Fall 10-19-2015

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HEADACHE BE GONE: CLEARANCE OF EXTRACTABLES AND LEACHABLES IN SINGLE-USE TECHNOLOGIES THROUGH ULTRAFILTRATION/DIAFILTRATION

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Key Words: Ultrafiltration/Diafiltration, Extractables, Leachables, Clearance, Single-Use Technology.

Application of single-use technologies in biopharmaceutical manufacturing can be driven by several factors such as reduced capital costs, reduced risk of cross-contamination, increased process flexibility, and reduced cleaning validation. However, implementation of single-use technologies have been restricted due to a number of concerns, with the most commonly cited being the presence of extractables and leachables (E/L) from single-use technologies. In general, overly conservative estimates of E/L are used in the risk assessment due to lack of data on clearance, resulting in a time-consuming, costly, and extensive E/L assessment for single-use technologies.

A proof-of-concept study is presented here to simplify these E/L assessments for qualification and implementation of single-use technologies in biopharmaceutical manufacturing. Results from the study indicated clearance of defined E/L in protein solutions. However, unexpected clearance phenomena were observed for specific groups of E/L, which will be discussed in detail.