ESAC 2026
Executive Seminars in Analytical Chemistry

From Invisible Impurities to Actionable Insight:

Host Cell Protein Identification by LC–MS in Biopharmaceuticals

By Max Kraner PhD, MBA,
Head of Department MS Characterization at Novo Nordisk

Max Kraner is the Head of Department MS Characterisation in Drug Product Research at Novo Nordisk, with expertise in mass spectrometry–based bioanalytics and peptide and protein characterization.

He and his great team operate at the interface of advanced LC–MS analytics, drug product research, and digital capability building across research and development.

His experience spans from in depth characterisation of proteins to the implementation of robust analytical workflows in regulated environments.

He is passionate about positioning mass spectrometry not only as an analytical tool, but as a strategic enabler of fast and high-quality decision-making in biopharmaceutical R&D.

Host Cell Protein Identification

Host cell proteins (HCPs) remain one of the most complex and underestimated impurity classes in biopharmaceutical development. While often present at trace levels, their potential impact on product stability, efficacy, and immunogenicity makes their reliable detection and identification a critical challenge. This becomes particularly important as drug modalities, expression systems, and manufacturing processes evolve.

In this keynote, Max Kraner will discuss how advanced LC–MS–based strategies identify HCPs across drug product development.

Drawing on real-world experience from large-molecule drug development, the talk will explore the transition from traditional global HCP assays, like ELISA, toward hybrid and MS-driven approaches, including peptide-level quantification and activity-based enrichment and subsequent identification.

The presentation will highlight practical considerations for implementing MS-based HCP workflows in biopharmaceutical environments, discuss current limitations and emerging opportunities. He will outline how mass spectrometry can move from a troubleshooting tool to a strategic guide for process development in biopharmaceutical R&D.