

516a A Rational Approach to Design an Efficient Primary Recovery Process for a Recombinant Protein from Microbial Biomass

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The paper describes development of a large scale process for efficient separation of a soluble recombinant protein from high density bacterial fermentation broth. Challenges for process development included (a) high solids level, (b) protein solubility limitations, (c) need to retain a soluble contaminant while passing product molecule through a suitable membrane and (d) process economics.

The paper will utilize an actual industrial application to illustrate how the above four issues, which are very common in primary recovery steps in bioprocessing can be tackled in a systematic fashion. First, the focus will be on how to narrow down the options for first-pass bulk removal of biomass (centrifugation, conventional filtration, microfiltration (TFF)). This will be followed by detailed description of membrane screening, optimization of microfiltration operational parameters, scale-up and integration within the rest of the process with the overall objective of maximizing product recovery. The particular process discussed in the paper was successfully scaled up 1000-fold in an industrial operation.