BIOANALYSIS: EXTENSIVE APPLICATIONS IN DRUG DEVELOPMENT

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ABSTRACT:

Bio-analysis is an enlightened discipline for which the future holds many exciting opportunities to further improve sensitivity, specificity, accuracy, efficiency, assay throughput, data quality, data management and processing, analysis cost and environmental impact. Standards set by regulatory bodies regarding method development and validation increasingly define the limitations between speed and superiority. With this emphasis in the use of PK/ toxicokinetics and the greater strengths of innovative drugs, a sensitive and specific bioanalytical method is necessary. Many scientific activities are dependent upon accurate quantification of drugs and endogenous substances in biological samples; the focus of bioanalysis in the pharmaceutical industry is to provide a quantitative measure of the active drug and/or its metabolite(s) for the determination of pharmacokinetics, toxicokinetics, bioequivalence and contact response (pharmacokinetics/ pharmacodynamics studies). Bioanalysis also applies to drugs used for illegal purposes, scientific investigations and environmental concern. Therefore, it is generally accepted that sample preparation and method validation are required to demonstrate the presentation of the technique and the reliability of the analytical results. Now it is widely accepted that bioanalysis is an integral part of the pharmacokinetic/ pharmacodynamic characterization of a novel chemical unit from the time of its discovery and during various steps of drug development, leading to its market authorization.

KEY WORDS: Bio-analysis, Regulatory bodies, Validation.

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