WHITE PAPER

THE COST OF VALIDATION AND USE OF ELECTRONIC SPREADSHEETS IN REGULATED ENVIRONMENTS

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Introduction

Existing procedures at many food processing plants have evolved out of common sense but without regard to proper validation in accordance with regulatory policies. Emerging regulations under the Food Safety Modernization Act promise to bring more scrutiny.

Compliance Using Excel Spreadsheets

Electronic spreadsheet applications such as Microsoft® Excel® are widely used in offices and manufacturing for data capture, data manipulation and report generation. Regulations such as HIPAA, Sarbanes Oxley Act and FDA's GxP and 21 CFR Part 11 have long required users of software and computer systems to demonstrate and document data accuracy, integrity and confidentiality.

Microsoft Excel has not been designed for regulated environments. Nevertheless, compliance is possible for companies with a good knowledge of Excel® capabilities, and good procedures and practices on how to validate and use Excel.

Manufacturers in the Food and Beverage industry should be cognizant of these requirements, the costs associated with adhering to them and, more importantly, the cost and other business risks associated with a finding of non-compliance. The reality is that existing procedures at many food processing plants have evolved out of common sense but without regard to proper validation in accordance with emerging regulatory requirements. New regulations under the Food Safety Modernization Act promise to bring more scrutiny.

Lessons Learned in Other Industries

There is every reason to believe that the FSMA will bring to Food and Beverage the type of process control discipline that already exists in other regulated process industries. Following is a brief sampling of the types of issues regulatory authorities focus on

when evaluating Excel worksheet controls:

"Your firm has failed to exercise appropriate controls over computer or related systems to assure that changes in master production and control records, or other records, are instituted only by authorized personnel. WL CMS#85885.

"5.b. Your firm's SOP 100-G-0110, "Creation and Use of Templates," stated that cells, in which data is entered, must be locked." WL 11-108087-01.

"Failure to validate software used as part of production or the quality system for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example, your firm did not validate use of an Excel spreadsheet . . ." WL-41-11

"Your firm failed to validate several computer databases that are used for quality functions including your Access database, your [redacted] software, and your MS Excel spreadsheet program as required by 21 CFR 820.70(i)." WL g1483d

"Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation " WL g1121d

"A manufacturer is required to validate computer software for its intended use according to an established protocol. For example, databases that are maintained for data analysis and other tracking and trending functions, including complaint and services access databases, have riot [sic] been validated for their intended use. WL g6173d.

It follows that Food and Beverage processing companies who continue to rely on Excel spreadsheets without proper controls will find themselves exposed to inspection issues, warning letters, fines and product recall.

Using Business Intelligence Software to Eliminate Excel Spreadsheets

Business intelligence software, using the Vigilistics vEMI Suite, is now being applied to eliminate the need for Excel spreadsheets and other forms of paper record systems for many functions in the plant. These systems, delivered as software products, automatically monitor, collect and store massive amounts of process data, and organize the data in a way that is repeatable and consistent from plant to plant.

These records are inexpensive to store, summarize and analyze. They can be recalled with minimum effort, and satisfy requirements of regulatory authorities, and provide a level of detail that cannot be replicated in a manual records management system. They offer high quality data that is consistent from plant to plant, with a level of granularity, agility and timeliness that is impossible to achieve with Excel.

More importantly, the compliance reports are constructed from raw data that is automatically collected from the plant, providing a near real time record that can be electronically validated, shared, and stored. Vigilistics offers a Paperless Reporting System that is validated to the most stringent requirements in Food and Beverage for electronic reporting. (FDA 2012) Because this type of product monitors and reports what is actually happening on the plant floor, it provides a closed loop management system with alerts, exception reporting and actual compliance records that are verifiable. By contrast, Excel relies on use input of data, does not offer database controls, and is difficult to control.[1]

The Costs of Retaining Excel-based Data Retention Systems

Those plants choosing to retain Excel (and other paper based) data retention systems need to be cognizant of the costs associated with doing so. Aside from increased Product Recall risk (see our

Article titled “the cost of product recall”), fines for non-compliance can reach $250,000 for a single incident, and a host of additional fees and penalties are also possible.

In order to prepare for an audit of these systems, plants electing to retain Excel-based spreadsheets should invest in developing and updating the following:

- User Manual with Excel functions that help to comply with FDA requirements
- SOP: Validation of spreadsheet applications
- SOP: De velopment and use of spreadsheets in regulated environments
- Gap analysis checklist for Macros and Spreadsheet applications

Particular skill sets needed include the following:

- How to design spreadsheets for FSMA compliance.
- When, what and how much to test?
- FDA and other agency’s requirements for spreadsheet validation: What do inspectors ask and what documents should be available?
- How to apply risk-based validation to spreadsheet applications.
- How to ensure spreadsheet security and integrity.
- How to document planning, specifications, installation, testing and changes

Companies that continue to use Excel and do not have the requisite experience in house will find themselves turning to consultants who can provide the expertise necessary to help a manufacturing plant prepare for an audit.

Summary

Business Intelligence Solutions for food and beverage processing plants can provide dynamic, real time proof of compliance that meets the requirements of regulatory inspectors, auditors, and internal management, without costly or technically intensive integration efforts. These solutions are an indispensible tool for helping to prevent the potentially catastrophic consequences of a failed safety audit or otherwise high cost of product recall, and they will also help companies to create a meaningful long term competitive advantage for their business.

Notes

1. In the process industry, it is common to extend control automation platforms for basic data collection and export this data for simplistic reporting. However, companies looking to build their own compliance reporting solution will face significant supportability and process control challenges not unlike Excel. Issues include developing a data model that scales, obtaining FDA validation, setting up enterprise application features, and accommodating “n-tier” deployment and supportability. A technical demonstrations of feature updates across an enterprise at every plant in a two-hour maintenance window, for both plant and enterprise views, is recommended.

About Vigilistics

Vigilistics, Inc. is transforming the way food and beverage operations use manufacturing data. Our software solutions monitor, record, analyze and optimize production and cleaning processes used in manufacturing operations, to deliver actionable real-time intelligence to managers and executives.

Our software is now in use by some of the largest food manufacturers in the world, and validated by the FDA for paperless compliance reporting. Our secret is a novel and patented data model that unlocks an ability to configure data collection to the nuances of each plant, and monitor every process step and parameter the same way, without using highly technical engineering resources. We offer solutions for receiving, pre-op inspections, CIP management, traceability, yield, and more.