



Future-Proofing Clinical Applications with Secure Cloud Environment

Court Square Group (CSG) is raising the bar for compliance by hosting sensitive data within a secure FDA 21 CFR Part-11 compliant environment. CSG accelerates research for life sciences companies by improving business decision-making and allowing companies to focus on their science and business rather than the computing environment.

Adherence to stringent regulations is essential for pharmaceutical products at every stage, from drug development to marketing and distribution. This can be achieved by investing in a trusted technology partner adept at managing different applications within a single cloud environment. The real issue focuses on the ability to maintain 21 CFR Part 11 regulatory compliance while also providing the flexibility to handle multiple applications in the same cloud environment. Many application providers offer a cloud-based option. However, integrating multiple cloud-based applications remains a daunting task. CSG enables faster adoption of a cloud-first strategy based on experience managing multiple apps within various cloud environments.

Central to CSG's offerings is the Audit Ready Compliant Cloud™ (ARCC), its flagship hosting platform that provides the highest level of data integrity to start-ups and software and SaaS providers. The solution is designed to meet and exceed the FDA regulatory requirements, offering a qualified and validated cloud environment as the secure foundation for all critical applications and ensuring audit readiness throughout the clinical and regulatory lifecycle.

"We enable our clients to concentrate on their science while we help them get their products to market sooner, providing patients with the needed advancements without having their IT environment become a hindrance to progress," says Keith Parent, CEO.

Excessive regulatory intricacies and various interpretations by quality and regulatory groups in



Keith Parent,
CEO

the pharmaceutical industry often leave clients concerned about the security of sensitive data. ARCC delivers as the optimal alternative, handling all aspects of security, compliance and audit readiness. By providing outstanding security, regulatory and IT frameworks, CSG helps its clients be as nimble as possible.

For instance, Domino Data Labs' (a leading provider of Statistical Computing Environments - SCE) clients recognized that their cloud environment provided a tremendous solution for statistical programming groups in pharma and biotech companies. However, they also needed the rigor required for submission of the data to regulatory bodies. CSG leveraged its expertise in managing the environment's infrastructure and facilitated hosting for its customers by providing the Domino Cloud for Life Science (DCLS). By incorporating DCLS into their go-to-market strategy for life science clients, they could get both the technological advancements provided by Domino and the regulatory compliance necessary. It has extended the applications for hosting the Domino cloud for life sciences across numerous contract research organizations in Europe, getting the software up and running within a short timeframe of initiating the contract.

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In another instance, CSG helped a client in their early phase by providing hosting services for their applications and handling all their clinical trial and regulatory submission requirements. This collaboration resulted in an ongoing partnership that has contributed to their growth ever since.

Delivering desired outcomes for clients begins with having all the pre-configured installation qualification documents to set up hosting environments. A public cloud version of ARCC is also provided within AWS and Azure to cater to individual client preferences. A case in point was when a client's image processing application faced challenges in handling terabyte-sized images



captured in their own computing environment. CSG set up an environment within AWS and got the application running for the biggest data sets. A production environment connected to numerous microscopes was created, allowing them to run their drug discovery initiatives. CSG earned a CIO award from the client's management for its contribution to the project.

Behind its success is a managed service and application support team that handles the majority of the functions across different units. A dedicated quality team ensures regulatory compliance and coordinates with regulatory bodies, network security and quality teams at client sites.

This level of professional commitment, coupled with the introduction of new applications, has propelled CSG to the forefront, with an annual growth rate of 25 percent over the years. It also partners with AI experts to incorporate AI-based solutions like a mergers and acquisitions tool and an advanced searching tool aimed at leveraging generative AI to create drafts of documents directly from stored data within the environment.

Working closely with industry behemoths like Pfizer for over three decades cements CSG as a reliable name in the industry, capable of managing infrastructure and applications at any scale while maintaining regulatory oversight. Its versatility in hosting multiple applications within a single cloud environment eliminates the need for clients to engage with numerous vendors to handle diverse products across different clouds.

CSG's ability to create a consistent framework by extending IT support services to pharmaceutical companies within the same cloud environment makes it the go-to partner for ensuring regulatory compliance throughout the product lifecycle. **CR**