

WuXi Biologics Expands Perfusion Cell Culture Capabilities

On top of its extensive perfusion-based cell culture capabilities, in 2016, WuXi Biologics will add perfusion-based commercial manufacturing services using ATF10TM system coupled with 1,000 L single-use bioreactors. WuXi currently supports process development and GMP clinical-scale perfusion culture with ATF2TM, ATF4TM and ATF6TM systems at 1 L to 250 L working volumes.

Perfusion-based Cell Culture Platform Features

Process Development

- 20 sets of ATF2 systems, expanding to 30 sets by 2016
- 2 sets of ATF4 systems
- ATF2 and ATF4 systems coupled with 1-10 L working volume bioreactors

Clinical GMP Production

- ATF6 coupled with Hyclone SUB to support 125-250 L working volume:
- ATF10 coupled with single-use bioreactors to support up to 1,000 L working volume

Commercial Production

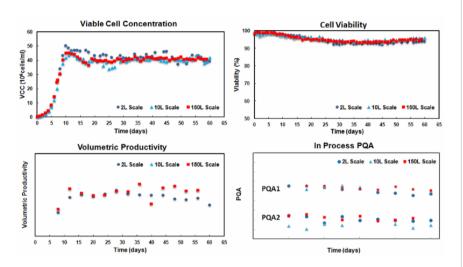
• ATF10 coupled with 1,000 L single-use bioreactors, available in late 2016

All systems use Delta V based control system to support fully automatic process control & perfusion operation.

Related Resources

WuXi Biologics Begins Construction of the World's Largest Mammalian Cell Culture Manufacturing Facility Using Disposable Bioreactors

Case Study: Steady state perfusion with high cell density and viability



Background

• WuXi was requested to produce a recombinant protein therapeutic with high productivity and product quality.

Challenge

- Protein therapeutic was a relatively unstable product.
- PQAs were very sensitive to cell culture performance (e.g., cell viability).
- Specific product productivity is limited due to the nature of the protein.

Solution/Results

- To achieve high productivity, high cell density was required and achieved.
- ATFTM system was introduced as cell retention device to achieve high viable cell density and
 achieve proper cell removal (bleeding) rate to maintain stable cell density and viability.
- Achieved long-term steady state perfusion (typically 60 days, up to 130 days) with stable cell growth performance, metabolism, productivity and PQAs.
- Clarified harvest from ATFTM allowed direct product capture in the downstream purification process.
- Perfusion process successfully scaled up to 250 L (with 150 L working volume) for GMP runs

For inquiry, please contact us at info@wuxibiologics.com.

Visit us at www.wuxibiologics.com.