INTRODUCTION

Affinity purification platforms such as Protein A or L are well-established in the manufacturing process of therapeutic monoclonal antibodies. However, with the development of engineered modalities such as bi-specific antibodies, fragments and Fc-fusion proteins, challenges in the downstream process of these molecules arise. Affinity chromatography resins, specifically developed to bind antibody-subdomain regions, can provide an alternative solution in the purification process of these new formats. Thereby, advancing the commercial production of new antibody therapeutics.

CaptureSelect technology – unique affinity purification solution

- Technology based on single domain antibody fragments (V\_H)
- High target purity in a single step, independent of feedstock
- Unique V\_H screening technology to determine final resin properties:
  - target specificity
  - mild elution
  - ligand stability
- Scalable & animal origin free technology
- Suitable for cGMP manufacturing processes

CaptureSelect resin family for therapeutic antibody development

A unique set of CaptureSelect™ affinity resins has been developed directed against a variety of antibody subdomains, supporting manufacturers to help facilitate purification of novel antibody formats.

Purification of antibody therapeutics - Examples

CaptureSelect™ CH1-XL affinity matrix – CH1 binding domain resin

- Scalable platform solution for efficient Fab fragment purification
  - No co-purification of free light chains (only correct assembled Fabs)
  - Efficient elution at milder pH (4 – 4.5)

CaptureSelect™ LambdaXP & KappaXP affinity matrices – C\_\_ Lambda and Kappa binding domain resins

- Solving purification challenges in the downstream process of bi-specific molecules
  - Efficient elution at milder conditions protecting the target molecule and smaller elution pool volumes
  - High dynamic binding capacity at shorter residence times

CaptureSelect™ FcXP affinity matrix – CH3 binding domain resin

- A purification platform for all IgG subclass molecules with an altered Protein A binding site or pH sensitivity such as Fc-fusion proteins
  - High dynamic binding capacity: >40 g/L at 4 min residence time
  - Efficient elution at milder conditions (pH 4-5) making it suitable for Fc fusion proteins

CONCLUSIONS

CaptureSelect antibody subdomain-specific affinity resins address the purification challenges in therapeutic antibody development by providing unique selectivity, high purity and yields in a one-step purification process.