

USING COMPLIANCE INITIATIVES FOR A COMPETITIVE ADVANTAGE



White Paper Series

Upwards of 40% of respondents in a recent Aberdeen survey reported they are using compliance initiatives as a competitive advantage.

Compliance initiatives typically have been viewed as overhead projects. In this white paper, learn how you can turn your compliance initiatives into a competitive advantage.

Turn your compliance initiatives into a competitive advantage. Admittedly, at first this seems counter-intuitive. Compliance initiatives have a reputation as overhead – not productivity. Several factors have converged in recent years that are changing the face of compliance initiatives.

1. Standards have shifted from a checklist approach to a process-based approach
2. Cost pressures continue in the manufacturing marketplace, making any initiative that can truly save money or reduce time to market one that is gaining traction.

The biggest shift has been the orientation – some would say the maturation of compliance initiatives to a process orientation. The advent of recent financial scandals exposed “compliance standards” as shells that often did not provide guarantees of execution as expected. ISO and other bodies have shifted their emphasis from an overview of checklists and manuals for certification, to an audit of the underlying processes as the basis for certifying an organization. It is not longer acceptable to simply “have the answers” – inspectors want to know “how” you got the answers.

Consequently, today’s compliance initiatives involved time and effort often to develop compliant processes as well as develop a way to demonstrate effective processes.

Given the level of effort to achieve current compliance standards, the jump to using these initiatives as a competitive advantage, no longer seems like such a large leap. Once an organization has developed the processes to be certified, taking the additional effort to optimize the processes to get a leg up on my competitor can turn an investment in compliance from a sunk cost, to an investment that shows immediate return. The advantages for a lifecycle-wide quality operations process far outweigh the effort to develop it:

- Reduced redundancy
 - Reduction in error prone data – improved decision making
 - Reduction in duplicate labor and redundant software packages
- Reduced scrap and rework
- Shortened time to deliver products, PPAP, and other critical deadlines

Compliance is not one-dimensional – particularly in manufacturing. It is not unusual for an organization to have 3-4 ongoing compliance initiatives, each with their own manual and checklists and set of steps to pass each individual test. The good news about a process orientation, is that once compliance is “built-in” to a process, the effort to demonstrate compliance requires minimal added labor, and audits go much smoother.

WHAT IS INVOLVED IN ORDER TO MAKE A PROCESS COMPLIANT?

1. Document the function
2. Link the inputs and outputs
3. Train on the function
4. Provide visibility/metrics of the process

Regardless of the function – if its approached with a systematic, process approach then the ability to comply with a whole host of industry, regulatory and customer requirements such as ISO9000, AS9100, 21CFR11, TS16949, GMPs, ISO13485, etc. can be easily met.

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As business and IT recognize the overlapping requirements of individual compliance mandates, leaders are taking steps to build out a sustainable architecture that minimizes time and cost while maximizing future reuse

– Source AMR Research

CENTRALIZATION AND REUSE IS KEY

A common framework for compliance initiatives is the backbone of process approach to built-in compliance. It allows for common information to be distributed, and kept up to date. It provides distributed teams with the ability to work together off of one source of information. In complex manufacturing this not only helps with compliance, but provides companies that employ this strategy with a competitive advantage to reduce cycle time, and reduce costs.

When AMR looked at how to develop this active compliance framework, they asked survey participants who had achieved best in class status how they had implemented the framework. The results are below:

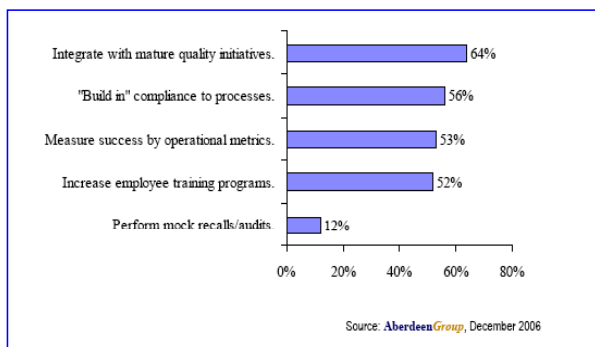


Figure 1

Not surprisingly, most organizations leveraged mature quality initiatives. For some, this is intuitive, for others familiar with quality/control and testing, this may seem like a bit of a stretch. The mature quality initiatives that AMR refers to are quality management programs that centralize and manage all aspects of quality, from the planning stage, through production and warranty stages.

Much like ERP streamlined the inventory and financial aspects of manufacturing, Enterprise Quality Management (ECM) is now providing that same streamlining function to the rest of manufacturing operations. Quality inherently follows similar tenants of document, link, train, review which makes it an ideal platform on which to base compliance initiatives.

WHERE DO YOU START?

Not to sound mundane – but you start at the beginning. Quality is built in from the planning and engineering stages. The building blocks for quality; specification, part characteristics, FEMAs, control plans, PPAPs etc are generated in the planning phase. Unfortunately, many quality issues arise from this important information being inconsistently shared with manufacturing, purchasing, and suppliers. The key to quality is one source of reliable information. The second key is the ability to easily share the information with people. Currently, most organizations are pulling information out of vaulted planning documents, and creating islands of information in spreadsheets, MSAccess databases, Outlook contact files etc. We have learned from ERP that we would never run accounting or inventory functions this way anymore, but we still function as islands when it comes to quality.

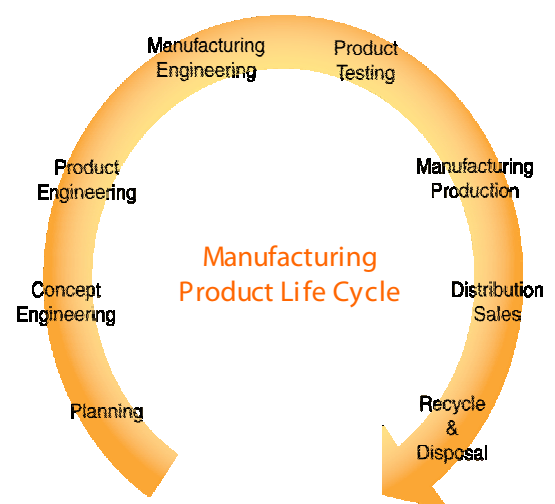


Figure 2

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MAPPING AND MODELING A COMPLIANT PROCESS

STEP 1 – INVENTORY ARTIFACTS

First, complete a physical inventory of all the artifacts you are currently using across your organization for your quality, environmental health and safety, financial (SOX) compliance efforts. This includes all the spreadsheets, reports, databases, purchased software and homegrown legacy systems – and don't forget to look in the file cabinet, and ask your resident "expert" for the information that s/he carries around in his or her head. The table below offers a guideline for the categories of information auditors will look for, as well as the type of artifacts the generally reference.

| Process Area | Data sources, Lists, & Activities | Your Organizations Assets |
|---------------------------------|---|---------------------------|
| Customers | Customer file and communication log. A customer survey system. | |
| Suppliers | Supplier file and communication log. A supplier audit system. | |
| Employees | Employee and communication log. A project team management, job descriptions, skills, and training system. | |
| Document Control | Master document list, change management, acronyms / definition library, audit schedule. Document change need to trigger a training event. | |
| Product Master | Master part information file, including: key characteristics, FMEAs, Process Flows, Control Plans, and change management. | |
| Process Documentation | A system explicitly designed to document processes in a relation database that allows definitions of suppliers, inputs, process, output, and customer (SIPOC) | |
| Equipment and Tooling | A preventive maintenance system with scheduling, record keeping, and statistical analysis. | |
| Calibration and R&R | A calibration system with scheduling, record keeping, and statistical analysis. A master library of all inspection and tests, driven directly from the master product key characteristics file, including change management | |
| Inspection and Testing | A master library of all inspection and tests, driven directly from the master product key characteristics file, including change management | |
| SPC | Basic SPC capability - control charts, histograms, Cp/Cpk analysis – with the ability to export data to advanced statistical tools | |
| Nonconformance/Incidents | Document the problem and define the action taken, take the action. | |
| Corrective Action | Based on trends, the ability to implement root cause corrective action, including the ability to update the inputs so that next time the change is implemented. | |
| New Part Validation (PPAP, FAI) | Specific process flow for validation new parts | |
| New Product Launch | Specific process flow for validation new product launch | |
| Quality Costs | Transactional quality costs based on the activity throughout the system | |
| Integration with Other Systems | Off the Shelf Integration with ERP, MES, PLM, and legacy systems | |
| Supply Chain Connectivity | XML based capability for data transfer (not document transfer) with customers and suppliers. | |

Figure 3

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STEP 2 – DOCUMENT “HANDOFFS” AND DEVELOP A PROCESS MODEL

Understanding the components of process is half the battle. Once you have the components, the next step is defining the interconnections – the handoffs. The handoffs make or break a process. It is the linkages that form the “quality safety net” and assure everyone associated with a process has what they need when they need it.

This is the point at which eyes generally role. This is the part of the process that requires large teams of participants and often teams of consultants to produce a straw-man process that defines as is. Then the team works on optimizing processes. The reality is, for complex manufactures, 80 – 90% of the process is common and can be defined in terms of customers, suppliers, products, parts, part characteristics, issues, remedies, (non-conformances / corrective actions) etc.

IQS has developed the an Integrated Quality Model™ that is the basis for the quality functions that span engineering to production; those same processes that auditors review for compliance. Started in 1985 with a \$1M grant from the US Air Force IQS was charged with designing a holistic model to define common business processes. The grant was focused on those processes other than accounting and inventory (today’s ERP) for which there were proven models and solutions. IQS delivered the process model and then continued to build a robust data model and software package to allow manufacturing clients to have a turnkey “quality safety net” that allowed them to build products right the first time – saving time and money.

As one might expect, a quality process model is detailed and complex. Figure 4 is a schematic that shows the primary process areas and their inter-relationships. Most organizations can’t even develop this level of detail, because the functions are so siloed. Those organizations are the ones that reap the most benefit from implementing a common model, because not only do they meet their compliance regulations, but they catch the errors that have been falling in the gaps as their changes and issues are passed “over the wall”. For example, consider a Supplier Engineering Change Request. How is it reviewed? How do you track approvals? How is the engineering change notice executed and all the related documents updated (FMEA, control plan, inspection plans, etc). How is receiving inspection notified? How is the Supplier PPAP / FAI status tracked? These are all addressed and linked in IQS’ Integrated Quality Model™ (IQM).



Figure 4

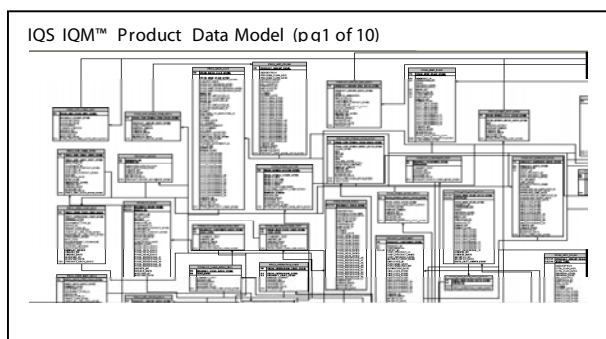


Figure 5

Figure 5 is 1/10 of the data model that shows the interconnectivity of part characteristics. The full part characteristic model is just a small section of the purple “product” ball in Figure 4 – illustrating how very complex this process is, and the level of detail needed to “connect all the dots” and assure that everyone in the process has what they need to do their jobs safely, and build products right the first time.

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BUILD VS. BUY – WHAT MAKES SENSE?

Organizations confronted the build vs. buy situation when Y2K forced a revisit of inventory and financial processes. Often a deadline and the availability of a process in software form can make that decision easier. Its important when considering a product that sits on top of a process, to make a thorough evaluation of the underlying process, and not just fall for “pretty screens”. Another key to help you from being a firm’s guinea pig, is to be sure that the firm you are working with has a proven track record in your industry.

IQS has expertise with over 500 organizations and 20,000 users in complex manufacturing; automotive, medical device, chemical, discrete and aerospace and defense. If you are in financial, insurance, or looking for specific compliance assistance like HIPPA, IQS is probably not the best fit for you. If you are in IQS’ are of expertise, it doesn’t matter if you are large or small. IQS’ client base is made up of large global organizations and smaller manufactures who have found innovative ways to compete and be cost effective in a global market. IQS has also been adopted by industry standards group such as IQS and ASQ.

“The ISO 9000 technical advisory group (TAG) has been studying IQS and its clients, TAG recognized that IQS leads the standards bodies by 10 years with its comprehensive approach to quality. TAC has incorporated many of the components of the IQS Integrated Quality Model into its standards.” -- Dr. Jack Small – ISO 9000 TAC Advisor & IBM ISO 9000 Director

IQS has hundreds of happy customers across many industries. Unlike our ERP cousins, IQS implementations are fast and efficient. Clients are up and running in weeks and months, -- not years. Typically in the first six to nine months customers are not only up and running but reporting tangible savings.

CLIENT CASE STUDY: POLYONE: 27 GLOBAL FACILITIES.

At PolyOne, they had 27 facilities were operating independently without a common system in place. The separate systems made addressing nonconformance issues very difficult and increased audit costs. They reviewed SAP Quality Module and found that it was not only very expensive, but it didn’t have the depth to meet the auditors needs. PolyOne needed a solution immediately. Their IT staff was still wrapped up with ERP deployments, so they chose IQS’ OnDemand implementation. PolyOne saw a savings of over \$155,000 in audit processing costs in the first year. Auditors now have real time access to data across the entire enterprise.

RECOMMENDATIONS

With IQS, clients are using a proven quality management model that inherently streamlines process and helps clients build product right the first time. An IQS implementation will help you meet the new generation of manufacturing compliance initiatives and reduce redundant labor, functions and software. By centralizing information, IQS assures that everyone in the process has the information they need to do their jobs, from suppliers to customers. If you “try on” the concept, IQS recommends you take a quick inventory of your companies assets. With that, IQS can help you do model mapping to understand which components of the model would be useful in your organization and how you might approach your compliance initiative.

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