Non-compliance – Audit Execution

We conduct comprehensive audits to evaluate the adherence between international regulatory standards (FDA and EMA) and internal SOPs, regarding Management of Non-compliance issues (Deviations, Incidents, and Investigations). Our expert team meticulously examines the background of activities, SOPs, records and evidences, to evaluate the scenario and propose adaptions, ensuring alignment with regulatory requirements

Activity Background Verification

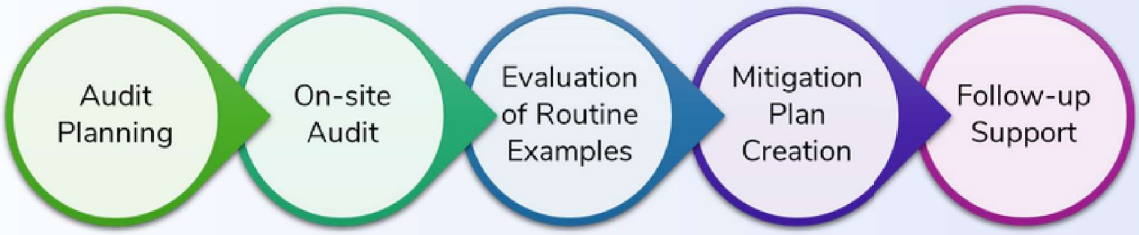
We conduct a thorough review of the background of non-compliance activities, including the documentation, procedures, and processes followed by the company. This involves verifying the alignment of activities with international regulatory references such as FDA, EMA, and WHO guidelines to ensure compliance and identify any discrepancies.

SOP Adherence Assessment

Our team evaluates the company's adherence to its own Standard Operating Procedures (SOPs) for managing non-compliance incidents. We assess whether the documented procedures are being followed effectively and identify any deviations from established protocols or procedural controls.

Record and Evidence Review

We meticulously review records and evidence associated with non-compliance incidents to determine the effectiveness of corrective actions taken by the company. This includes verifying the completeness, accuracy, and timeliness of documentation, as well as ensuring that corrective measures are implemented in accordance with regulatory requirements and best practices.



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

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