

DEVELOPING RE-PURIFICATION STRATEGY FOR CLINICAL MATERIAL

GOAL: Fortune 500 company client urgently needed to re-purify 25g of protein biologic (made at another CMO) headed for the clinic that was unusable, as it did not meet a predetermined purity specification.

CHALLENGE: Client and original CMO had already made several unsuccessful attempts to develop conditions to allow identification of and removal an impurity closely related to the size of the active protein, and they needed it done quickly. Then, client realized the sample also contained excessive endotoxin levels.

OUTCOME: In only a few weeks, the experienced team at Florida Biologix had scouted multiple column chemistries and buffer conditions, developed HPLC test methodology and determined best method to re-purify protein. We provided a scalable solution to remove endotoxin and reduce impurity levels.

PROCESS DEVELOPMENT STEPS:

- Sourced all raw materials, including multiple types of column chromatography platforms and buffers
- FB purification scientists suggested plan of action and tested a variety of column (PPA, HEA, MEP, Capto Adhere, Capto MMC) and buffer (pH, acetate, citrate, MES, urea) conditions
- Analysis of samples was done both at FB and at offsite testing lab in Europe
- Continual, clear client communication and results sharing allowed rapid development of strategy
- Time and materials contract allowed flexibility
- Client took the process back for the final cGMP purification, although Florida Biologix was fully capable of this activity