CONQUERING THE CHAOS OF COMPLIANCE WITH INFOSYS GLOBAL REGULATORY CONTROL FRAMEWORK

Elevating Quality, Security, and Compliance Standards

NAVIGATING THE REGULATORY MAZE:

In the US pharma and medical device industry in 2023 being attributed to inadequate In an era of increasing scrutiny and complex regulatory measures, it becomes imperative to understand, interpret, and apply regulatory requirements by defining controls apt for business needs.

These challenges are also needed to be addressed due to issues such as:
- 30% of findings understanding of regulations
- Manual control design processes that are time-consuming and error-prone
- Isolated quality and information security teams that lead to inconsistent control implementation

INTRODUCING INFOSYS GLOBAL REGULATORY CONTROLS FRAMEWORK

Infosys presents a cutting-edge solution designed to meet these challenges head-on. An end-to-end, AI-driven solution that:
- Covers 14 standards/regulations
- Encompasses ~300 controls across 14 control areas and 22 sub-control areas
- Provides a risk-based approach to control definition

BRIDGING THE GAPS WITH A COMPREHENSIVE APPROACH

- **Unified Control Framework** to ensure standardized control implementation across the industry
- **Automated Gap Analysis** for better visibility into organizational compliance
- **Risk-Based Remediation Guidance** to reduce regulatory findings due to misinterpretation

- **Compliance with Industry Best Practices** to improve patient safety through comprehensive risk management

REAL RESULTS, REAL FAST: Successful SaMD Integration

We helped a major pharmaceutical firm penetrate the Software as a Medical Device (SaMD) market by:
- Assessing gaps in existing control registers
- Implementing FDA guidance on Medical Device Cybersecurity
- Enhancing controls based on ISO 27001, HIPAA, Cloud Control Matrix, NIST, and Data Privacy regulations
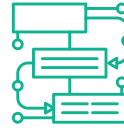
READY TO SIMPLIFY YOUR WORLD AND CONQUER THE CHAOS?

Partner with Infosys to create a more secure, compliant, and efficient pharmaceutical industry. Our Global Regulatory Controls Framework is not just a tool—it's a paradigm shift in how we approach regulatory compliance.
To book a consultation, contact: [Your Contact Information]

Control Areas	Sub-Control Areas
Access Management	Access Control
	Access Provisioning
	Logging and Monitoring
Asset Management	Asset and Inventory Management
Business Continuity Management	Business Continuity
	Backup
	Disaster Recovery
Business Information Management	Data Management
	Archive Management
Change and Configuration Management	Change Management
	Configuration Management
Cryptography and Encryption	Cryptography and Encryption Key Management
Data Privacy	Data privacy – US HIPAA
	Data privacy – EU GDPR
Incident and Event Management	Quality Incidents/ Events
	Regulatory Incidents
	Security Incidents
Mobile Devices	Personal Mobile Devices
	Work dedicated Mobile Devices
Network Security	Network and Infrastructure Security
Risk Management	Governance and Risk Management
	Threat and Vulnerability
	Third Party Risk Management
Social Media Account Management	Social Media Account
System Development and Operations	Software Development (Security and privacy by design)
	Software Operations
Website Management	Website and Microsite Management

For more information, contact askus@infosys.com

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