

Reducing the Cost Of Sterilization Validation: Aligning With USP 1229.5



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By

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**3M's 1262 Biological Indicator Attest
designed for the control of steam
sterilization processes.**

One critical factor to understand and consider during the implementation of controls for BI's is the fact that they are considered process aids, not raw materials. The regulatory requirements and standards for the industry related to BI's can be found in the United State Pharmacopoeia (USP). USP55 and 1229.5 describes the applicable regulatory requirements for BI's. Understanding the current requirements found in USP55 and 1229.5 is critical for companies to manage their BI program in alignment with regulatory requirements without incurring in unnecessary cost. Inadequate interpretation...

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