PDA Filtration Interest Group Meeting September 16, 2013 Meeting Summary

The PDA Filtration Interest Group met on September 16, 2013, in conjunction with the PDA/FDA Joint Regulatory Conference in Washington, D.C. Approximately 8 people attended.

The meeting consisted of a panel discussion of topics suggested by the attendees. Panelists included Ross Acucena (EMD Millipore Corporation), Michael Moussourakis (Pall Corporation), Paul Priebe (Sartorius Stedim Biotech), and A. Mark Trotter (3M Purification, Inc.). Topics discussed included the potential for electrostatic discharge damage to membranes used for air filtration (might be controlled by grounded housings and limiting airflow), leachables and extractables and the best model solvents to use to simulate product, whether to place the 0.45 µm sizing filter in-train or off-line for size control in bacterial challenge studies (in-line deemed better), and whether it is necessary to formally qualify integrity test flush volumes during post-filtration integrity testing where the product is not the integrity test fluid (thought not to be necessary if the final integrity test value had stabilized as a function of rinse volume).

The next filtration IG meeting is tentatively scheduled for the 2014 PDA Annual Meeting, April 14-16, in San Antonio, Texas. Date, time and topics will be announced as soon as finalized.

Please feel free to submit topic ideas to Madsen@TheWilliamsburgGroup.com.

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