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Host cell protein characterization for bioprocess and product improvement

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Abstract

Host cell proteins (HCPs) are biomanufacturing process-related impurities which must be closely monitored to ensure process consistency and patient safety. ELISA is the most common method for HCP quantification. Validation of HCP ELISA with orthogonal methods is required by FDA to ensure that in-house developed ELISA assays are able to detect the majority of HCP impurities. We have implemented advanced analytical technologies (such as 2D western and LCMSMS) for HCP quantification and characterization.

In this talk, I will present results on:

1. Evaluation the applicability of commercial ELISA kits for assaying in-house CHO cell lines.

2. Applications of HCP characterization in downstream purification processes development

3. Identification of specific HCP that impact product quality, which can be used for manufacture process and product monitoring.

Our HCP characterization methods can also applied for biomarker identification in drug discovery, development, and disease diagnosis.