

Quality Systems - Routine Support

We offer support for the execution of all activities related to Quality System routines, including Batch Record review, Change Control management, CAPA and Deviation management, and Internal Audits execution. With our partnership, we ensure that your Quality Systems remain efficient, compliant, and aligned with best practices, without delays or lack of SOPs adherence

Change Control Management

Our team assists in managing Change Control processes, ensuring that any proposed changes to processes, procedures, or systems are thoroughly evaluated, documented, and implemented in compliance with regulatory standards. We facilitate the review and approval of requests, assess potential impacts on quality, and oversee the execution of approved changes.

Deviation Handling

We provide support in investigating and managing deviations from established processes or specifications, identifying root causes, and implementing corrective actions to prevent recurrence. Our consultants guide the deviation investigation process, facilitate cross-functional collaboration, and ensure timely resolution to minimize impact on product quality and compliance.

CAPA Implementation (Corrective and Preventive Actions)

We assist in the implementation of corrective and preventive actions (CAPAs) derived from deviation investigations, audits, or other quality events. Our team helps develop CAPA plans, track progress, and verify effectiveness, ensuring that identified issues are addressed comprehensively to prevent recurrence and improve overall quality systems.

Batch Record Review

Our experts ensure that batch records are complete, accurate, and compliant with regulatory requirements, identifying any discrepancies or deviations that may impact product quality or regulatory compliance.

Internal Audit Execution

Our team plans, executes, and reports on internal audit activities, identifying areas for improvement, verifying the effectiveness of corrective actions, and ensuring ongoing compliance and continuous improvement.

