

## **PROCESS CHARACTERIZATION FOR AN UPDATED LEGACY PRODUCT**

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A commercial Chinese Hamster Ovary (CHO) cell culture process was updated using current technologies to improve productivity, ensure consistent product quality, and meet current Health Authority expectations. In order to achieve comparable product quality with the current commercial process, the updated cell culture process has a unique pH drop step. Site- and scale-independent cell culture characterization studies were executed to support this new process. A Critical Quality Attribute (CQA) assessment was performed prior to completion of process characterization because the original product control strategy was developed without formal CQA identification. Since non-CQAs remain part of the product control strategy, they were also considered for process characterization. This work will describe the process characterization approach and results for the updated cell culture process. In addition, an outline on how both CQAs and non-CQAs were considered in the assessment of Critical Process Parameters (CPPs) will be presented.