

Case Study

Development of a Modified Purification Process for a Monoclonal Antibody Therapeutic-Yield Improvement

Benefits of the Case:

- Improved yield of Mab product from bulk harvest by 1.8 fold
- Simplified downstream purification process by eliminating the collection of fractions and the need for stat assays during manufacturing operations
- Eliminated the use of resins that were difficult to pack and resulted in declining yields with short life cycles

Background of Challenge:

- The Mab product had been manufactured at the 2,000L scale.
- Production at the 10,000L cGMP manufacturing scale was planned.
- The Mab product harvest contained several product variants.
- Mab product variants had very similar biophysical properties to Mab of interest.
- Yield of Mab was unacceptably low.
- Collection of column fractions was required to obtain desired Mab purity.
- Host cell modifications were not acceptable.

Strategy

- Evaluate alternative chromatography resins for efficient removal of the product variants.
- Eliminate collection of fractions by using step gradients.
- Optimize process to increase product through put and reduce process costs.

Development Data

- The purification process was modified by developing an intermediate and final high resolution polishing step.
- Purity specifications the Mab product were maintained.
- Yield of Mab was increased 1.8 fold.

Value for the Client

- The yield for a Mab antibody therapeutic was significantly improved.
- The purity specifications for the Mab product were maintained.
- The need for collection and stat analysis of chromatography fractions was eliminated.
- A significant manufacturing issue was eliminated.