M7, Continuous DSP Commercial Technology

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Chromatographic processes are an important part in the downstream processing of bio-

molecules. These processes capture, purify and polish fermentation products such polypeptides, proteins, enzymes, viruses and antibodies, or purify synthesized bio- molecules. Their scale ranges from a few kilograms a year of very potent compounds to large bulk productions of several tons. Over last 10 years, a significant shift in downstream purification approach has taken place, especially after the tremendous increase in the upstream expression levels of monoclonal antibodies. Research groups not only from academia but also from PRD organizations started to pay attention to continuous operating modes such as simulated moving bed (SMB) and multi-column continuous (MCC) chromatography to overcome the “bottleneck” of the chromatographic steps and to further improve their through-put. Although, the SMB technology has a proven record to bring synthetic pharmaceuticals faster to the market and to purify non- pharmaceutical bio-molecules at a large industrial scale; barriers still remain to

implement the technology into the bio-pharmaceutical industry. What are these barriers? How can we remove them? In particular, eliminating barriers related to column and equipment hardware, packing material, solvent systems, CIP of the systems and bio- molecule characteristics to allow continuous chromatographic processes such as SMB to become part of the processing platform in the bio-pharmaceutical industry.



Dr. Mihlbachler joined Lewa as a global development director. Before Lewa, she worked at CBPE Department at NJIT as a Sr. University Lecture in the Fall 2011. During the previous 10 years, Dr. Mihlbachler worked in the pharmaceutical industry with an emphasis on process chromatography. As a Sr. Researcher at BMS, Eli Lilly and Company, and Pfizer, she worked on the development, scale-up and manufacturing of purification/separation processes for chiral and non-chiral compounds, peptides and proteins, in particular to implement continuous processes. Dr. Mihlbachler studied Chemical Engineering at the O.-v.-Guericke University Magdeburg, Germany. She received a M.S. in Biomedical Engineering from Rose- Hulman Institute of Technology, Terre Haute, IN. The research for her doctoral degree in Chemical Engineering, she conducted under the advice of Profs. G. Guiochon and Seidel-Morgenstern at the University of Tennessee Knoxville and Oak Ridge National Laboratory. Her dissertation thesis on Enantioseparation via SMB Chromatography was successfully completed with summa cum laude at the O.-v.-Guericke University. Since 2011 Dr. Mihlbachler has been the AIChE Programming Chair of Area 2g BioSeparations. She is also an active member of the Scientific Committee of the International Symposium on Preparative Chromatography. At its annual meeting she has led a workshop on Process/Preparative Chromatography of Pharmaceutical Intermediates and APIs for the last 10 years. Her research results she presented at international renowned meetings and published in peer reviewed journals. Furthermore, she also contributed two scientific book chapters: Simulated Moving Bed Chromatography in Advances in Large-Scale Biopharmaceutical Manufacturing and

Scale-Up Production, 2nd Ed. 2007, and Preparative Chromatography in B. Cue and W. Zhang, ed. Green Techniques for Organic Synthesis and Medicinal Chemistry, Wiley, 2012.