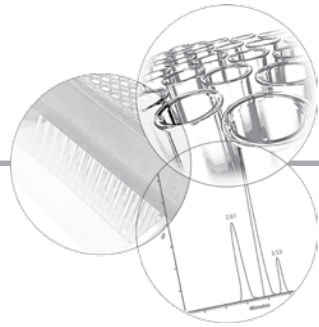

Request for Global Harmonization of the Guidance for Bioanalytical Method Validation and Sample Analysis

Open letter to the bioanalytical community. Sent to the US FDA/European Medicines Agency in February 2010

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The 2001 US FDA Bioanalytical Method Validation (BMV) guidance document has been widely accepted and adopted by the bioanalytical community worldwide. As such, it has become the cornerstone of regulated bioanalytical laboratory procedure. In recent years, clarifications to these FDA guidelines and subsequent enhancements were discussed at North American- and European-hosted meetings and conferences. The outcome of these meetings, published in White Papers, conference reports or recommendations, are currently being implemented in many bioanalytical laboratories around the world. Nevertheless, differences in expectations or interpretation of the guidelines from individual auditors/inspectors or regional health authorities are a growing concern for the bioanalytical community.

Further globalization of the pharmaceutical industry is also impacting the bioanalytical community. Bioanalytical labs are booming in regions outside the EU and North America, and regional authorities are looking to accommodate this growth or being confronted with the lack of guidance within their own regulations. Consequently, this creates a stimulus for these countries/regions to draft or issue their own guidance documents. The European Medicines Agency (EU), Medicines and Healthcare Products Regulatory Agency (UK), Agência Nacional de Vigilância Sanitária (Brazil) and Therapeutic Goods Administration (Australia) are the most prominent and recent examples. Although the 2001 FDA BMV guidance is often the basis of the emerging guidelines, there is an inherent risk that new sets of quality standards or nuances to the existing guidance will become effective.

Over the last few months, following discussions at international meetings that brought together health authorities and industry experts on bioanalysis, the industry has expressed their concerns that multiple regulations on a similar topic will not benefit data generated in bioanalytical laboratories worldwide. Bioanalysis has become a true global discipline and, as such, the bioanalytical community should be served with globally harmonized standards.

Therefore, the undersigned would like to ask health authorities worldwide to consider a collaboration and work towards a global harmonization of the guidelines on bioanalytical method validation and sample analysis for preclinical and clinical studies. Standardization and harmonization will largely contribute to the quality, transparency and efficiency of the data generated. These aspects are clearly of immediate benefit for the health authorities (ease of review of data) and laboratories (one set of standards), but eventually also for the patient and the community.

We are confident that all involved parties (health authorities and industry) will be equally supportive of this initiative. We are open to any suggestion on how to reach this goal and want to help wherever possible (e.g., cross-pharmaceutical–health authorities working groups, which can prepare a single discussion document, organization of a global meeting focused on harmonization).

The undersigned appreciate your consideration of the request outlined above. We are all willing to help coordinate respective efforts to support the harmonization of bioanalytical regulations and look forward to discussing such an initiative.

Sincerely,

Philip Timmerman (for the European Bioanalysis Forum [EBF]),
Steve Lowes (for the American Association of Pharmaceutical Scientists [AAPS]),
Douglas M Fast (for the Applied Pharmaceutical Analysis–Boston Society for Advanced Therapeutics [APA-BSAT]) and
Fabio Garofolo (for the Calibration and Validation Group [CVG])

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