Summer Update 2005

CSI Profile

Recognizing a critical need in the pharmaceutical and biotech industry to supply expertise in the area of FDA compliance, CSI was formed in 2004. CSI's strength lies in its 60 years combined experience integrating computer science with pharmaceutical science. CSI's principal consultants are committed to using their knowledge base to ensure project quality and customer satisfaction.

What we do

CSI provides a full spectrum of system life cycle management services supporting process compliance with CFR predicate rules and 21 CFR Part 11 including design, development, validation and implementation of:

- LIMS and lab automation
- Computer Systems
- Regulatory Compliance
  - GLP auditing
  - Clinical trial management
- SAFE and Part 11 compliant systems

Working with CSI

The broad experience and expertise of COMPLIANT SYSTEMS INTEGRATION, INC., has helped companies raise the performance bar, advance new product cycle times and achieve the *quality compliance* necessary for successful licensure. We work with in-house staff in a collaborative partnership, adding our expertise to the success of larger projects / initiatives.

Professional Qualifications

In the evolving regulatory environment, knowledge of GxP is increasingly more important to the success of a business. Principal Consultant **Sally Quataert has received RQAP-GLP certification as** a Registered Quality Assurance Professional in GLP. CSI can perform a GLP audit on your lab, facilitate remediation, and provide lab specific GLP training.

SAFE

In 2003, SAFE-Biopharma, LLC a non-profit association of pharmaceutical companies was formed with the mission to create and manage a worldwide electronic signature standard. SAFE, an acronym for Secure Access For Everyone is a set of legal, business and technical policy standards that provide strong identity authentication and legally enforceable digital signatures for Business-to-Business and Business-to-Government transactions within the global biopharmaceutical industry.

CSI has gained SAFE experience providing:

- expertise for quality management of projects necessary for integrating business processes within a SAFE initiative to provide legally enforceable electronic signatures to regulatory documents.
- guidance on interpretation of the SAFE standards for application in process design and validation of identity and digital signature systems.
- implementation of SAFE–enabled applications and software within a compliant environment.

CSI Consultants have worked with several of the leading pharmaceutical companies in the industry.

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