



## A Case Study: Overcoming the Purification Challenges of a Bispecific Antibody

### Client Project Goals:

- Generate clinical batch material within client's projected timeline (12 months) and budget
- Improve product quality
- Improve product yield (overall product yield of client transferred process was at 50%)

### Key Milestones:

Based upon client's transferred upstream (cell culture) and downstream (purification) processes performed at a small (development) scale, the following milestones were achieved:

- Developed and optimized an improved purification process including removal of high molecular weight aggregates during the purification
- Overall yield of purified product was increased by 50%
- Utilized appropriate excipients to stabilize the in-process intermediates and the purified product
- Successfully performed Process Development, Scale-Up, cGMP manufacturing runs, and Aseptic Fill and Finish within the client's projected timeline (<12 months) and within budget