

Quality Management System Landscape – GAP Assessment

Our service offers a meticulous evaluation of the entire QMS landscape, ensuring alignment with global regulatory standards set forth by the FDA, EMA, and WHO. We conduct a comprehensive review of SOPs governing key Quality activities such as: Non-conformance Management, Change Controls, CAPA, Market Complaints, Qualifications and Validations, Training Management, and Batch Release processes

SOP Analysis and Review

Our team conducts a detailed analysis of existing SOPs related to Quality activities, assessing their content, clarity, and alignment with regulatory requirements and industry best practices.

GAP Identification and Analysis

Through systematic evaluation, we identify gaps and deficiencies within the SOPs, comparing them against international references and regulatory guidelines.

Our experts analyze identified gaps to determine their impact on compliance, risk management, and overall quality performance within the organization.

Recommendation Development

Based on the findings of the GAP assessment, we develop tailored recommendations and action plans to address identified deficiencies and improve SOP content.

Our recommendations focus on enhancing SOPs to align with international standards, addressing GAPs in compliance, improving process efficiency, and strengthening overall quality management practices.

