# Case Study

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## Project Goal

To address biopharmaceutical industry needs by developing fast, accurate, standardized methods for qualitative and quantitative Host Cell Protein (HCP) analyses, to help lead to safer biotherapeutic drugs.

## The Challenges

- Detecting HCP contaminants that could adversely affect the drug product or provoke immunogenicity in a patient.
- Achieving reproducible detection of extremely low levels of HCPs present with high concentration of biologic product.
- Ensuring confident HCP detection, without sacrificing sample throughput.

## Solution

An LC-MS solution with high-performance sensitivity & linear dynamic range, with comprehensive data independent acquisition, and software to interpret the data.

## The Outcomes

- Since the TripleTOF 6600 MS can detect even ppm quantities of HCPs, adverse effects of a drug product or provoking immunogenicity can be avoided.
- Unbiased SWATH Acquisition collects data for all detectable species to enable identification and quantification of each HCP reliably in drug batches.
- Utilizing this technology Alphalyse can provide an HCP service that customers can trust.

"Mass spec is going to be the gold-standard for HCP analysis, as it provides more detailed information about individual HCPs compared to ELISA assays. Adding SWATH for unbiased identification and quantification of proteins leads to high reproducibility and sensitivity. With this solution, standardization of the methods to any given set of biotherapeutic samples becomes possible, providing us with a huge advantage."

**Type of Organization**
Contract research organization (CRO), specializing in protein chemistry, mass spectrometry, and bioinformatics.

**Goals**
To reliably identity and quantify each host cell protein (HCPs) in batches in a timely, cost effective manner for safer pharmaceuticals.

**Applications**
SWATH® Acquisition: Data Independent (DIA) Scanning for Host Cell Protein Detection

**SCIEX products**
- TripleTOF® 6600 System
- SWATH® Acquisition
- ProteinPilot™ Software
- PeakView™ Software
- BioPharmaView™ Software

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