

Customer case study

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“LC-MS/MS is a leading technology for assay development of large molecules in drug discovery, and SCIEX has been a valuable enabler to augment organizational capabilities and deliver turnkey projects to clients.”



Project goal

To address biopharmaceutical industry needs by developing fast, accurate, standardized methods for qualitative and quantitative peptide analysis, which consequently leads to safer biotherapeutic drugs

Biggest challenges

- To achieve adequate resolution of interferences from a biological matrix that could affect the quantification of new biological entities (NBEs) in different biological matrices across developmental species (mouse, monkey and human)
- To achieve high quantification sensitivity, regardless of the biological matrix and sample preparation intricacy
- To achieve reproducibility in detection of NBEs at extremely low levels within complex biological matrices containing impurities at potentially high concentrations
- To achieve metabolite-related information on new chemical entities (NCEs) with clearance data at high throughput from different in-vitro and in-vivo matrices

The solution

- Highly sensitive and robust LC-MS/MS solutions from SCIEX—namely, the QTRAP® 4500 LC-MS/MS System, the QTRAP® 5500 LC-MS/MS System and the SCIEX Triple Quad™ 6500+ LC-MS/MS System with superlative linear dynamic range—enabled us to develop reproducible methods at very low LOQs for a diverse set of new chemical entities
- The TripleTOF® 5600+ LC-MS/MS System with unique SWATH® Acquisition workflow was key in comprehensive data-independent acquisition and quantification, along with competent software to interpret data
- The TripleTOF® 5600+ System—equipped with MetabolitePilot™ Software for metabolite identification—yielded reliable data for clearance at high throughput
- Front-end ultra-high-performance liquid chromatography (UHPLC) facilitated the removal of unwanted interferences from analytes of interest with less carryover for peptides analysis

Outcomes of research

- Creation of highly reproducible methods for a large number of complex projects with low sample volumes and without sacrificing sample throughput for hit-to-lead stage NCEs and NBEs
- A novel peptide molecule was successfully quantified in a preclinical biological matrix (plasma), which helped in progressing the project on a timely basis

“Constant support from multifunctional SCIEX teams reduced instrument downtime and empowered Syngene to exceed client expectations with respect to timelines and data quality through meaningful results.”

Organization

Incorporated in 1993, Syngene International Ltd. is an innovation-focused global discovery, development and manufacturing organization that provides integrated scientific services to the pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical industries around the world. Syngene supports both large pharmaceutical and biotech companies across the globe in their drug hunting efforts.

Goal

DMPK at Syngene is a functional arm of Discovery Biology. It is responsible for helping global drug discovery professionals and companies with high-throughput absorption, distribution, metabolism and excretion (HT-ADME) assays and pharmacokinetic candidate optimization of NCEs and NBEs, so that they can progress to the next phase of development in quick design, make, test and analyze (DMTA) cycles.

SCIEX products

- SCIEX Triple Quad™ 6500+ LC-MS/MS System
- TripleTOF® 5600+ LC-MS/MS System
- QTRAP® 5500 LC-MS/MS System
- QTRAP® 4500 LC-MS/MS System
- SCIEX Triple Quad™ 4500 LC-MS/MS System
- MultiQuant™ Software 3.0.3
- Analyst® Software 1.6 and 1.7
- MetabolitePilot™ Software 2.0