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Nicholas Margarian

Genentech Inc, margarian@gene.com

Kate Lee

Genentech Inc

Kunal Nagpal

Genentech Inc

Ken Skidmore

Genentech Inc

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MONITORING CLEARANCE OF EXTRACTABLES AND LEACHABLES FROM SINGLE-USE TECHNOLOGIES BY NMR

Nicholas Magarian, Genentech, Inc.
magarian@gene.com
Kate Lee, Genentech, Inc.
Kunal Nagpal, Genentech, Inc.
Ken Skidmore, Genentech, Inc.

Key Words: Quantitative NMR, Single-Use Technologies, Ultrafiltration/Diafiltration, Extractables and Leachables, Process impurity testing

Process validation at Genentech requires NMR methods capable of detecting and reliably quantifying trace levels of process impurities and leachables. Measurements must be done in solutions which are far from ideal for NMR. Depending on the application, high protein and buffer concentrations, along with the presence of water, necessitate an approach to NMR measurements and data interpretation which differs greatly from traditional NMR methods. Here, we show how we deal with these complications, and how our methods may be applied to measuring the concentrations of leachables from single-use products.