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	green	red	green	red	red	red
Glycation	green	red	red	green	red	red
High Mannose	green	red	red	red	green	red
Methionine Oxidation	green	red	red	red	red	red
Signal Peptide	green	red	red	red	red	red
Glycosylation	green	red	green	yellow	red	red
CDR Tryptophan Degradation	green	red	green	red	red	red
C-terminal Lysine	green	red	green	red	red	red
Misincorporations	green	red	red	red	red	red
C-terminal amidation	green	red	green	red	red	red
Fucosylation	green	red	red	red	red	red
Residual Protein A	green	red	red	red	red	red
Host Cell Protein	green	red	red	red	red	green
Aggregate	red	green	red	red	red	red
Cysteine Adduct Assessment	yellow	red	yellow	yellow	red	red

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

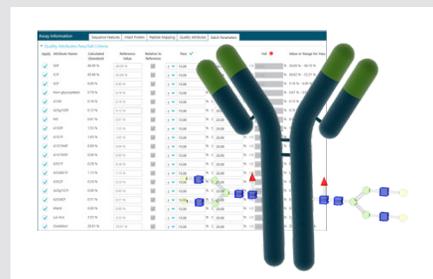## Benefits of SCIEX Workflow for MAM

Reproducible and robust LC-MS data to detect and quantify known components and confidently perform purity tests
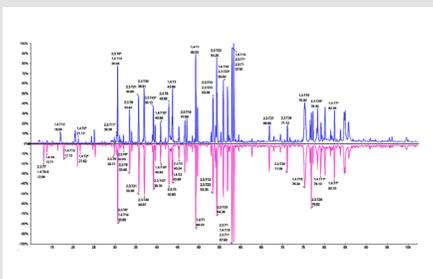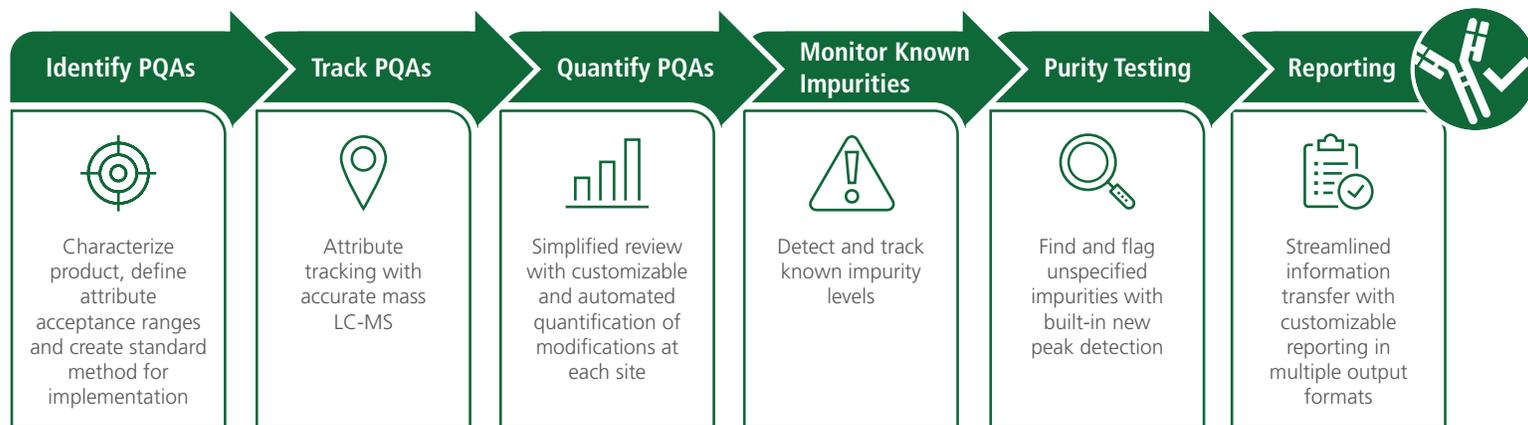
Flexibility to run advanced characterization assays and develop a powerful MAM workflow on the TripleTOF® 6600 System

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

Streamlined MAM with SCIEX TripleTOF® 6600 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	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 all-in-one BioPharmaView™ Software 3.0.

SCIEX