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Preparing for phase I unit regulatory inspections

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Clinical research organizations and industry have seen a paradigm shift towards the regulatory inspection scenario and data integrity standards that have taken the primary focus on the rights, safety and well-being of the trial subjects. The DI standards have become one of the key attention areas for the regulatory inspections, not that the inspectors are looking for fraud and maleficence. The systems used in the research industry have become more complex in terms of metadata that is being generated across the companies. The metadata that is created in a clinical trial is enormous and the inspectors are very aware of the possible DI issues that occur from time-to-time. The functions such as user access, data backup policies, audit trail, etc. have become the focus of attention. ALCOA principle is applicable to both paper and electronic data, thereby to ensure that the DI standards are followed all the time by all the personnel involved who generate the clinical trial data. To ensure that the DI standards are maintained across the life cycle of the clinical trial, quality systems should be in place and the rigor of sustaining the checks can be on a continual mode. This will ensure that the clinical trial data generated will meet all the applicable regulatory requirements. No doubt, in the coming days, the DI requirements shall be more demanding and key focus in clinical research.

Biography

Sudheendra K has his expertise in managing the GCP quality management systems at Syngene Clinical Development in the conduct of Phase I, bioequivalence, bioavailability studies. He has hosted many international regulatory inspections such as US FDA, EMA, ANVISA, Thailand GLP at Syngene Clinical Development. He is a trained Biochemist and has been associated with GCP QMS management for the last 14+ years. He has also audited many vendors and service providers who provide support for the contract research organizations for the conduct of early phase studies. He has also audited many complex clinical trials, Phase II and Phase III trials that have been conducted at different hospital sites.

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