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Harmonizing best practices in bioanalytical methods

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Application of chromatographic methods to quantitatively determine active drug constituents in biological matrices continues to be the subject of much debate. The definitions of validation parameters required in support of bioavailability, bioequivalence and pharmacokinetic studies have been suggested by scientists and regulators from the US Food and Drug Administration (FDA), the European Medicines Agency (EMEA), the UK Medicines Control Agency, the International Conference on Harmonization (ICH) and similar bodies from Canada, Japan and other countries. At the interface between the bioanalyst and the regulator, problems still occur due to the following reasons: (1) the problem-solving role of chemical analysis is not emphasized as a process or a chain of operations, as a consequence, bioanalysts are consigned to pigeonholes where they function as sample drop-off points, rather than active participants in solving analytical problems, (2) many of the technical terms used for evaluating analytical methods in different sectors of analytical measurements vary in terms of their definition and method of determination, (3) little emphasis was given to method development procedures and its merits of performance, which has also been confused with method validation processes, (4) the application of statistical methods to method development and validation data was relegated to a subordinate role in validation literature. Consequently, acceptance criteria was generalized while quantifying uncertainty was casually mentioned, (5) fitness for purpose bioanalytical methods were not emphasized nor practiced, and (6) both the analytical and pharmaceutical sciences are dynamic disciplines in which today's regulations do not fit tomorrow's problems. The above contributed to the misinterpretation of guidances among non-research based bioanalytical laboratories and regulators in different parts of the world. Examples will be presented based on experience with 400 bioequivalence studies.

Biography

Professor Maha Tutunji obtained her Ph.D. degree in Analytical Chemistry from Loughborough University of Technology, UK and her Masters degree in Physical Chemistry from Emory University, USA. She started her professional life at the Department of Chemistry, University of Jordan where she taught various undergraduate and graduate courses and supervised over thirty masters and Ph.D. students. She has conducted over 400 bioequivalence studies, in addition to phase III and phase IV therapeutic clinical studies. Her professional experience includes consultancy and advisory work for global pharma industry, science research laboratories, and governmental institutions including bioequivalence studies and disposal of industrial hazardous chemical waste. Professor Maha is the chief executive officer of Clinicalquest "Clinical Research Organization".

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