BioPharmaView™ Software 3.0

Innovations for Biotherapeutic Characterization and Multiple Attribute Methodology (MAM) Workflows

The biotherapeutics market is pressuring organizations to speed development and become more efficient in the production and monitoring of their biologics products. Simplifying the processing of biotherapeutic characterization data during development can dramatically improve productivity. BioPharmaView software accelerates characterization and comparability studies and simplifies reporting so that you can make better decisions, faster.

Now with a complete and streamlined Multiple Attribute Methodology (MAM) workflow you can monitor and quantify product quality attributes (PQAs), track known impurities, and perform new impurity testing in a single software solution. By directly detecting and measuring PQAs by LC-MS you can reduce the number of assays needed for process development and product release, thereby accelerating development and reducing the cost of quality.

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Key Challenges in Biologics Characterization and MAM Workflows

- Accurate deconvolution of intact protein and subunit data is necessary to achieve confident molecular weight determination of biotherapeutics, and to assess drug to antibody ratio of antibody drug conjugates (ADCs)
- Comprehensive peptide mapping data can require complex and time-consuming data processing to determine sequence coverage, post-translation modifications (PTMs) and PTM ratios, as well as localization of disulfide bonds
- Detecting any new components that may be present in a biologic product is critical for a MAM assays to ensure product purity
- Manual calculations to determine PQA ratios is time-consuming and prone to errors, but is necessary for comparing LC-MS data output to other analytical testing outputs
- Monitoring known impurities in important to ensure that the product quality is maintained.

NEW Capabilities in BioPharmaView 3.0 Software

Single Software Solution for Complete MAM Workflow

- Perform product characterization, define PQAs as well as acceptable limits and automatic flagging parameters for routine MAM analysis
- Monitor and quantify PQAs, track known host cell protein contaminants, perform purity testing in one method
- Create a final report using the pre-defined report templates or create your own

Purity Testing with New Peak Detection

- Detect new features present in a sample compared to a defined standard with the New Peak Detection Algorithm
- Set user-defined thresholds for New Peak detection based on XIC area or as a percent of total XIC area/Max XIC area
- Option to fail batch if new peaks are found
- Identified impurities are listed in a separate tab which can be reviewed

Track Known Impurities

- Easily identify specified impurities
- Define a set of impurities, such as host cell protein contaminants, to track in samples
- Option to set Batch Fail if impurity is found
- Known impurities and their values are listed in a separate tab which can be reviewed

Save Project Parameters for Simplified Method Transfer

- Save processing parameters as well as modification sets and PQA acceptable limits to share with collaborators and ensure standardized workflow implementation
- Easily share attibute lists and custom formulas across projects

Define Complex Calculation and Acceptable Limits

- Customize complex calculations, such as modification ratios, to automatically report information in user-friendly format
- Define a parameter once and use it for multiple calculations
- Customize reporting table and define acceptable limits for automated outlier flagging and pass/fail assessments
- Set pass/fail limits and also marginal outlier limits

BioPharmaView Software Features and Benefits

Simplified processing setup

- Getting started is easy with intuitive main window
- Define the biotherapeutic sequence and choose from common post-translation modifications of interest
- Easily add custom modifications like proprietary linkers and drug conjugates
- Processes LC-MS data (TOF-MS, IDA, SWATH® Acquisition), as well as CESI-MS acquired data
- Enhanced data processing algorithms speed data analysis from hours to minutes

Rapid and accurate protein deconvolution of intact protein or subunit data

- Protein deconvolution in seconds
- Protein form matching and automated ratio calculations for PTMs, including glycosylation
- Ability to save and use batch processing parameters
- Multi-pane view allows you to see processed and raw data from multiple samples side by side
- Enhanced visualization tools, such as mirror plots and overlays

Automated drug to antibody ratio (DAR) calculations for antibody drug conjugates (ADCs)

- No more manual calculation of DAR
- Quickly visualize drug load on ADCs

Simplified Peptide mapping analysis

- Comprehensive list of identified peptides and modifications
- Visualize peptide mapping sequence coverage
- Direct visualization of raw MS level data and annotated high-resolution MS/MS data
- Easily localize post translational modifications and apply to future analysis
- Ability to easily filter peptide list based on multiple criteria, such as mass accuracy, for simplified viewing
- Assess data quality and processing parameters with enhanced MS/MS scoring

Automated PTM ratio calculations

- Save time and energy when comparing modified peptide levels
- Obtain modified peptide ratios for all your important PTMs, such as oxidation and deamidation
- Customize calculations to match your scientific questions

Automated disulfide bond localization

- Quickly and accurately map disulfide bond locations
- Bond localization confirmation using high-resolution, annotated MS/MS data for both peptides involved in the disulfide bond

Incorporation of UV data viewing

- Simplify data comparisons to other analytical techniques utilizing UV acquisition
- Easily compare UV trace data to MS data traces
- Enhance method portability to later stage analyses

Comprehensive Reporting

- Reports available in multiple output formats
- Show products that passed or failed your customized flagging criteria
- Easily transfer processed data exports to electronic notebook applications

BioPharmaView 3.0 Software Compatibility Matrix

Operating System	Windows 7 64-bit, SP1 Windows 10 64-bit
Supported Mass Spectrometers	X500B QTOF System TripleTOF® 5600 system TripleTOF 5600+ system TripleTOF 6600 system ***Note:** Compatible with CESI 8000 Plus High-Performance Separation-ESI Module up-front of TripleTOF 5600+ or 6600 systems
Compatible Analyst TF® Software	SCIEX OS 1.3 software SCIEX OS 1.2 software Analyst® TF 1.5.1 software Analyst TF 1.6 software Analyst TF 1.7 software Analyst TF 1.7.1 software

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