

Management of Compliance Situations

When compliance issues are encountered, it is critical to rapidly identify and understand the root cause, develop an appropriate and sufficient corrective action plan, and effectively communicate with the involved parties. Missteps in the handling of potential recall situations or in responding to regulatory compliance observations can lead to increased scrutiny, supply chain disruption, delays in approvals, and the loss of confidence of patients, doctors and investors. We assist in the management of critical compliance situations and provide meaningful sustainable remediation guidance.

Auditing Is Not Monitoring

An audit is not the same thing as ongoing monitoring. Audits are discrete experiences, akin to projects, and are usually conducted by disinterested outsiders. Monitoring is an ongoing effort to ensure that controls accurately guide processes. Monitoring is also the responsibility of management.



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