

## **Introduction**

The Pharmaceutical Solutions Group is dedicated to providing control systems and validation solutions for FDA regulated industries, specializing in compliance with 21CFR parts 11, 210, and 211. Balancing the latest technology with rapid development and deployment, the Pharmaceutical Solutions Group consistently provides a wide range of systems that drive, monitor, adjust, and support operations within your business environment.

## **Design Services**

Our engineering, programming, and validation staff has extensive experience within regulated industries. What that means to you is we have the experience and knowledge to design, implement and program solutions for you that are validatable. Projects managed by our Pharmaceutical Solutions Group integrate validation throughout the entire project, reducing costs and time for post-design remediation efforts.

## **Project Management**

At Frakes Engineering we recognize that project management can be the difference between just meeting customer expectations and exceeding them. All of the projects managed by the Pharmaceutical Solutions Group are under the direction of a Project Management Professional certified by PMI®, the world's leading association for the project management profession.

## **Validation Services**

Computer System Validation (CSV) involves providing documented proof that a computerized system will repeatedly and reliably do what it is supposed to do. Our work is focused on helping clients achieve compliance with FDA expectations. Frakes Engineering possesses the experience and skills necessary to create all required validation deliverables. Whether you follow GAMP 4 or your own standards, we help you maintain cGxP and can perform gap analysis to determine current levels of compliance. Our professional staff of engineers and programmers has the expertise to provide remediation services for those systems that have fallen out of compliance, providing the client with turnkey solutions to their engineering needs.

## **About Frakes Engineering**

Frakes Engineering, Inc. is a full service independent control system integration engineering firm, serving the automation needs of the industry since 1978. We have a team of Project Managers, Engineers, Microsoft Certified Professionals, and Technicians that have 175 years of collective experience. Frakes Engineering, Inc.'s typical staff member has been with us for over 12 years.

## **Industry Qualifications**

Frakes Engineering is a certified member of the Control System Integrators Association (CSIA), the largest organization of independent control system integrators in North America. We have earned "Certified Member" distinction, meeting stringent performance standards as measured in an intensive audit process conducted by an independent third-party consulting firm. The audit focuses on best practices in general management, financial management, project management, quality management, technical management, human resources, and business development.

Frakes Engineering is proud of our status as a Microsoft Certified Partner. Our focus on computer systems has also led to membership in the Authorized Reseller programs of Hewlett-Packard and Compaq.

## **How We Can Help**

From envisioning a new solution, through planning, developing, and validating existing systems, Frakes Engineering has the experience to address your needs at any phase of a project. Find out today how Frakes can help you get the most out of your resources and drive your operations in the direction you want it to go.

## **Contact Us**

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