



## Ensuring compliance

Host Cell Protein analysis  
you can trust

Host Cell Proteins (HCPs) pose significant risks during biomanufacturing, affecting product quality and regulatory compliance. RSSL delivers fast, reliable data to help ensure purity, prevent production issues and meet the highest standards clients require with confidence.

Produced by the host organism during biotherapeutic manufacturing, most HCPs are very low in abundance relative to the therapeutic product and easy to remove by downstream purification steps such as affinity chromatography and size exclusion.

However, some HCPs have the potential to co-purify with therapeutic products, making removal difficult, compromising both product quality and clinical safety. Studies have shown that residual HCPs can affect drug efficacy and patient safety, necessitating rigorous monitoring and analysis.



## The challenges of measurement

Regulatory agencies classify HCPs as critical quality attributes (CQAs) that must be monitored and reported throughout a product's lifecycle. HCP analysis is also vital in biopharmaceutical comparability studies to evaluate the impact of process changes on upstream expression and downstream clearance.

The challenge lies in the complexity of HCP populations—present in low quantities, highly diverse, and variable. Bioprocessing samples can contain thousands of protein species with vastly different properties. Developing a single assay with broad coverage is difficult, especially given the need for high sensitivity (detecting as low as a few ppm) and a wide dynamic range to accurately track HCP levels against therapeutic proteins.

### ELISA

- The gold standard for immunogenic HCP quantification
- Offers unmatched sensitivity, fast turnaround, and cost efficiency
- RSSL provides tailored ELISA solutions for every stage of your product lifecycle
- Trusted partnerships with leading antibody suppliers ensure accurate, reliable results

### Mass Spectrometry (MS)

- A powerful, universal platform for deeper insights into HCP profiles and clearance patterns
- Vital orthogonal method to ELISA for detailed HCP characterization
- RSSL's advanced MS proteomic services provide comprehensive HCP profiling
- High-accuracy proteomic approaches and database integration to identify and monitor individual HCPs

## About RSSL

Leading biopharmaceutical companies worldwide rely on RSSL for expert HCP analysis. Our team of skilled scientists delivers tailored solutions, offering ELISA, Western Blot, SDS-PAGE and advanced mass spectrometry methods alongside method development, validation, transfer, troubleshooting, and GMP batch release.

With a comprehensive, end-to-end approach, we help optimise purification processes to meet safety and regulatory requirements, ensuring your products stay ahead in an evolving regulatory landscape.

Choose RSSL for expertise you can trust and results you can depend on.



Reading Scientific Services Ltd  
The Reading Science Centre  
Whiteknights Campus  
Pepper Lane, Reading  
Berkshire RG6 6LA

Tel: **+44 (0)118 918 4076**  
Email: **lifesciencesales@rssl.com**

For more information, please visit  
[www.rssl.com](http://www.rssl.com)