ADVANCES IN HOLLOW FIBER MEMBRANE TECHNOLOGY FOR HIGH DENSITY PERFUSION CELL CULTURE

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Continuous manufacturing, a trend for the production of biopharmaceuticals, holds significant promise for achieving higher productivity and lower cost. Next generation cell culture perfusion processes are among the most sought after to deliver on this promise. While the concept of continuous cell culture is not new, hurdles in the robustness and consistency of cell retention devices slow current adoption. The inherent lot-to-lot variability in commercially available hollow-fiber membrane (HFMs) often requires operators to adjust process parameters during the course of the perfusion process. Reproducible process intensification using HFM devices for cell retention requires membranes with consistent flux (LMH), bubble point (BP), and effective filtration area (EFA) optimized for each cell culture process. The selection of suitable membranes must depend on our knowledge of flux and BP, rather than on arbitrary membrane porosity designations. We found that the lot-to-lot distribution range of flux/BP in HFM devices is essential and must be within narrow limits to ensure consistent process performance. We present data on a novel well-characterized HFM device, SepraPor™, which is ideally suited to achieve reproducible results with constant process parameters.