# The Compliant-Ready LC-MS Workflow for MAM
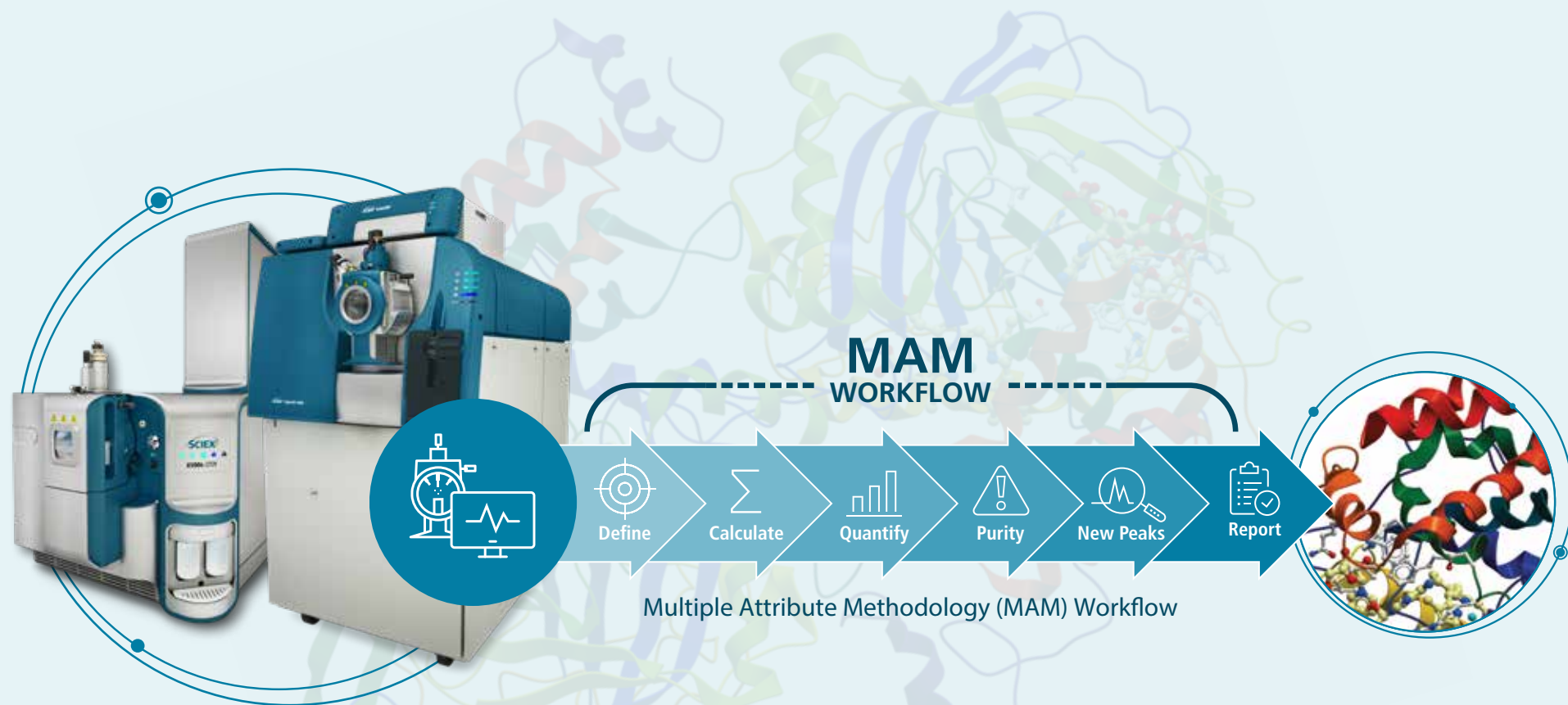
Multiple attribute methodology (MAM) for biotherapeutic attribute monitoring and purity testing



MAM WORKFLOW

Define → Calculate → Quantify → Purity → New Peaks → Report

Multiple Attribute Methodology (MAM) Workflow

SCIEX

The Power of Precision

# Multiple attribute methodology (MAM) by accurate mass LC-MS

## MAM with confidence and compliance

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
- ☑ Use the same workflow for intact or peptide-level analysis.

**The powerful, yet straightforward SCIEX Workflow for MAM offers a compliant and flexible solution for simplified PQA definition, monitoring, quantification and reporting.**

| 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 | green | red |
| CDR Tryptophan Degradation | green | green | red | 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 | green | green | red | red |
| Cysteine Adduct Assessment | yellow | red | yellow | red | red | red |

In a single LC-MS/MS assay, get direct physical information about many of your most important product quality attributes

# The SCIEX flexible solution for MAM

Complete solution for accelerating biotherapeutic analysis throughout development

### Ultimate workflow flexibility in a powerful accurate mass platform

Gain the flexibility to do comprehensive characterization, MAM method development, quantification 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

### 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.

### Compliant-ready acquisition and decision making

SCIEX OS automates key steps of analysis, streamlines all your workflows, and enables you to make informed decisions quickly. Enables MAM workflows at the peptide, subunit or intact level.

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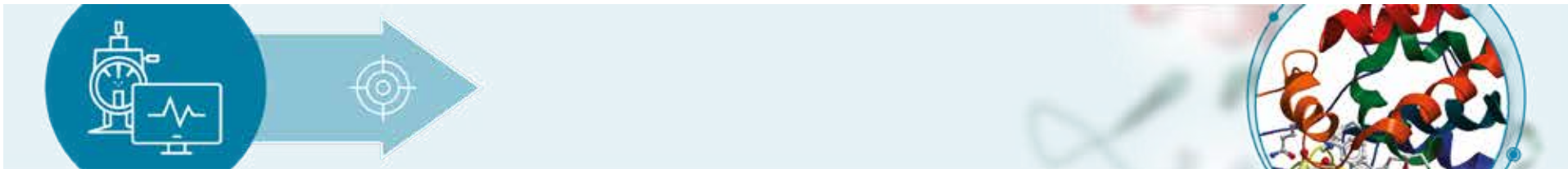
# Attribute discovery

Expedite attribute characterization and simplify MAM method development:

## Comprehensive Characterization with Complete Detection

- Simple and comprehensive detection of attributes
- Attributes can be at the level of peptide, subunit or even intact
- Easily acquire high resolution TOF MS, high resolution MS/MS with IDA or comprehensive and unbiased high resolution MS/MS with SWATH Acquisition
- Intuitive and easy-to-use viewing and filtering options in BPV Flex allow you to quickly dig into the attributes of most interest

## The flexibility to work with other software

If you prefer to do your attribute definition in another software, no problem. SCIEX OS supports the import of attribute definitions from several other software vendors including Protein Metrics and GeneData.
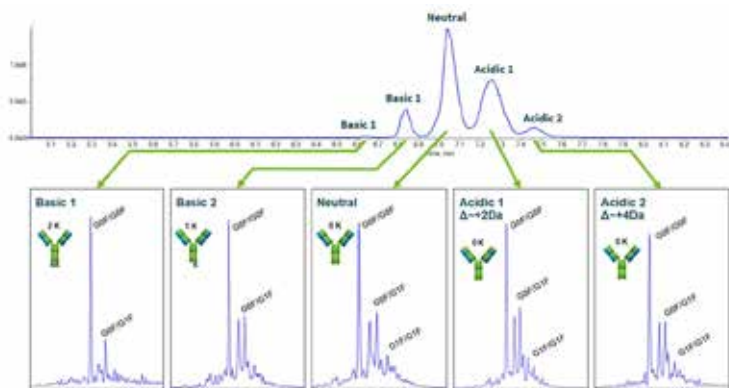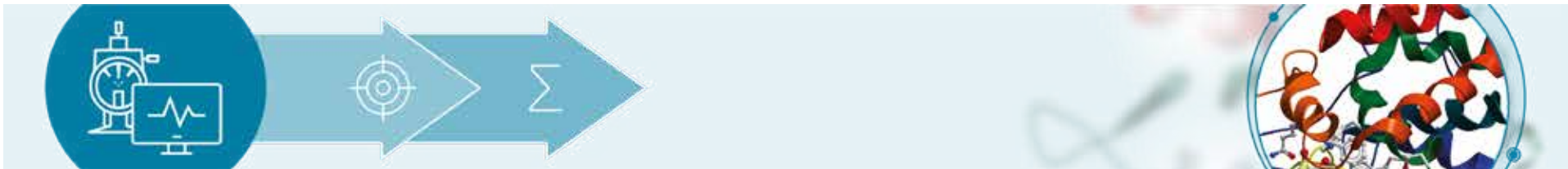
# Attribute calculation

## Customize how you calculate and quantify your attributes

### Full control of quantification

- Adjustable reconstruction and quantification parameters
- Parameters can be optimized per attribute and changes can be applied in real time

### Full control of calculation

- Customize how and what peak areas you use
- Customize the statistics of your peak areas (sum, max, mean, etc.)
- Customize how you calculate your percentages

# Attribute review

## Easily make insights about your MAM results

### Easily set acceptance criteria

Define pass/fail criteria based on upper limit, lower limit, ranges or % deviation from reference values.



### One click leads to the information you need

A live interface ties together attributes, visualizations, MS and MS/MS data.



Failed attributes

Visualization

# Impurity detection

## Built-in unspecified impurity testing to discover new species or contaminants

**Use chromatographic (ie retention time) or spectral (ie area ratio) information to easily identify new species.**

**Reliably and automatically find new peaks.**



| Rule name | AreaControl |
| --- | --- |
| Flag a results column | Area Ratio Control ⌄ |
| Flagging criteria | Range ⌄ |

| Rule name | RTDelta |
| --- | --- |
| Flag a results column | RTDelta ⌄ |
| Flagging criteria | Upper limit ⌄ |

**All new species have live links back to their chromatographic, MS and MS/MS information.**
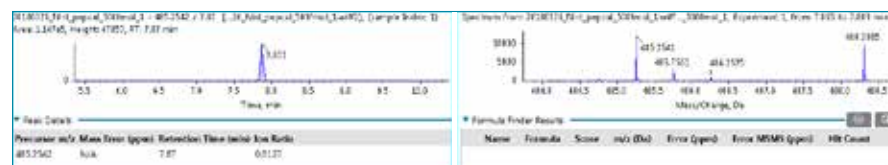
# Compliance ready

## Achieve all of your MAM functionality in a fully compliant-ready environment

### Full complement of compliance features

- Customizable user roles and security
- Password-protected method locks and recorded events

### A detailed audit trail

- Changes can be tracked in detail
- Before and after states can be viewed from changes
- All user changes are recorded

# Reporting

## Reporting that's quick to set up and easy to interpret

### Flexibility extends to reporting too

- Export to text files, PDFs or a variety of other formats.
- Use included templates or easily create your own
- Export all of the fields and parameters or just the ones you need
- Not just data – report trends and visualizations

| A compliant-ready system | Characterize product | Fully customizable calculation engine | Simplify review with automated quantification | Automatically flag deviations or fail attributes | Find and flag impurities with new peak detection | Streamline customizable reporting |
|---|---|---|---|---|---|---|
| • A compliant-ready system<br>• Easy to use acquisition software<br>• Auto tune and calibration | • Characterize product<br>• Define unlimited attributes, acceptance criteria and integration parameters | • Fully customizable calculation engine<br>• Make your attributes how you like them | • Simplify review with automated quantification<br>• Change quantification parameters on the fly | • Automatically flag deviations or fail attributes<br>• Easily review with real time data investigation | • Find and flag impurities with new peak detection | • Streamline customizable reporting<br>• Visualization and trend analysis tools |

# The SCIEX flexible solution for MAM

The flexibility to work across peptide level, subunit level or intact analysis of therapeutic proteins in a trusted, compliant-ready environment. The SCIEX flexible solution for MAM will accelerate your protein therapeutic development.

**Learn how your lab can stay at the forefront and leverage powerful LC-MS methodologies to support faster, more confident biotherapeutic development. Explore more at: sciex.com/content/SCIEX/na/us/en/applications/pharma-and-biopharma/protein-therapeutics/multiple-attribute-methodology-workflow**

## 20
### out of the top
## 20

**Pharma and BioPharma companies use SCIEX compliant LC-MS software solutions.**

**21 CFR Part 11 compliant-ready**
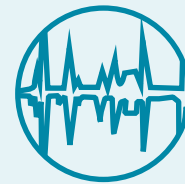
**Intact MAM capable**

**Peptide level MAM capable**

# SCIEX Now™ Support Network
## The destination for all your support needs

**Data integrity**

Increase your confidence with compliance services to help you safeguard your data, confirm data integrity and ensure system modifications can be traced.

**Onboarding**

We register you to SCIEX Now Online, enroll you in your SCIEX University™ learning path and send you a welcome email.
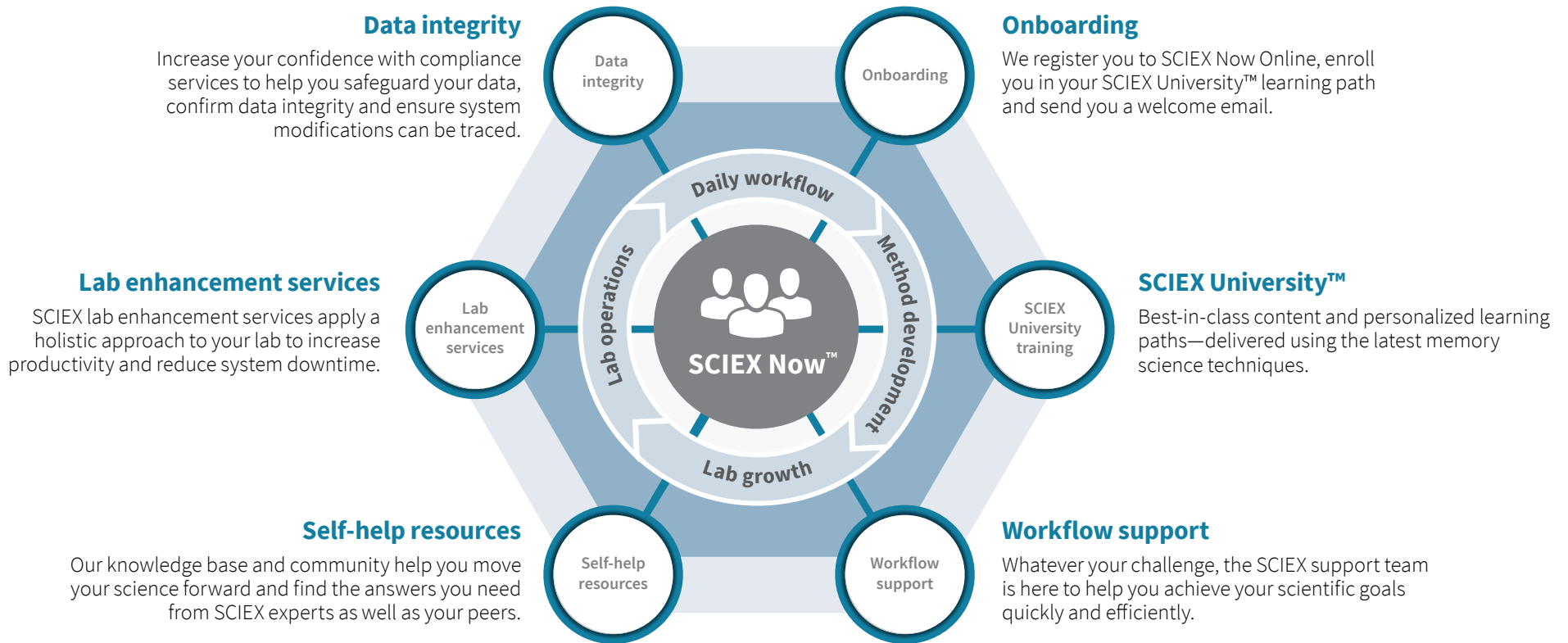
**Lab enhancement services**

SCIEX lab enhancement services apply a holistic approach to your lab to increase productivity and reduce system downtime.

**SCIEX University™**

Best-in-class content and personalized learning paths—delivered using the latest memory science techniques.

**Self-help resources**

Our knowledge base and community help you move your science forward and find the answers you need from SCIEX experts as well as your peers.

**Workflow support**

Whatever your challenge, the SCIEX support team is here to help you achieve your scientific goals quickly and efficiently.



Daily workflow · Method development · Lab growth · Lab operations

Data integrity · Onboarding · Lab enhancement services · SCIEX University training · Self-help resources · Workflow support · SCIEX Now™

**Start your path to success now: sciex.com/sciexnow**

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