

Conquering the Chaos of Compliance with Infosys Global Regulatory Control Framework

Elevating Quality, Security, and Regulatory Risk Compliance



BREAKTHROUGHS
FOR LIFE



NAVIGATING THE REGULATORY MAZE

In today's environment of heightened scrutiny and intricate regulations, it's crucial to interpret and implement regulatory requirements by creating controls tailored to the business needs.

However, defining these controls presents two key challenges:

- Interpreting and aligning multiple regulatory requirements with business objectives.
- Multiple teams working in isolation, manually mapping controls, often leading to process gaps or overlapping efforts.



INTRODUCING INFOSYS GLOBAL REGULATORY CONTROLS FRAMEWORK

To tackle these key challenges, Infosys developed a comprehensive and unified control framework through its cutting-edge technology solution, Global Regulatory Control Framework that:

- Addresses 14 standards/regulations like ISO 27001, SOC 2, SOX, GDPR, HIPAA, ISO 9001, and ISO 13485 on information security, data privacy, and medical devices.
- Includes over 300 controls covering 14 control areas, including access management, business continuity, availability, and risk management, as well as 22 sub-control areas like access control, provisioning, and logging/monitoring. (Refer to Table 1.0 for a detailed list of control and sub-control areas.).
- Delivers automated gap analysis to enhance visibility into visibility into compliance across the organization.
- Offers risk-based remediation guidance to address regulatory findings and minimize the risk of misinterpretation.
- Ensures standardized control implementation across the pharmaceutical and medical device industries.



REAL RESULTS, REAL FAST: SUCCESSFUL CONTROLS INTEGRATION

We assisted a leading pharmaceutical company streamline controls across 14 standards and guidelines by:

- Identifying gaps in their current control registers and recommending mitigations.
- Enhancing controls based on key standards and regulations like ISO 27001, SOC 2, SOX, GDPR, HIPAA and ISO 9001.
- Assisting them in their transition from pharmaceuticals to medical devices (ISO 13485) by analyzing the differences between their existing pharma controls and those required for medical devices, including cybersecurity for medical devices.



READY TO SIMPLIFY YOUR WORLD AND CONQUER THE CHAOS?

Partner with Infosys to establish a more secure, compliant, and efficient Risk Management Organization (RMO). Our Global Regulatory Control Framework is more than just a tool; it introduces a paradigm shift in how you achieve quality excellence and information security / regulatory adherence with minimal effort.

WANT TO KNOW MORE? REACH OUT TO OUR TEAM OF EXPERTS!



Nandini Diwakar

*Associate Partner - Business
Consulting, Infosys
nandini_diwakar@infosys.com*



Sridhar Sarva

*Senior Principal - Business
Consulting, Infosys
venkatasridhar.s@infosys.com*

 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
Governance and Risk	Quality, Information Security and Regulatory 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

Table 1.0: List of Control Areas and Sub-Control Areas

For more information, contact askus@infosys.com

Infosys[®]
Navigate your next

© 2024 Infosys Limited, Bengaluru, India. All Rights Reserved. Infosys believes the information in this document is accurate as of its publication date; such information is subject to change without notice. Infosys acknowledges the proprietary rights of other companies to the trademarks, product names and such other intellectual property rights mentioned in this document. Except as expressly permitted, neither this documentation nor any part of it may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, printing, photocopying, recording or otherwise, without the prior permission of Infosys Limited and/ or any named intellectual property rights holders under this document.