Why CSI?

Pharmaceutical, biotechnology and medical device industries must meet increased government regulation in the global market place. Success in the drug and medical device industries depends on accelerating the development and clinical testing process while meeting the quality standards for licensure and registration. Automated computer systems are essential to realizing this acceleration and must comply with (U.S. 21 CFR Part 11) regulations as well as validation standards. By utilizing the expertise at COMPLIANT SYSTEMS INTEGRATION, INC., companies can raise the performance bar, improve new product cycle times and achieve *quality compliance* necessary for successful licensure.

Compliant Systems Integration

is poised to meet
the challenges
of accelerated drug and
medical device development
providing compliant
integrated system solutions.

Look for more information at our website:

www.csirochester.com

or contact us at:

COMPLIANT SYSTEMS INTEGRATION, INC.
P.O. Box 25428
Rochester, NY 14625

585-349-2747
info@csirochester.com

Compliant Systems Integration

Investigates all your laboratory needs

Quality...
integrated
in every solution

Quality & Compliance is our business

- We help people re-engineer their business process leveraging their expertise for success.
- We integrate information technology into business process solutions and provide implementation and validation to ensure regulatory compliance.
- Our experience ensures timely acquisition and implementation of compliant systems.
- Computer system life cycle management services are available to lead your team's project from inception to implementation.

"When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented."

Rule from Title 21 of the Code of Federal Regulations (CFR)

Meet the CSI Management Team

The strength of CSI is in the 60 years combined experience that integrates computer science with pharmaceutical science. CSI principals are committed to using their knowledge base to ensure project quality and customer satisfaction.

Dr. Sally Quataert holds a Ph.D. in microbiology/ immunology from the University of Buffalo. She has been a scientific leader in both start-up and big pharma/medical device companies including Wyeth, Corning, ENI, Inc., and Praxis Biologics, directing laboratory operations and QA systems.

Janice Skuse earned her SUNY AAS and BS in medical technology and biology respectively. She has experience working in clinical laboratories and data management and has worked for Wyeth for the last 18 years. Her work experience includes detail oriented process design, efficiency improvements, laboratory operations and robotic automation, implementation and training program design.

James Joy earned his BS in computer science from Rochester Institute of Technology and an MS in Information Technology from the University of Rochester's Simon School. His work experience comes from pharmaceutical R&D/Manufacturing, medical device and biotechnology with industry leaders Bausch & Lomb, Wyeth, Fisons and Medeva.

Compliant Systems Integration

Provides the full spectrum of services and support throughout the process life cycle compliant with U.S. 21 CFR Part 11 including:

Laboratory Validation and Support

- Laboratory design
- Facility master validation
- Equipment validation (IQ/OQ/PQ)
- Bioanalytical method validation

Computer Systems Validation

- Life cycle management
- Database management systems (LIMS, Clinical data systems)
- Assessment and remediation of existing systems
- Acquisition, implementation and validation

Regulatory Compliance

- QA systems design
- Documentation (SOPs, validation plans, protocols and reports)
- GCP, GLP, GMP laboratory pre-approval inspections (PAI) and audits
- Risk assessment/Gap analysis
- Training