S2.5.2 - *Faster Media & Membranes Evaluation for Cartridge Makers Through Use of Validation Package*

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Evaluation of new media for depth and membrane cartridges is costly and requires significant time and investment from cartridge makers and end-users. There are significant regulatory and standards complexity in evaluating this media primarily because; 1/ the product flows through the cartridge, 2/ that product is often a pharmaceutical, and 3/ other applications are often takers of these standards, even if they do so unknowingly. By following the best practices already established in the sterilizing grade membrane market, where manufacturers publish a Validation Package, cartridge makers and end-users can pursue new media evaluation faster and with greater confidence in their vendors. The Validation Package is a 30 – 50 page document covering:•Microbial Retention (ATCC 19146)•Endurance to Steam Sterilization, Autoclaving, and other Cleaning Methods•Water Flow Characteristics•Extractables Testing (ASTM D3681)•Biological Safety (USP Class VI)The standards established for proteins, mAbs, foods, and beverages are used in other microfiltration markets, even if the users don't realize that their products

conform to these standards.By organizing, collecting, and sharing this information porous media producers can shorten product evaluation cycles. Element makers can have confidence that cartridges suitable in faster-moving markets, like industrial filtration, will not require modification when the more highly regulated markets are encountered. The authors discuss the specific standards under each of the sections mentioned above, show how to test for and evaluate media for these standards, and discuss future changes to the standards. Finally, the authors discuss how other criteria for liquid filters can be evaluated within the format of a Validation Package – including protein binding and element life.

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