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GLP and GMP in Contract Testing of Drugs and Biologics— What’s the Difference?



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There is confusion regarding the appropriate applications of good laboratory practice (GLP) regulations and good manufacturing practice (GMP) regulations, especially with regard to when they should be applied. There may be a preference for working under GLP based on the belief that GLP regulations are less onerous and less costly than GMP. The GMP definition of “manufacturing” includes testing and quality control of drug products. GLPs are intended for non-clinical laboratory studies. GMPs apply to products manufactured for administration to humans. FDA has recently issued CGMP for Phase 1 Investigational...

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