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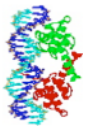

GLP and Your Company

GLP refers to the Good Laboratory Practice regulations first promulgated by the US Food and Drug Administration (FDA), and followed around the world. These regulations are written into the US Code of Federal Regulations (21 CFR Part 58) and have the full force of law. Good Laboratory Practices ensure the quality, integrity and reliability of nonclinical toxicology and safety studies performed in connection with the development of new drugs, but they have since become integrated into a much wider realm of drug and device industry operations.

GLP regulations were established by regulatory authorities beginning in the late 1970s to standardize and improve the methodology and practices for animal safety testing of investigational drugs in pre-clinical development. All investigational drugs are required to undergo safety testing in animals before regulatory authorities will allow the compound to advance and be tested in human clinical trials.

GLP covers many areas of laboratory operations and data acquisition. It requires proper procedures for keeping laboratory notebooks, data archiving, calibrating and validating equipment, labeling and handling of test articles and reagents, etc.

GLP also stipulates requirements for a quality assurance system and its independence from the management of the studies undertaken. This is to ensure the proper review, approval, documentation and archiving of the laboratory data and final report.

Formally, GLP is required for animal toxicology and safety testing and failure to comply with GLP regulations can result in serious consequences for the companies that prepare test data for human drug development.

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Although other kinds of pre-clinical testing activities may not required to be performed under GLP, most regulators and companies look for the same GLP practices in the conduct of their laboratory operations in other areas. In fact, a principle route of enforcement in the application of GLP to non-animal studies are the sponsor companies themselves, since they are ultimately responsible for their product and data to their countries' regulatory agencies.

Most GLP requirements appear very general and open-ended. This appears to allow flexibility, but in practice, auditors and regulators look for proven, industry-wide practices and procedures to ensure quality in the process. Good laboratory practice stresses the importance of the following main points:

- Organization
- Personnel
- Facilities
- Equipment
- Protocols
- Standard Operating Procedures
- The Study Director and His/Her Responsibilities for Study Control
- Characterization of Test Items and Test Systems
- Documentation, Including Raw Data, Final Report and Archives.
- Quality Assurance Unit (QAU) and its Independence from Management

GLP is not only a requirement for study conduct; it is also a good business tool that improves the performance of your company. GLP requirements lead to a quality approach using a system of continuous improvement. It assures you and your clients and regulators that the test methods and equipment are validated, that samples were received and documented properly, that the data that is generated is reliable and that the report and data were QA-approved and archived under secure conditions.

Before your company embarks on the path to GLP, it is necessary to establish a QA Unit and a quality system, such that all of your company's efforts are approved, implemented and documented in a traceable way. QA then establishes a system for documentation and control, including

SOPs and archives for data and reports.

All personnel working in GLP departments in the company, including the QAU, should be trained (to varying degrees) in GLP and other industry standards. All training must be documented by QA for each individual. This includes:

- Laboratory Workers and Operators,
- Quality Assurance Staff
- Study Directors
- Technicians
- Animal Care Personnel
- Support Staff
- Facility Managers
- Validation and IT Staff

Commitment to GLP and quality is critical at all levels of the organization, starting with top management. If you foster commitment, you will help make GLP a lifestyle in your company.

Enforcing GLP requires auditing to ensure that your efforts have been successful in establishing a GLP culture in the company. Audits can be internal, when performed by the quality assurance department as required by GLP, and external, which can consist of an FDA audit, a consultant checking your compliance status, a potential client's audit to establish your suitability as a contractor or supplier, or a vendor audit. The results of audits will determine if you need to modify your standards of performance. Of course, no procedures should be changed without documentation and approval from quality assurance in advance.

It is very difficult and time consuming to undertake the establishment of a GLP system without the help of organizations and experts that have done it before. Unless experienced personnel manage this process, you cannot be sure that your company will be compliant. BTK and its staff of experienced professionals stands ready to be your partner your quest for GLP excellence!

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