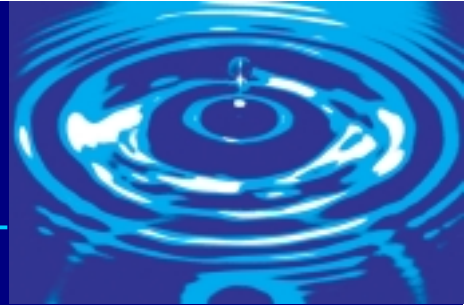# Gould Professional Services, Inc.

Regulatory Security Services

Regulatory Security Compliance & Validation

As technology continues to grow, government regulation also grows in an effort to ensure the safety and reliability of technology. Regulatory attempts to address sociological issues are often fraught with challenge. Haste in issuing regulation or law frequently results in a more confusing operational environment for business and organizations – poorly defined requirements, ambiguous regulatory language, multiple conflicting regulation from different authorities, even sometimes inappropriate enforcement.

Our solution to this challenge is to provide clients with world-class technology expertise, using certified consultants who are not only proficient with specific technologies, but who also bring significant business expertise to interface with government and standards bodies to resolve ambiguous language, requirements and conflicts. As a consulting company, we interface with regulators while protecting our client's identities, allowing for resolution of these challenges without significant risk for our clients. Once issues are resolved satisfactorily, our deliverable documents provide superb record of the issues, solutions and rationale, including, where necessary, letters of clarification from regulators.

The Health Insurance Portability and Accountability Act (HIPAA)

Regulators, wanting to leave the industry considerable freedom in compliance solution choices, deliberately left areas of this act vague. The regulatory goal was to avoid specification of specific technology implementation within the regulation, yet some of the specified minimum standards dictate specific solutions. Additionally, systems and networks must be certified to meet the requirements of HIPAA. As experts with both regulation and technology, we can help you readily solve these issues. We provide an analysis of technology risks, implementation choice analysis, and architecture rationale together with validation services to both meet the regulatory requirements and formally document the justification for your chosen compliance direction. Our staff members developed one of the first audit, validation and compliance methodologies to address HIPAA requirements, widely used throughout the industry. At the forefront of our process is the recognition that you are in business and need to balance and optimize mitigation of risk, regulatory compliance and expense. Our expertise allows you to meet those needs effectively and with efficiency.

The Gramm-Leach-Bliley Act (GLB)

Concerns over privacy of individual information, new technology-enabled information collection and aggregation capabilities, and a few instances of misuse prompted legislators to restrict the use of some specific types of personally identifiable information. Formal privacy policy, methods for customers to opt-out of the distribution of their information, and restrictions on the sale of customer lists are now required to protect personal information in the financial industry. Banks and other financial institutions must comply with this new legislation. We bring extensive policy and business experience together with audit and compliance methodologies to help you meet these requirements cost-effectively and with a minimum of disruption.

Digital Signature & Electronic Documents (FDA regulation 21 CFR 11)

The Food and Drug Administration has been working on Digital Signature and Electronic Documents standards for nearly 10 years. This legislation is comprehensive and addresses the use of digital signatures and electronic documents to meet government and regulatory requirements. While the scope of this regulation applies only to industry under FDA authority, the extensive interaction of the FDA with other government agencies, the National Archives, and NIST suggests that this framework is likely the model the entire government will follow as digital signature becomes more widely used. In 21 CFR 11, the FDA placed significant requirement on the control of systems where data and signatures are applied or stored, as well as formal Validation requirements for these systems and the software that manages the underlying data. Significant system security, audit capability, user authentication, access control, data integrity and signature authenticity are required and must be validated. Applying our extensive systems security, validation and regulatory expertise, we are uniquely positioned to help you meet this challenge.

Contact us to discuss your specific concerns and learn how we can help meet these challenges effectively.