



ELECTRONIC DOCUMENT MANAGEMENT:
A Business Case for Implementing an Electronic Document Management (EDM) System for the Food & Beverage Industry

Food and beverage processing companies are quickly being forced to implement Electronic Document Management (EDM) systems to meet government regulatory requirements. Although the recent Bioterrorism Act is the primary driving force, EDM systems can be the engine for improved product tracking and tracing, quality management, production efficiency improvement, and increased production profitability across all departments throughout an organization. Section 306 of The Bioterrorism Act requires the establishment and maintenance of records. Although not required now, it is anticipated that the FDA will eventually require "electronic document" records and "electronic process" records. Therefore, it is prudent that food and beverage processors immediately embrace electronic record keeping since cost effective solutions do exist.

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The following business case has been developed for Fresh Food Processors Inc. to support the cost justification for purchasing and implementing an EDM system within its organization.

Impact on Business Processes

An Electronic Document Management system can positively impact the following business processes within Fresh Food Processors Inc.:

Quality Management: Enable real-time collection, analysis, and reporting of quality, HACCP, and SPC data in an electronic format.

Production/Operations Management: Enable real-time collection, analysis, and reporting of production, OEE, and WIP data in an electronic format.

Specification Management: Enable Research & Development, QA, and/or Technical Services to manage specifications in an electronic format governed by strict revision and control routing.

Maintenance Management: Enable plant managers to track and maintain maintenance management records in an electronic format and integrate maintenance schedules into the electronic plant scheduling process.

Finance: Provide for electronic access and management of activity based costing information which can be calculated into detailed SKU cost models.

Contract Management: Enable a company to retain all contracts in an electronic format that can be linked to historical grower or supplier performance records.

Customer Complaint Management: An electronic document management system can electronically maintain historical customer complaint information, track repeat customer complaint violations, and maintain electronic digital still shot pictures and videos.

Training: An EDM system can be used to train new employees, test new and existing employees, and keep electronic records of historical test results.

Impact on Business Processes (Continued)

Research and Development: An EDM can be used to maintain all recipes, formulas, and nutritional information in an electronic format with a powerful "key word" search engine.

Nutritional Labeling Management: An EDM system can be used to maintain time stamped revision control (as well as a historical record) of ever changing nutritional labeling information.

Packaging Labels: An EDM system can be used to maintain time stamped revision control (as well as a historical record) of all package labels.

Benefits to Fresh Food Processors Inc. Internal Operations

Fresh Food Processors Inc. could expect to achieve significant improvement within the following internal business process areas:

Specification Management: An EDM system would enable Fresh Food Processors Inc. to create, store, retrieve, revise, and manage all past, present, and future product and process specifications. Since "specifications" are the basis for production line performance, finished goods product quality, and buying and selling transactions, it is vitally important that all specifications are real-time accessible, up-to-date and accurate, governed by a controlled, time-stamped revision process, enabled for "key word" electronic searches, and electronically linked to legal customer or supplier contracts. Although additional reasons could be cited, an electronic specification management system is one of the primary justifications for implementing an electronic document management system within a food processing company. **The Specification Management system is the first line of "quality defense" for a food processor.**

Process Performance Compliance: A second justification for an EDM is the real-time process performance compliance capability achieved through integration with a Statistical Process Control (SPC) application. Integrating SPC functionality to an EDM system provides real-time noncompliance alert notification for out-of-control production processes. As a result the line supervisor can take immediate corrective action, and quality assurance has a time stamped reason code and product traceback capability.

If the unexpected occurs and the production process strays from the specification, **the nonconformance alert notification provides the second line of "quality defense" behind the specification line of defense for a food processor.** Nonconformance Report management functionality is a sole purchasing determinant for many current EDM users.

Quality Management: An EDM system provides a third line of defense against a company's product quality and performance integrity through an electronic quality management system. EDM provides a real-time electronic record of all quality and HACCP conformance information. If the food processor integrates the system with live electronic data feeds, Fresh Food Processors Inc. can rest assured that no quality information has been errantly transcribed from manual spreadsheets or falsely entered on the production floor. Once all quality and HACCP data is electronically stored within the plant (or corporate) quality database, the information is instantly accessible for internal reference, mock recalls, or required government recalls. For a Bioterrorism Product recall, an EDM system will provide electronic tracking and tracing one level below (i.e. supplier ingredient tracing) and one level above (i.e. customer finished goods tracking) the real-time processing plant floor activity. (Note: Many times an EDM system enhances pre-existing electronic HACCP programs which do not have supporting, high functionality electronic databases.

In addition, the Quality Assurance department can maintain electronic versions of all past, present, and future Certificates of Analysis. Bar code information from incoming goods and outgoing finished goods cases can also be stored in the EDM system. One current EDM customer used shelf-life testing program cost reduction as the ROI justification for purchasing an EDM system.

ISO Certification: The EDM system can be used to develop and implement an ISO certification process for Fresh Food Processors Inc... EDM can be used to manage standards required for ISO Certification maintenance. For many food companies, ISO Certification is becoming a required business process and/or a requirement for international trade. As a result, **the ISO Certification functionality of an EDM system becomes the fourth line of quality, brand, and business integrity defense to a food processor.**

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Employee Training and Testing

Program Management: An EDM system can be (and already has been) used to execute employee training and testing programs. Entire training manuals and documents, corporate policy, and Human Relations documents can be stored in this central repository for ready access to any and all individuals throughout an organization. In addition, individualized employee tests can be developed and provided to new employees as a precondition to employment or employment re-certification. Employee testing failure reason codes can also be stored for future reference. **A properly executed, disciplined employee training and testing program now becomes the fifth line of defense against product quality failure within an organization.** Some organizations also use EDM for HACCP retraining with Electronic signature requirements.

Electronic Contract Management: An EDM system can electronically store, manage, and keep time-stamped electronic revisions of all purchasing contracts, grower contracts, and customer contracts with electronic links to relevant specifications, legal documents, or other relevant historical information such as prior performance data.

Electronic Document Management: Although inherently implied, an EDM system allows virtually all documents within an organization (including digital pictures, videos, CAD drawings, etc.) to be stored, managed, and time-stamped revised. All of these documents are readily accessible to all employees within an organization, or they can be restricted by the EDM administrator as desired.

Internal Document Revision Management Process: The EDM product also provides a "schema" for event or process escalation that is email based for document review, change notification, or approval that is individual or group driven.

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Other Specific Benefits include:

- **Development Tool for Product Work Flows**
- **Key Word Search Engine**
- **Product Rework Management**
- **Research and Development Formula or Recipe Management Program**
- **Ability to send recipes from R&D or MRP to the Production Line Supervisor**
- **Paperless Manufacturing Environment**
- **Benefits to Fresh Food Processors Inc. Retail and Foodservice Customers**

Customer Complaint Program Management: The EDM system is an effective way to electronically manage Fresh Food Processors Inc. customer complaint program. Since the EDM system is web-based, it provides an easily accessible way to exchange complaint information in a document, digital picture, or digital video format between suppliers and customers.

Finished Goods Product Tracking: The EDM system can be used to comply with existing real-time, electronic product recall government requirements. Transition from manual to electronic product recalls is a MUST to food processors, and a change that must occur NOW!

Benefits to Fresh Food Processors Inc. Suppliers

Incoming Goods Product Conformance and Tracing: An EDM system like EDM allows food processors to maintain an electronic record of each incoming product received from their suppliers, log all relevant product and supplier information, compare current analytical and product information to a pre-existing specification before a product is removed from a truck, and enable product or ingredient tracing once a product begins to be incorporated into a processors finished goods. **This is another strategic line of defense against nonconforming product quality.**

Annual Customer On-On Site Audit Programs: Many customers (foodservice in particular) require food manufacturers to provide regular audits to monitor their QA, HAACP, Sanitation, Pesticide programs and Plant Physical conditions. This is a time consuming and costly expense that could be reduced to one annual on-site visit through a web-based electronic audit program.

Business Justification Summary

The above discussion highlights the most common reasons manufacturing companies across diverse industries purchase and implement electronic document management systems. With additional thought, an individual company can identify other numerous reasons to justify the cost of implementing an EDM system within their organization. EDM systems are new to the food processing industry, but they have become required common practice in other highly regulated industries like pharmaceutical. EDM is relatively inexpensive compared to equivalent applications in pharmaceutical plants that can cost as much as \$250,000 per plant.

EDM stands out in particular to the food industry because it enables food processors to comply with current and emerging government electronic product tracking, tracing and signature requirements. In addition, it is ISO compliant and represents the most cost-effective, high functionality product identified within the industry to date.

Return on Investment (ROI) Summary

Since the beneficiaries of an Electronic Document Management system are spread across almost every department within an organization, logical follows that the cost should be spread across the departments that will derive direct benefit from its application. Many companies initially view EDM as a quality or HACCP application, but our previous discussion outlines the broad cross-departmental functionality.

For example, if the total cost of a fully implemented EDM system is \$50,000¹ for a company, then the cost allocation across ten individual departments would be a mere \$5,000. Departments with a disproportionate usage could be asked to share a proportional cost.

How quickly could \$5,000 savings be achieved? If a company pays an individual \$10 per hour (fully loaded) to transpose and key manual data into a electronic access database, the cost to this department could be recovered in a mere 3 months. The cost of a higher paid R&D or QA manager who takes time to do key word searches or manually change recipes for production trials could be recovered within a month.

On top of these hard costs are other indirect soft savings to an organization. Those benefits include:

- **ISO Certification compliance**
- **Permanent electronic data entry that cannot be falsely or inadvertently entered manually**
- **Electronic audit and exception reports to customers**
- **Electronic Specification Management System**
- **MSDS, CoA's, certified Training records**
- **And many other benefits already discussed**

¹ Cost example includes 30 named users, 10 concurrent users, one designated server, and the EDM product – in addition to 2 days of administration and user training plus 8 single days of training in 8 individual departments. Department implementation training usually includes ½ day electronic document management training and ½ work process flow training. This example is only an example of cost components. A precise cost estimate based on a company's specific business requirements can be obtained directly from EDM. Integrated SPC functionality and real-time plant production and QA data collection infrastructure to the EDM system are not included in this example.

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