

# Sage ERP X3 | White Paper

## Managing Government Regulations with ERP: Key features to look for when selecting your new system

By Tom Heinricher, Senior Business Consultant, Sage ERP X3



## Introduction

More and more, companies are under pressure to maintain their competitiveness while complying with an increasing array of regulatory requirements. And more than any other sector, manufacturers bear the highest share of the cost.

How companies manage their response to these mounting regulations can have a significant impact on the bottom line. And having a process in place that is capable of collecting the information needed – while being easily tailored to specific company requirements – is paramount to the success of the business.

## Compliance is Costly and Burdensome

While all public companies have to comply with the Sarbanes Oxley Act, manufacturers across a variety of industries have their own specific regulations with which they must comply. Chemical companies are subject to OSHA Hazard Communication Standard, SARA Title III, ANSI and the European Union REACH legislation. Medical device manufacturers and pharmaceutical companies are concerned with current Good Manufacturing Processes and 21 CFR Part 11. Food and beverage producers have to manage the Bioterrorism Act and HACCP. And now, there is the U.S. Food and Drug Administration's new Reportable Food Registry electronic portal, which attempts to thwart potential cases of food borne illness by requiring food industry officials to alert the FDA within 24 hours if they find a reasonable probability that an article of food will cause severe health problems or death to a person or animal.

While managing government regulations is a necessity, it is also burdensome and costly. In fact, a recent survey by the National Association of Manufactures found that, in the U.S., the cost of complying with federal regulations is steep – about \$10,000 per employee or over \$162 billion annually. This cost can be reduced by automating most of the compliance process. As a matter of fact, an Aberdeen Group report<sup>1</sup> found that only 8 percent of the manufacturers surveyed have eliminated manual processes for their compliance programs. These manual processes can lead to inaccuracies and time delays that ultimately defeat the purpose of maintaining such information.

An ERP solution, often called the “backbone” system for enterprise transactions and planning, plays a central role in regulatory compliance. Because it maintains one common database, the ERP system can help minimize reporting costs by providing a convenient and efficient way to gather and monitor relevant information and eliminating manual procedures throughout the manufacturing process.

## Seek an ERP System that Promotes Compliance

Companies in government regulated industries need an ERP solution that includes integrated functionality designed to promote compliance. Some important features to look for include:

### Lot Traceability

Traceability can be utilized as a competitive advantage by automating and giving visibility to continuous improvement initiatives. When lot traceability and automated batch processing information is easily accessible to those who need it, root cause analysis and real-time CAPA (corrective and preventive actions) become attainable best practices.

To be most effective, the ERP system should manage complete forward and backward traceability for each ingredient and finished product. It should also include user-defined technical sheets and operational detail instructions, along with lot and sub-lot control.

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<sup>1</sup> “The Compliance and Traceability in Regulated Industries Benchmark Report, Aberdeen Group, December 2006

## Audit Trail

Audit trails are essential to address compliance requirements for how data is obtained, used, managed and secured. The ERP system should, at a minimum, authenticate user name, date, time, previous data, new data and the reason for the change. Additionally, it should be able to maintain an archive of historical transactions for multi-year periods.

## Digital Electronic Signatures

With digital electronic signatures, companies can improve security and control over their internal automated workflow, which are required for passing corporate governance audits in addition to complying with various industry regulations. The ERP system should provide an electronic signature framework which includes tables, programs, actions and objects to store, configure and collect unique e-signatures that are permanently linked to the object and can not be modified or copied.

## Quality Control

A fully integrated quality control process helps companies automate and streamline their paper processes for increased efficiency and regulatory compliance. Through a rules-based orientation, the ERP system should enforce inspections at key event points to assure item conformance to any required product characteristics, operational tolerances or expected results. The system should automatically quarantine items that fail any inspection rules, as well as suspicious items, and designate them for disposal or further inspection.

## Document Signatures

For documents requiring handwritten signatures – such as Certificates of Analysis or Technical Sheets – scanned, digital or flattened digital signatures are appropriate. The ERP system should generate documents with an image linked to the specific document and control the image plate while linking it to the user profile.

## Security Features

It's important to have security standards in place to safeguard against unauthorized use of the system and protect against both outsider crime, like industrial espionage, and insider crime, like embezzlement. The ERP system should, at a minimum, include features for automatic logoff after a period of inactivity, automatic logout after too many failed logon attempts and logging of all user activity.

Additionally, life science companies will require effective software validation processes and procedures. The ERP vendor should provide documentation describing the various process controls deployed. These scripts should be flexible in design and associated with clearly identified and documented procedures. The scripts also should be easily transferred or incorporated into custom validation and cGMP documents to support company initiatives.

## Find a Flexible Solution That's Easily Tailored to Unique Business Processes

As mentioned earlier, manufacturers are under increasing pressure to remain competitive while complying with a variety of regulatory requirements. And it's likely that new regulations will continue to be enacted in the coming years. Companies can protect their investment in an enterprise system by selecting an ERP system that offers a two-fold approach to dealing with changing requirements.

First, the system should easily adapt to the company's unique needs. An ERP system that offers an integrated development environment (IDE) enables easier personalization of the system and enables the use of the company's formulas, rules and conditions without making programming changes.

Second, the system should offer flexibility in adapting to changing business conditions. Change is the norm in business today. Not only do companies need a software solution that's capable of supporting existing business processes, they need a system that can adapt to future business processes as well ... one that offers simple parameterization features to make adjustments to information flows and procedures quickly, without additional development. The value of a flexible ERP system should not be underestimated.

## Achieve Best-in-Class Status

The same Aberdeen Group report found that 93 percent of manufacturers still relying on manual processes to manage compliance and traceability programs were unable to achieve Best-in-Class status. To become Best-in-Class, manufacturers should utilize automated solutions to "build in" compliance and traceability to production processes.

An advanced ERP solution will enable manufacturers to capture information electronically, helping them to achieve better compliance and to save the huge costs of managing paper-based systems. It can also increase the speed of product release, identify supplier issues and gain agility by being able to obtain the needed information quickly.

With real-time visibility into production processes and automated traceability, companies have a competitive advantage with the ability to address issues while still in process. During continuous improvement initiatives, manufacturers without these capabilities are often relegated to recreating situations and conducting root-cause analysis days after the events have occurred.