Vertically Integrated Quality

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VERTICALLY INTEGRATED QUALITY

COMMITMENT TO QUALITY IS A GIVEN

Every manufacturer has a commitment to product quality and most dedicate significant efforts into any number of quality programs and systems. Studies have shown that the true overall cost of quality can be as high as 40% of a manufacturer's operational sales revenue. Even best-in-class manufacturers report that the cost of quality is significant and typically at 10% to 15% of sales.

The challenges and competitive pressures on the modern manufacturing enterprise have only served to further emphasize the need for both high quality product and the control of the cost to achieve that quality. Many legacy manufacturing environments are supported by a number of disparate systems that each addresses some aspect of quality management. These individual quality systems are often paper-based manual activities and have typically evolved over time to serve isolated needs. Even when individual systems are automated there is frequently little system to system integration. This results in significant duplication and a lack of synchronized quality activities.

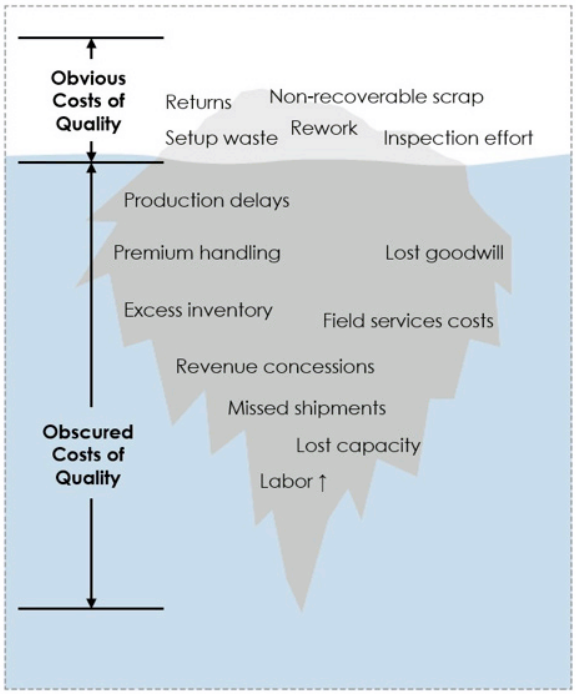
To better meet the competitive and legacy system challenges, modern manufacturers must choose a vertically integrated quality management system (QMS). The QMS must allow for business wide coordination of quality activity. This coordination ranges from pre-production quality planning through quality control during operational execution and includes quality data collection. Finally, a fully effective QMS includes nonconformance tracking both within the manufacturing environment and with aftermarket support of customers.

COST OF QUALITY EXCEEDS WHAT CAN BE MEASURED BY THE WEIGHT OF YOUR SCRAP BIN

Nearly every manufacturer can produce a report with details around scrap rates and associated costs. The parts in the scrap bin are a highly visual quality measurement. There will also be identifiable costs associated with a continuing series of reactive quality investigations around process variation and identifications of root causes. All of this is necessary quality-based blocking and tackling.

In most cases the less obvious costs of quality far exceed what can be measured in the weight of the scrap bin. Figure 1 depicts the classic portrayal of the obvious costs of quality as only the tip of the iceberg. In many instances the cost of the parts in the scrap bin are less than 10% of the overall cost of quality.

Figure 1. Hidden Costs of Quality



The less obvious costs include but are not limited to:

- Cost of quality verification – inspection material and personnel that are engaged continuously as part of operations.
- Cost of quality documentation management – product customization puts a strain on traditional document management.
- Cost of rework and scrap remediation.
- Cost of quality investigations and research.
- Management of version control and associated verifications.
- Training coordination to insure operator capability and accountability.
- Alignment effort with product development for quality design and manufacturability.
- Alignment with product development around nonconformance as the basis for continuous improvement.
- Premium freight associated with responding to quality-based product replacement.

All these quality costs are even further accentuated by the business risks of poor quality once product quality issues become externalized. Quality issues identified after the manufacturer has shipped the product to the customer result in costs associated with returned material and rework/replacement. Frequent product quality returns often result in a reactive increase in inspection and costly nonconformance prevention efforts. These quality issues also put future business with that customer at risk. Repeated quality issues may require the manufacturer to make concessions on price and will make even the most loyal customer seek an alternative source of product.

VERTICAL INTEGRATION IS THE KEY TO AN EFFECTIVE QUALITY EFFORT

Vertical integration is defined as the integration of all upstream and downstream processes that contribute to the quality aspects of manufacturing of a product. At one end of the vertical functional integration is the design of the product and selection of materials. A vertically integrated QMS will include the quality definition of the designed product and the specifications of the contributing materials. The other end of the integrated quality-related functionality covers the management of product that has already been put into use at the customer.

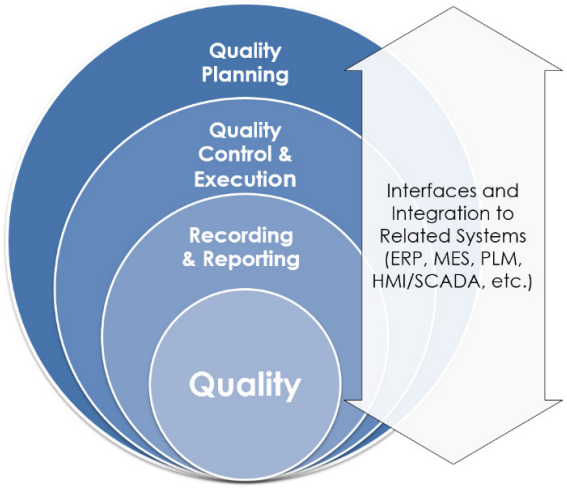
The symbolism of a vertically integrated set of functions should not imply a strict sequential integration where elements only interact with adjacent elements. A critical element necessary for true vertical integration is a foundation for data sharing and coordination between all of the elements that comprise and contribute to the quality system and the associated production and planning systems.

It might seem like the notion of integrating all aspects of a QMS is obvious. It is. Quality functions and efforts, however, can often historically be one of the most disjointed aspects of manufacturing. There are a number of factors that can contribute to the disjointed efforts of quality within in the manufacturing environment, including:

- Quality efforts can suffer from a lack of centralized organizational responsibility. How many meetings or poster boards include some form of “Quality is everyone’s business?” If quality is everyone’s business, then everyone is a stakeholder and coordination becomes more challenging. Although there may be a quality department by name in the manufacturing organization, virtually every other department is engaged in quality-related activity.
- Certain quality functions are difficult to pre-plan. Quality functions like product- specific nonconformance management or quality tracking only evolve once operations for that

product are established. There will always be unanticipated opportunities and challenges affecting product quality.

Figure 2. Elements of a Quality Program



Regardless of the reason, the quality function of many manufacturing entities still operates with myriad loosely coupled manual systems and challenging functional handoffs. As depicted in Figure 2, the overall quality effort can be represented by three major functional levels and an omnipresent requirement to interface to external functions:

- **Quality Planning.** Whether it is accomplished through a formal process such as Advanced Product Quality Planning (APQP) or with a self- developed set of Standard Operating Procedures (SOP), quality planning is the backbone of the quality effort.
- **Quality Control and Execution.** Once a plan is established, there are inspection and verification activities that need to be performed as part of the quality effort. Within the scope of execution is the investigation of the root causes of identified problems in an attempt to prevent their recurrence or to prevent occurrence, known as CAPA/NC.
- **Recording and Reporting.** Overlaying all of the planning and execution is the ability to record and report on the actual quality events both within manufacturing and with suppliers.
- **Interfaces and Integration.** Much of the data that is the basis of quality efforts exists in other systems and there are many interrelated systems with an interest in quality information.

Correspondingly, many product inspection characteristics are stored in a quality systems and may be needed for operational production activity. System design and functional requirements will define the owner/master of data sets and the corresponding accessibility of the data. Active and effective interfaces with Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES) improve accuracy of information and simplify business processes.

A FAILURE TO PLAN . . .

Quality rarely just happens. Manufacturers must engage in numerous planning activities which include the list depicted in Figure 3.

Figure 3. Quality Planning Activities

When discussing an integrated quality plan, it almost always revolves around the development and management of the supporting quality documents. Nearly every quality–based

activity has some level of documentation. In an increasingly dynamic manufacturing environment, systemic management of the myriad documents is critical to quality.

In this context, the term “document” is used in the broadest way. These documents can range in format from detailed product drawings, simple work instructions, critical specifications, inspection directives and even short videos that provide instructions on inspection or processing steps. The management of these documents and the associated information nearly always involves multiple manufacturing applications and supporting systems. System implementation decisions drive the vertical integration of these systems and correspondingly the effectiveness of the supporting document management.

Even the most basic example of vertically integrated quality can drive significant benefits. The definition of the product and associated quality plan starts in engineering and may include a formal Product Lifecycle Management (PLM) system or may be based on well-defined SOP. The quality plan data in these designs include the definitions for part quality in terms of physical dimensions, weight and other potential inspection values. Too often this data must be manually transposed for use in execution systems. This manual transposition is potential point for human error and overall system delays.

Automated document management should be a foundational element in vertically integrated quality. This is true of both quality planning documents and the documents and records identified in the plan that will be used during execution. The vertical set of systems can include the passage of documents or associated values from a PLM/SOP to an ERP system. The documentation management would then also include the integration of quality information to the QMS from the ERP or directly from the PLM/SOP.

Often there are incremental data structures and definitions that are added to the core data and managed in parallel at the ERP and/or QMS level.

The key is that the quality planning function lays the foundation for this vertically integrated information. Document management allows for this information to be the backbone of a vertically integrated quality system.

It is important to recognize that document management is critical in two distinct ways:

1. The effective vertical integration allows for multiple systems and organizational functions to share a common view of the source of this information. A vertically integrated system removes the recurring questions on the plant floor around where someone could find a drawing or the details necessary to produce a product. This cross-functional quality plan alone can have a dramatic change on the effectiveness of the quality aspects of manufacturing.

2. The quality data issues are further exacerbated with products that have frequent revisions and changes. Competitive pressure and market demand is making frequent product revisions and rapid introduction of new/changed product the new normal for many manufacturers. Mass customization has resulted in many manufacturers making products or SKUs that are unique to a single customer. Although each product may be a variant to a basic item, the quality inspection data may vary for each production order. Systemic approaches to document management of this level of variation may be the only way to effectively handle these types of environments.

Quality planning also includes the documentation associated with supplier management. Each product is based on a set of raw material or

sourced components. A vertically integrated quality plan can be integrated with sourcing systems to drive supplier performance metrics, in-coming quality inspection requirements, managing supplier-provided quality certifications and much more. Automated planning and documentation can provide significant benefits in terms of material evaluation and collaboration with suppliers around both production demand and quality expectations.

An integrated quality plan includes the specification that will be used by Quality Control (QC) and other quality execution efforts. These specification values can include production specifications like machine settings and product dimension tolerances. These specifications can also include operational specifications such as equipment qualifications, operator training certifications and product sampling rates. All this information can be managed across a single vertically integrated quality system that may include PLM/SOP, ERP, MES and the QMS.

Finally, the management of the quality plan and its associated documents must also include security over document control. In most cases, quality planning and quality execution documents are considered “controlled” material. Only selected individuals will be authorized to make document modifications. This level of control will be supported by an approval workflow for reviewers and cross-functional personnel.

In certain industries, the overall management of the quality planning process is identified as the Production Part Approval Process (PPAP) which manages the process from design through production launch. The concepts of PPAP can be expanded across industries and be the basis for long term support of quality initiatives within the manufacturing environment.

QUALITY IS NOT (JUST) A DEPARTMENT

Quality control planning lays the foundation for the execution of quality operations within the manufacturing environment. An overview of the elements of quality control and execution are depicted in Figure 4.

Figure 4. Quality Control and Execution Activities

Quality operation execution can be tightly threaded within the manufacturing or run independently in parallel to core manufacturing activity. Some manufacturers may have a formal MES that may include quality operation execution functionality. Whether a manufacturer has deployed a formal MES or has isolated quality as a distinct set of operational activities, the underlying systems would ideally be a part of the vertically integrated quality system.

When manufacturing a product in high volumes, the quality operations are often built into the high-speed production. Tightly integrated vision systems or scales verify label position and fill weights during production. The settings for those specifications need to be communicated from the quality plan to the equipment either through direct connections to the equipment or through directed operator action. The manufacturers of low-volume and high-mix Printed Circuit Boards (PCB) also often have tightly threaded integration of quality and production. The inherent nature of the PCB product dictates that quality inspections

and verification points are built into the production routing.

Operations such as electrical integrity checking are as much of a manufacturing step within the production routing as the operations for chip insertion or wave soldering.

Conversely, other manufacturing environments execute quality operations as a parallel set of activities to the actual production routing. The manufacturing quality department acts as an independent organization that performs sampling, spot checks and responds to production anomalies. Dedicated quality department personnel perform a range of quality operations based on the information in the PLM, ERP, MES and QMS systems based on production orders and equipment profiles.

Regardless of the nature of the relationship between core manufacturing activity and quality activity, vertically integrated quality can drive an increase in overall effectiveness. Integrated quality control specifications, released/active production order data from the ERP, operational settings and line-side orchestration of operator activity from the MES should ideally be part of integrated quality information set. The following are examples of operational execution information that should be maintained centrally and available to all aspects of a vertically integrated quality system:

- The attribute parameters for an operator inspection should be automatically delivered line side from the quality plan.
- The quality document delivered via a line side display or mobile device should always be the appropriate version as dictated in the vertically integrated quality plan.
- Operator prompts and directives should be based on the customized requirements specific to the current order.
- Resource verification such as equipment qualification or operator training certification should be verified against the integrated quality information.
- Conditional workflows can be utilized in performing normal flexible quality analysis or in the guidance of nonconformance disposition.
- Quality execution results and documented guidelines lay the foundation for identifying root causes, performing corrective actions and designing preventative actions (CAPA)
- Test specification management and core quality control processes such as acceptance, in process and release testing should be accessible.

The support of quality operational execution in many current manufacturing environments is still based on paper travelers or manual information transition activities. The automated vertical integration of quality diminishes the opportunity for human error in manual processes. Vertical integration also shortens the execution time of quality operations by eliminating the need for searching and verifying of quality information. Test specification management and core quality control processes such as acceptance, in process and release testing become more effective and deliver improved results.

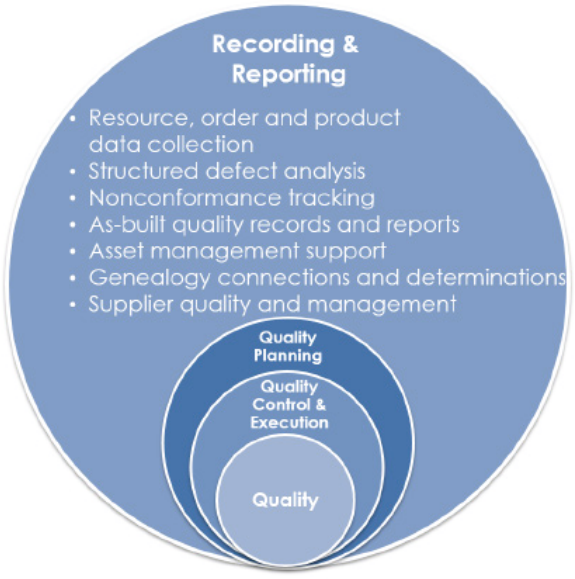
One of the most challenging production environments is the manufacture and assembly of complex equipment. Competitive pressures require the near- constant revision of equipment and subcomponent design to incorporate rapidly advancing technology. In order to adapt, manufacturers are often forced to employ stringent and costly procedures, burdening them with potential delays in product rollouts, impeding innovation or hindering business processes. Historically this process includes the use of manual planning and record keeping that requires considerable personnel intervention with limited process visibility and inhibits continuous improvement efforts. Disparate manual systems cannot quickly or easily respond to changing customer requirements, regulatory compliance requirements or process improvements. An

automated, vertically integrated system can quickly respond to dynamic manufacturing variations by rapidly implementing new processes and workflows, ensuring affected staff is trained and enforcing the new quality operations at the point of work.

QUALITY RECORDING AND REPORTING – THE CLIPBOARD IS NO ONE'S FRIEND

The vertical integration of quality planning and quality operational execution activity becomes the foundation for integrated quality data recording and correspondingly reporting. Key elements of quality recording and reporting are depicted in Figure 5. When data capture activities are separate and distinct from the system with quality operational definitions, there are many opportunities for human error, data inaccuracy and invalid history records.

Figure 5. Quality Recording and Reporting



The definitive example for disconnected quality data recording is the line-side clip board. The manual clipboard is no one's friend in a manufacturing environment. Most floor level operators perceive the clipboard and the manual recording of values as low priority task and the quality/integrity of the collected data reflects that attitude. Clipboard data are typically infrequently collected and the aggregation of that data into spreadsheets often results in charts and metrics of little value.

Vertically integrated quality recording starts with the contextual checking of expected and acceptable data ranges. The data recording is immediately associated with the quality plan and the connected dynamic data sets including equipment settings, current operator and specific timestamps. The automated collection of quality data and the contextual access to the data results in tremendous opportunities for impactful analysis and reporting.

The automation of vertically integrated quality data provides the basis to address the majority of the hidden cost of quality. Structured evaluation of equipment performance, product yields and sources of variation result in improvements in product quality and improved customer service levels.

Vertically integrated quality information can make a significant impact in the response to post-production quality issues. Manufacturers can use quality data and associated with ERP order data to power functionality for backward and forward lot track and trace functionality. Existing information can often identify root causes without special case studies or exception-based investigations.

The vertically integrated quality data becomes the basis and in many cases the impetus for continuous improvement. This continuous improvement can immediately address the manufacturing operations but can also directly impact product improvements. The association of quality results between the operational production systems such as MES/ERP and design systems such as PLM can drive "designed for quality" initiatives.

Ideally the information technology supporting

the vertically integrated quality system will allow for reporting and analysis using standard data management tools. More than one good-intentioned quality initiative has been thwarted by the burden of an effort that required manual combinations of data from disjointed sources and silos of spreadsheets. Accessibility and transparency to the data drives the effectiveness of the solution. In modern manufacturing this includes concepts like data marts and access through mobile devices.

VERTICALLY INTEGRATED QUALITY AND JUSTIFICATION CONSIDERATIONS

The case has been made for the value of a vertically integrated quality system. In many manufacturing firms, quality management systems are often a collection of point solutions administered by distinct departments using combinations of paper and isolated off-the-shelf software programs. Unlike an integrated, automated QMS, disconnected systems present challenges and deficiencies that can compromise operational and planning effectiveness.

The value of a vertically integrated quality management system is clear, and provided with infinite resources every manufacturer should see this as a desirable goal. Every manufacturer, however, has to address a number of challenges in moving toward that goal. Cost, risk and "transition while operating" are all separate considerations in making progress to a vertically integrated quality system.

The challenges of cost and risk are two critical and often interrelated components that manufacturing companies must keep in mind as they develop their business processes and procedures. Manufacturers must balance the costs of quality and conformance measures with the potential risks of reduced quality or nonconformance. For certain regulated products such as Life Sciences or Food & Beverage, the cost of nonconformance includes a specific need to meet the requirements of regulatory compliance agencies. For all manufacturers there are risks that may result in costs from warranty or the damage to brand reputation and market position caused by public perception of a manufacturer's poor quality or unsafe products.

Another very real consideration is that the adoption of a vertically integrated quality approach will have to be accomplished without interrupting the current ability to manufacture product. Migrations plans will have to allow for the selective migration of manual systems and the development of interfaces while production continues. Technology selection of a potential QMS should ensure the presence of clear and open integration points and the incorporation of flexible/modern architectural elements that allow for a systemic transition to a fully integrated quality system across the entire vertical enterprise. Even interim partial-automation projects will yield positive results and lay the foundation for the complete migration to a vertically integrated QMS.

CONCLUSIONS

A vertically integrated quality system that allows for systemic coordination between PLM, ERP, MES and production systems best positions a manufacturer to address the full cost of quality and deliver the following benefits:

- Overall improvement in product quality and consistently applied quality processes.
- Automate analysis to gain insights into trends and risks as well as provide the ability to drive continuous improvements.
- Improve profitability from reduction in overall cost of quality.
- Product improvement and extended product viability through closed loop business planning and execution.

For more information on how QAD can help your company address the full cost of quality and deliver the above benefits, contact QAD at +1-805-566-6100 or email info@qad.com.

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