Strategy for Implementation of 2018 FDA Bioanalytical Method Validation Guidance and Proactively Addressing the ICH M10 BMV Draft Guideline Internally and/or with Outsourcing Partners

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The recently issued 2019 ICH M10 Bioanalytical Method Validation (BMV) draft guideline will replace regional guidances, such as the 2018 FDA Guidance for Industry or the 2011 EMA Guideline on bioanalytical method validation, once finalized and adopted by the member countries. Given the importance of this document, much focus has been given to gathering and compiling comments and providing feedback to regulators. In particular, the annual Global CRO Council (GCC) meeting in April was dedicated to going line by line through the draft document, and additional meetings were sponsored by the EBF and AAPS throughout the spring and summer. This talk will summarize feedback to the draft guideline from the perspective of a contract research organization working in the LC-MS/MS bioanalytical field. The general industry reaction to the ICH guidance and the major changes that we foresee as a result of its adoption will be presented.