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AAPS eCT: Updating Regulated Assays in Anticipation of ICH M10

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Overview

The adoption of ICH M10 will introduce several operational changes in the regulated bioanalytical laboratory. While most of these changes are minor, depending upon the stage of development for a drug discovery program, they will need to be incorporated into the bioanalytical assay for future sample analysis. Among these changes are significant differences in the handling of dilution QCs during sample analysis, alterations to the placement of the mid-level QC in the analytical range, universal adoption of multi-aliquot stability QCs and specific instructions for validation experiment requirements for co-administered compounds. None of these changes represents major alterations to the bioanalytical assay; however, any change to a regulated method will warrant consideration and likely some level of validation. If additional validation is required, a priori acceptance criteria need to be established to demonstrate that the changes to the method to bring it into compliance with the ICH M10 guidance do not impact the integrity of the previously collected data or the integrity of any upcoming analysis.