



International Alliance for
Biological Standardization

Europe



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Background:

Monitoring host cell proteins (HCPs) is critical in biopharmaceutical production due to their nature as heterogeneous process-related impurities and their classification as a Critical Quality Attribute (CQA) with potential safety implications. Effective HCP quantification ensures process consistency and product safety, making this a focal point for regulatory scrutiny from agencies like EMA and FDA.

Challenges:

The implementation of HCP monitoring using Enzyme-Linked Immunosorbent Assay (ELISA) methodology presents several challenges. These include securing the long-term supply, storage, and characterization of critical reagents necessary to support the ELISA platform for multiple products throughout their lifecycle. Additionally, the process demands large quantities of these reagents which necessitates meticulous reagent preparation and management. Rigorous characterization efforts are required to ensure ELISA suitability for new products, typically through mock run evaluations, adding to the complexity.

Proposed Approach:

Platform assays offer a standardized approach to HCP detection by utilizing a single antibody set and assay format across the pipeline, facilitating consistency and comparability. This strategy is feasible because HCP profiles tend to be similar across various products and cell lines, enabling the use of unified assays. The benefits include operational efficiency, streamlined regulatory approval processes, and the building of a comprehensive knowledge base.

Conclusions:

This presentation will provide insights into the importance of HCP monitoring, the methodologies employed, the advantages and feasibility of platform assays, and the challenges encountered. By addressing these scientific and regulatory aspects, the approach ensures the safety and efficacy of biopharmaceutical products throughout their development and lifecycle.

