

ACHIEVING PRODUCT QUALITY COMPARABILITY WHILE MAKING CELL CULTURE PROCESS CHANGES

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Demonstrating product quality comparability while making cell culture process changes during development can be challenging. The stage of development as well as an understanding of the product mechanism of action and how product quality impacts pharmacokinetics/pharmacodynamics and safety help inform the relative risk of process changes on productivity and product quality. This poster will document two case studies showing cell culture processes that underwent extensive process changes to improve productivity while also maintaining product quality comparability. Changes to culture duration and medium additives were implemented to modulate both charge and glycosylation profiles in order to achieve comparable product quality observed from earlier process versions. Results from small-scale and pilot scale experiments were used to assess the impact of these changes before scale-up & implementation in GMP manufacturing.