



Why Life Science Organizations Are Cited by the FDA

Citation Reason and CFR Rule	How Sentinel Helps PREVENT The Citation
<p>Failure to validate with a high degree of assurance, and approve according to established procedures, the results of a process that cannot be fully verified by subsequent inspection and test, and failure to document the validation activities and results. [21 CFR § 820.75(a)]</p>	<p><i>Sentinel provides you complete process history, including a detailed change log of status and activity. Authorized managers and auditors can access complete process history.</i></p>
<p>The firm failed to establish procedures to ensure that all equipment was appropriately designed, constructed, placed, and installed to facilitate use.</p>	<p><i>Using Sentinel's powerful template capabilities, you can establish processes and procedures for verifying all equipment placed in operation. Once defined, you can evaluate and validate and store all documentation required to support your findings.</i></p>
<p>Failure to document acceptance activities including the acceptance activities performed, the date acceptance activities are performed, the results, the signature of the individual conducting the acceptance activities, and, where appropriate, the equipment used. [21 CFR § 820.80(e)]</p>	<p><i>Sentinel serves as a system of record for all activities managed throughout your business. Activity approval includes electronic signature verification by appropriate personnel.</i></p>
<p>Failure to implement procedures for quality audits and conduct such audits to assure that the quality system is in compliance with quality system regulation, as required by 21 CFR 820.22.</p>	<p><i>Sentinel provides complete audit functionality, including the ability to self-assess and verify control activities governing processes and procedures at your business. With Sentinel scheduling auditors can plan out an entire year of audit evaluation.</i></p>



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<p>Failure to establish and follow written responsibilities and procedures applicable to the quality control unit. [21 CFR 211.22(d)]</p>	<p><i>Sentinel provides complete written instructions to assignees, including appropriate documentation, work papers and checklists to ensure accurate and timely completion of tasks.</i></p>
<p>Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. [21 CFR 211.110(a)]</p>	<p><i>Sentinel's control framework allows you to monitor and manage control performance throughout your life science enterprise.</i></p>
<p>Failure to fully establish and follow written procedures describing the handling of all written and oral complaints regarding a drug product</p>	<p><i>Sentinel provides comprehensive process definition and management, providing standardization of methods and practices precisely defined by your Standard Operating Procedures.</i></p>
<p>Failure to establish an adequate and effective quality system that has been fully implemented and maintained at all levels of the organization, 21 C.F.R. 820.20(a).</p>	<p><i>Sentinel allows you to document and manage a quality system throughout your business. Because it integrates documents directly with processes, you can be assured that your SOP requirements are followed exactly as defined.</i></p>
<p>Failure to establish and maintain procedures to control all documents,</p>	<p><i>Sentinel is a document control system. It controls access to documents by authorized users only, as well as providing the ability to define and then monitor document control processes.</i></p>
<p>Failure to establish and maintain procedures for implementing corrective and preventative</p>	<p><i>Complete Remediation and CAPA management is easy and effective to manage on Alinion Sentinel. In addition to its remediation management and</i></p>



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<p>action (CAPA) and to document all CAPA activities and their results as required by 21 C.F.R. 820.100.</p>	<p><i>monitoring, Sentinel also includes help ticket functionality, allowing authorized users to assign specific issues and track them through to completion.</i></p>
<p>Failure to assure that a process whose results can not be fully verified by subsequent inspection and test, has been adequately validated and approved according to established procedures, as required by 21 C.F.R. 820.75(a).</p>	<p><i>Sentinel provides complete change log and testing capabilities of activities and controls that are being managed and monitored. Using its powerful Roles and Permissions functionality, seats with limited views to information can be established, including those for external auditors and inspectors.</i></p>
<p>Failure to document the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date, as required by 21 C.F.R. 820.72(b)</p>	<p><i>Using Sentinel Work Papers, organizations can fully document the calibration of all equipment. Sentinel can schedule on-going calibration programs and provide complete evidence required by the Code of Federal Regulations.</i></p>
<p>Employees were not adequately trained. Employee training was not fully documented [21 C.F.R. 820.25(b)].</p>	<p><i>Sentinel deploys and manages all training programs, including keeping a record by organization and training program of those who participated in the program. Sentinel automates the creation and tracking of all training programs, including those supporting Standard Operating Procedures.</i></p>