Click. Compare. Report.

Innovation for Biotherapeutic Comparability with BioPharmaView™ Software

SCIEX

Answers for Science.
Knowledge for Life.™

Comparability is Critical

Comparability is at the core of biologics characterization. You need to understand how the attributes of your biotherapeutic may have changed as it moves through your pipeline, or how a biosimilar stacks up to an innovator. And the faster you can assess the comparability of your biologic, the faster you can take the next step.

SCIEX understands how critical it is to confirm comparability. That's why we've built a fast and simple automated tool to help you keep your biotherapeutic moving. BioPharmaView™ Software enables you to quickly assess intact mass and peptide mapping analyses, and easily identify differences from site-to-site and from lot-to-lot, even with large data sets.

Everything You Need in One View

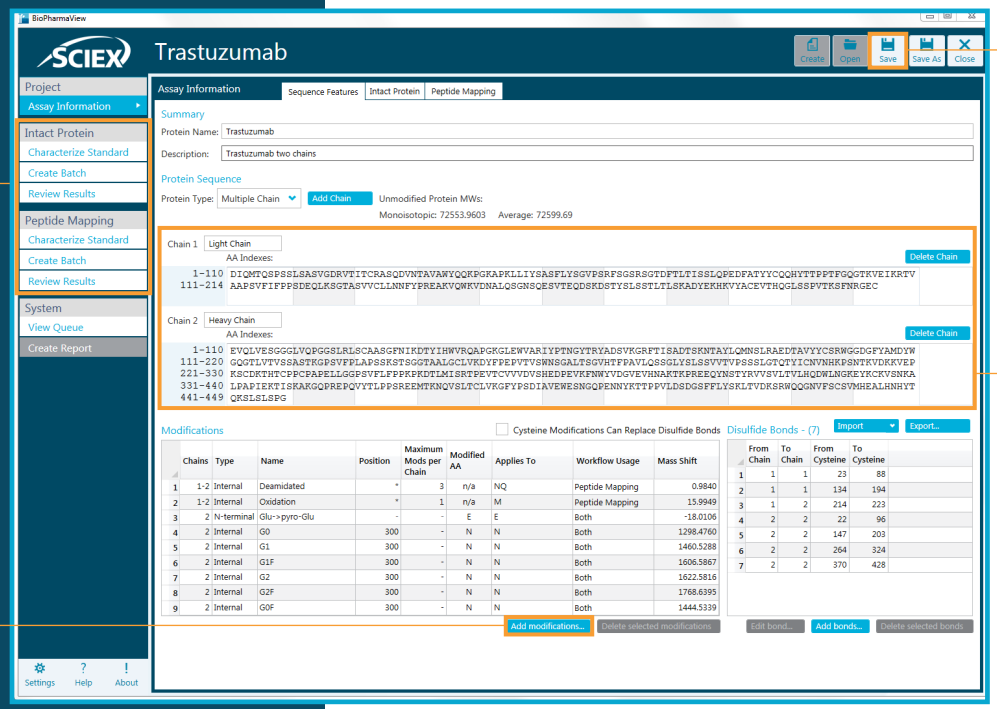
Getting started with BioPharmaView software is easy. From the main window, you can input your assay information and save your batch processing parameters. You can also define the biotherapeutic sequence and choose from common post-translational modifications, or easily add custom modifications of interest.

Compare it and Share it

When it comes time to report your results, BioPharmaView software provides you with comprehensive reports in multiple output formats. You'll be able to quickly show the products that passed or failed your custom flagging criteria, and easily transfer your processed data export to electronic notebook applications.

Gain a comprehensive view by analyzing the intact protein or protease digested forms in reduced or non-reduced states. Now with the ability to process data-independent SWATH® Acquisition

Easily add custom modifications like proprietary linkers and drug conjugates



Save assay information and parameters for batch processing

Simply define your biotherapeutic sequence and modifications of interest

Quick Look Intact Mass Comparability is Now a Reality

Perform accurate intact protein deconvolution in seconds.

The hardest part of Intact Mass Analysis is processing the data and comparing biologic product characteristics. BioPharmaView Software makes it easy with one click batch processing, protein form matching, and automated ratio calculations for post translational modifications, including glycosylation. The multi-pane view in the main window allows you to see the processed and raw data from multiple samples side by side, so you can be confident about your comparability conclusions.

One click batch processing and automated flagging on Pass/Fail comparability criteria

Mirror plot or overlays for easy visual comparison between samples

Powerful automated ratio calculations for modifications, including glycosylation

Increase confidence in the final output with direct link to raw data

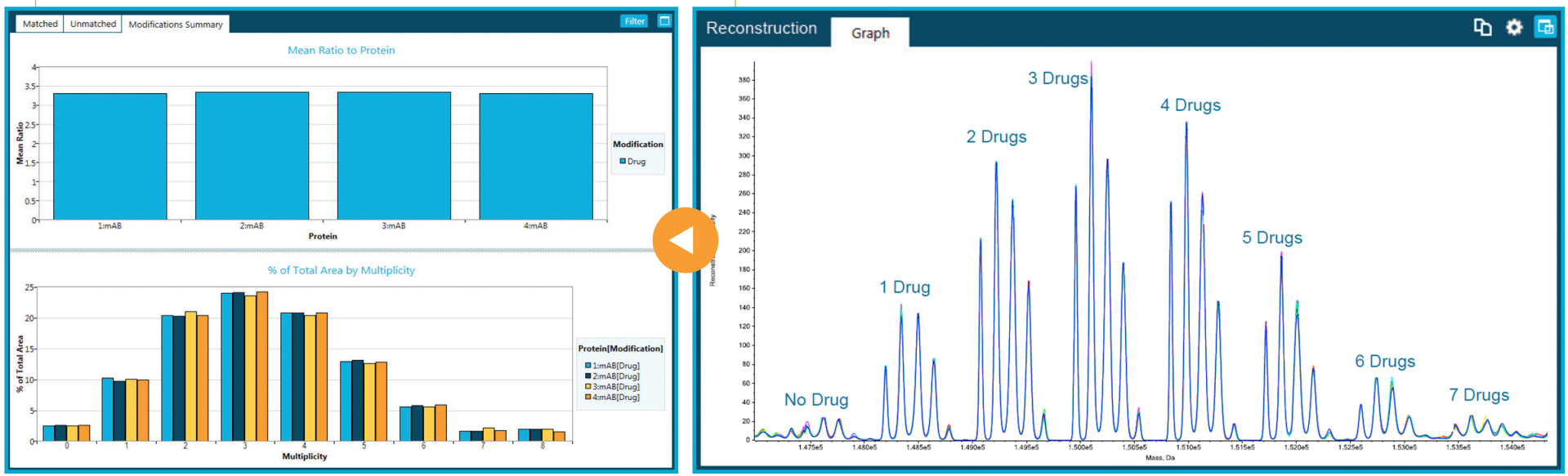
View of deconvoluted and matched protein samples

Intact analysis of 3 lots of therapeutic mAb protein. The first lot has significantly higher intensity than the assay standard, and is flagged by the Pass/Fail parameters, while the next two lots show comparable MS intensity. The graphical view of the glycosylation levels indicates all three mAb samples have comparable glycosylation patterns.

No Fear of Antibody Drug Conjugates

Intact analysis of antibody-drug conjugates (ADCs) can be challenging because of the size and complexity of the molecules. There's no need to worry about your ADCs with automated drug-antibody ratio (DAR) calculation and visualization, as well as a simplified—yet highly accurate—view of protein deconvolution in BioPharmaView Software. Comparing ADC products is much easier when you can see drug load and DAR across multiple samples, so you'll be clear on just what you've got—and how much.

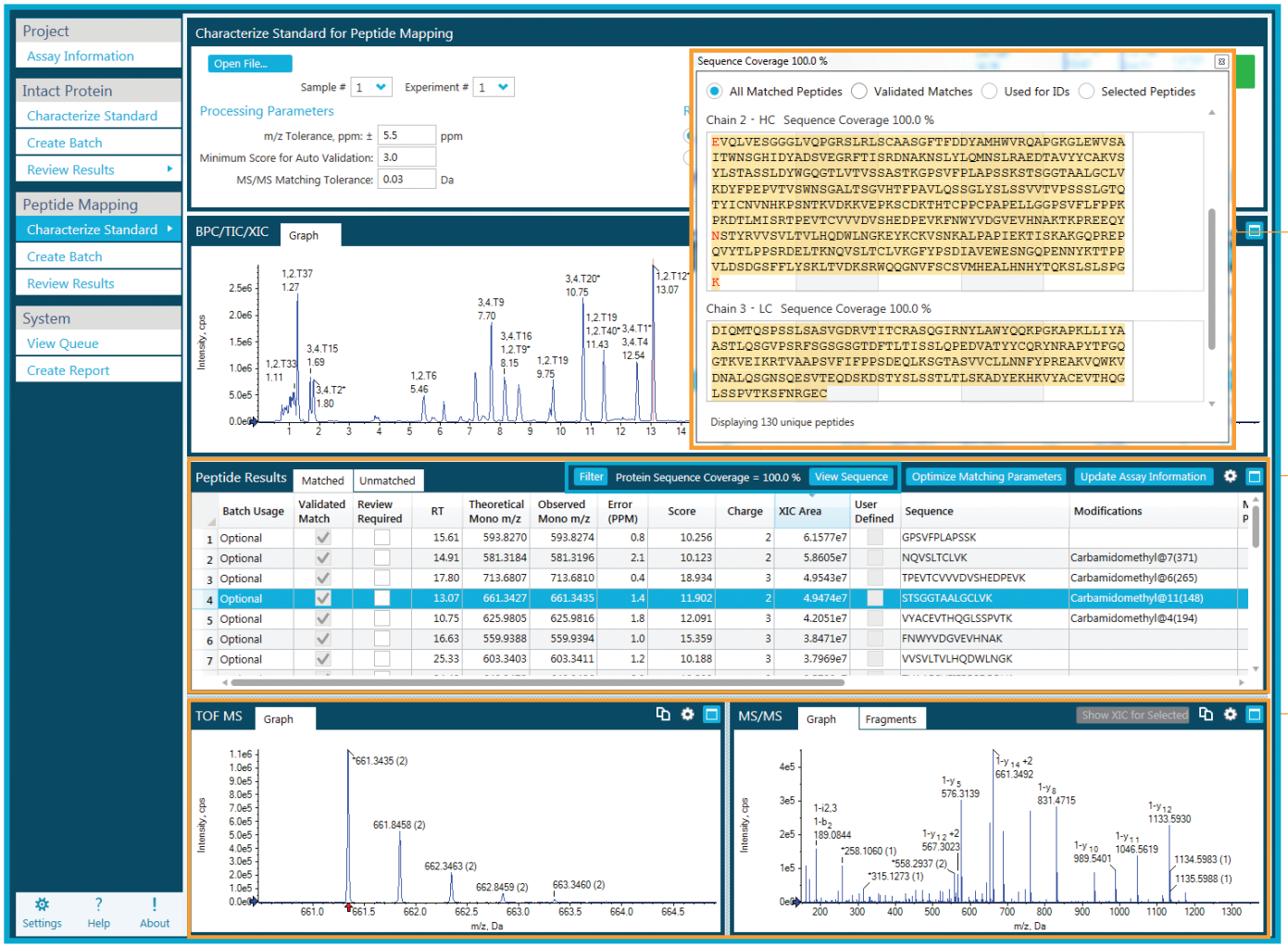
- Quickly visualize drug load on an Antibody Drug Conjugate and compare average DAR across multiple samples with the automatic DAR calculator
- Simplified protein deconvolution to view ADC drug states with high precision



Intact analysis of four lots of antibody drug conjugate therapeutic samples. The precise overlay of the deconvoluted spectra on the right indicates highly similar samples across the lots, for all drug states. The graphical view of the drug states and calculated drug to antibody ratio (DAR) on the left shows highly similar proportions of drug-protein form between all four ADC samples analyzed.

Peptide Maps in a Flash

Comparison of peptide sequences across samples is much faster and easier than before in BioPharmaView Software. Everything you need to see for peptide map comparability is available in one view: from comprehensive sequence coverage and PTM ratios, to the raw MS/MS data you need to see to confirm modifications, BioPharmaView Software provides an easy to use dashboard for Peptide Mapping. At a glance, you can compare peptides, PTMs, PTM ratios and disulfide bond localization.



Quick look visualization of peptide mapping sequence coverage across all mAb chains

Comprehensive list of identified peptides and modifications

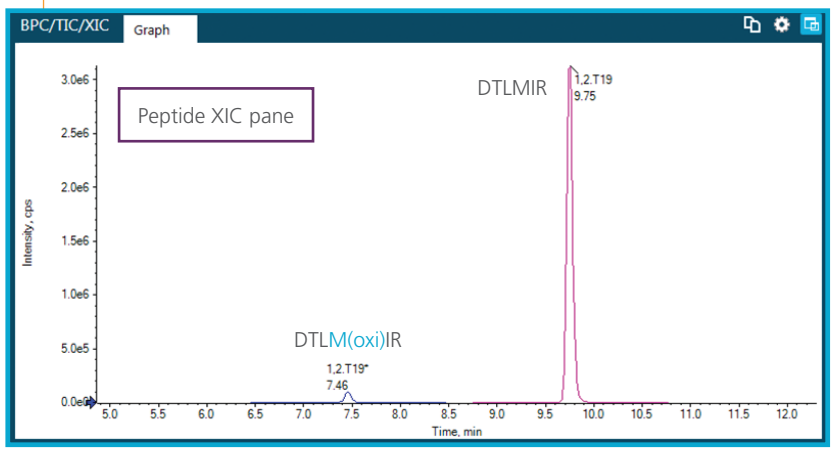
Direct visualization of raw MS level data (left) and annotated MS/MS data (right)

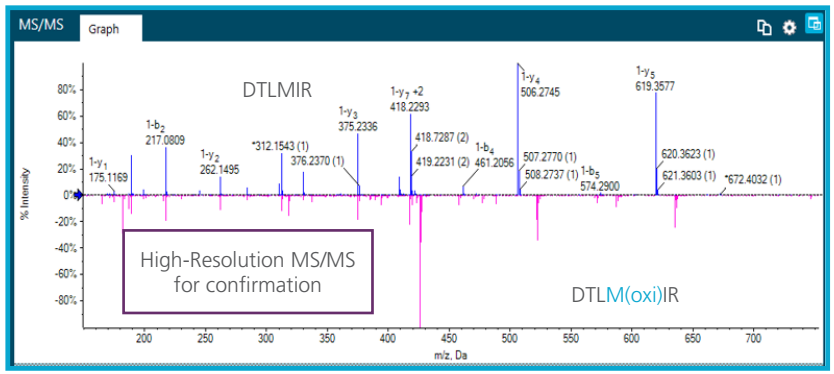
Peptide mapping using SWATH® analysis with 100% sequence coverage of adalimumab biotherapeutic on a TripleTOF system. Now with dramatically improved processing speed.

Low Level Modifications Can't Hide from SWATH® Acquisition

When performing Peptide Mapping of biotherapeutics, you have to determine where post-translational modifications are. Using SWATH® Acquisition and BioPharmaView Software processing, you can detect low level modifications—as well as confirm them in the high-resolution MS/MS spectra—all in a single run. Plus, automated calculation of PTM ratios means you can spend more time understanding your data, and less time crunching the numbers.

- Acquire complete high-resolution MS/MS data in a single run with SWATH Acquisition to ensure important peptide and PTM information is not missed.





Trypsin digested therapeutic mAb analyzed by SWATH Acquisition. Top pane shows high resolution XIC extraction of the MS1 level for the modified and unmodified peptide. Bottom pane displays the high-resolution MS/MS data for the unmodified peptide in blue, with alignment to the modified peptide on bottom in pink, allowing for simple and fast confirmation of the peptide identification

- Save time and energy with the automated PTM ratio calculation.

Peptide Details

	Validated Match	RT	Observed Mono m/z	Charge	XIC Area	Sequence	Modifications	Modification Percent
1		7.45	851.4295	1	6.7285e4	DTLMISR	Oxidation@4(256)	2.2% ±1.1 (Oxidation@4(256) : None@4(256))
2	✓	7.46	426.2202	2	4.7631e5	DTLMISR	Oxidation@4(256)	2.2% ±1.1 (Oxidation@4(256) : None@4(256))
3	✓	9.75	418.2221	2	1.3938e7	DTLMISR		97.8% ±1.1 (None@4(256) : None@4(256))
4		9.75	835.4351	1	5.9211e6	DTLMISR		97.8% ±1.1 (None@4(256) : None@4(256))

Detailed % modification is automatically calculated between the modified form of the peptide and the unmodified form. For the DTLMISR peptide 2.2% contains oxidation of the M residue

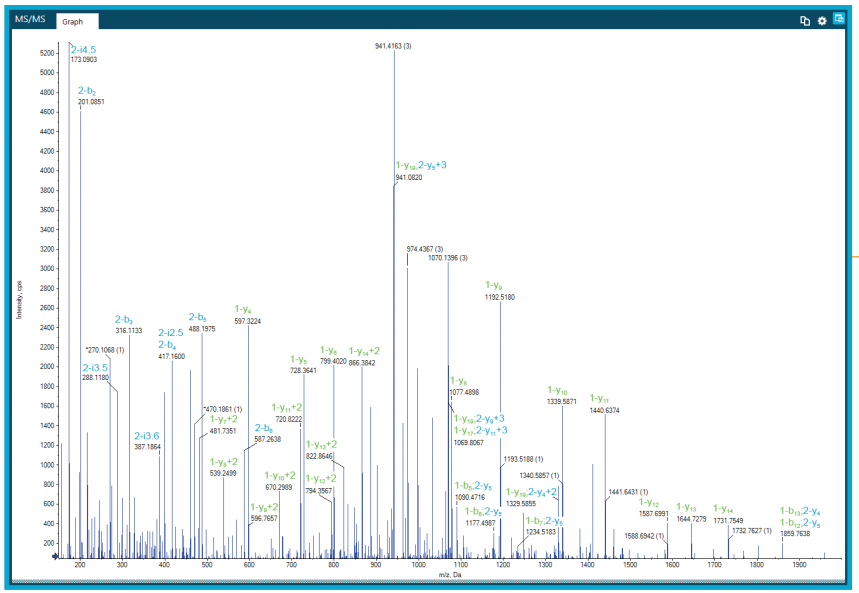
Where are the Disulfide Bonds?

Localizing disulfide bonds is no easy task. But the algorithms in BioPharmaView software make quick work of defining the bond locations and presenting the high-resolution, annotated MS/MS spectra for confirmation.

Quickly and accurately map disulfide bond locations in an automated fashion to simplify your data analysis. Confidently assign bond localization using the high-resolution, annotated MS/MS spectral data.

Peptide Results | Matched | Unmatched | Filter | Protein Sequence Coverage = 99.1 % | View Sequence | Optimize Matching Parameters | Update Assay Information

	RT	Theoretical Mono m/z	Observed Mono m/z	Error (PPM)	Score	Charge	XIC Area	User Defined	Sequence	Disulfide Bonds	Notes	Peptide
19	21.47	1186.2570	1186.2567	-0.2	15.366	3	5.6358e5		SGTASVVCLLNNFYPR VYACEVTHQGLSSPVTK	(3,4)T20@4(194)=(3,4)T13@8(134)	Validated match	T13 T20
20	22.45	852.6256	852.6272	1.8	16.824	4	9.7560e5		LSCAASGFTFDDYAMHWVR AEDTAVYYCAK	(1,2)T3@3(22)=(1,2)T9@9(96)	Validated match	T3 T9
21	24.57	764.7626	764.7643	2.2	6.016	5	9.4508e5		VTITCR FSGSGSGTDFTLTISSLQPEDVATY...	(3,4)T2@5(23)=(3,4)T7@27(88)	Validated match	T2 T7
22	24.57	1273.9329	1273.9346	1.3	13.438	3	1.0835e6		VTITCR FSGSGSGTDFTLTISSLQPEDVATY...	(3,4)T2@5(23)=(3,4)T7@27(88)	Validated match	T2 T7



Unreduced, trypsin digested therapeutic mAb analysis. Disulfide bond locations are automatically determined and output with corresponding MS/MS for confirmation.

LSCAASGFTFDDYAMHWVR

AEDTAVYYCAK

Fast view confirmation with high-resolution, annotated MS/MS data for both peptides involved in the disulfide bond.

Your Success is Our Success

We take it personally

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