

# Mass Spectrometry-based Host Cell Protein Analysis in Biologics Development

**BioAnalytix**

A Protagen Protein Services Company

## Introduction

Host cell proteins (HCPs) are impurities present in all therapeutics derived from biological sources, and as a critical quality attribute (CQA), they must be characterized in detail and controlled through the manufacturing process and in the final drug product.

The individual protein contaminants that make up the HCP profile may vary significantly among individual biologic products including cell and gene therapies and expression systems, even for very closely related molecules. As such, the HCP profile must be analyzed to identify even low levels of potentially concerning species in a biologic drug.

## Highlights

Advantages of LC-MS based HCP profiling for development of complex biologics include:

- ✓ Sensitive Detection of Peptides
- ✓ Excellent Accuracy and Precision
- ✓ Fast Estimate of Concentration Based on Selected Peptides
- ✓ Rapid Assessment of Relative Amounts
- ✓ Effective Comparison Among Samples
- ✓ No Custom Immunoreagents Required

