Master Data Management (Computerized Systems) – GAP Assessment

This service entails a comprehensive evaluation of the implemented Master Data Management (MDM) background, including SOPs, activities and documents, to ensure compliance with FDA, EMA, and GAMP5 regulations. The primary objective is to identify potential GAPs and improvements in the MDM system's adherence to international guidelines, thereby enhancing data integrity and regulatory compliance

Documentation Review and Analysis

Our team conducts a thorough review of all relevant documentation, including SOPs, work instructions, data management procedures, and validation protocols.

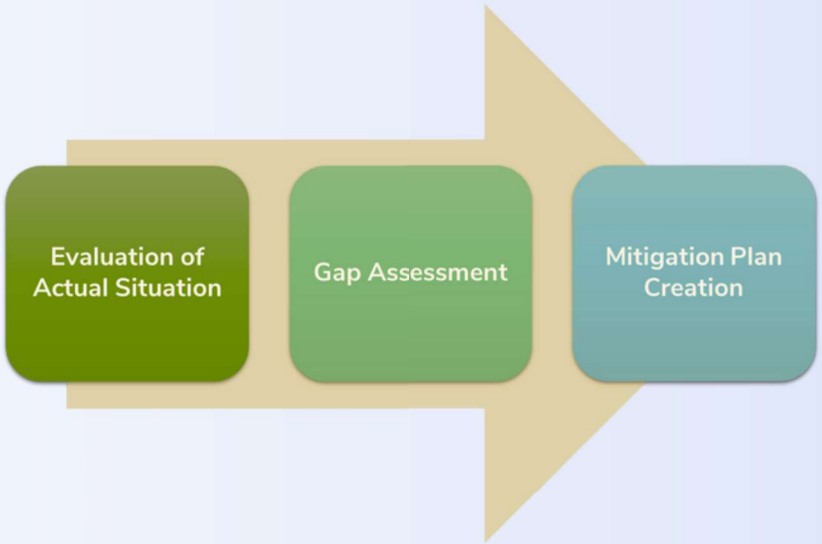
We analyze these documents to assess their alignment with FDA, EMA, and GAMP5 requirements, focusing on data integrity, electronic recordkeeping, audit trails, and data security measures. Any discrepancies or deficiencies identified during the review are documented and categorized based on their impact on compliance and data integrity.

Process Evaluation and GAP Identification

We evaluate the existing processes and procedures to identify GAPs or deviations from regulatory expectations. This assessment encompasses data entry and verification processes, data migration activities, data maintenance procedures, and data archival practices. Through detailed process mapping and gap analysis, we pinpoint areas where the current processes may fall short of regulatory requirements or industry best practices.

Regulatory Compliance Assessment

Our experts review the system's adherence to regulatory guidelines for electronic signatures, audit trails, change control, and data retention, among others. Recommendations are provided to address any identified non-compliance issues, ensuring that the master data management system meets regulatory expectations and supports data integrity objectives effectively.



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

Contact:
quality-services@zamann-pharma.com
www.zamann-pharma.com