

Medical Devices EU Registration – GAP Assessment

Zamann Pharma Support provides service dedicated to evaluating the client's existing processes for conducting EU registration of Medical Devices. We conduct a comprehensive assessment to identify any GAPS or discrepancies in the implementation of regulatory requirements

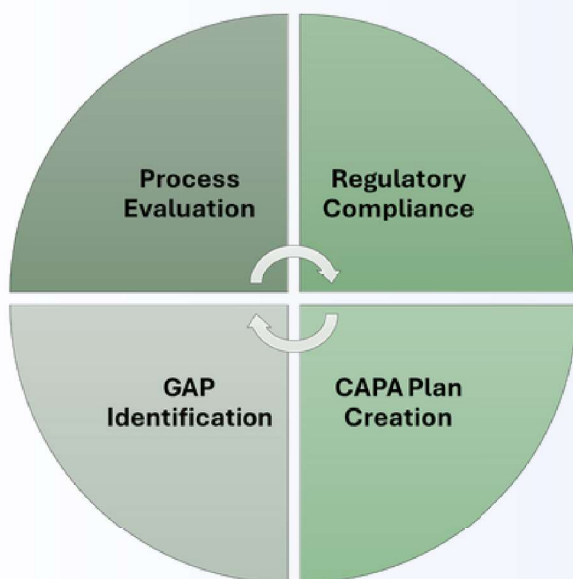
Process Evaluation

Thoroughly examining the client's SOPs, work instructions, and other relevant documentation to assess their completeness and alignment with regulatory requirements. We map out the existing processes for EU registration of Medical Devices to identify potential bottlenecks, redundancies, or GAPS in the workflow.

Regulatory Compliance Analysis

Evaluating the client's processes against the regulatory framework provided by authorities such as the FDA and EMA, including applicable directives, regulations, and guidelines.

Performing a risk assessment to identify potential areas of non-compliance or regulatory risk within the client's processes for EU registration of medical devices. Conducting a systematic comparison between the client's current practices and regulatory requirements to identify any discrepancies or gaps that may exist.



GAP Identification and Reporting

Clearly documenting and categorizing identified GAPS or deficiencies in the client's processes related to EU registration of Medical Devices, including areas such as Documentation, Validation, Risk Management, and Quality Management.

Investigating the root causes behind identified GAPS to understand why they exist and develop a comprehensive remediation plan that outlines specific actions, responsibilities, timelines, and resources required to address identified GAPS and enhance regulatory compliance.