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Integrated continuous processing for the manufacture of monoclonal antibodies

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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.