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日本におけるバイオアナリシス分析法バリデーションの実施に関する指針（バイオアナリシスフォーラム素案）について

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Draft Guideline on Bioanalytical Method Validation in Japan by Japan Bioanalysis Forum

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Summary

This report presents the draft guideline on Bioanalytical Method Validation (BMV) in Japan, prepared by Japan Bioanalysis Forum (JBF) in response to a request from the Ministry of Health, Labour and Welfare (MHLW) working group, led by Dr Yasuo Ohno at the National Institute of Health Sciences. This draft guideline was developed because no detailed BMV guideline has yet been issued in Japan, though regulatory guidelines on BMV were published by the Food and Drug Administration (FDA) in the United States in 2001 and by the European Medical Agencies (EMA) in 2011.

JBF was founded in August 2011, and includes BMV experts from industry, academia and government agencies in Japan. After receiving the request from the MHLW working group, JBF promptly organized the JBF Guideline Task Force, a working group dedicated to preparation of the draft BMV guideline and consisting of members of the Steering Committee of JBF. The Task Force quickly prepared a preliminary draft of the BMV guideline. This preliminary draft was subsequently reviewed by the Steering Committee and further modified or clarified. The draft BMV guideline thus prepared by JBF will be the subject of further discussion after being submitted to the MHLW working group.

This report is composed of a preface and the following seven chapters and definitions: (1) Introduction, (2) Scope, (3) Reference standard, (4) Method validation, (5) Analysis of study samples, (6) Documentation and (7) Supplement. The contents of this draft BMV guideline are not significantly different from the published regulatory guidelines from the FDA and the EMA, though the initial scope of the draft BMV guideline in Japan is limited to the bioanalysis of small-molecular compounds using chromatographic analytical methods. Some new terminologies are proposed in this report, as proper definitions have not yet been established as a result of the lack of a detailed BMV guideline in Japan so far.

It is hoped that this draft guideline prepared by JBF will contribute to further discussion and development of BMV in Japan.

Key words

Regulated bioanalysis, Guideline on Bioanalytical Method Validation (BMV) in Japan, Japan Bioanalysis Forum (JBF), Biological sample, Chromatography, Pharmacokinetics, Quantitative determination, Toxicokinetics