

Project Goal

To analyze cohorts of IgGs and mAb based modalities using mass spectrometry characterization using a complete analytical workflow on a single workhorse instrument.

The Challenges

- Require a single, complete MS platform that can handle a diversity of the analytical workflows- intact mass, peptide mapping in reduced and non-reduced conditions, and relative quantitation of post-translational modifications
- Need an easy-to-use MS system that does not require extensive training. Walk-up resource, ready to use instantly.
- Want automated calculations and customized reporting for data that relies on minimal external intervention.

Solution

The X500B QTOF System, a robust LC-MS platform with:

- Good sensitivity & linear dynamic range
- User-friendly data acquisition system
- Dedicated BioPharmaView[™] Software to do a full characterization of biotherapeutics

The Outcomes

- After a guick calibration, the X500B QTOF is ready to use within minutes
- The system is easy-to-use. New users in the team can be trained within a few hours, and are completely operational.
- After six-months of operation, and around 2000 injections, no downtime has occurred, and there has been minimal cleaning of the source.
- The BioPharmaView software solution allows for step-by-step biotherapeutic characterization, for naked antibodies and even immunoconjugates.

"The accuracy and sensitivity of the X500B LC-MS instrument, with improved robustness, allows for monitoring of manufacturing batches with increased analytical throughput."

Type of Organization

Sanofi S.A. is a global healthcare leader in biopharmaceuticals. The structural analysis department specializes in mass spectrometry and structural analysis for biologics characterization.

Goals

To gain better knowledge of biopharmaceutical products in development by reliable mass spectrometry characterization at the intact protein and peptide level.

Applications

SWATH® Acquisition:

- Data Independent Acquisition (DIA)
- Peptide Mapping
- Intact Protein Analysis
- Post-Translational Modification Analysis

SCIEX products

- X500B QTOF System
- SCIEX OS Acquisition Software
- BioPharmaView[™] Software

"The follow-up of post-translational modifications with non-targeted and targeted (MAM) workflows is becoming mandatory to develop a new project."

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