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Proceedings

Fall 11-3-2015

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Daniel Karst

Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, ETH Zürich

Fabian Steinenbach

Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, ETH Zürich

Massimo Morbidelli

Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, ETH Zürich

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Recommended Citation

Daniel Karst, Fabian Steinenbach, and Massimo Morbidelli, "Integrated continuous processing for the manufacture of monoclonal antibodies" 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/78

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Integrated Continuous Processing for the Manufacture of Monoclonal Antibodies

Daniel Karst, Fabian Steinebach and Massimo Morbidelli

Institute for Chemical and Bioengineering, Department of Chemistry and Applied Biosciences, ETH Zürich, CH-8093 Zürich, Switzerland

Continuous manufacturing is currently being considered by the Biopharmaceutical Industry not only for the classical reasons which make continuous operation preferred over the batch one, but also for recent initiatives of the regulatory agencies. We discuss here a series of experiments where a perfusion reactor with CHO cells for the production of a monoclonal antibody has been operated in the continuous mode and connected to a two column continuous protein A chromatographic unit for product capture. A few steady states are examined and the use of simulation models for process design and control is illustrated.