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Harmonizing best practices in bioanalytical methods

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Application of tandem mass spectrometry to quantitatively determine several analytes including active drug constituents in complex 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 Medicine 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, the MS spectoscopist, 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 pigeon holes 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 tandem MS methods in different sectors of analytical measurements vary in terms of their definition and method of their determination, (3) little emphasis was given to method development procedures and its merits of performance. This has also been confused with method validation parameters, (4) the application of statistical methods to method development and validation data has been relegated to a subordinate role in MS literature. Consequently, acceptance criteria was almost generalized, while quantifying uncertainty was casually mentioned, (5) the fitness for purpose bioanalytical tandem MS methods were not emphasized nor practiced, (6) both the analytical and pharmaceutical sciences are dynamic disciplines in which today's regulations may not fit tomorrow's problems. The above mentioned points contributed to the misinterpretation of guidances among non-research based bioanalytical laboratories and regulators in different parts of the world. The definition of the analytical requirement in support of bioanalytical data for new drug applications or INDAs including bioavailability, bioequivalence, pharmacokinetic, and pharmacodynamics data is still vague. Bioanalytes are still confused as to drawing a clear line between method development and method validation. Despite the advancement of state of the art analytical instruments such as tandem MS, which clearly enhanced sensitivity, the analytical science still lacks clear definitions which causes several serious analytical pitfalls.

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