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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