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Advancing monoclonal antibody production with improved purification technology

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Chromatin from dead cells persists in cell culture harvests as heteroaggregates. They bind more strongly to most chromatography adsorbent than most biological products. They reduce binding capacity by blocking pore access and increase peak width by interfering with pore egress. They will also inflate contamination during product elution by leaching of contaminant subsets from still-bound chromatin elements. Chromatin-directed clarification enables many capture options and a reduction of processing steps. In this study, we show that this new clarification method enabled a wide variety of protein A affinity chromatography media to support dynamic capacities that equaled or closely approached values determined with purified IgG. Contaminant content after single protein A step were reduced to <1 ppm HCP, DNA to <1 ppb, protein A leakage to <1 ppm, and aggregates to 1% with an IgG step recovery of 99.4%. Addition of a single polishing step reduced aggregates to <0.1% and all other contaminants beneath their limits of detection, with a step recovery of 96% and overall process recovery, including chromatin extraction, of 90%.

Biography

Nian Rui earned a PhD degree in Chemical and Biomolecular Engineering from National University of Singapore in 2008. He is currently a Professor and Leader of Biological Protein Materials Group in Qingdao Institute of Bioenergy and Bioprocess Technology, Chinese Academy of Sciences (QIBEBT). Prior to joining QIBEBT in 2015, he worked in Downstream Processing Group of Bioprocessing Technology Institute (BTI, A STAR, Singapore) and focused on the development of next generation bioseparation technology since 2012. He was the Lead Scientist at A-Bio Pharma (Singapore) and took in charge of the downstream process development of various biosimilars in lab-scale and pilot-scale between 2010 and 2012.

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