

Water Systems Validation (WFI, PW and Pure Steam) – GAP Assessment

Through detailed GAP assessments, we scrutinize the implemented SOPs and executed validations to ensure alignment with international standards set by the FDA and EMA. Our comprehensive analysis identifies any discrepancies or deficiencies in the validation process, enabling clients to enhance compliance and mitigate regulatory risks effectively

SOP Review and Analysis

We conduct a thorough examination of the client's SOPs related to Water Systems Validation, assessing their completeness, accuracy, and compliance with regulatory requirements.

Our experts analyze SOPs governing system installation, operation, maintenance, and performance qualification to identify any gaps or inconsistencies. By scrutinizing SOPs against regulatory expectations, we provide actionable recommendations to strengthen procedural controls and ensure compliance with industry standards.

Validation Documentation Assessment

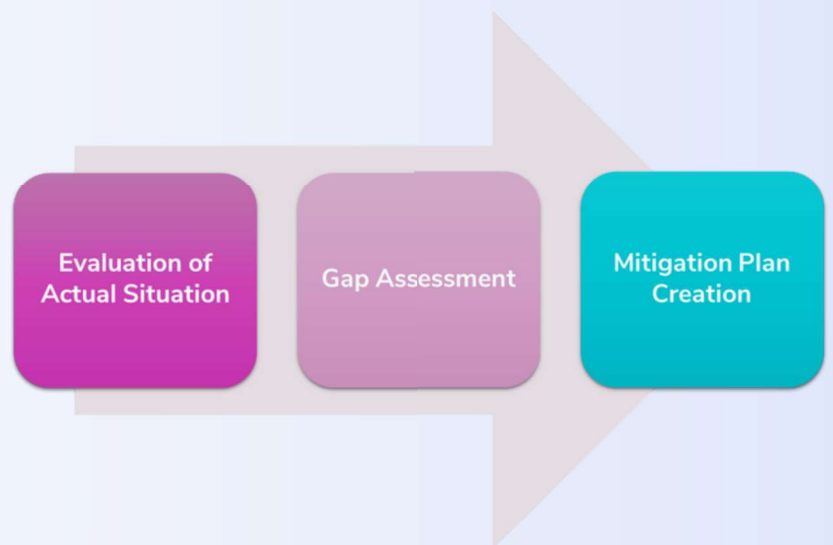
We review the validation documentation associated with water systems, including protocols, reports, and validation data. Our team evaluates the adequacy of validation studies conducted for WFI, PW, and Pure Steam systems, ensuring they meet regulatory requirements and industry best practices.

Through meticulous document analysis, we identify any deficiencies or deviations from regulatory expectations, providing clients with insights to improve the quality and integrity of validation records.

Compliance Gap Analysis

Utilizing compliance GAP analysis techniques, we assess the identified deficiencies in the water systems validation process. Our experts conduct a comprehensive comparison of validation practices against FDA and EMA guidelines, identifying areas of non-compliance or regulatory risk.

By prioritizing corrective actions based on the severity and impact of identified gaps, we assist clients in developing targeted strategies to address compliance challenges.



- Quality Consulting and Risk Management
- Qualification and Validation

- Personnel Qualification
- Customer-specific provision of QMS