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Review

Guidelines on good clinical laboratory practice: Bridging operations between research and clinical research laboratories

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Abstract

A set of Good Clinical Laboratory Practice (GCLP) standards that embraces both the research and clinical aspects of GLP were developed utilizing a variety of collected regulatory and guidance material. We describe eleven core elements that constitute the GCLP standards with the objective of filling a gap for laboratory guidance, based on IND sponsor requirements, for conducting laboratory testing using specimens from human clinical trials. These GCLP standards provide guidance on implementing GLP requirements that are critical for laboratory operations, such as performance of protocol-mandated safety assays, peripheral blood mononuclear cell processing and immunological or endpoint assays from biological interventions on IND-registered clinical trials. The expectation is that compliance with the GCLP standards, monitored

annually by external audits, will allow research and development laboratories to maintain data integrity and to provide immunogenicity, safety, and product efficacy data that is repeatable, reliable, auditable and that can be easily reconstructed in a research setting.

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Keywords

Good clinical laboratory practice standards; GCLP; Quality control; Verification; Review

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