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Leveraging Prior Knowledge for Process Parameter Classification in mAb Protein A Chromatography

Background:

Protein A (ProA) affinity chromatography is a widely used process in the pharmaceutical industry for purifying monoclonal antibodies and its analogues. The platform power of Protein A chromatography has fostered substantial knowledge and experience through mAb process development and commercialization over the past decades. While prior knowledge has been instrumental in streamlining design of experiments (DOE) study designs, an innovative step remains unexplored, i.e., the complete elimination of product-specific small-scale studies by solely leveraging prior knowledge for process parameter classification.

Materials & Methods:

We have leveraged prior knowledge from prior ten molecules for process parameter classification of the ProA unit operation, eliminating product-specific small-scale studies in developing manufacturing control strategies for monoclonal antibodies and derivatives. Statistical analysis using a Bayesian hierarchical model was used to predict a pooled (platform) estimate for each process parameter effect based on the experimental data from historical studies.

Results/Conclusions:

By leveraging this historical data package, we directly supported the classification of ProA process parameters for new therapeutic antibodies, effectively replacing the need for product-specific process characterization evaluations. This approach has been positively received by global regulatory agencies during the market authorization filings for two Lilly's products.

