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Bioequivalence inspection

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Statement of the Problem: Bioequivalence study is conducted on healthy volunteer/patient to compare pharmacokinetic parameter of test product and reference product. Generic company conducting/sponsoring the study should be aware of risks of rejection and non-compliance.

Methodology & Theoretical Orientation: Current topic will cover list of inspection findings from various regulatory agencies like US, EU and WHO and how to be ready for unannounced inspection, presentation will discuss current inspection trends and queries asked during dossier assessment.

Conclusion & Significance: This presentation will critically review inspector and assessors expectation on bioequivalence Understanding such expectation will help for early and successful approval of the product.

Biography

Ashish Mungantiwar is a PhD Pharmacologist by profession. He is working as President Medical Services in Macleods Pharmaceuticals Limited. He heads various departments like Bioequivalence, Clinical Trial and Pharmacovigilance. As Head of Bioequivalence he served as Study Director for more than 2000 bioequivalence studies. He has successfully handled more than 25 inspections from USFDA, WHO, EU and ANVISA. He has attended meeting with regulators of WHO and EU during approval process of the product. In order to keep his academic temperament alive, he works as PhD guide in industry and has already guided 5 PhD students. He is invited speaker in various international conferences.

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