



White Paper Series

Obtaining And Maintaining ISO 9001 Compliance Using Ingenuus

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Introduction

Provide a general Introduction

ISO certification is an on-going investment

Companies make a considerable investment in obtaining their ISO 9001 certification. However, often not taken into consideration is that the investment in maintaining certification will be substantially greater than the original investment made in simply obtaining it. This is particularly evident in the software companies typically select to assist them in the initial pursuit of obtaining ISO certification. ISO software solutions typically provide assistance in creating a quality manual and procedures, performing pre-assessment audits, and correcting compliance issues. These are helpful and certainly will assist in bringing the company to initial compliance with ISO requirements, however can assist them no further. Their value lies only in the initial task of obtaining certification but not in the greater ongoing task of maintaining certification throughout the following years on a day-to-day basis. Companies also need to consider software that will not only assist in obtaining initial certification but will also continue to provide assistance in maintaining ISO certification in subsequent years.

The pursuit of ISO certification often overlooks the purpose for certification.

The focus on obtaining initial ISO certification often overlooks the real purpose behind ISO certification, which is to control of the business processes that can impact the quality of the product and services provided to the customer. For example, ISO not only requires each process be documented in a procedure, but requires that the procedure and other required documentation is readily available to the employees assigned to perform the process and requires any subsequent changes to the procedure and applicable documents be controlled and approved. ISO also requires employees have access only to the latest approved revision of procedures and documents and that employees have been trained on the procedures applicable to the tasks they are responsible for and on any subsequent changes. Periodic internal audits are required to assure employees are following procedures, that the quality system is operating as designed and is still in compliance to ISO and internal requirements. ISO requires that records be maintained as evidence of compliance.

Initial certification can be achieved by setting up the required processes, documenting them in procedures, establishing record requirements, implementing, and showing that the quality system works (for a short period of time). However, continued certification is dependant upon the company employees consistently following their procedures. How well employees continue to follow the procedures applicable to them will be very dependant upon how accessible those procedures are, that procedural training is consistently provided and including any procedural changes subsequent to initial training, and that employees are held accountable for their compliancy to the procedures applicable to the tasks they perform. Accountability is dependent upon consistently conducting periodic assessments to determine how well established procedures are being followed, a thorough management review of the assessment results, and the corrective action taken wherever required. Continued certification is particularly dependant on the religious maintenance of required records as evidence of the completion of required activities and overall ISO compliancy.

Surprises can be costly

Many a Quality Manager and General Manager have been surprised during a periodic third-party ISO assessment to find that, unaware to them, critical processes were not being followed, resulted in the unplanned additional costs of evaluating the potential quality impact to products and services as a result of the procedural nonconformance. Substantial additional costs can be incurred in correcting the products and services found to be impacted by the nonconformance, plus the cost of the additional rounds of assessments

by the auditors to assure corrective action has been taken. However, the greatest potential cost is the business impact from customers that were affected by the nonconformance. Severe noncompliance may result in the loss of ISO certification for an undetermined period of time impacting any business requiring ISO certification.

Automating critical ISO processes will provide GREAT value and increase profits.

In light of this, an automated system providing the ability to make the most current (and only the most current) documents easily accessible to employees, to manage changes made to controlled documents (such as, procedures, design and manufacturing documents - including Bills of Materials), manage employee training, manage internal auditing, manage corrective action, and manage electronic storage access of required records would be of great value to a company pursuing initial ISO certification or currently maintaining their existing ISO certification. The soon to be released *ISO SmartSuite* by *Ingenuus* will provide such a system. The system includes a secure vault (repository) to electronically and securely store all documents, bills of materials (BOM) and records. The value of the system is increased by an internal Smart Expeditor designed to drive each process in the system to completion and will provide automatic notification whenever a task is not getting done within the allotted timeframe, and can even escalate upwards through several management levels until the task is completed, assuring that a scheduled assignment can no longer fall in the crack. The system value is again increased with an internal recorder that automatically maintains an audit trail of every task performed within each process in the system. In addition, even greater value has been added by designing the entire system to be web-based, enabling access from any computer connected to the company intranet, and global access through the Internet (access is controlled by permissions). Finally, we greatly enhanced the system value by designing into it the ability to automate other business processes important to the customer and the flexibility to modify existing automated processes when needed to accommodate the continuous ongoing changes needed by customers to continuously improve their business processes and overall quality systems. On top of the already incredible value of this system is a typical return on investment (ROI) of only four months after system implementation. Add to this an implementation period of only a few months and the result is a suite of ISO e-solutions of incredible value that can be quickly implemented, will pay for itself in only a few months, then continue to increase ongoing profitability in the months and years to come while greatly enhancing the ability of your company to gain AND maintain ISO certification.

The initial release of *ISO SmartSuite* is scheduled for the 3rd quarter of 2002. The initial value of the suite will continue to be expanded with additional automated ISO solutions planned for later releases.

Smart Expediter (SE) Platform

Smart Expediter is everything when it comes to establishing, implementing, and maintaining a complex quality system that accomplishes the goals and objectives for which it was designed. Assuring that critical processes are followed and completed, a network for essential communications is in place and being used as planned, the required records keeping is kept up in an accurate and timely manner, and maintaining necessary disciplines and individual accountability is absolutely crucial to a success on-going quality system implementation. This is the purpose of the *Ingenuus Smart Expediter Platform*, which is the very heart of the *ISO SmartSuite* and other *Ingenuus* solutions.

The SE Platform contains such components as the *Smart Expeditor* to command, control, and force action automatically. The *Smart Expeditor* assures that nothing falls in the crack by driving, escalating, and controlling your processes from beginning to end.

The SE Platform allows the flexibility to adapt in real time to the changing requirements of customers, quality standards, and your business. The SE Platform is proactive, providing instant communications to those who need to take action, instant information to those who need it, and monitors whether those notifications were acted upon. Global communications and access to critical documents are confidently

provided through multi-layered security and permissions, protecting critical information against intruders and unauthorized access.

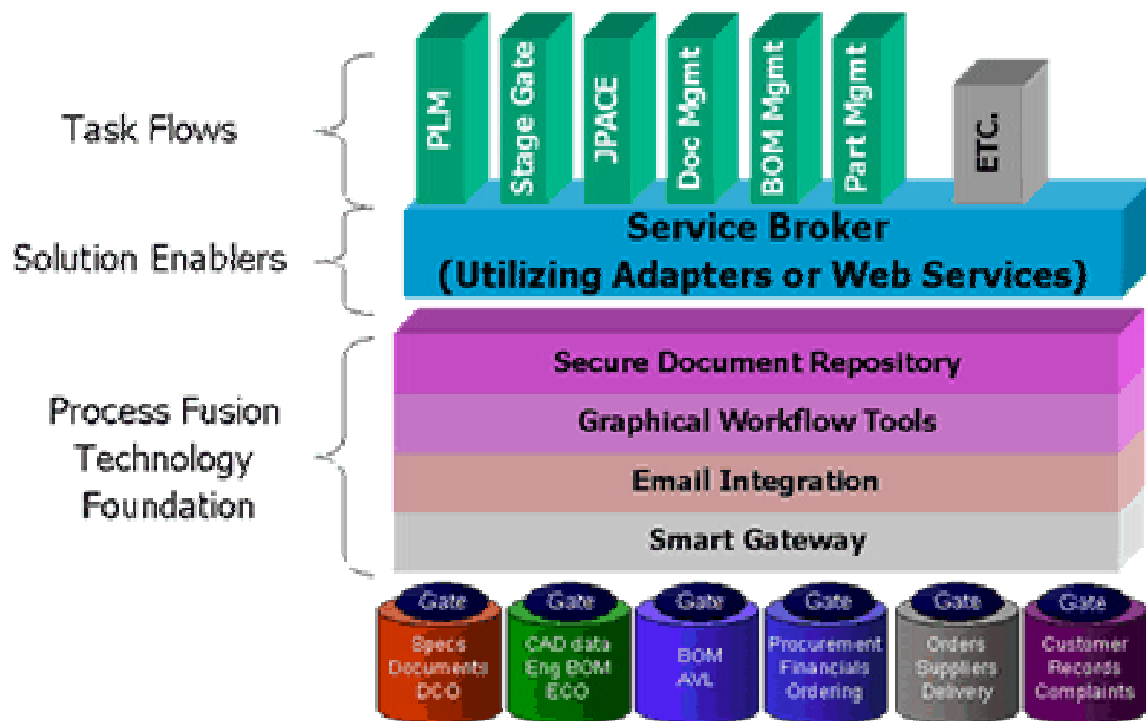
The SE Platform also contains the *Integration Gateway* that allows the synchronization of information and processes with other applications, such as MRP/ERP systems, CAD systems, and various database applications.

The entire system is web-based eliminating obstacles related to distance and time. Processes and communications that are inter-departmental, inter-divisional or require supplier or customer involvement can be easily handled through a web browser and standard email.

All Ingenius automated processes ride on top of the SE Platform and access its capabilities. The Flow Designer provides the ability to easily design or modify virtually any process, providing the ability for the value of any solution to grow with time.

The below picture provides a graphic description of the SE Platform, containing the initial Smart Suites available in the 2nd Quarter of 2002.

Smart Expediter Architecture



Overview of ISO SmartSuite

The initial release of *ISO SmartSuite* in the 3rd Quarter will include the following solutions. Each solution consists of several automated processes.

Design Change Control

Design Change Control is a tool that will enable your organization to consistently meet the requirements of ISO 9001 7.3.7 – Control of design and development changes by controlling all design changes, such as changes to Bills of Materials, Assembly Drawings, Schematics, Process Travelers, Approved Vendor Lists,

etc. Obsolete revisions are automatically removed from user access and archived. Only the most recent approved and released revisions are available for viewing by users.

The initial and subsequent revisions of the BOM packet, including associated drawings and documents are electronically routed for approval or comments. Notification is provided to those with approval responsibility through email, and the entire approval cycle is handled by a browser over a web interface. If rejected, the packet is returned for correction and then rerouted again for approval. Upon approval, notification is sent by email to all applicable users that the new or revised BOM, drawings, and/or documents are available.

Personnel responsible for any activities required as a result of the change, such as removal of parts from stores, rework of product in WIP, recall of product from customers, etc. are notified by email that they have implementation responsibilities.

The Smart Expeditor within the SE Platform monitors each activity and is aware of when they are to be completed. When a task is overdue, notification is sent to the responsible person as a reminder that the task is overdue. If the task is not quickly completed, the notification is then escalated to the responsible supervisor.

All users with permission can access and view BOMs, drawings or documents using a web browser. ECRs or engineering change requests can also be generated over the web interface.

Document Control

Document Control is a tool that will enable your organization to consistently meet the requirements of ISO 9001 4.2.3 – Control of documents and works the same as Design Change Control, except that it does not handle BOMs. It is designed to control only documents and is the primary means for controlling initial releases and subsequent revisions of documents such as process and quality procedures, inspection check lists, the quality manual or any other type of document not directly related to BOMs, but are required to be under revision control. It assures that the most recent approved and released version of the documents are accessible and available at the points of use. In addition, the system provides a reminder for each document requiring a periodic review.

DCRs or document change requests can also be generated over the web interface.

Training Control

Training Control is a tool that will enable your organization to consistently meet the requirements of ISO 9001 6.2.2 – Competence, awareness and training, overseeing and controlling individual employee training as well as group training. Requests for training can be made over the web interface. The system oversees the process for the individual training of employees requiring training/certification or retraining/recertification including subsequent training validation. Those responsible for validation are automatically notified upon completion of training. Upon completion of employee training and validation, the system schedules and automatically notifies the training coordinator when periodic retraining is required again. The system stores and provides authorized access to employee training/certification records. In addition, for those with group training requirements, the system handles the periodic updating of the Master Training Schedule and oversees the scheduling, notifications, and record keeping for each class.

Internal Auditing Control

Internal Auditing Control is a tool that will enable your organization to consistently meet the requirements of ISO 9001 8.2.2 – Internal audit, overseeing and controlling the internal auditing process. The system handles the periodic updating of the Master Auditing Schedule or Plan, the scheduling of and activities during each individual audit, initiates the corrective actions required to correct any nonconformances detected during the audits, and maintains and provides authorized access to audit records. In addition, it provides an audit report packet for the periodic Management Review meeting per the requirements of ISO 9001 5.6.2(a) that requires the results of the internal audits are included in the Management Review.

Corrective and Preventive Action Control

Corrective and Preventive Action Control is a tool that will enable your organization to consistently meet the requirements of ISO 9001 8.5.2 and 8.5.3 – Corrective and Preventive action, overseeing and controlling the corrective and preventive action processes, including the initiation, routing, approval, implementation, and validation of each corrective or preventive action requirement and schedules follow-up validations to determine the effectiveness of the action taken. It also maintains and provides authorized access to corrective and preventive action records. In addition, it provides a corrective / preventive action report packet for the periodic Management Review meeting per the requirements of ISO 9001 5.6.2(d) that requires the status of corrective and preventive actions are included in the Management Review.

Electronic Record Control

Electronic Record Control is a tool that will enable your organization to consistently meet the requirements of ISO 9001 4.2.4 – Control of records, overseeing and controlling electronic record keeping. Records are stored in a manner that is accessible only by those with access permission. Stored records may not be altered except when specifically allowed, the administrator may make authorized alternations. Whenever a record has been authorized for alteration, the original record is maintained in the system, and an explanation for the alteration is recorded. The system maintains the retention period for each record. The system provides auto archiving of records that have reached a particular age.

Summary

Revision History

Date	Version	Author	Comment
June 14 th , 2001	0.5	Vivek Prasad	Draft for initial review