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A global approach for the validation of bioanalytical methods and the assessment of measurement uncertainty

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During last decade, enormous efforts have been made to harmonize international validation procedures for bioanalytical assays. Different European and American authorities such as FDA, ICH and ISO continuously develop validation guidelines and directives about experimental design and data evaluation in the field of bioanalytical method validation. However, the utility of some of the recommendations is disputed, particularly given the lack of suggestion for the practical execution of a validation study. In the light of this critique, we have developed recently, a new global strategy for the validation of bioanalytical methods and the assessment of measurement uncertainty. Our purpose facilitates analytical validation by providing a decision tool based on both the uncertainty profile and the β-content, γ-confidence tolerance interval. Three different procedures were proposed to calculate the tolerance interval.

On the other hand, the measurement uncertainty is as an essential subject as analytical validation or even more. In fact, the estimation of measurement uncertainty is considered the major problem for Pharmaceutical and Medical laboratories because it requires a higher degree of technicality and mastery of statistical tools. One major advantage of the proposed methodology is that it can, without any additional experiments, give an estimation of measurement uncertainty based on the information from validation stage.

The applicability and flexibility of our approach was demonstrated by the validation of diverse bioanalytical procedures, which use different instrumental techniques such as liquid chromatography (LC-UV, LC-MS), gas chromatography (GC-FID, GC-MS), capillary electrophoresis (CE, CE-MS) and enzyme-linked immunosorbent assay (ELISA).

Biography

Taoufiq Saffaj received his Ph.D. in Chemistry from the University of Hassan II-Mohammadia, Casablanca, Morocco, in 2005. His research has focused on several lines: development of methodologies for pharmaceutical and biomedical analysis, and quality assurance for drug assays; chemometric pattern recognition covering methodological developments; experimental design and optimization of the analytical process; validation of analytical methods and estimation of the measurement uncertainty. He has published about 20 scientific papers on these subjects.

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