

A Workable Sampling Plan Using a Quality Risk Management Approach Relative to the PQ Phase of the Upgraded Purified Water Generation System at the Pilot Plant/Small Scale Level—A Validation Engineering Perspective



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Hence, the intent of this paper is to discuss and illustrate how the points of testing/frequency determined in the PQ phase at the pilot plant scale level have been established through the use of a science risk-based tool (i.e., a quality management approach) by factoring in the sampling of critical points/components rather than sampling every purified water generation sampling-point with high volumes of daily frequency testing. It should be noted that other methods can be employed when deciding to sample a portion of the purified water generation system. A “robust routine monitoring” (discussion...

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