Change Control – GAP Assessment

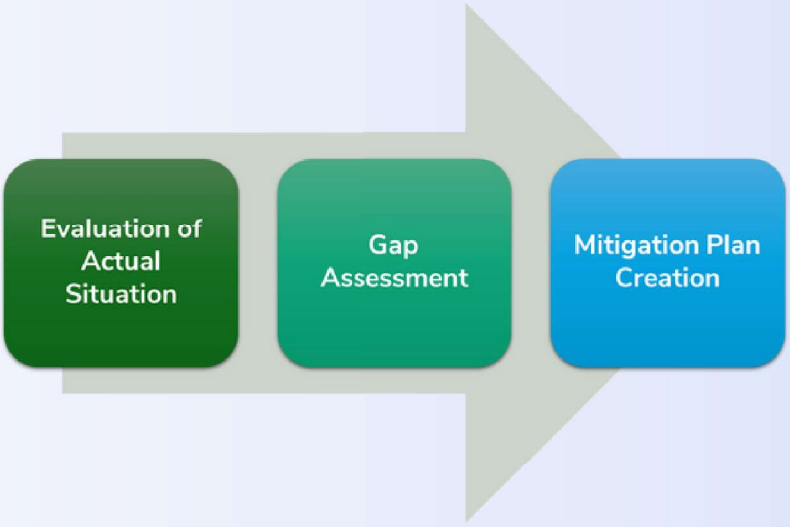
Our service is designed to evaluate the existing Change Control processes implemented by pharmaceutical companies, to ensure their compliance with international regulations such as FDA and EMA. Our experts conduct a thorough assessment to identify potential GAPs, providing valuable insights and recommendations for improvement

Document Review and Analysis

We review existing documentation related to change control, including policies, SOPs, and change records, to assess their alignment with regulatory requirements and industry standards.
Our team analyzes the content and effectiveness of these documents in facilitating the change control process, identifying any deficiencies or inconsistencies that may impact compliance.

Process Evaluation and GAP Identification

We conduct a comprehensive evaluation of the change control process workflow, from initiation to closure, to identify potential GAPs, bottlenecks, and areas of non-compliance. Our experts assess key aspects such as change request handling, impact assessment, risk evaluation, approval workflow, and documentation practices to pinpoint areas needing improvement.



Regulatory Compliance Assessment

We compare the findings of the GAP assessment against relevant regulatory requirements, guidelines, and industry best practices, such as FDA 21 CFR Part 11, EU GMP Annex 11, and ICH Q10. Our team provides a detailed compliance report highlighting GAPs and recommendations for corrective actions to bring the change control process into alignment with regulatory expectations.

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

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