

DEVELOPMENT OF INTEGRATED CONTINUOUS BIOPROCESSING USING CONTINUOUS COUNTERCURRENT TANGENTIAL CHROMATOGRAPHY (CCTC) PLATFORM FOR CAPTURE AND POLISHING OF MONOCLONAL ANTIBODIES

Oleg Shinkazh, CEO of ChromaTan Corporation

Dmitriy Fedorenko, Associate Director of Process Sciences, ChromaTan Corporation

Dr. Andrew Zydney, Bayard D. Kunkle Chair and Professor of Chemical Engineering; Director, Center of Excellence in Industrial Biotechnology

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Several recent studies have demonstrated the potential of using continuous countercurrent tangential chromatography (CCTC) for the purification of monoclonal antibody products. CCTC operates with a flowing resin slurry, exploiting traditional approaches of countercurrent staging to achieve > 10-fold increases in productivity compared to traditional batch columns in a truly steady-state low pressure (<15 psi) unit operation that can be directly integrated into a fully continuous biomanufacturing process. The featured data shows productivity and product quality outcomes from Protein A capture, as well as Anion exchange and Cation exchange polishing steps for purification of a commercial mAb. Another unique aspect of CCTC is the ability to use small particle size resins with improved binding kinetics and better system productivity but without any increase in pressure. The data also features our strategy for integrating the unit operations into a single process train incorporating an integrated in-line sampling strategy. In addition we discuss the potential of this platform to enable efficient processing of sensitive biologics because of significantly reduced residence time (<10 min from binding to elution), as well as rapid in-line buffer adjustments of eluted product.