

Change Control – Audit Execution

By conducting focused Audits, we support pharmaceutical companies to ensure the effectiveness and compliance of their Change Control processes. Our expert auditors meticulously review various aspects, including adherence to international references such as FDA and EMA, alignment with company SOPs, and the accuracy of records and evidence

Documentation Review and Verification

Our auditors scrutinize all relevant documentation, including change requests, impact assessments, approval records, and change implementation reports, to ensure they meet regulatory requirements and internal SOPs.

We verify the accuracy, completeness, and timeliness of documentation to ascertain if the change control process has been properly documented and executed.

SOP Adherence Assessment

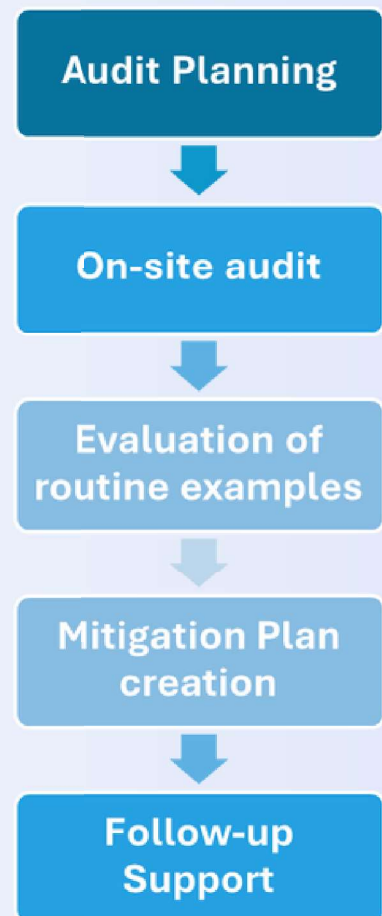
We assess the company's adherence to its own standard operating procedures (SOPs) governing the change control process.

Our auditors evaluate whether the procedures outlined in the SOPs are being followed consistently across departments and functions, identifying any deviations or discrepancies that may indicate non-compliance.

Process Evaluation and Compliance Check

We conduct a comprehensive evaluation of the entire change control process workflow, from initiation to closure, to ensure compliance with regulatory standards and industry best practices.

Our auditors verify if the change control process is effectively managing changes, assessing risks, obtaining necessary approvals, and implementing changes in a timely and controlled manner, highlighting any areas of non-compliance and providing recommendations for improvement.



- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS