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Next generation clarification for processing high density cell culture fluids supplemented with a flocculating agent

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The first step in the purification of a therapeutic product is clarification that typically combines multiple separation technologies such as centrifugation, tangential flow microfiltration and depth filtration. Recent advances in mammalian expression systems have led not only to very high cell density cultures and increased protein titers, but also for low viability feed streams with high proportion of solid fraction that made those techniques less attractive. Complexity and issues at scale-up limits the use of the centrifugation, while clarification of such high density cell harvests solely by depth filtration can be costly due to high filter areas required. In this study, we present a complete clarification solution that combines cell harvest pretreatment with a polycationic flocculating agent (pDADMAC), followed by depth filtration using enhanced depth filters that were specifically developed for filtration of flocculated or precipitated feed streams. Multiple antibody feed streams have been treated with pDADMAC and filtered using Clarisolve depth filters resulting in improved removal of cells and cell debris, efficient reduction of DNA and high process yield. Overall, this innovative clarification approach leads to reduced filter area, enhanced impurity removal and process simplification of high density cell harvests that can be readily incorporated into current clarification platforms.

Biography

Sladjana Tomic Skrbic has studied Biotechnology at Beuth University of Applied Sciences, Berlin, Germany and completed her PhD at Max-Planck-Institute of Biochemistry, Germany and Heidelberg University, Germany. She was a Post-doc at the Martin Luther University Halle-Wittenberg, Germany. Presently she is a Senior Process Development Scientist at Merck KGaA in Darmstadt, Germany, where she provides high quality scientific and technical support to Merck customers developing or manufacturing biopharmaceuticals. She also publishes and presents at conferences on bioprocess technologies.

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