

White Paper

Theme: Best Practices for Bioanalytical Methods: Recommendations from the Global Bioanalysis Consortium
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Small Molecule Specific Run Acceptance, Specific Assay Operation, and Chromatographic Run Quality Assessment: Recommendation for Best Practices and Harmonization from the Global Bioanalysis Consortium Harmonization Teams

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Abstract. Consensus practices and regulatory guidance for liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) assays of small molecules are more aligned globally than for any of the other bioanalytical techniques addressed by the Global Bioanalysis Consortium. The three Global Bioanalysis Consortium Harmonization Teams provide recommendations and best practices for areas not yet addressed fully by guidances and consensus for small molecule bioanalysis. Recommendations from all three teams are combined in this report for chromatographic run quality, validation, and sample analysis run acceptance.

KEY WORDS: bioanalytical assay validation; LC-MS/MS; sample analysis; small molecule.

INTRODUCTION

This summary is based on the discussion among scientific representatives from Mexico, Brazil, Argentina, Japan, India, the UK, Germany, Switzerland, and the USA serving on the Global Bioanalytical Consortium S1, S2, and S3 harmonization teams (HT). These are recommended best practices for

specific laboratory operations associated with run acceptance, assay operation, and chromatographic run quality assessment not addressed clearly or not addressed at all in current regulatory guidances or guidelines. In some cases, the team assessing an activity intentionally chose to recommend practices based on good scientific principles that are different from what current regulatory guidances may

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