CourtSquareGroup
Drive The Business Of Science

Pharmaceutical Regulation Impact

When a client was required to comply with data validation and storage regulations mandated by the FDA, the ripple effect was felt in every aspect of the company. Court Square Group was called in to ensure that any new server or network component introduced into the IT environment would meet the FDA 21 CFR Part 11 regulatory requirements and mitigate the risk of non-compliance.

CASE STUDY

SUMMARY

The government's enforcement of FDA regulation 21 CFR Part 11 into the pharmaceutical industry directly impacted the computing infrastructure of every pharma, biotech and CRO organization. Our client was required to ensure that data collected during the course of the organization's research, pre-clinical and clinical activities was properly managed to ensure that no data was at risk of becoming irrecoverably corrupt or lost. In addition, the client had to be prepared to produce sufficient documented evidence to prove that each server introduced to the production environment would be built, and was capable of being re-built, in a consistent and compliant manner.

APPROACH

The past practice had been to have machines configured by vendors or business units. This introduced variables into the infrastructure that were uncovered during regulatory audits. Court Square worked with key stakeholders to map the entire server build process and identify key handoffs between technology teams. The active collaboration of key constituents resulted in a Master Qualification Plan for all information technology infrastructure services, including a detailed infrastructure lifecycle methodology to be used when installing or implementing new infrastructure components. The approach outlined in the Master Qualification Plan was designed to ensure the organization's approach to infrastructure services minimized and managed risk in a clearly documented and easily understood manner. The plan included four very specific areas of focus:

- Design Qualification (DQ)- Protocols and specifications outlining minimum requirements for unique configurations of system hardware, software and ancillary software tools.
- Installation Qualification (IQ)-Documents that all hardware and software are installed according to vendor recommendations and client configuration specifications.
- Operational Qualification (OQ) - Provides evidence that infrastructure components are consistently operating within established configuration and operating ranges
- Performance Qualification (PQ)- Provides evidence that existing engineered standards and designs are properly maintained and consistently produce expected results.

RESULTS

A process for building qualified systems was an important part of regulatory compliance. This qualification process is now used for all IT platforms and environments to ensure that a consistent method is used regardless of computing platform. Court Square's infrastructure group is able to produce qualification documentation and user signoff from any point in a server's life cycle.
The benefits achieved in this project include:

- A more secure infrastructure
- Performance has improved over time and servers are no longer crashing due to lack of storage
- The infrastructure is much more manageable
- The network has a central administration.

ABOUT COURT SQUARE GROUP

Court Square Group (CSG) is the leading provider of an Audit Ready Compliant Cloud™ (ARCC) platform for Life Science companies. The ARCC cloud platform and out-of-the-box tools provide a validated and cost-effective way to manage all digital content (EDMS/documents, voice, data, and video) in a regulated and compliant environment. CSG also provides cloud-based backup solutions for data integrity and data protection for in-house systems. At every stage of the development and manufacturing lifecycle, Court Square's cloud, collaboration and regulatory submission solutions reduce costs, complexity and risks associated with sharing, storing, and submitting information for regulatory requirements. With over 1,000+ submissions and twenty-five years' experience and a 95% client retention rate, CSG has a proven track record as one of the most cost-efficient solutions in the life science market.

CourtSquareGroup
Drive The Business Of Science

Court Square Group, Inc.
CourtSquareGroup.com

1350 Main St., Fifth Floor
Springfield, MA 01103

info@courtsquaregroup.com
(413) 746-0054