Innovators 10
Clinical Trial Management Solution providers
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COURT SQUARE GROUP :

REMOLDING THE PARADIGM OF CLINICAL TRIAL MARKET

The continually shifting nature of highly regulated industries like pharmaceuticals and biotech require stakeholders to effectively manage, validate and qualify their IT systems while lowering costs and improving efficiency. The complexity, cost, and risks in aligning with the compliance requirements are some of the key challenges that affect CROs and sponsors of all sizes. Court Square Group—a leading provider of the Audit Ready Compliant Cloud™ (ARCC) platform for Life Science companies— is bridging the gap by providing validated and cost-effective software and infrastructure to manage all digital content (EDMS/ documents, voice, data, and video) in a regulated and compliant environment for the life science industry. "Having served the Life Science industry for over 25 years, we've learned how to put together both the hardware and software infrastructure and qualify all of the environments to stand up to regulatory scrutiny. We can host any validated applications within this environment," explains Keith Parent, CEO.

At every stage of the development and manufacturing lifecycle, Court Square Group's cloud, collaboration, and regulatory submission solutions reduce costs, complexity, and risks associated with sharing, storing, and submitting information for regulatory requirements. The company's professionals translate business objectives into technical solutions based on specific FDA 21 CFR Part 11 regulations.

Keith Parent, CEO

Built on the Audit Ready Compliant Cloud, their RegDocs365—provides regulated content and collaboration solutions for Life Sciences companies. Court Square Group's team understands how to qualify and validate the appropriate portions of such applications by taking a risk-based approach and then utilizing the technical advances of the most popular software to enable a smoother experience for the customers. Rather than just being an IT provider, Court Square Group's Audit Ready Compliant Cloud provides all the SOPs, work instructions, and procedures just like the largest IT departments of Pharma giants do. "We start with industry best practices utilizing both the DIA EDM, and eTMF reference models to provide a framework and then we hold specific configuration workshops with our clients to flexibly configure their systems to provide an environment that fits the way the client wants to conduct their trials," adds Marco Marchettini, Director of Application Support.

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An instance that demonstrates Court Square Group's value proposition is when a client who was using off-the-shelf software, needed a solution to ensure compliance with FDA requirements. The client was using a commercial-grade product to capture voice recordings between clinicians and patients. However, the application was not 21 CFR Part 11 compliant, so the Sponsor of the study was concerned about the usability of the voice recordings as part of the overall study. "By utilizing our RegDocs365 system we were able to copy those recordings as soon as they were made and then file them into a specific structure based on the various sites within the study. We included a 21 CFR Part 11 "wrapper" around the data which provided the full audit trail and governance around the data required for regulatory compliance. The trial was able to continue and we have successfully used this methodology for other clinical trial initiatives including video capture," explains Parent.

Court Square Group's team continues to work with multiple Sponsors and CROs and looks to different therapeutic areas that need technologically innovative techniques to provide new methods for clinical trials. By using the subject matter expertise of partners and their specialization in regulatory compliance and technology solutions the company is expanding their platform usage of the RegDocs365 system in ever more innovative ways for the clinical trial market. "We are continuously looking forward, seeing where technology is heading in this industry and trying to make sure that we adapt to those changes in the industry. Utilizing Court Square Group's expertise, many applications that are used every day for the consumer market can provide new tools for the clinical trial market that they never thought possible in the past. Why not change the paradigm of the clinical trial market and use the tools that people want to use but add the regulatory compliance to make them applicable to this market," Parent concludes.