



## QA Edge Audit Overview

- Company Introduction/Background
  - Possible Data Flow/Operations – e.g. system/s demonstration
  - Project Review (company, roles, responsibilities, scope)
- In-depth review of SOPs including SDLC deliverables, Change Control Processes, disaster recovery, business continuity procedures and production control SOPs (backup, archive and retrieval, computer operations & safety, data modification & audit train, disaster planning/recovery, and document management)
- Inspection of all validation document/deliverables to compare with the audited supplier's SOPs, compliance with 21 CFR Part 11 and adherence to the requirement of predicate rules. These inspections may include review of the following document types:
  1. Project Plans
  2. Performed Supplier Audits
  3. URS
  4. FS/TS (system specifications)
  5. Validation Plan – to determine strategy
  6. Test Plans – to determine testing approach
  7. Test Scripts and Results
  8. Validation Summary Report
  9. System Release Documents (IQ, OQ, PQ)
- 21 CFR Part 11 compliance discussion including gap analysis review
- Data center inspection and document data center operations, if applicable
- In-house Support Model
  1. Problem reporting through to resolution
  2. Change Control
  3. Error Tracking
  4. Client communications and response times vs Service Level Agreements (SLA)
- Review of personnel records (resumes, CVs, training records) to demonstrate adequate education and training for their current job descriptions

For more information, [contact](#) us.

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