Executive Brief

Multiple Attribute Methodology (MAM) by LC-MS

Overview

Multiple analytical assays are currently used for product quality attribute (PQA) monitoring and product purity testing throughput biotherapeutic development and production.

Accurate mass LC-MS using a Multiple Attribute Methodology (MAM) can:

- **Directly detect** and measure biologically relevant attributes
- Give increased confidence using an **Orthogonal assay** in process development and product release
- **Accelerate development** and reduce cost of quality

Moving to an LC-MS based MAM assay has historically been challenging due to:

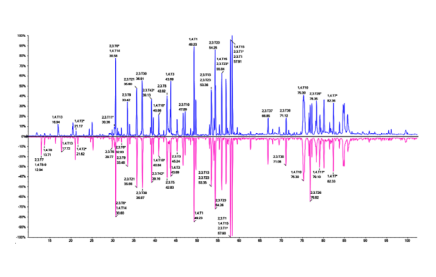
- Complex system setup and data acquisition
- Multiple steps and software platforms required to perform ID, quantitation, purity testing and reporting
- Software processing that limits the number of PQAs it can handle

Biologic PQA Assessments	LC-MS MAM Workflow	SEC	CEX	CE-SDS	HILIC	ELISA
Deamidation						
Glycation						
High Mannose						
Methionine Oxidation						
Signal Peptide						
Glycosylation						
CDR Tryptophan Degradation						
C-terminal Lysine						
Misincorporations						
C-terminal amidation						
Fucosylation						
Residual Protein A						
Host Cell Protein						
Aggregate						
Cysteine Adduct Assessment						

The new **Streamlined SCIEX Solution for MAM** removes these barriers, and puts powerful mass spec capabilities into the hands of all analytical scientists.

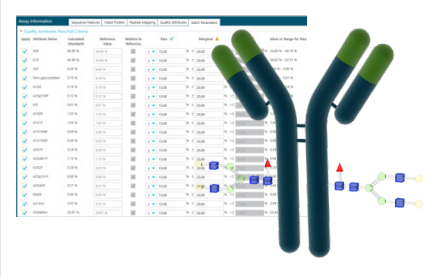
Benefits of SCIEX Workflow for MAM

Reproducible and robust LC-MS data to detect and quantify known components and confidently perform purity tests



Simplified development and running of MAM assay on X500B QTOF System with easy-to-use SCIEX OS user interface

Single software for identification, quantitation, new peak detection and reporting with BioPharmaView™ Software 3.0



Streamlined MAM with SCIEX X500B QTOF and BioPharmaView™ Software 3.0

Identify PQAs	Track PQAs	Quantify PQAs	Monitor Known Impurities	Purity Testing	Reporting
Characterize product, define attribute acceptance ranges and create standard method for implementation	Routine attribute tracking with accurate mass LC-MS	Simplified review with customizable and automated quantification of modifications at each site	Detect and track known impurity levels	Find and flag unspecified impurities with built-in new peak detection	Streamlined information transfer with customizable reporting in multiple output formats

Bottom Line: This streamlined methodology can be used to complement several conventional process development, QC, and release methods in a single simplified analysis. Moving to a powerful high-resolution, accurate mass LC-MS based MAM assay has never been easier with the user-friendly X500B QTOF System, and all-in-one BioPharmaView™ Software 3.0.

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