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Court Square Group Unveils Quality and Audit Services

Court Square Group has launched a new line of audit services that will be delivered by its Life Sciences Practice. The new services span a range of quality and compliance issues, including software quality assurance, service and vendor audits, infrastructure and a complete GxP audit management solution..

Springfield, Mass., March 25,2008 – Court Square Group, Inc., a strategic and professional consulting firm specializing in information technology, business processes and project management, announced today that the Quality and Compliance group within its Life Sciences Practice is ready to deliver a wide array of services to biotech and pharmaceutical companies.

“During the past year, Court Square has expanded beyond its traditional managed services and project management offerings to include a full suite of audit and compliance services,” said Keith Parent, CEO of Court Square Group.

“Today, our clients span a broad range of disciplines and industry segments, including pharmaceuticals, biotechnology, contract research, medical devices and more. And their business and regulatory challenges go well beyond mere Part 11 compliance.” They need a complete suite of audit and compliance services, and we intend to deliver them,” said Christopher Port, Senior Vice President of the Life Sciences Practice.

Court Square has provided software validation and hardware qualification services to the life sciences industry for many years. The new audit and compliance services extend this knowledge to software quality assurance audits, IT service provider and application vendor audits, infrastructure audits, and more. The highlight of the new services is a complete audit management service of GMP, GLP and GCP requirements.

“Too many life sciences companies take a reactive approach to compliance, which leads to an endless cycle of remediation projects and lost productivity,” said Kathleen Pelley, Director of the Quality and Compliance Group at Court Square. “Our proactive audit and compliance services identify business process and technology issues before the FDA inspectors arrive, and rectify these problems by recommending improved management processes or better IT infrastructure. Most clients find that sound auditing services pay for themselves in a very short period of time. In addition, our audit management services eliminate the confusion that results from multiple audit companies using disparate approaches and reporting methodologies. ”

Infrastructure audits are another way to ensure compliance and improve productivity. Court Square’s years of experience in managing data centers, networks and other infrastructure for leading life sciences companies gives the company great insight

into how risk-based analysis can be used to streamline operations while never failing an FDA inspection.

“Many life sciences companies simply don’t know which systems are likely to be inspected by FDA or how deeply,” said Pelley. “In fact, all IT systems should be audited, but risk-based analysis helps you determine which ones need the most attention. Many companies waste time and money because they fail to understand this process. Our highly-trained auditors know which systems need more attention than others.”

New trends are taking hold in the life sciences industry, including the adoption of outsourcing and collaboration to control costs and accelerate the business. But regulations can make this difficult. “In the past, life sciences companies were vertically integrated, but now that they outsource and partner throughout the drug lifecycle, their supply chain is only as strong as its weakest link,” said Pelley. “Companies must ensure that their IT service providers comply with the same regulations that FDA others require of them.

Court Square’s auditing services are available to companies of all sizes and in all stages of drug development and commercialization. The company has served many of the largest and smallest life sciences companies in the US for more than 13 years. Court Square is widely known for its Good Systems Practice approach to providing IT management services, and all of its projects are delivered using Project Management Institute methodologies that are standardized for life sciences.

Court Square Group, Inc., is a strategic consulting firm providing solutions to the life sciences industry. The company’s Good Systems Practice services are based on the most stringent quality service methodologies, and are optimized for government-regulated environments. Court Square has offices in Massachusetts, Connecticut and New Jersey. The company serves pharmaceutical, biotechnology, medical device and radiology/imaging companies throughout the Northeast.

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