Cleaning Validation – GAP Assessment

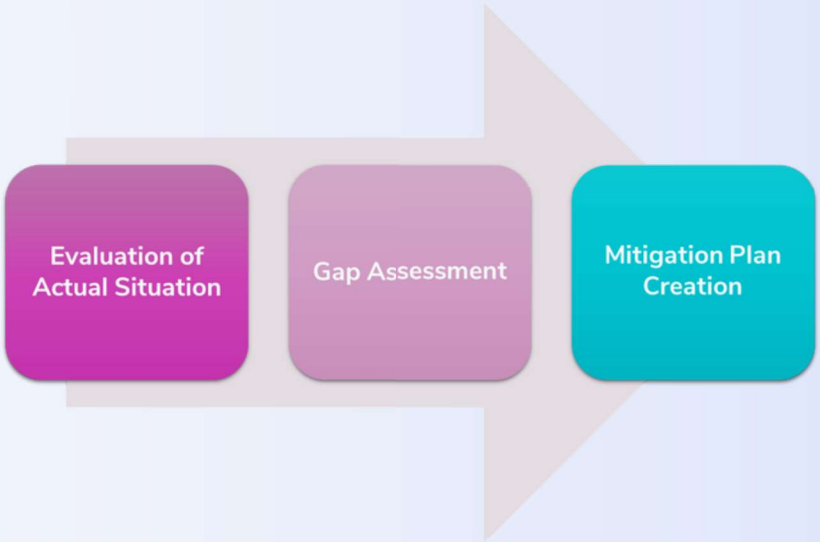
We offer consultancy services, dedicated to conducting comprehensive assessments of clients' Cleaning Validation processes. Our focus is on evaluating the existing procedures and executed validations, to identify any GAPs or deficiencies in compliance with international standards set by regulatory bodies like the FDA and EMA. Through rigorous GAP assessments, we provide clients with valuable insights and recommendations to enhance their cleaning validation practices and ensure regulatory compliance

Documentation Review

We meticulously review clients' existing cleaning validation documentation, including SOPs, protocols, reports, and risk assessments, to assess their alignment with regulatory requirements.
Our team identifies any discrepancies, inconsistencies, or deficiencies in the documentation, highlighting areas for improvement and corrective actions.

Process Evaluation

Zamann conducts thorough evaluations of clients' cleaning validation processes, examining key steps such as cleaning procedures, worst-case scenario identification, sampling methods, and acceptance criteria.
We assess the effectiveness and robustness of the processes in place, identifying any weaknesses or gaps that may impact the quality and safety of pharmaceutical products.



Compliance GAP Analysis

Our consultants perform a comprehensive GAP analysis to compare clients' cleaning validation practices against applicable regulatory standards and guidelines.
We identify areas of non-compliance or potential risks and provide detailed recommendations for remediation, prioritizing actions to address critical gaps and ensure regulatory adherence

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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