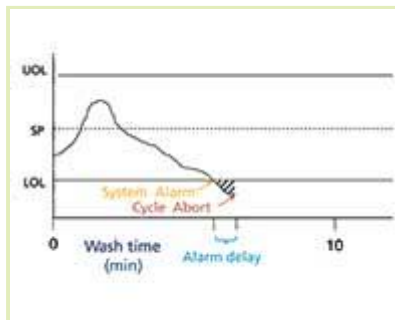


## Parametric Release for Cleaning—Part II: Process Monitoring

May 13, 2013 9:53 am EDT



The primary advantage of parametric release is that the process is continually monitored, which obviates the need for time-based revalidation also known as periodic monitoring. There are several limitations to the periodic monitoring approach. First, periodic verification of the effectiveness of a cleaning procedure provides limited assurance that the procedure was effective throughout that period. Further, periodic monitoring runs are not designed to challenge the system under worst-case cleaning conditions; instead, they are typically performed with the CPPs at their respective...

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