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An overview of regulatory expectation and guidance on incurred sample analysis

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Incurred Sample Analysis has been a hot topic since few years, ISR is used as a tool to prove bioanalytical method robustness and validity of sample analysis and the outcome of ISR experiments may open investigation process so as to address out of specification values. Regulatory bodies expects logical approach for such out of specification investigations, efforts must be made to obtain accurate study concentrations which in turn will decide accuracy of pharmacokinetic / bioequivalence data.

Biography

D. Vijaya Bharathi has completed her MSc from Osmania University and MPhil, Ph.D from Jawahar Lal Nehru University, school of Chemistry. She is working as Head- Bioanalytical in Dr.Reddys Laboratories, an emerging global pharmaceutical company. She has about 16 years for industrial experience. She has brought around 13 years of expertise in mass spectrometry in terms of analytical and bioanalytical research including identification, characterization of unknown impurities, metabolites and quantitative bioanalysis. She has published more than 35 papers in reputed journals. She has guided thesis of PhD, M Pharm, MSc, BTech students. She is the recipient of excellence award in the area of Bioanalysis.

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