

# 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, the author will present results on: ? Evaluation the applicability of commercial ELISA kits for assaying in-house CHO cell lines ? Applications of HCP characterization in downstream purification processes development ? 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.

**Received date:** May 11, 2022; **Accepted date:** May 18, 2022; **Published date:** May 29, 2022

## Biography

Rong Rong Zhu is an accomplished protein analytical chemist with over nineteen years pharmaceutical and biotechnology industrial experience, encompassing all phases of protein therapeutic development, from discovery, to development, to commercial manufacturing. She has in-depth knowledge in analytical chemistry with

expertise in biophysical/biochemical characterization of therapeutic antibodies and proteins. She is an experienced speaker who presents at multiple international conferences.