

Contents

A Framework for Systems Validation for the FDA environment	4
Overview of Impact of 21CFR Part 11 on Information Systems	9
Best Practices in Internal Audit	12
Here comes TS 16949	15
Impact of Regulatory Compliance on Quality and Profits	16
Incorporating Audits in your Operational framework	18
Incorporating quality into management style	21
Managing Quality at Outsourced Manufacturing Operations	22
Roadmap for compliance with 21 CFR Part 11	24
Supplier Charge-backs	29
What is Your Company's Cost of Poor Quality - Tools for calculating and reducing it	31
Workplace Safety Compliance: The New Approach	35
Corrective Action (CAPA) Systems at Innovative Companies	39
Ensuring Regulatory Compliance through Training and Certification	41
IT Systems Validation for Regulatory Compliance	43
Implementing a well designed audit program	49
How to build a Business Case for a Quality Management System	52
Using a Compliance Platform to build Custom Quality and Compliance Applications	61
Raising your Audit Score through effective Document Control	67
Reducing New Product Introduction (NPI) time using a packaged software solution	70
New User Access Requirements for 100% Compliance	73
Smart Investment Strategies for a Compliance Platform: A Ten Step Guide	76
How to give a Quality Score to your Supplier	79
Can't get budget approval for your Quality Management System?	84
Paper-based quality system is more costly than you think	87
Role of a Quality Management System in Six Sigma Deployments	89

A Framework for Systems Validation for the FDA environment

21CFR part 11 requires that all systems that govern any cGXP process - including Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), and Good Clinical Practices (GCPs), should be validated. FDA issued a very comprehensive guidance on systems validation in a document released in January 2002. This white paper uses that FDA guidance as an input to define an “easy-to-implement” framework for systems validation. Finally the paper identifies a best practice which calls for IT organizations and software vendors to proactively audit their software development and implementation processes on an ongoing basis to identify and correct any systemic issues to lower the cost of compliance.

Why System Validation?

Current Good Manufacturing Practices (cGMP) are mandated by the FDA to ensure that the products manufactured by the industries such as pharmaceutical, biotech and medical devices, meet specific requirements for identity, strength, quality, and purity. In order to comply with cGMP, companies are required to record, track, manage, store and easily access various production documents and their detailed change history including Standard Operating Procedures (SOPs), Master Production Batch Record (MPBR),

Figure 1: Scope of 21CFR Part 11 Requirements Source: CGE&Y