



Good Laboratory Practice Regulations vs. Good Manufacturing Practice Regulations: A Review of Their Intended Purposes and Requirements

by David M. Stephon

GLP and GMP regulations are compared and contrasted in detail. The author presents a thorough overview of this subject matter, as well as reviews specific critical regulations. Regulatory basis, operational environments, as well as a comparison chart for easy reference, are included in this article.

ARTICLE EXCERPT BEGINS

Regulation Differences: GLP and GMP

GLPs

“...As we review GLP and GMP regulations, we observe that many differences exist between these two sets of underlying regulations that govern the pharmaceutical industry. GLP is most often thought of as being personnel-oriented regulations. That is, there are actual defined positions within GLP regulations that are required in an organization or department that conducts nonclinical research. Specifically, GLP regulations require that there be a QAU, study director, and facility management. For this reason, GLP regulations are viewed as being prescriptive as compared to GMP regulations.

GMP

On the other hand, GMP regulations were promulgated in a manner that state much of the *what*, but not the *how* of compliance. This presentation of GMP regulations has been explained by FDA and industry experts alike as promoting innovation in industry to determine *how* the company actually complies with the *what* of 21 CFR Parts 210 and 211. This allows *current*, the lower case *c*, in cGMP, to be continuously refined by FDA enforcement, resulting in the evolution of “best of industry” practice into industry standard practice.

GMP regulations provide for a process-driven approach to compliance. In this environment, personnel play a critical role, but not the only role. GMP regulations present a holistic approach to how a company manufactures and controls the quality of the GMP process output, a safe, pure, and effective drug product of the correct identity and potency, whereas, the output from a GLP nonclinical research laboratory study is high quality, accurate, and reliable data.

Shared Attributes

These differences aside, there are indeed commonalities between GLP and GMP regulations. In GMP, a manufacturing operation is required to be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations to ensure that a product meet its pre-established specifications. GLP regulations require separate areas adequate to ensure proper separation of test systems, isolation of individual projects, animal quarantine, and routine or specialized housing of animals, as necessary, to achieve the study objectives. For a comparison of GLP and GMP requirements, please see *Figure 1*, starting on page 58...”

ARTICLE EXCERPT ENDS



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