SPIN-OFF DIVISION NEEDS RAPID APPLICATION INTEGRATION AND 21CFR PART 11 COMPLIANT HOSTING TO MEET FDA SUBMISSION TIMELINE

When corporate IT was unable to address their needs, a fledgling division of a large life science company turned to Court Square Group for FDA compliant clinical application integration and hosting.

Executive Summary

In order to meet their first FDA submission deadline aspin-off division of a large life science company needed to implement Electronic Document Management Systems (EDMS), electronic Common Technical Document (eCTD)solutionsto manage their documents, clinical trial information, and FDA submissions. The division had a corporate directive to filetheir initial NDA (New Drug Application) with the FDA in less than a year. Due to already overstretched resources, the corporate IT department would not be able to initiate an evaluation or begin the implementation of EDMS and eCTD solutions for at least one year.

Court Square Group (CSG) implemented and hosted multiple applications within CSG's Audit Ready Compliant Cloud™(ARCC) environment and provided a fully functioning submission environment in less than three months.Court Square Group's solution enabled the client to implement, train and submit the necessary documentation to the FDA for their first approval even earlier than the anticipated deadline.

About the Client

The client is a new pharmaceutical start-up division of a large medical device manufacturer that was tasked with producing the first pharmaceutical products for the company. The client had a drug candidate that they intended to bring to market within the year.

The Challenge

The client's regulatory team requested the assistance of the corporate IT department to manage the project of selecting and implementing an EDMS and eCTD system. However, the corporate IT department was facing a significant backlog of IT related projects and informed the division that they would not be able to start the project for at least 12 months.

The client's clinical and regulatory IT requirements were multi-faceted and required the integration of several solutions. Each of the individual software companies were willing to host their own applications but were not able to host any of the other applications. The integration of the individual components of the solution was clearly their most serious challenge. They needed a complete and integrated solution that included EDMS, eCTD, OCR, and FDA specific PDF rendition capabilities.

The client needed a solution that would not only allow them to integrate and host multiple applications in a 21 CFR Part 11 compliant environment, they also needed to securely access the environment from both inside the company and for external contributors.

Sidestepping their own corporate IT department the client selected Court Square Group to develop a solution that not only met their user, technical and regulatory requirements but could also met their timeframe for the submission of the drug data within the 12 months they were not able to get internal IT support.

The Solution

Court Square Group worked with multiple EDMS and eCTD vendorsto design an IT Infrastructure built within CSG's Audit Ready Compliant Cloud™ (ARCC) environment. This integrated solution provided the 21 CFR Part 11 compliant ecosystem necessary to process the thousands of documents needed for the submission. Court Square Group started by designing and implementing a computing infrastructure and qualifying it based on the needs of the various applications to be implemented.

After the infrastructure was in place, Court Square Group worked with each of the software vendors to implement their applications and create a seamless integration across all of the software applications. Court Square Group also provided the client with the applicable SOPs to establish specific procedures to provision the internal and external users. The solution enabled the environment to be accessed not only internally within the corporate infrastructure but also provided secure access to external partners via the web.

The Results

Court Square Group provisioned the entire environment within a three-week period. This rapid response enabled the client to quickly make use of multiple application environments (Dev/Test/Prod). Working with multiple vendor's implementation teams these applications were installed, integrated and usable within the first three months of the project. The swift implementation helped the client to work more efficiently by providing more time to train users on the functionality ofeach system and enabled them to successfully process thousands of documents for their FDA submission.

Industry expertise and quick action from Court Square Group enabled the client to submit their first drug application to the FDA within 10 months - beating their original timeline by months. Within two and a half years the client had submitted three separate drug applications to the FDA. When the corporate IT department cleared their backlog of projects, Court Square Group helped them to migrate all of the systems and data into their own corporate datacenter.

Next Steps

If time to market is critical for your organization or if internal IT resources are spread thin, contact Court Square Group to learn how our team of life science computing infrastructure experts can quickly provide support to help you meet your business objectives.

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