

A comparison of different intensified upstream processes highlighting the advantage of WuXiUP in improved product quality and simplified downstream process

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June 27, 2022

Abstract

WuXiUP, WuXi Biologics' Ultra-high Productivity platform, is an intensified and integrated continuous bioprocess platform developed for production of various biologics including monoclonal antibodies, fusion proteins and bispecific antibodies. This process technology platform has manifested its remarkable capability in boosting the volumetric productivity of various biologics and has been implemented for large scale clinical material productions. In this report, case studies of the production of different pharmaceutical proteins using two high producing and intensified culture modes of the WuXiUP and the concentrated fed-batch (CFB), as well as the traditional fed-batch (TFB) are discussed from the perspectives of cell growth, productivity, and protein quality. Both WuXiUP and CFB outperformed TFB regarding to volumetric productivity. Additionally, distinctive advantages in product quality profiles, such as charge variant, fragmentation *etc.*, in the WuXiUP process are revealed, and therefore a simplified downstream purification process with only two chromatographic steps can be developed to deliver the target product at a satisfactory purity.

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