EVOSEP

Webinar digest

Controlling Host Cell Proteins in Biopharma with Advanced MS-based Proteomics Approaches

Introduction

In the world of biopharmaceuticals, ensuring product quality and safety is paramount. One of the key challenges in this field is the identification and control of Host Cell Proteins (HCPs), which are impurities derived from the host cells used in manufacturing. Advanced LC-MS-based proteomic approaches are at the forefront of addressing these challenges. In a recent hosted Evosep webinar, valuable insights were shared into the innovative techniques that are shaping biopharmaceutical process development.

The Journey of Biopharmaceutical Development

The intricate process of biopharmaceutical development encompasses cell line development, upstream cell culture, downstream purification, and formulation development. Proteomics has been widely used in the discovery phase to identify drug targets and understand the mechanisms of action. However, once a drug is discovered, the next question is how to manufacture it and ensure its quality.

A critical aspect of this process is the identification of HCPs, which can potentially impact the safety and efficacy of biopharmaceutical products. It is important to minimize these impurities, as certain residual HCPs can have potential adverse effects, including immunogenicity, acute toxicity, and product stability.

Leveraging Advanced Technologies: The Evosep One System

To tackle the challenges associated with HCP identification, cutting-edge LC-MS-based proteomic approaches are utilized. A standout technology in the toolkit is the Evosep One system. This system combines sample cleanup and chromatographic separation, significantly enhancing the throughput and sensitivity of HCP analysis.

The advantages of the Evosep One system include the ability to remove aggregates and load less material compared to typical analytical flow LC systems, increasing the HCP analysis throughput. This system has proven particularly effective in analyzing both high-concentration HCP samples, such as monoclonal antibodies, and low-concentration samples, such as vaccines and cell and gene therapies.

Evosep One: A Game-Changer in HCP Analysis

The Evosep One system has been instrumental in addressing key challenges in HCP analysis. By streamlining the workflow, it has reduced sample loading time and increased robustness as highlighted in the webinar.

In a case study, a monoclonal antibody cultured under various conditions and harvested at different time points achieved good reproducibility and identified over 2,000 HCPs, including high-risk ones. This level of precision and efficiency would not have been possible without the advanced capabilities of the Evosep One system.

The Future of LC-MS-Based Proteomics in Biopharmaceuticals

The immense potential of LC-MS-based proteomics in biopharmaceutical process development and manufacturing is underscored by the ability to identify and quantify HCPs with high sensitivity and throughput. Advanced LC-MS and mass spectrometry techniques enable robust process development and risk assessments for controlling high-risk HCPs.

Collaboration across analytical, process, and formulation departments is instrumental in driving innovation in this field. The work supported by the Evosep One system and standardization of methods, exemplifies the power of precision in biopharmaceutical development, paving the way for safer and more effective therapies for patients.

In conclusion, the advancements in LC-MS-based proteomics, supported by technologies like the Evosep One system, are making significant strides in biopharmaceutical process development. As the field continues to evolve, these insights and innovations will undoubtedly play a pivotal role in shaping the future of biopharmaceuticals, ultimately benefiting patients worldwide.

Want to learn more?

This digest was created based on the presentation from the webinar Rapid, Robust, and Reproducible Host Cell Protein Analysis with Evosep One by Shawn Li, Principal Scientist at Merck.

Watch full presentation.