

Spring 5-12-2016

# Toward development of continuous bioprocesses: Comparison of fed-batch and perfusion upstream production processes in early development

Jean McLarty

*Sanofi*, [jean.mclarty@sanofi.com](mailto:jean.mclarty@sanofi.com)

Daryl Powers

*Sanofi*

Christine Hamel

*Sanofi*

Betsy Simons

*Sanofi*

Ken Karey

*Sanofi*

Follow this and additional works at: [http://dc.engconfintl.org/cellculture\\_xv](http://dc.engconfintl.org/cellculture_xv)

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

---

## Recommended Citation

Jean McLarty, Daryl Powers, Christine Hamel, Betsy Simons, and Ken Karey, "Toward development of continuous bioprocesses: Comparison of fed-batch and perfusion upstream production processes in early development" 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/161](http://dc.engconfintl.org/cellculture_xv/161)

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](mailto:franco@bepress.com).

TITLE: TOWARD DEVELOPMENT OF CONTINUOUS BIOPROCESSES: COMPARISON OF FED-BATCH AND PERFUSION UPSTREAM PRODUCTION PROCESSES IN EARLY DEVELOPMENT

Jean McLarty, Sanofi BioPharmaceutics Development, Framingham, MA  
Jean.Mclarty@sanofi.com

Daryl Powers, Sanofi BioPharmaceutics Development, Framingham, MA  
Christine Hamel, Sanofi BioPharmaceutics Development, Framingham, MA  
Betsy Simons, Sanofi BioPharmaceutics Development, Framingham, MA  
Ken Karey, Sanofi BioPharmaceutics Development, Framingham, MA

Key Words: Continuous, bioprocess, perfusion, development, upstream,

Continuous Processing is an exciting development in the field of bioprocessing. The potential for quick response to market demands, decrease in infrastructure, increased flexibility and consistent product quality has resulted in a growing interest in Continuous Processing for production of all types of protein drugs (high or low volume, stable or unstable). Sanofi is developing a novel Integrated Continuous Manufacturing platform for biologics that utilizes an upstream perfusion process. While cell culture perfusion processes offer substantial benefits for commercial biologics production, implementation may present challenges in early development, where speed to first in man studies is critical. Here we present a comparison of candidate Phase I fed-batch and perfusion processes resulting from our upstream development work for a monoclonal antibody. The report focuses on process productivity, product quality attributes, and development timelines. Assessment of the advantages and challenges for both processes informs strategy for Continuous Process platform development.