

Process Validation – GAP Assessment

Zamann Pharma Support offers consultancy services, specializing in conducting thorough assessments to evaluate the current state of Process Validation within client organizations. Our focus is on identifying potential GAPS in the existing practices and assessing their compliance with international standards (e.g.: FDA and EMA)

Documentation Review

We conduct a detailed review of the client's existing Process Validation documentation, including validation protocols, reports, and related records. Our team evaluates the completeness, accuracy, and compliance of the documentation with regulatory requirements and industry best practices.

Process Evaluation

Zamann assesses the client's Process Validation procedures and practices, including planning, execution, and reporting. We analyze the effectiveness and adequacy of the client's validation methodologies, risk assessment processes, and acceptance criteria to identify any areas for improvement or enhancement.

Regulatory Compliance Assessment

We evaluate the client's Process Validation activities against relevant regulatory guidelines and requirements issued by authorities such as the FDA and EMA.

Our team ensures that the client's process validation practices align with current regulatory expectations and industry standards, identifying any non-compliance issues and providing recommendations for corrective actions.

