Engineering Conferences International ECI Digital Archives

Integrated Continuous Biomanufacturing II

Proceedings

Fall 11-2-2015

Enabling technologies for integrated / continuous downstream processing of biologics

Jeff Salm Pfizer, jeff.salm@pfizer.com

Marcus Fiadeiro Pfizer

Raquel Orozco Boehringer Ingelheim

Jill Kublbeck Pfizer

Aaron Noyes Pfizer

See next page for additional authors

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



Part of the Biomedical Engineering and Bioengineering Commons

Recommended Citation

Jeff Salm, Marcus Fiadeiro, Raquel Orozco, Jill Kublbeck, Aaron Noyes, Jeff Horne, Daniel LaCasse, Ashley Sacramo, Suhani Gupta, John Coffman, and Robert Fahrner, "Enabling technologies for integrated / continuous downstream processing of biologics" in "Integrated Continuous Biomanufacturing II", Chetan Goudar, Amgen Inc. Suzanne Farid, University College London Christopher Hwang, Genzyme-Sanofi Karol Lacki, Novo Nordisk Eds, ECI Symposium Series, (2015). http://dc.engconfintl.org/biomanufact_ii/

This Conference Proceeding is brought to you for free and open access by the Proceedings at ECI Digital Archives. It has been accepted for inclusion in Integrated Continuous Biomanufacturing II by an authorized administrator of ECI Digital Archives. For more information, please contact franco@bepress.com.

is Fiadeiro, Raquel Orozco, Jill Kublbeck, Aaron Noyes, Jeff Horne, Daniel LaCasse, Ashley i Gupta, John Coffman, and Robert Fahrner

ENABLING TECHNOLOGIES FOR INTEGRATED / CONTINUOUS DOWNSTREAM PROCESSING OF BIOLOGICS

Jeff Salm, Pfizer

Jeff.salm@pfizer.com

Marcus Fiadeiro, Pfizer

Raquel Orozco, Boehringer Ingelheim

Jill Kublbeck, Pfizer

Aaron Noyes, Pfizer

Jeff Horne, Pfizer

Daniel LaCasse, Pfizer

Ashley Sacramo, Pfizer

Suhani Gupta, Boehringer Ingelheim

John Coffman, Boehringer Ingelheim

Robert Fahrner, Pfizer

Key Words: integrated, continuous, purification, chromatography, filtration

Pfizer Bioprocessing R&D is focused on developing enabling technologies that will reduce capital and operational expenses, decrease equipment scale, increase automation and utilize fewer FTEs. To realize this vision, Purification Process Development has piloted new technologies and operational strategies that have enabled a fully integrated downstream process. Our current work has demonstrated a continuous process that includes tangential flow filtration harvest from a perfusion bioreactor, Protein A capture, inline viral inactivation/conditioning and AEX polishing. This process was fully automated and demonstrated at the 100 L scale. We have also shown feasibility of multi-day virus reduction filter operation and a continuous ultrafiltration/diafiltration using counter-current single-pass tangential flow filtration. These technologies and strategies are critical elements of our long term goal of establishing a fully integrated process from bioreactor to drug substance. With this process, we hope to remove product supply as a critical path activity for both toxicology and clinical needs.