

# Risk Management – GAP Assessment

Our service assists companies in evaluating their existing Risk Management processes to ensure compliance with international regulations such as FDA, EMA, and ICH. We assess whether there is a robust risk-based approach integrated into all Quality processes and identify any GAPs or deficiencies in the current risk management framework

## Regulatory Compliance Review

We conduct a thorough review of the Risk Management framework against applicable regulatory requirements and guidelines, including FDA Risk Assessment Framework, ICH Q9, and EMA Risk Management Plans. This involves assessing the alignment of Risk Management practices with regulatory expectations and identifying areas of non-compliance.

## Process Mapping and Analysis

Our team maps out the end-to-end risk management process within the organization, from risk identification and assessment to risk mitigation and monitoring. We analyze each step of the process to identify GAPs, redundancies, and areas for improvement, ensuring a comprehensive understanding of the risk management landscape.

## Risk-Based Approach Evaluation

We evaluate the extent to which a risk-based approach is embedded across all quality processes within the organization. This includes assessing the integration of risk management principles into activities such as deviation management, change control, validation, and batch release. We provide recommendations for enhancing the implementation of a risk-based approach to drive efficiency and compliance.

