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Managing US Food and Drug Administration inspections at Indian clinical trial sites-CRO perspective

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The U.S. Food and Drug Administration (FDA) conduct clinical site inspections under what is known as the Bioresearch Monitoring Program. The agency now conducts several hundred inspections of clinical investigators annually to obtain compliance with the regulations and to ensure that data submitted to the FDA are substantiated by appropriate records. The Inspection is simply a quality assurance process used to verify clinical data and regulatory compliance. However it can still be an unnerving experience, particularly if you are not prepared. Its important to know who gets Inspected? It may be because of High enrollment at sites, suspected data (no AEs, too many AEs and data not trending like other sites), large number of deviations, complaints against site etc. Data auditing and validate the data from the study is a Primary focus of FDA inspectors during the GCP BIMO inspections conducted at clinical investigator sites it helps to confirm credibility of data. The FDA inspectors verify the site delegations, study conduct and most importantly the documentation. Indian sites are not used to any audits or inspections of their medical practice or clinical research from any agency. Hence, they underestimate the importance of FDA inspection. It could result into a casual attitude to inspection. The Principle Investigator needs to devote 4--5 days time required for the inspection. The seriousness of the regulatory inspection should be percolated into every staff member of the institute. It requires a lot of planning from the team. The FDA inspection should not to be left to CRA and QA personnel. There should be a strong Management oversight. The investigator and his team should be appraised about the deficiencies in the conduct of trial and the site documentation, and advised about how to respond to FDA inspector's inquiries and findings, by training them in dos and don'ts for the interview and the inspection process.

Biography

Ashutosh Jani has completed his Ph.D from L. M College of Pharmacy, Gujarat University. He is the Head of Clinical Trials at Accutest Research Laboratory, Ahmedabad, a premier Independent Contract Research organization in India. He has published more than 10 papers in reputed journals and serving as an editorial board member of reputed journals.

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