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Audits and inspections- bioavailability and bioequivalence studies

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'Quality-the degree of excellence' is one of the most important aspect that human strive for, especially when it is related to human life and well being. Quality assurance audits and regulatory inspections are an important and essential part of clinical research with aim to evaluate the quality of the research conducted by sponsors, CROs and other institutions. Quality of clinical research revolves around two main parameters: Rights, safety and well being of subjects; and integrity of the data generated and submitted to regulatory authorities. Because of the steep increase in Bioavailability and Bioequivalence (BABE) centers and studies conducted in India, there is an increase scrutiny by the regulatory authorities across the globe to visit India based BABE centers to confirm quality of study conducted and to verify the integrity of data submitted. The outcomes of these inspections are mixed but sometimes negative with huge implications for sponsors. Although regulatory inspections for BABE studies generally occur after submission of data to regulatory authorities. These can something be unannounced and hence companies routinely runs 'inspection readiness and 'mock inspection programs'. The presentation aims to cover following topics: Brief introduction on quality in clinical research; quality control, quality assurance and regulatory inspections; process followed during audits and inspections; audit and inspections finding classifications; findings noted from recent regulatory inspections; and impact of regulatory inspections on BABE studies/centers and sponsors.

Biography

Bipin Patel has completed his Master in Pharmacy (specialization in Quality Assurance) in the year 2000 from Gujarat University (India). Since the year 2000, he has a worked as a Clinical Quality Assurance professional in various pharmaceutical companies and clinical research organization. He is currently the Director of Quality at RS Serve, a specialized clinical quality consultancy firm providing GxP services to pharma, bio tech and medical devices organizations. He has conducted more than 300+ GCP audits in Asia Pacific and EU regions. He has successfully faced regulatory inspections from DCGI – India, UK MHRA, US FDA, EMEA, Taiwanese FDA, Vietnamese MoH, South Korean FDA, ANVISA – Brazil, WHO, MCC – South Africa and Israel – MoH.

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