



Importance of Prefiltration in the Biopharmaceutical Manufacturing

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Abstract

Prefilters are used extensively in a wide variety of Biopharmaceutical applications. A typical bioprocess comprises various unit operations beginning with Media Preparation & sterile media addition into a Bioreactor or a Fermentor, several stages of clarification for cell harvest post-fermentation, followed by three to four stages of purification using a series of chromatography columns & ultrafiltration/diafiltration (UF/DF) steps for concentration and buffer exchange, prior to formulation, fill and finish.

Prefilters are principally used in upstream processing for media filtration and cell harvest clarification. The primary goal of these Prefilters is to protect final sterilizing grade membrane filters, thereby reducing filtration costs as well as overall filtration times. In downstream processing, Prefilters are used for reducing Bioburden and removing precipitates prior to loading filtrate onto chromatography columns. In such cases, their key function is to protect downstream processing equipment. They remove contaminants in order to ensure optimal downstream processing. Prefilters could also have an indirect impact in providing high production yields.

This presentation gives an overview of different cartridge-type membrane and depth pleated filters and their use in various unit operations aforementioned. Data will also be presented on typical flow rates and throughputs observed in some of these applications.



Biography

Mandar Dixit is the Product Manager for Sterilizing Grade Filters at Sartorius Stedim North America Inc. located in Edgewood, NY. He has over 14 years of experience in filtration and separation technologies. He currently supports the North American Biopharmaceutical market for Filtration Technologies with special focus on Sterilizing Grade Filters and Prefilters. He is a member of PDA and ISPE. Mr. Dixit has co-authored papers in trade journals on Prefiltration as well as Filter Optimization and Scale-up studies. He received his Bachelor's Degree in Chemical Engineering from IIT-Bombay in India and his Master's Degree in Chemical Engineering from Louisiana State University in Baton Rouge, LA.