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Strategies for optimizing a cell culture platform to achieve high recombinant protein titer without impacting product quality

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STRATEGIES FOR OPTIMIZING A CELL CULTURE PLATFORM TO ACHIEVE HIGH RECOMBINANT PROTEIN TITER WITHOUT IMPACTING PRODUCT QUALITY

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Recent advances in cell line development and in the design of culture media have significantly increased both the volumetric and specific productivity of fed batch processes, which is our standard platform technology for synthesis of therapeutic proteins. Cell culture processes are generally simplified when needed as a robust platform technology to meet the imperatives of speedy timelines for early process development and ease of manufacturing. However, both culture media and feeding strategies need to be customized for specific cell lines when there is a need to achieve higher titer due to higher product demand. This presentation will focus on the specific changes that were made in order to enhance the platform cell culture process for achieving much higher titers. A case study will be used to demonstrate that changes made to feeding strategy, feed media and other process parameters have the potential to maximize productivity but also to alter the product quality profile. It is critical to ensure that these process changes do not adversely impact product quality. Strategies used to control the acidic charge variant profile, which was elevated in these enhanced cell culture processes, will be discussed.