

## Membrane Technology for the Production of Biopharmaceuticals

## Prof. Andrew Zydney Bayard D. Kunkle Chair and Professor of Chemical Engineering The Pennsylvania State University

Membrane systems have been used for the purification of biological molecules since the very beginnings of the biopharmaceutical industry. However, most of these applications involved relatively straightforward separations of species with very large differences in size. Recent advances in membrane science and technology have led to the development of membranes / processes that can accomplish much finer separations, opening up exciting opportunities for using membrane technology for the purification of monoclonal antibodies, vaccines, and gene therapy agents. This talk will provide an overview of how new advances in membrane science coupled with an improved understanding of the underlying transport phenomena have led to exciting new applications of membrane technology in bioprocessing. This includes the use of virus removal filtration in the production of monoclonal antibodies for the treatment of cancer, in which state-of-the-art membranes can provide selectivities of more than 1000-fold even though the small parvoviruses are only about twice the size of a monoclonal antibody. Recent work in our group has demonstrated that ultrafiltration can be used for the purification of conjugated vaccines, enabling the removal of residual free polysaccharides in the production of novel vaccine products. It is even possible to separate different plasmid DNA isoforms, in this case by exploiting differences in the elongational flexibility of biomolecules with nearly identical size but different topological structures. These developments are likely to have a major impact on the downstream processing of novel biopharmaceuticals for many years to come.