

Spring 5-13-2016

Moving from a bioreactor scale-up/scale-down approach to a more holistic operational design space view

Gene Schaefer

Janssen R&D, eschaefer@its.jnj.com

Rick Yeager

Janssen R&D

Ted DeLoggio

BioProcess Consultants

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



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

Recommended Citation

Gene Schaefer, Rick Yeager, and Ted DeLoggio, "Moving from a bioreactor scale-up/scale-down approach to a more holistic operational design space view" 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/243

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.

MOVING FROM A BIOREACTOR SCALE-UP/SCALE-DOWN APPROACH TO A MORE HOLISTIC OPERATIONAL DESIGN SPACE VIEW

Gene Schaefer, Janssen R&D
ESchaefer@its.jnj.com

Rick Yeager, Janssen R&D

Ted DeLoggio, BioProcess Consultants

Key words: bioreactor, scale-up, scale-down, reduced scale model, design space

Scale-up of bioreactor processes for biologic products has been an area of focus in the industry for over 50 years and the results have generally been successful through the application of a number of specific correlations across scales for mass transfer, mixing, etc. However, the ability to visualize and understand the bioreactor design space in terms of these parameters has generally been limited as has any general understanding of how close a given process comes to certain sensitivity limits at various scales. As part of a project which involved establishing scale-down models at two different sites with long-term objectives of moving processes to multiple scales and sites, two-dimensional operational design space diagrams were constructed using power per volume (P/V) and superficial sparge gas velocity (V_s) as the axes. The use of such an operational design space to identify and visualize process sensitivity boundaries such as interfacial or turbulent eddy shear limits as well as pCO_2 isobars will be presented for both small and large scale operations. This visualization of the operational design space allows for a clearer assessment of time-dependent process sensitivities over the duration of a bioreactor run. The use of process sensitivity analysis will also be discussed in terms of fine tuning reduced scale models to lessen the impact of specific sensitivities, especially when operating at the edge of a design space at certain times, and improvements to the overall process robustness.