research aspects, pre-clinical and clinical features of GLP.