

Spring 5-11-2016

Bioreactor process improvements in a legacy perfusion-based process

Rakesh Motani

Genzyme, rakesh.motani@genzyme.com

Gonzalo Milet

Genzyme

Gregory Walsh

Genzyme

Lada Laenen

Genzyme

Follow this and additional works at: http://dc.engconfintl.org/cellculture_xv



Part of the [Biomedical Engineering and Bioengineering Commons](#)

Recommended Citation

Rakesh Motani, Gonzalo Milet, Gregory Walsh, and Lada Laenen, "Bioreactor process improvements in a legacy perfusion-based process" in "Cell Culture Engineering XV", Robert Kiss, Genentech Sarah Harcum, Clemson University Jeff Chalmers, Ohio State University Eds, ECI Symposium Series, (2016). http://dc.engconfintl.org/cellculture_xv/147

This Abstract is brought to you for free and open access by the Proceedings at ECI Digital Archives. It has been accepted for inclusion in Cell Culture Engineering XV by an authorized administrator of ECI Digital Archives. For more information, please contact franco@bepress.com.

BIOREACTOR PROCESS IMPROVEMENTS IN A LEGACY PERFUSION-BASED PROCESS

Rakesh Motani, Genzyme – A Sanofi Company
Rakesh.motani@genzyme.com
Gonzalo Milet, Genzyme – A Sanofi Company
Gregory Walsh, Genzyme – A Sanofi Company
Lada Laenen, Genzyme – A Sanofi Company

Key Words: enzyme, perfusion, productivity, scale-down, at-scale

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.