

CONTINUOUS BIOPROCESSING WITH ULTRA-HIGH PRODUCTIVITY TO EXPEDITE BIOLOGICS DEVELOPMENT

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Ultra-high productivity continuous bioprocesses have been developed for production of various biologics including monoclonal antibodies, fusion proteins and bispecific antibodies. This enables, for example, 2,000L disposable bioreactors to achieve comparable productivity as traditional 20,000L stainless bioreactors, and to significantly reduce manufacturing cost of goods. This process technology platform consists of continuous cell culture and continuous direct product capture, and is being scaled up and implemented for production of clinical materials. Several case studies, which achieved a cell culture productivity of 2-3 g/L/day, and a similar purification yield of the traditional purification process, will highlight advantages of this integrated continuous process platform in terms of productivity gains and speed to clinic. Scale up and implementation challenges will also be discussed.