



Answers for Science.
Knowledge for Life.™



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Case Study

Project Goal

Develop characterization workflows for complex biopharmaceuticals through various stages of product development to enable drug approvals.

The Solution

- To develop strong LC-MS/MS workflows to decipher various critical quality attributes (CQAs) such as glycan attributes, conjugation sites, disulphide linkages, in the protein of interest
- To characterize and quantify product related impurities
- To integrate LC-MS/MS data with data from other orthogonal methods to provide an overall picture

Biggest Challenges Right Now

- Native high-resolution mass spectrometry of heavily glycosylated molecules
- Risk based development of powerful data mining software
- Regulatory friendly concise reporting of complex MS data

Outcomes of research

- Co-development of BioPharmaView™ Software (DSB analysis module)
- Superior sensitivity and high resolution of SCIEX TripleTOF® 5600+, enabled released N- and O glycan annotation and product related impurity characterization of complex biopharmaceuticals
- Strong characterization data package facilitated Global Business Development

“Comprehensive analytical data justifying the impact of differences along with tailored clinical investigation will be key to biosimilar development in future.”

Type of Organization

Lupin limited is a fully integrated generic pharmaceutical company, 4th largest by market capitalization, in the global arena.

Goals

Lupin works toward end-to-end biosimilar product development, manufacture, pre-clinical and clinical studies leading to regulatory filing globally.

SCIEX HARDWARE

- TripleTOF® 4600 System
- TripleTOF® 5600+ System

SCIEX SOFTWARE

- Analyst® 1.6 and 1.7
- PeakView® 1.2 and 2.2
- BioPharmaView™ 1.0, 1.1, 1.2 and 2.0

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