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Comparability study to support upstream and downstream process development

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Abstract

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 quality attributes and process parameters ultimately help us to understand our manufacture process and assist in both upstream and downstream processes.

In this talk, I 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). I will also present how modified downstream process has improved mAb product quality (lower aggregation and lower process related impurities).