

Customer case study

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Project goal

Develop a characterization method for adeno-associated virus vectors.

Challenge

- We needed to develop a method for adeno-associated virus vectors with complete profiling of critical quality attributes (CQAs), and we had to train a user base with intermediate-level knowledge of mass spectrometers.
- The capsid protein has a tendency of aggregating to form a complex larger molecule of ~2 mDa, making analysis difficult.
- This molecule is also highly glycosylated, which adds another dimension of complexity due to its resistance to ionization.

The solution

The X500B QTOF system from SCIEX was a single solution for all the previously mentioned challenges. SCIEX provided the recommendation to reduce, alkylate and deglycosylate the protein to improve the signal quality, and use double digestion and sample preparation to improve the sequence coverage. Application support and services from SCIEX trained us on the system and helped us with method development.

Outcomes of research

- The method development helped us support the process development team to elucidate the CQAs and screen at the preliminary stage.
- The sample prep procedure and data analysis—including disulfide mapping, reduced mapping and peptide mapping—helped us understand the capabilities of the instrument and bandwidth of the software, which led to regular use of the system now that the SCIEX team is supporting our in-process team with the sample analysis.
- The method is highly reproducible, and we have checked the reproducibility in 6 batches.
- Using this method has saved us around 6 months' worth of effort related to fulfilling the regulatory norms of protein characterization.

“The SCIEX X500B QTOF system is easy, fast and one point solution for characterization of subunit vaccine. The machine is indeed useful in proteomic analysis.”

Type of organization

CPL Biologicals aims to be a leading provider of high quality, affordable vaccines, biologics and diagnostics through world-class research and innovations combined with cost effective and efficient manufacturing to address current and future global health challenges.

SCIEX products

- X500B QTOF system
- SCIEX OS software