Driving the Pharmaceutical, Biotech and Medical Device Industries towards Excellence

IT STRATEGY & COMPUTER SYSTEM GXP (21 CFR PART 11) COMPLIANCE

Compliance is part of larger picture of using business processes and computer related systems to foster innovation, cost-effectiveness and competiveness in today's rapidly changing technological world.

NDA Life Sciences views compliance as an opportunity to innovate, provide a basis for flexibility and manage constant change. NDA dispels the myth that compliance is costly, complicated, unwieldy or incongruous to today's business needs. NDA incorporates compliance as part of our solutions to provide a seamless integration of business and technology best practices.

NDA Life Sciences have the cross domain experience, knowledge and insight to enable pharmaceutical and biotech industry clients to leverage business and IT resources to meet business goals and exceed expectations. This allows us to be effective in addressing needs that cut across business functions such as recent serialization requirements and response to 21 CFR Part 11 audits.

Our multifunctional team provides clients a unique perspective, by providing a combined business and technical strategy that clearly identifies the possibilities available and provides a practical approach to implementation of a workable solution.

We do this by partnering with you to develop and implement strategic and tactical plans that:

- Identify key business drivers and opportunities
- Include:
  - business impact assessment
  - technology assessment
  - compliance assessment
- Project planning and management
- SOP management
- Requirements and design
- Document management
- Data management and disaster recovery
- Implementation
- Operational readiness and ongoing operational process
- Change Management

LIS SYSTEM 21 CFR PART 11 COMPLIANCE CASE STUDY

ISSUE:

A leading national health care organization with a centralized lab service required their existing laboratory information system (LIS) to be FDA compliant including 21 CFR Part 11.

OBJECTIVE:

Analyze SOPs and computer systems to create and execute a validation plan and mentor staff on compliance requirements and process.

DELIVERABLE:

An analysis of lab SOPs and system technical information was conducted in collaboration with lab directors, lab managers and IT. A Validation Master Plan and a Project Plan was then developed with establishment of a cross departmental Project Team. The plan was based on a retrospective validation approach and minimal documentation changes to meet compliance guidelines.

SOPs were drafted to execute the Validation Plan to meet compliance requirements as well as establishing the processes required to maintain the system in a validated state.

Project managed the successfully execution of the Validation Master Plan and trained staff in compliance requirements and related SOPs.

Provided document management and data management solutions.

Executed the Validation Master Plan which resulted in the following deliverables:

- Qualification of production servers
- Qualification of testing environment server
- LIS Requirements Specification including 21 CFR Part 11 compliance
- LIS Design Specification
- LIS Installation Qualification to Testing Environment
- LIS Operational Qualification
- LIS Installation Qualification to Production Environment
- LIS Requirement Traceability Matrix
- LIS Validation Summary Report

Contact Us

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