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Bioreactor process improvements in a legacy perfusion-based process

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BIOREACTOR PROCESS IMPROVEMENTS IN A LEGACY PERFUSION-BASED PROCESS

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The legacy manufacturing processes for production of the enzyme products at Genzyme include long-term bioreactor perfusion-based cell culture platform. For the process with tight filed ranges and limited characterization, a phased approach is being used to improve bioreactor productivity. In the first phase, short-term process changes that are within filed and historical ranges were implemented. In the second phase, long-term process improvements that are outside the filed ranges will be implemented for a significant improvement in bioreactor productivity. Results from lab and at-scale study have confirmed that there was no adverse impact of phase 2 process improvements on cell culture, downstream processes and product quality. After finalizing the regulatory strategy, process validation campaigns to qualify phase 2 process improvements are currently being planned.