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PeopleSense INC.

WHITE PAPER
COLLECTION

3 Ways Intelligent Information Management is Transforming the Manufacturing Industry

INTRODUCTION

The business of tracking information, materials and financials as they move across the supply chain has long been riddled with complexities. This is especially true for manufacturers managing quality and regulatory compliance activities across global business entities, systems and processes – from supplier, to manufacturing subcontractor, to wholesaler to retailer. Even in the information age where data access and sharing are easier than ever before, manufacturers face new sets of IT and operational challenges in the quest to protect sensitive data, optimize the management of standard operating procedures (SOPs), and continually improve performance.

Successful supply chain management requires the effective coordination and integration of workflows across the entire manufacturing operational landscape to ensure that all activities related to a product's lifecycle are recorded, traceable and compliant. In this pursuit, one of the greatest challenges manufacturers face is the ability to monitor the full lifecycle of a product-- from the point of its origin, which involves the sourcing of various materials and components — to the point of consumption, whether by the mass market or within a specific customer installation.

Further complicating these efforts are the various sets of standards and regulations manufacturers must comply with designed to ensure the quality and safety of products delivered, be they cosmetics, food, pharmaceuticals, transportation equipment or nuclear systems.

Enterprise Information Management (EIM) is a solution designed to improve the management of all structured data and unstructured content that is critical to manufacturing business operations, helping simplify the age-old complexities that have plagued supply chain efficiency and compliance efforts.

Using an EIM system, manufacturers can exercise greater control over unstructured content such as CAD drawings, product sheets, certificates, specifications, invoices, purchase orders and bills of material (BOM) as well asstructured data objects such as customers in a CRM system or projects in an ERP solution. The ability to connect unstructured content with structured data objects with an EIM solution has many benefits, such as enabling backward traceability and proof of compliance across the entire product lifecycle.

This paper addresses the issues facing today's manufacturers and the benefits afforded to procurement, quality control and supply chain managers, as well as to business partners, through the implementation of an EIM solution.
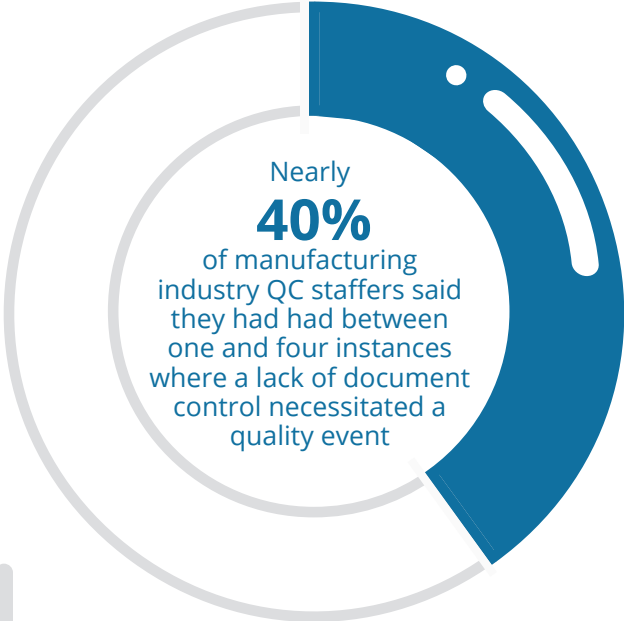
> *"Successful supply chain management requires the effective coordination and integration of workflows across the entire manufacturing operational landscape ..."*

BY THE NUMBERS

INTELLIGENT INFORMATION MANAGEMENT AND THE MANUFACTURING INDUSTRY

Workers in the manufacturing industry **spend 20-40% of their time** gathering information before they can even begin completing daily task

Nearly **40%** of manufacturing industry QC staffers said they had had between one and four instances where a lack of document control necessitated a quality event

The top document control concern for the manufacturing industry was an inefficient and/or ineffective document control system, **cited by 30% of those surveyed**

In the manufacturing industry, **nearly 21% of companies** say a lack of document control resulted in 5-10 (or more) documentation remediation incidents at their companies.

The average office employee spends **1.5 hours per day** looking for things like paper documents. That's 6 weeks' worth of man-hours for EACH employee.

$7.50

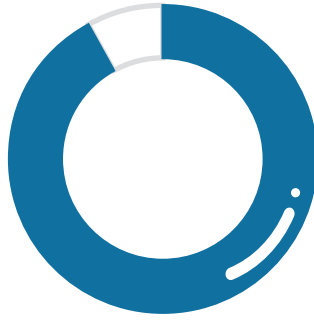It costs **$7.50** every time a piece of paper is touched

BY THE NUMBERS

DIGITAL TRANSFORMATION

Almost half (48%)
of top-performing organizations believe they are at least 75% of where they want to be by 2020 in their Digital Transformation journey. Only 8% of bottom performing organizations feel similarly.

86% of companies
see failure to digitize and standardize (and automate) business inputs as a key transformation bottleneck

92% of organizations
believe that something needs to change and that they must modernize their information management strategy.

COMMON MANUFACTURING CHALLENGES

Explosive Regulations, Employee Engagement

Real risk from quickly changing regulations with steep penalties. Difficult to keep good employees trained and in compliance with local laws

Manual Processes, Disparate Systems

Manual processes slow down work and keep employees from being responsive. Disparate systems that don't communicate require double work and delays

Complex Supply Chain

Complex, global supply chain, multiple overlapping systems lack of communication and control

Global Operations

Global operations are complex with a myriad of dependencies, unique regulations, language and culture changes

PAPERLESS QUALITY MANAGEMENT YIELDS IMPROVED PERFORMANCE

According to a study by Aberdeen Research, 53 percent of manufacturers surveyed are still utilizing paper-based systems for quality management. The report stresses that implementing manual systems to manage quality and production processes is merely a stopgap as performance cannot be accurately improved – a limitation that defies the core tenet of manufacturing processes. More than 60% of best-in-class manufacturers have migrated away from manual quality systems, and consequently, experience 13% higher operating margins when compared to their paper-based counterparts. These benefits are similar to those experienced by manufacturers leveraging EIM for information and quality management.

CASE STUDY | ROAL

Roal — one of the world's largest enzyme manufacturers — exports 90% of its products worldwide. The company produces enzymes used by baking, food and feed industries, as well as active agents found in everything from detergent to textile fabrics. As a biotech company, quality and information management are essential to Roal's operations, and ISO certifications require that they establish and maintain up-to-date information management practices. Before implementing an EIM system, non-conformances in the production department were documented on handwritten pieces of paper, which were later submitted to the quality control unit to be logged into Excel spreadsheets. The process required multiple steps across various operational departments, and compliance reporting was disjointed and time-consuming.

Since replacing paper records with intuitive online forms within their EIM system, it has become quick and easy for factory floor employees to complete documentation for non-conformance events in real time. And with the ability to connect those forms to people and related workflows, Roal can now monitor incidents and corrective actions, and make more data-driven decisions to better optimize production and quality processes.

Paper-based processes are simply out-dated and cannot be expected to meet modern manufacturing demands. EIM solutions can help manufacturers control, record and continually improve quality processes and performance. Roal maintains a wide range of quality documents, many of which require periodic review and updates. With their EIM system, those documents are assigned a period of validity and, in advance of expiration, responsible departments and personnel are notified via email. If a quality document reaches its valid-till date without update or approval, the document then becomes inaccessible to all permissioned users. Offering the capability to assign metadata attributes to documents, people and processes and automate their connected workflows, EIM unleashes new benefits—benefits that are not afforded by manual, paper-based processes.

PAPERLESS QUALITY MANAGEMENT YIELDS IMPROVED PERFORMANCE

Electronic-based systems not only help to improve quality performance, but they also enable manufacturers to validate compliance with the various standards and regulations they must adhere to such as ISO 9001: 2015, NQA-1 (Nuclear Quality Assurance-1), 21 CFR Part 11 or numerous other FDA or EU regulations.

In the manufacturing environment, nearly every process is documented and controlled under the guidance of internal SOPs and/or external mandates — be it equipment operations, product assembly or maintenance procedures. EIM solutions are effective platforms for managing all manufacturing documents and processes and provide a record of all related compliance activities.

CASE STUDY | LESSONIA

France-based Lessonia is a manufacturer of cosmetic products and a supplier to the world's largest beauty brands such as L'Oréal, Estee Lauder and Johnson & Johnson. The company works with a wide range of customers—from small cosmetic companies to the most respected and trusted providers of beauty products around the globe. Lessonia partnered with French consulting firm Sedasis to deploy an effective method of managing documentation associated with Good Manufacturing Practices (GMP) and at the same time become more responsive to customer inquiries while offering the highest level of security.

Lessonia manufactures several hundred cosmetic products and must manage documentation and audit trails. For each shipment lot, the company must develop analysis certificates, product specifications, delivery notes and invoices with lot serial numbers. All of this documentation needs to be stored in a safe and secure repository, but also made easily accessible to various people and partners across the supply chain. Using an EIM solution, Lessonia can define and track the processes critical to GMP and ensure that supporting documentation is both accurate and up-to-date. As a result, the globally dispersed staff can now collaborate on all commercial documents from each manufacturing batch including invoices, orders and technical files. As an added benefit, compliance reporting is now automated for periodic audits conducted by several different organizations.

CASE STUDY | VIGOR

There are few industries under greater levels of scrutiny and regulatory requirements than the nuclear sector. Vigor is a diversified industrial company that builds and modernizes large vessels and fabricates equipment and systems for hydro, nuclear and aerospace industries. The company's Nuclear Division serves three heavily regulated segments: the Department of Defense, the Department of Energy and commercial nuclear markets. In its organization-wide commitment to quality and safety, Vigor tracks the compliance events that are relevant to industry regulations, including both 10 CFR 50 Appendix B (enforced by the Nuclear Regulatory Committee/NRC) and ASME NQA-1, the nuclear quality assurance measures aimed at controlling the safety of products within nuclear facilities.

There are several compliance activities that Vigor needs to monitor and audit, and it does so by using their EIM solution. For example, as a nuclear supplier, Vigor maintains strict requirements for its subcontractors, which must be certified by audit before a project advances in the manufacturing process. In addition, Vigor's Nuclear Division has rolled out its own internal supplier performance program to measure the quality and efficiency of supplier network partners. The ability to capture historical progress, incidents and corrective actions offers Vigor the backward traceability capabilities needed to further optimize quality and safety at every point in the supply chain.

STREAMLINE BACKWARD TRACEABILITY ACROSS THE SUPPLY CHAIN

There are key drivers behind a manufacturer's quest for greater visibility into the product lifecycle across the supply chain, and the desire to enable backward traceability. First, manufacturers are casting a wider net for sourcing materials to help reduce supply costs and increase profit margins. As a result, they are procuring more components from a constantly growing network of global suppliers. At the same time, industry is seeing a significant uptick in outsourcing operations, yet also aiming to make manufacturing processes more competitive and profitable. Both trends require streamlined processes together with suppliers, subcontractors and distributors in order to optimize the management of product recalls notices, replacements and repairs, while also ensuring external partner compliance with internal and regulatory-sanctioned quality and safety processes. Furthermore, manufacturers are facing increased demands for transparency from customers, business partners and regulatory agencies for everything from real-time project status to proof of supplier certifications.

In addition to verifying compliance, backward traceability is a critical tool in the event of recalls, warranties and repairs. With the ability to log training processes, factory floor incidents and corrective actions, along with supplier certifications, manufacturers can automate the processes of pinpointing quality vulnerabilities in the event of a recall and share up-to-date information as it relates to maintenance and repairs. Without a holistic record of all manufacturing processes and documentation from product origin to distribution, the process of reactive response to unexpected incidents can be devastating to customer loyalty and brand-affinity.

At Vigor, mentioned previously, a large volume of project and process documentation needs to be traceable, from the earliest stages of development through the life of the product, which could span 150 years. By using an EIM solution to capture every project component (contracts, authorizations, suppliers, etc.) and organizing those pieces in chronological order and around sets of processes, Vigor gains important visibility into its supply chain. Just as Vigor requires periodic audits from its suppliers, it too must provide an audit trail of all supply chain activities to comply with 10 CFR 50 Appendix B and NQA-1.

CASE STUDY | BROWN MCFARLANE

For Brown McFarlane, a global steel processing and manufacturing company based in Stoke-on-Trent, United Kingdom, having a digital documentation trail is critical for backward and forward traceability. With its products deployed offshore in waste and recycling applications and within other high-risk environments, the company must ensure that the metals it uses can be verified to meet stringent quality and material standards. Certificates from independent testing labs are provided with the sourced metal, and the connection between the metal used in each installation and its associated certificate is key: Brown McFarlane customers are not allowed to operate their installations without these certificates.

Keeping track of thousands upon thousands of test certificates – as well as providing fast and easy access to them -- has presented a document management challenge for the company. After wrestling with this challenge for years, the company now uses an EIM system to manage the process. EIM has given Brown McFarlane a paperless and more streamlined approach to certificate management, allowing its team to work more efficiently and reduce operating costs. And whereas previously the company had several people assigned to certificate management to keep up with demand, by digitizing and automating the process with its EIM solution, these Brown McFarlane employees now have more time to work on other aspects of the business.

PRACTICAL APPLICATION: A MORE INTELLIGENT WAY TO HANDLE BILLS OF LADING

So what does Enterprise Information Management look like in a real scenario common to the manufacturing industry?

One of the most critical documents in the manufacturing industry is a bill of lading (BoL). The three principal purposes are (1) it acts as a receipt for shipment, (2) it demonstrates the contract of carriage and (3) serves as a document of title. All details needed to process the progress of goods through the supply chain are contained in the BoL. It also serves as a guide to invoice those goods correctly.

How can an EIM platform help manage Bills of Lading?

The most obvious answer lies in intelligent capture — a process of scanning documents on site and suggestion contextual cues to classify those documents. With intelligent capture, processing BoLs is more efficient and integrated with accounting processes. No more manual data entry. Users can automatically extract, classify and validate BoL data against core systems.

Results

• Increase on-time shipments with higher throughput and fewer errors
• Produce invoices faster and minimize the time-to-revenue collection
• Process more BoLs with fewer mistakes at a reduced cost
• Assign employees to more valuable tasks beyond manual data entry

CAPTURE
Gather logistics documents from any source and any location across the enterprise

EXTRACT
Content on paper becomes information that can be validated and with your core system

PROCESS
Smart workflow that uses business rules and hierarchies to process tasksm identify exceptions, and highlight mismatches
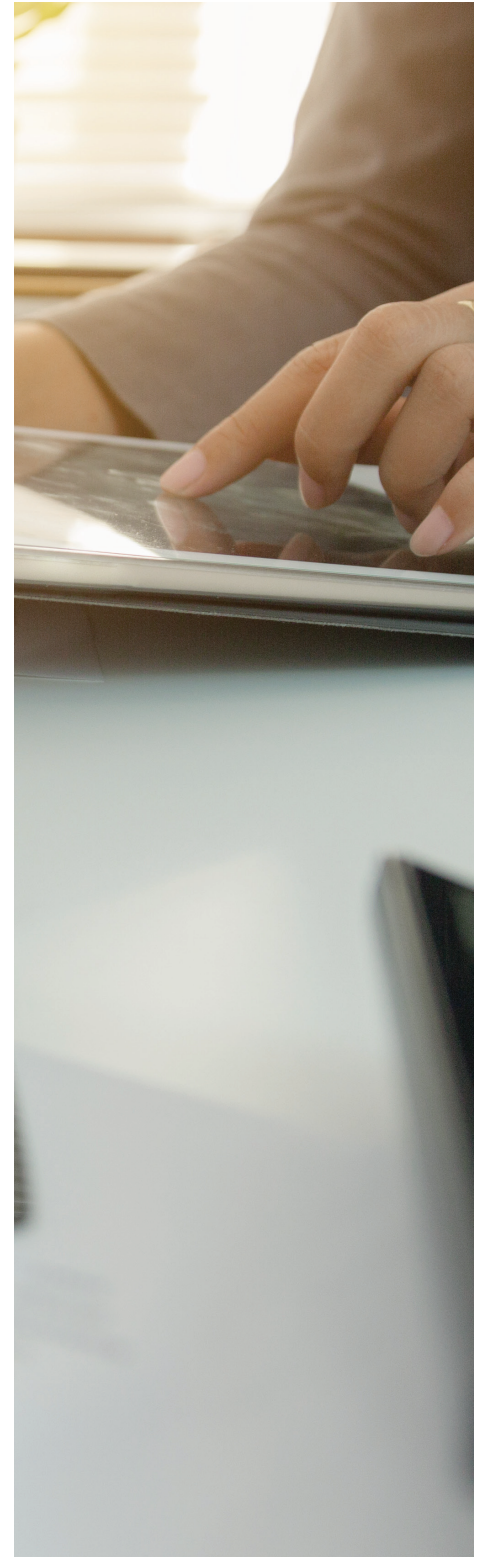
INTERFACE
Get validated, enhanced logistics data into your ERP or core business applications

DOCUMENT
Record electronic copies to support customers and internal controls and audits

MUST-HAVE TECHNOLOGY TOOLS FOR AUTOMATING MANUFACTURING PROCESSES

Data shows us the best-in-class manufacturers are those that have migrated from manual processes to electronic automation of quality processes. But to do so effectively, they must rely upon a system that can control all the information assets and workflows that are critical to manufacturing processes to enable backward traceability and continually improve performance. A technology solution should provide businesses the following tools and features to track the entire lifecycle of a product, thus priming them for the most successful manufacturing outcomes:
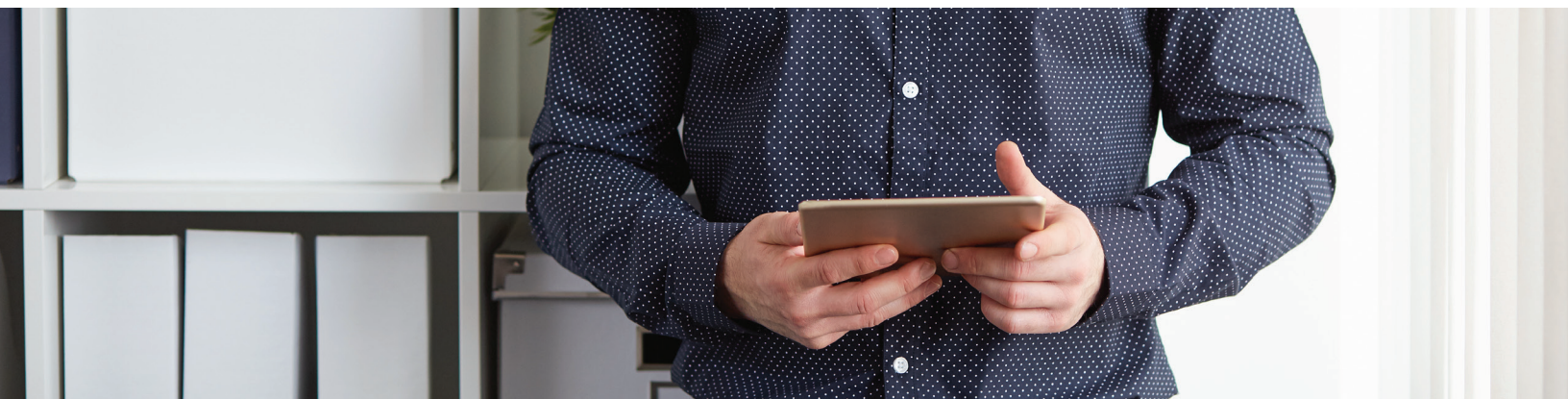
Fast Access to Manufacturing Information - No Matter Where It Resides: EIM systems enable manufacturers to eliminate information silos created when important data and documents are scattered among different business systems, departments and devices. With EIM, content is not tethered to a specific location - it can be accessed and synced between various systems and devices - with no duplication of content. And with the ability to link structured data (such as ERP-native data) with unstructured content (such as purchase orders, invoices, product delivery documentation, etc.), manufacturers gain a 360-degree view of all aspects of their supply chain. This approach enables manufacturers to trace a product (and all its components) through the distribution network to the end customer and execute backward traceability to the supplier-level in the event of quality issues or events.

Security and Permission Controls: EIM systems can be extended to authorized suppliers and distribution partners to ensure security is controlled across the supply chain. With advanced security and permission controls, manufacturers can link any

external party, service or good to part of a process, providing controlled and secure transparency. Sophisticated security and permission controls are critical to monitoring supply chain quality processes (such as SOP management and tracking of training/learning requirements), and serve to verify that only the necessary certificates, material declarations and safety data sheets are accessible to specified classes of personnel and/or partners.

E-Signatures: In a manufacturing environment, any new version of an SOP must be authorized with a supervisor's signature. Similarly, when new employees or partners access and read training manuals, quality managers must be able to prove that they have done so. With integrated e-signature capabilities, EIM systems capture proof of authorizations and process completion, and if any significant deviation is discovered, a related CAPA can be documented and implemented across the supply chain in near real-time. With e-signatures, manufacturers can track change controls to verify that the impacted individuals have read and understood the new SOPs associated with the CAPA and provide proof of adherence to both quality processes and change controls.

Audit Trails: The ability to organize, capture and recall up-to-date documentation, training and manufacturing processes demands time-stamped audit trails. To meet these requirements, EIM solutions organize and manage all quality-related documents and associated processes with complete version history, security, workflow and publishing. This feature is particularly important to manufacturers in heavily regulated industries, where proof of compliance is both stringent and on-going.

ABOUT M-FILES

M-Files provides a next-generation intelligent information management platform that improves business performance by helping people find and use information more effectively. Unlike traditional enterprise content management (ECM) systems or content services platforms, M-Files unifies systems, data and content across the organization without disturbing existing systems and processes or requiring data migration. Using artificial intelligence (AI) technologies in its unique Intelligent Metadata Layer, M-Files breaks down silos by delivering an in-context experience for accessing and leveraging information that resides in any system and repository, including network folders, SharePoint, file sharing services, ECM systems, CRM, ERP and other business systems and repositories. Thousands of organizations in more than 100 countries use M-Files for managing their business information and processes, including NBC Universal, OMV, Rovio, SAS Institute and thyssenkrupp.

For more information, visit **www.peoplesenseerp.com**.

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