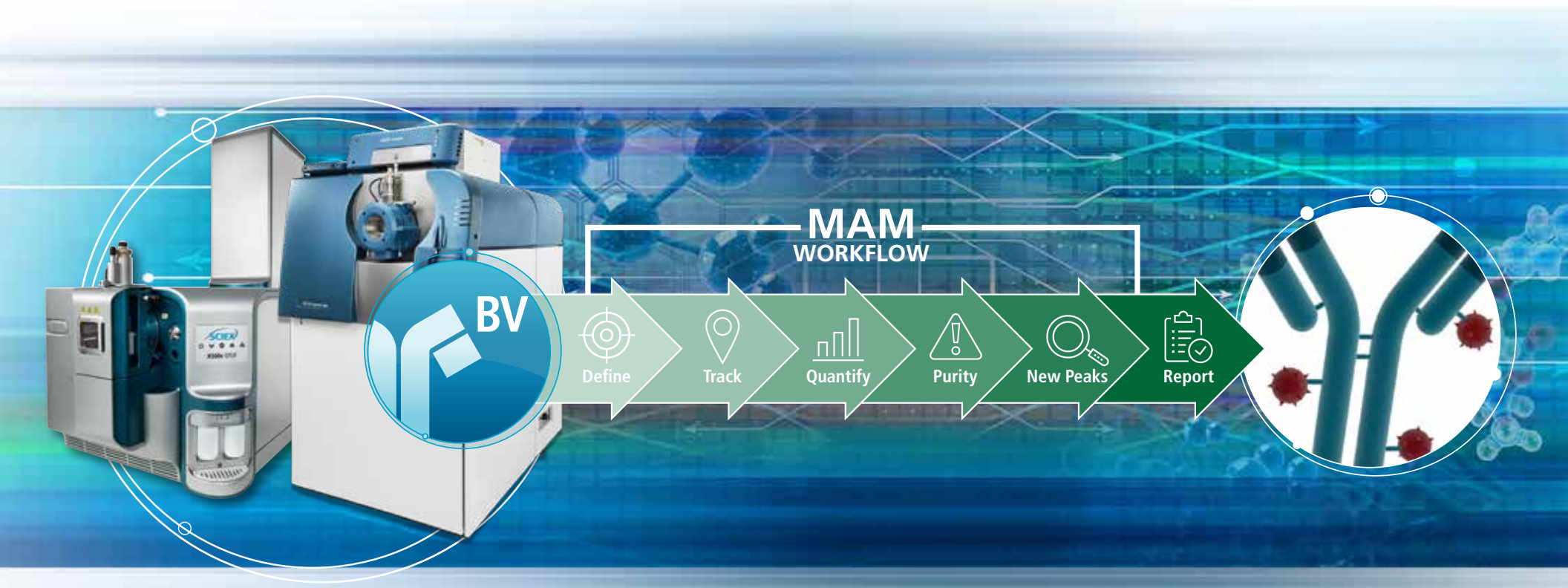
Streamlined and Complete LC-MS Workflow for MAM

Multiple Attribute Methodology (MAM) for Biotherapeutic Attribute Monitoring and Purity Testing



SCIEX

Answers for Science.
Knowledge for Life.™

See More, Do Less, with MAM

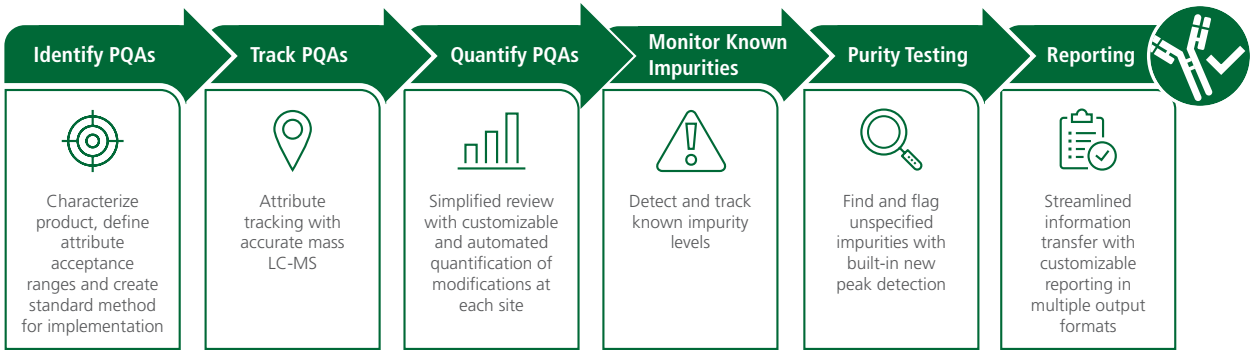
In biotherapeutic process development, evaluating and tracking potential product quality attributes (PQAs) is crucial to ensure quality, safety, and efficacy. Currently, multiple analytical assays are used for PQA monitoring throughout biologic development and production, which is resource intensive.

You can streamline your workflows with a faster, more in depth view of your biologic with Multiple Attribute Methodology (MAM) using Accurate Mass LC-MS:

- Directly detect and measure biologically relevant attributes
- Track known variants and contaminants
- Detect and flag the presence of unspecified impurities

The powerful yet straightforward SCIEX Workflow for MAM offers a single software solution for simplified PQA definition, monitoring, quantitation, purity testing and reporting.

Multiple Attribute Methodology (MAM) by Accurate Mass LC-MS



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						

Gain increased confidence by using an orthogonal assay, with more specific data on biologic attributes, by using accurate mass LC-MS technology in process development

SCIEX Streamlined Workflow for MAM

Complete Solution for Accelerating Biotherapeutic Analysis Throughout Development

Simplified Set-Up for Accelerated Results in a Compact Footprint

The **X500B QTOF** system is an easy-to-use, robust platform for streamlining your biologics characterization studies. Create, save and run methods easier with the intuitive **SCIEX OS** user interface.

Ultimate Workflow Flexibility in a Powerful Accurate Mass Platform

Gain the flexibility to do comprehensive characterization, MAM method development, quantitation, and high throughput comparability studies on the powerhouse **TripleTOF® 6600 System**.

Unparalleled Robustness with Ultra-Low Downtime

The **ExionLC™ AD** delivers excellent accuracy, reliability and repeatability across thousands of injections, with maximum uptime

Your All-in-One Software for Biotherapeutic Analysis

Power all your core biologics characterization analyses with **BioPharmaView™ Software 3.0**, now with tools to enable a complete MAM Workflow, including detection of unspecified impurities. Simplify biotherapeutic feature tracking with new software capabilities.

Explore the complete workflow and learn how to accelerate your biotherapeutic development.

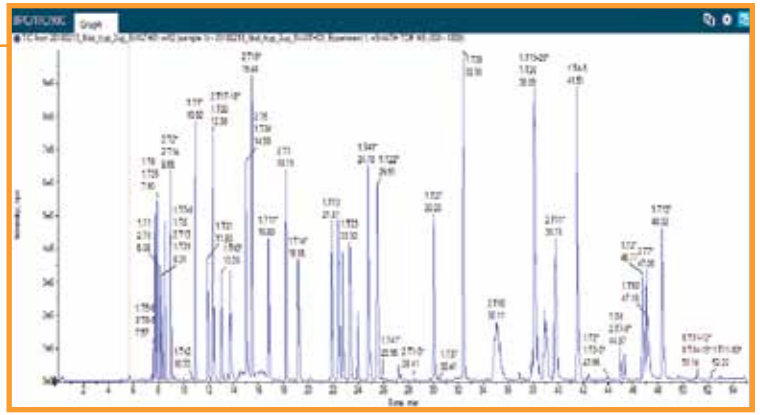
Identify PQAs

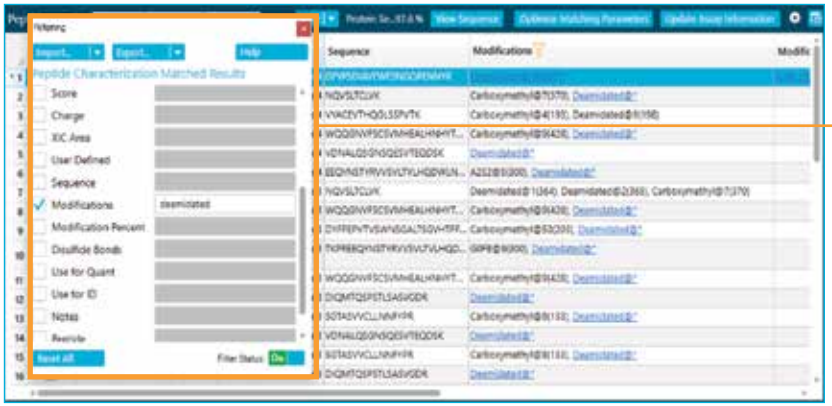
Expedite Attribute Characterization and Simplify MAM Method Development:

Comprehensive Characterization with Complete Detection

Get a more complete understanding of your biologic and track attributes that may be critical for safety and/or quality of the drug product.

With SCIEX proprietary SWATH® Acquisition, high-resolution MS/MS are acquired for all detectable precursor ions, providing truly comprehensive and unbiased data collection.





Focus on The Data That Matters to You Most

Intuitive and easy-to-use filtering options allow you to quickly dig into the attributes of most interest, such as deamidated peptides. Customizable tracking allows lets you to focus on the scientific questions at hand.

The Ultimate Confidence in Attribute Tracking

Get direct detection of modification levels for highly confident PQA identification and characterization.

Acquire high-resolution, accurate mass MS and MS/MS spectra of even low abundance peptides and post translational modifications (PTMs), such as deamidated species.

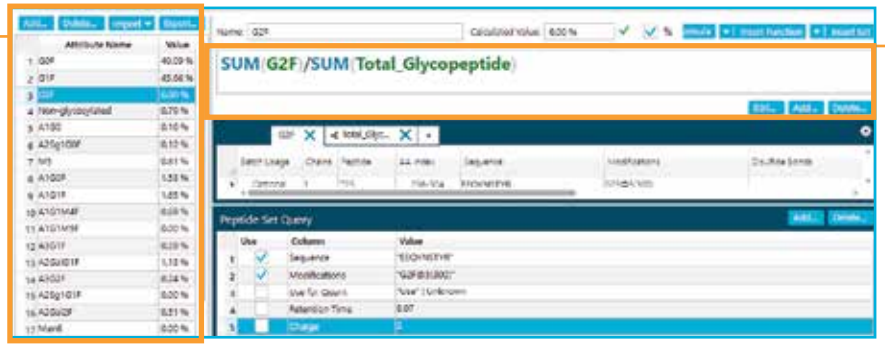
Track PQAs

Quantify PQAs

Customize Your View for Accelerated Analysis

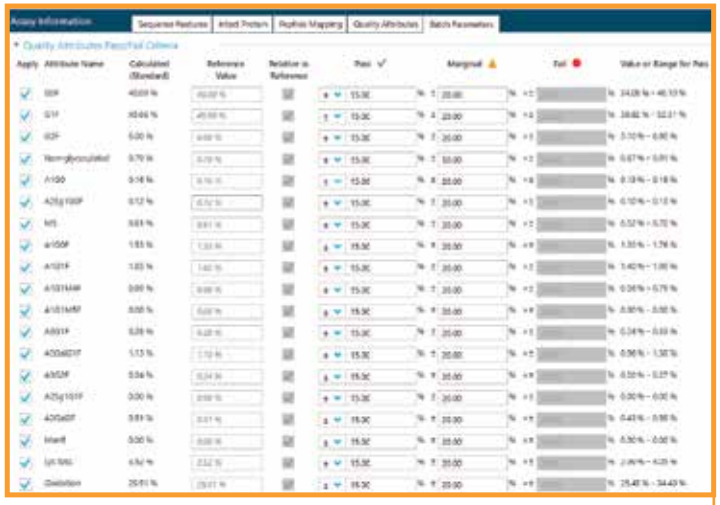
Simple Attribute Interest List

Get to what you need quickly and easily, define a list of attributes of interest and see defined acceptance values.



Customized Calculations for Simplified Review

With the flexibility to completely customize calculations for attribute comparisons, and modification ratios, you can make comparisons with orthogonal assays easier. Filter for peptide set creation to focus in on only what you care about.



Powerful Attribute Acceptance Criteria

Use your characterization results to define upper and lower acceptable boundaries for each attribute with powerful, yet flexible capabilities.

Acceptance levels are reflected directly in downstream studies with easy to understand flags.

Detailed Review and Interrogation

Each attribute can be interrogated in detail, with high-resolution MS and MS/MS data readily available.

Fast Batch Results Review

Attribute level batch results let you easily determine the 'pass' and 'fail' status at a glance.

Monitor Known Impurities

Simplify Analytical Complexities with Confident Identification, Monitoring and Flagging of Known Impurities, such as:

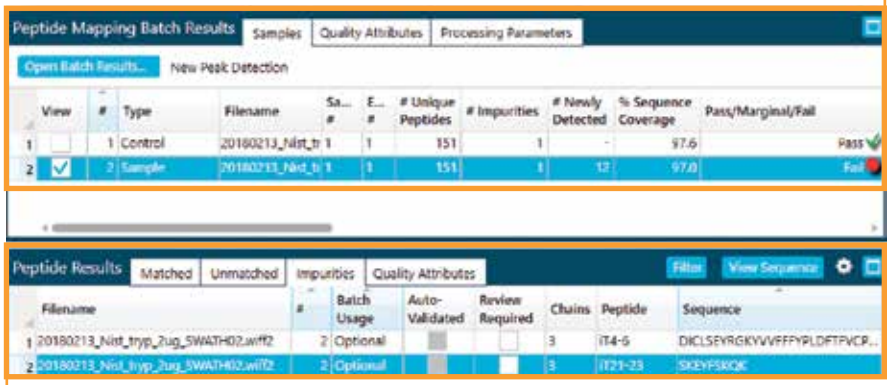
- Residual Protein-A to assess the quality of purification columns
- Fast check for host cell protein clearance
- Tracking of protein/peptide cell culture contaminants

Define Known Impurities for Automated Tracking

Simply define full protein sequences, or signature peptides, which are known and may be present in assays. Impurity sequences are searched along side biotherapeutic in all samples.

Clear Batch Level Pass/Fail Flagging of Impurities

'Pass' or 'Fail' criteria can be applied to known impurity levels, and may determine overall 'pass' or 'fail' status for the sample.



Get Detailed Impurity Information

Defined impurities can be viewed separately from the biotherapeutic product, and are uniquely annotated- expediting investigation of their presence or absence. Detailed information for the peptides detected from an impurity are listed in the results.

Purity Testing

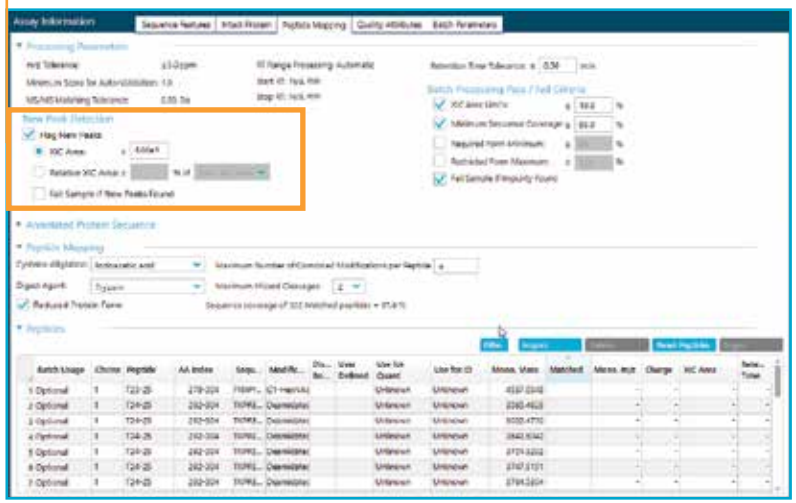
Built-In Unspecified Impurity Testing to Expedite Development

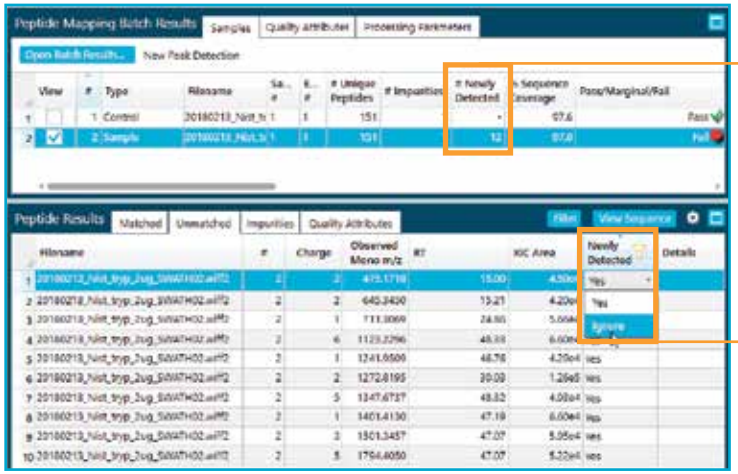
Accelerate your development process with a simplified approach to screen for unspecified impurities in a biotherapeutic product. In the same sample analysis used for PQA tracking and quantitation, you will get a confident and sensitive screen for the presence of any new components.

Innovative New Peak Detection Algorithm

Find and flag new, unspecified impurities that may be present in the product sample above a defined threshold.

Option to flag and 'fail' a sample if new peaks are found in the assay compared to reference standard.





Easily See New Peak Presence at a Glance

Batch results provide a rapid view indicating if new peaks are detected within a sample.

New Peak Flagging and Detailed Review

Peptide result data displays only new components with relevant information about each peak detected. If detected peaks are already known, or are not of concern, they can be set to 'Ignore' so you don't spend time reviewing them, giving you more time to focus on potential NEW impurities found in the product.

Capability to input descriptions for appropriate documentation and tracking of impurity detection.

Reporting

Reporting That's Quick and Easy to Interpret

Newly developed report templates for the MAM Workflow give you:

- Detailed acquisition and processing parameters
- Chromatographic separation information
- Attribute modification summary table
- Sample batch pass/fail table
- Specified impurities detected
- New unspecified impurities detected

Reports are available in simple, sharable formats for quickly assessing the levels of important attributes

Your Single Interface Solution for a MAM Workflow

In a single, accurate mass LC-MS method you can gain direct, detailed information on your biotherapeutic. Experience greater confidence in your biologic product with powerful orthogonal data, compared with other process development assays in use.

Develop → Optimize → Transfer → Run

Learn how your lab can stay at the forefront and develop powerful LC-MS methodologies to support faster, more assured biotherapeutic development.

Explore More at: sciex.com/MAM

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