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# Bioreactor process improvements in a legacy perfusion-based process

Rakesh Motani

*Genzyme*, [rakesh.motani@genzyme.com](mailto:rakesh.motani@genzyme.com)

Gonzalo Milet

*Genzyme*

Gregory Walsh

*Genzyme*

Lada Laenen

*Genzyme*

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## **BIOREACTOR PROCESS IMPROVEMENTS IN A LEGACY PERFUSION-BASED PROCESS**

Rakesh Motani, Genzyme – A Sanofi Company  
[Rakesh.motani@genzyme.com](mailto:Rakesh.motani@genzyme.com)  
Gonzalo Milet, Genzyme – A Sanofi Company  
Gregory Walsh, Genzyme – A Sanofi Company  
Lada Laenen, Genzyme – A Sanofi Company

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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.