

Risk Management – Audit Execution

By carrying out focused Audits, we evaluate the Risk Management processes to ensure regulatory compliance and effectiveness. We holistically evaluate the aspects that make up the activity, ensuring adherence to international references (e.g.: FDA, EMA, and ICH) and compliance with internal SOPs

Preparation and Planning

We begin by thoroughly planning the Audit, including scope definition, objectives, and criterias. This involves reviewing relevant regulations, guidelines, and internal policies to establish the audit framework and identify key areas for assessment.

Auditing

Our experienced auditors conduct on-site or remote audits to assess the implementation and effectiveness of the risk management processes. This includes interviewing relevant personnel, reviewing documentation and records, and observing procedures to verify compliance with regulatory requirements and internal standards.

Audit Reporting and Follow-up

Following the audit, we compile detailed audit reports that summarize findings, observations, and recommendations for improvement. We work closely with the client to discuss audit findings, address any discrepancies or non-conformities, and develop corrective action plans to enhance the risk management landscape. Our team provides ongoing support to ensure timely resolution of issues and continued compliance with regulatory expectations.

