Non-compliance – GAP Assessment

Our service is designed to help pharmaceutical companies evaluate their existing Quality processes for Deviations, Incidents, and Investigations. We are able to suggest improvements by mapping the applicable international regulatory standards (e.g.: FDA and EMA) and conducting a thorough evaluation of the related SOPs and records to identify any GAPs. Based on our findings, we collaborate with the client to create a comprehensive CAPA plan to address these deficiencies and align the company's practices with

Regulatory Reference Mapping and Review

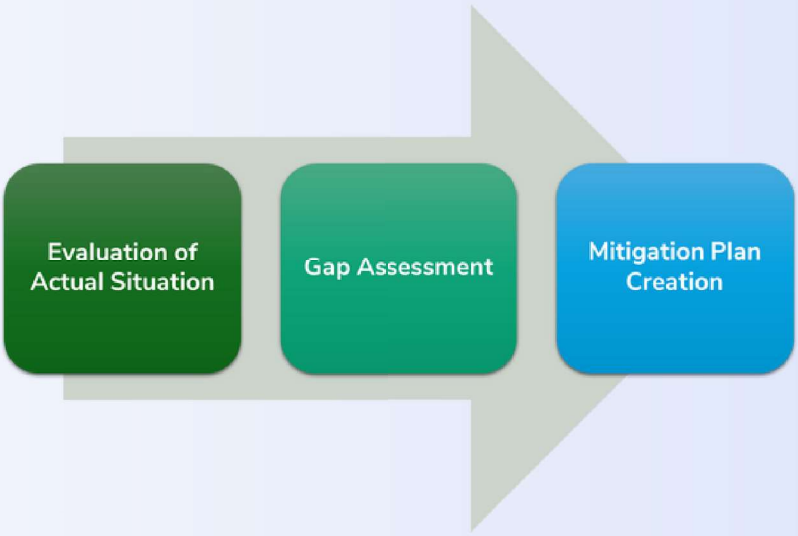
We meticulously review and analyze applicable regulatory references, including FDA, EMA, and WHO guidelines, to ensure a comprehensive understanding of the requirements.
This involves identifying key regulations, standards, and best practices relevant to deviations, incidents, and investigations management in the pharmaceutical industry.

SOP and Record Evaluation

We conduct a detailed evaluation of the company's existing SOPs and records related to deviations, incidents, and investigations.
This includes assessing the adequacy, completeness, and compliance of SOPs and records with regulatory requirements and industry standards, identifying any gaps or deficiencies in documentation and procedural controls.

CAPA Plan Development

Based on the findings of the GAP assessment, we work closely with the client to develop a comprehensive CAPA plan to address identified deficiencies and non-compliances.
This involves prioritizing corrective and preventive actions, defining timelines and responsibilities for implementation, and ensuring alignment with regulatory requirements and best practices to enhance Quality processes and compliance readiness.



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- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS

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