ERP & SOFTWARE VALIDATION

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Enterprise resource planning (ERP) software plays a key role in helping companies to satisfy regulatory mandates such as cGMP, GAMP, FDA 21 CFR part 11 and FDA 21 CFR part 820. From an enterprise-wide framework, an ERP system is key to managing FDA-mandated documentation and integrating all external and internal information in a single system. Manufacturers in FDA-regulated industries such as medical device manufacturing and the field of life sciences must consistently validate ERP software with each vendor update that impacts an enterprise's keystone IT functions. To align ERP systems with FDA regulations, IQS offers ERP software validation services to FDA-regulated enterprises.

DEFINING ERP IN THE CONTEXT OF SOFTWARE VALIDATION REQUIREMENTS

ERP systems are widely available, but enterprises use these systems to perform many different functions both internally and externally. In general, ERP systems integrate software for supply chain management, finance and accounting, human resource management, customer relationship management and various manufacturing software systems. For example, manufacturers utilize ERP software to automate the timely flow of information among key quality-related departments within an enterprise and among outside stakeholders accordingly.

The precise configuration of an ERP system depends upon the operational requirements of the specific business and software validation requirements are governed by the particular FDA-regulated industry. Thus, as vendors implement, update and/or phase out ERP software, validating the ERP system can becomes complex and very challenging for enterprises bound by those FDA regulatory pressures. Software validation projects must be able to account for various ERP configurations at a low cost.

THE CHALLENGE OF COORDINATING ERP AND SOFTWARE VALIDATION

The process of ERP software validation can typically consume a large amount of resources to execute properly the first time. With every update of an ERP system, FDA-regulated industries must re-validate the ERP software, or portions of it, without losing sight of the impact that these changes will have on satisfying FDA 21 CFR part 11, for example.

One common misconception is that coordinating software validation and ERP implementation are separate chal-

lenges, where in fact, they should be addressed together to ensure that quality impacting functions of the software are clearly identified and validated. FDA-regulated enterprises that decline to deploy a proven test strategy achieve minimal results with respect to software validation. In the worst-case scenario, inadequately validated ERP software can lead to regulatory fines, thereby increasing costs throughout the enterprise. To overcome these challenges, FDA-regulated industries require a proven service that coordinates ERP systems alongside software validation mandates.

IQS'S ERP SOFTWARE VALIDATION SERVICE

IQS's ERP software validation service adheres to a risk management and process analysis strategy. For example, the broad scope of ERP systems deployed in the medical device manufacturing industry requires that software validation services accommodate the intertwined complexity of business and production processes. By deploying a structured methodology, IQS's software validation service presents FDA-regulated industries with the opportunity to validate ERP software, by concentrating on what matters most to each enterprise.

Through IQS's software validation service, FDA-regulated enterprises can take advantage of cost savings by pinpointing opportunities to adapt and revalidate ERP systems as required by law. By working in concert with an enterprise's unique ERP configuration, IQS's software validation services allow enterprises to identify key opportunities to manage risk and mitigate long-term software validation costs.

Among FDA-regulated enterprises, successful ERP software validation hinges on deploying a proven, structured approach such as IQS's software validation service. Otherwise, companies face the risk of inadequately creating and executing software validation projects, with potentially very expensive associated costs down the line.

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