

MUCH-EFFICIENT AND COST-EFFECTIVE MANUFACTURING OF ANTIBODY BIOTHERAPEUTICS EMPLOYING INTEGRATED NEGATIVE CHROMATOGRAPHY TECHNOLOGY

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New approaches for fully connected and integrated downstream processes to reduce costs and improve efficiency are being assessed with the implementation of the NCAP Project (negative chromatography antibody purification).

This project aims to resolve the manufacturing bottleneck facing modern antibody bio-therapeutics through exploring the great potential of the negative chromatography technology, i.e. purifying antibodies by binding all the surrounding impurities instead of binding target antibodies. High-throughput, miniaturised technologies have been implemented to enable the screening of multiple novel ligands based on a custom agarose backbone.

The objectives are: (1) replace the conventional expensive and fragile protein-A affinity chromatography medium with inexpensive and more robust small-ligand-based media; (2) investigate novel downstream processes incorporating as many negative chromatography steps as possible to achieve much-efficient and capacity-unlimited manufacturing of biopharmaceuticals; (3) upstream and downstream process integration, and intensification by pushing the boundaries of the negative chromatography technology.

This process is independent of the expression level in the upstream and should bring enormous potential cost benefits; providing a platform for truly continuous and integrated manufacturing processes, reducing hold times, enabling faster throughput and reducing the cost of raw materials.