

Comparability study to support upstream and downstream process development

Rong-Rong Zhu
EMD Millipore, USA

Manufacture process changes often result in changes in biological product quality. Comparability studies are typically performed to assess whether the change(s) is likely to affect product quality, safety and efficacy. The correlation between product qualities attributes and process parameters ultimately help us to understand our manufacture process and assist in both upstream and downstream processes.

In this talk, the author will give a few case studies on how upstream process changes (cell line, cell culture media and harvest time) affect product qualities (glycan and charge profile changes). The author will also present how modified downstream process has improved mAb product quality (lower aggregation and lower process related impurities).

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.

rong-rong.zhu@emdmillipore.com