For manufacturers in industries that produce some of the world’s most complex products, effective quality management continues to be a competitive advantage. Whether in automotive, aerospace and defense, industrial equipment, electronics, or medical devices, companies are increasingly moving to a customer-centric model that includes social media monitoring and big data analytics at the point of sale. Even slight quality issues can have a ripple effect felt through the entire organization.

In today’s mobile and always connected environment, it is critical that discrete manufacturing companies can quickly and effectively sense and respond to quality issues originating anywhere in the value chain. This is possible with a holistic approach to quality. However, there is only a small minority of companies that have aligned the necessary leadership, business process, and technology capabilities to start taking an enterprise approach to quality.

This Research Spotlight aims to highlight best practices for managing quality across the enterprise, specifically as it pertains to creating a closed-loop quality management environment with the use of PLM-based corrective and preventive action (CAPA) software. It will touch on the following areas:

- Market drivers pressuring discrete manufacturers to focus on improving the quality of processes and products
- Addressing market drivers by taking a PLM approach to quality software
- A look into the Key Performance Indicators (KPIs) companies are using to measure the effectiveness of quality initiatives
- The people, business process, and change management capabilities needed to ensure successful technology deployments
- Actionable recommendations for deploying PLM-based CAPA functionalities

By reading this Research Spotlight, executives on the quality management journey will be able to refine their approach to quality software, enabling communication and collaboration across the value chain. This holistic approach to quality will help create a market-leading customer experience in today’s unforgiving environment.
Market Drivers for Discrete Manufacturers

Before discussing strategies for effective quality management in discrete manufacturing industries, it is helpful to first understand and compare executive focal points. The 2012-2013 LNS Research Quality Management Survey asked a comprehensive set of questions regarding people, processes, and technology. Two of those questions pertained to executive objectives and challenges.

**Top Strategic Objectives for Quality Management**

The Quality Management Survey asked executives what their company’s top quality management objective was for 2012. As illustrated in the chart above, executives from discrete industries – aerospace and defense, automotive, electronics, industrial equipment, and medical devices – were primarily focused on two objectives: reducing the total cost of quality and reducing nonconformances in manufacturing. Reducing the cost of quality was the top objective for automotive (49%), electronics (46%), and aerospace and defense (38%), while reducing nonconformances in manufacturing was the top objective for industrial equipment (35%) and medical devices (28%).

Because these two objectives catalyze improvements in the customer experience, it comes with little shock that a majority of executives chose them over “Improve customer experience.” Measuring the cost of quality across the enterprise can
provide the granular level of detail needed to identify key areas for improvement in quality management. This goes hand in hand with the objective of reducing nonconformances in manufacturing, as both objectives are impacted by the ability to catch quality deviations and issues early in the design process.

**Top Challenges for Quality Management**

The Quality Management Survey asked executives what their biggest quality management challenges were in 2012. Each participant was not limited to one response. Effecting at least 40% of discrete manufacturers, the top two responses stand out as major challenges. Across all industries in the analysis, a considerable majority of companies expressed difficulties with effectively measuring quality metrics, with the aerospace and defense industry having the highest response rate of 65%. Close behind, organizations also said that disparate quality systems and data sources were a major challenge.

As the ability to effectively measure quality metrics heavily relies on a seamlessly architected quality system, both of these challenges are closely interconnected. In all industries, not solely discrete manufacturing, organizations face a challenge with leveraging the full potential of a disconnected set of applications, solutions, and data sources. Without a unified information management system around quality, efforts for both making use of metrics and improving processes tend to be localized rather than across the enterprise.
Around CAPA specifically, organizations face several challenges with disparate quality systems. These include:

- **Time to Closure** – Without a centralized system for quality, completing a corrective or preventive action can be an arduous and long process. As opposed to using automation capabilities, organizations have to rely on manual processes around emailing documents, obtaining signatures, escalation, and communicating the resulting root cause to the broader enterprise.

- **Time and Effort** – In addition to the challenges around completing a corrective or preventive action with manual processes, organizations face difficulty with aligning and executing on deliverables for preventing a root cause from reoccurring in the future. Deliverables may include changing work instructions, educating employees, communicating root causes to the broader enterprise, or an engineering change order. These deliverables touch many areas across the engineering process and broader value chain, such as design, control plans, production processes, equipment, facilities, materials, and more.

- **Rework and Repeat Actions** – Companies with disparate quality systems tend to have higher rework rates and more repeat efforts in regard to the identification of a specific root cause. Reasons for this include incomplete investigations due to lapses in manual processes, poor documentation and communication of previous root cause analysis efforts, and inconsistent processes between plants, facilities, and business units.

- **Increased Risk** – Without a centralized system for communicating and collaborating on corrective and preventive actions, root causes have a greater chance of both not getting resolved and not being communicated to the broader enterprise. The lack of visibility with manual processes increases risk at the point of the root cause, as well as in all dependent processes across the value chain.

**The Role of Quality in the Extended Value Chain**

To ensure the delivery of high quality products and processes, organizations need to optimize quality in each specific area of the value chain as well as in the interconnection of processes across the value chain. Although each company typically has a similar value chain, focal points – engineering, manufacturing, service, and so on – may vary by industry and position in the supply chain. As a consequence, it is common for companies to develop deep expertise and functionality in each stage.
Because quality is an organizational issue, leading discrete manufacturers have focused on orchestrating end-to-end business processes that extend across multiple areas in the value chain. From design through service, as products flow downstream toward the customer, it is important that companies have the ability to communicate and collaborate on quality data in both directions. LNS Research refers to this concept of creating a feedback loop to previous stages in the value chain as closed-loop quality management.

Although quality impacts each area of the value chain, it is important to understand that it starts with design. Specifically, the earlier an organization infuses quality management processes with engineering and product development processes, the more effective it will be at managing quality. In terms of closed-loop CAPA processes, companies need the capability to provide quality data back to engineering based on processes from suppliers, manufacturing, and customers. In addition to expediting and improving the corrective and preventive action process, this can tangentially help to continually improve product design, manufacturing processes, work instructions, quality instructions, and risk and reliability data found in failure mode and effects analysis (FMEA).
PLM-based CAPA Software

For most manufacturing companies, ERP has been deployed as the enterprise application for inventory management, production scheduling, and financials. Generally, these companies have invested in several additional platforms – including PLM, Manufacturing Operations Management (MOM), or Customer Relationship Management (CRM) among others – to extend and deliver depth in functional areas that create synergies and competitive advantages for a company. In discrete manufacturing specifically, where organizations tend to have a portfolio of complex products and processes, there is often a PLM solution in place.

In developing an integrated enterprise IT architecture, organizations have traditionally neglected quality. As a consequence, challenges previously mentioned such as disparate quality management processes and data sources and the inability to effectively measure quality metrics have become performance roadblocks for many large, global organizations today. However, to overcome this, leading discrete manufacturers are leveraging an emerging quality solutions category, Enterprise Quality Management Software (EQMS). EQMS helps to automate a number of quality functionalities, including:

- Compliance
- NC/CAPA
- Doc Control
- Audit Management
- Training & Certification
- Reporting

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Research Spotlight
The Benefits of PLM-based CAPA Software

- Non-Conformances/Corrective and Preventive Action
- Compliance/Audit Management
- Supplier Quality Management
- Risk Management
- Statistical Process Control
- Failure Mode and Effects Analysis
- Complaint Handling
- Advanced Product Quality Planning
- Environment, Health, and Safety
- Hazard Analysis & Critical Control Points
- Production Part Approval Process

EQMS is a global platform for communication and collaboration on quality content and processes. It standardizes, centralizes, and streamlines quality process data from across the value chain to facilitate the holistic management of quality. EQMS automates traditionally manual processes, considerably helping to reduce operational risk and instances of internal and external deviations. One of its most important characteristics is in its ability to enable closed-loop quality management. The platform creates an environment for cross-functional interaction on quality issues that would otherwise be difficult to obtain.

Although there are a number of quality functionalities, companies typically automate them with EQMS where there are global synergies. Some processes can significantly benefit when standardized and streamlined and managed on a centralized platform. For this reason, methods for deploying EQMS tend to be unique to each organization. With existing IT architecture playing a critical role in the delivery model for EQMS functionalities, companies can now implement EQMS as a standalone solution or as an extension of one of the existing enterprise IT applications found in the figure above such as ERP or PLM.

Because of existing investments in PLM and engineering capabilities, many leading discrete manufacturers are implementing EQMS and functionalities such as CAPA as an extension of PLM. For engineering-intensive organizations, this not only helps to interconnect quality processes during the design process, it also enables quality integration with new product development processes and launch business operations. Extending CAPA and other EQMS functionalities with PLM strengthens the feedback loop, allowing critical downstream data to be consumed and utilized earlier in the value chain.

**Synergies of taking a PLM approach to CAPA**

There are a number of reasons to use existing investments in PLM as the platform for deploying EQMS but most notably is how well positioned PLM is to address the strategic objectives discrete manufacturing companies have today for quality.
management. First, for reducing the cost of quality it is well documented that the closer to the customer a defect or nonconformance is identified, the more costly it is; whereas the closer to the supplier or engineering the less costly it is. Second, for reducing nonconformances in manufacturing, again many of these defects originate with either engineering or supplier issues. In both cases, PLM is well positioned to identify nonconformances and orchestrate the appropriate response.

There are also technical and functional reasons why PLM can act as a strong platform for deploying EQMS. PLM systems have long had strong capabilities for workflow orchestration, collaboration, document management, mobility, and interoperability with other enterprise systems like MOM and ERP. Because the CAPA process, as well as other quality processes like audit management can benefit from these capabilities, it is a prime example of a business process that can deliver global synergies when automated with PLM. When CAPA is delivered globally as part of PLM, users have the capability to streamline the routing and delivery of CAPA processes such as personnel notifications, escalating issues, approving corrective and preventive actions, and communicating nonconformances to the broader enterprise.

Furthermore, by taking a PLM-based approach to EQMS and CAPA, organizations can capitalize on the quality management functionality that has already traditionally been delivered by PLM as well as speed up the response time of engineering organizations to quality issues. Many engineering organizations are already using PLM to conduct risk analysis with tools like Failure Mode and Effects Analysis to ensure that companies can explicitly manage the reliability of products and processes. Additionally, when issues do arise, the simulation tools in PLM help companies quickly and cost-effectively implement changes. Finally, the change management capabilities in PLM allow companies to effectively manage engineering and product data changes over time.

Unfortunately there are also some challenges and barriers that companies have traditionally faced when trying to extend PLM generally, and PLM-based quality specifically. First and foremost, many companies view PLM as the engineering organization’s toolset and similarly many engineering organizations take ownership and control of the application. Additionally, many PLM vendors have targeted these organizations and purpose built the solution as well as pricing or licensing structure to fit within engineering; all of which has made it difficult in some cases to extend PLM across the enterprise. Luckily, there are a few PLM vendors which have taken concrete steps to address this gap, including purpose-built EQMS functionality like CAPA on top of the PLM platform as well as licensing and deployment options specifically designed for these quality applications. In the next section, a framework for ensuring a successful deployment of PLM-based EQMS and capitalizing on the investments made by leading PLM vendors in quality will be discussed.
Ensuring a Successful Enterprise CAPA Deployment

Organizations have found success with rolling out CAPA and other EQMS functionalities by focusing on three key resources: people, processes, and technology. The LNS Research model of operational excellence focuses on the alignment and then optimization of these key resources in the context of broader strategic initiatives: financial, operational, and quality. To make progress toward these objectives, market leading organizations are making decisions today based on long-term strategic vision of enterprise quality to drive improvements in all three strategic objectives.

When deploying enterprise CAPA, the following focal points are critical for aligning and then optimizing people, processes, and technology.

**People and Leadership**

- Make quality an executive priority; position quality as critical to achieving company goals like revenue growth and customer satisfaction
- Put in place cross-functional teams to manage quality across design, manufacturing, and suppliers
- Engage all levels of the organization so that quality is not viewed as a policing function or department but rather a priority and shared responsibility
- Include quality metrics on the executive dashboard to determine quality’s impact on different areas of the enterprise

**Business Process Capabilities**

- Identify global synergies in quality functionalities and processes while avoiding having multiple systems across departments or business units; connect processes together for improved efficiency, for example, change management is an important part of a successful CAPA process
- Develop a formal NC/CAPA process across the company for capturing issues from each stage of the value chain; many companies only collect nonconformances from a few areas like manufacturing or customer complaints, but do not forget suppliers, engineering, or service
**Enterprise IT Architecture**

- Assess existing IT architecture and applications to identify current strengths and gaps in performance and technology capabilities regarding closed-loop quality management
- Build closed-loop CAPA processes capitalizing on current strengths, enabling communication and collaboration across the value chain
- Integrate CAPA processes with other processes like FMEA, change management, and quality or work instructions
- Move to improve real-time visibility of quality performance through capabilities like role-based workflow orchestration, mobility, and analytics

**Defining and Benchmarking Critical Metrics**

Because organizations need to make measureable and continuous improvements toward strategic objectives over time, it is vital for any operational excellence model to incorporate a strong metrics program. Through the use of benchmarking, data on key metrics can help companies quickly identify pain points and gaps in performance. By benchmarking metrics data, executives can leverage a comparative view of performance in relation to internal plants, facilities, and business units as well as externally against close competitors.

For a quality executive or manager, a metrics program may include:

- **Cost of Quality** is an important metric that should be thought of as an optimization of investments made in the cost of good quality and reductions made in the cost of poor quality
- **First Pass Yield** examines how effective production processes are and how well re-work and scrap is eliminated
- **Successful New Product Introductions (NPI)** is a holistic measure of successful innovation but should go beyond just hitting time and volume ramp up targets and also include the time to hit quality specifications and plans
- **Overall Equipment Effectiveness (OEE)** can help companies understand the impacts of quality, efficiency, and maintenance on overall production performance but it is important to put OEE in the context of the overall supply and demand network
- **On-Time and Complete Shipments** does not always include quality but it should, any quality issues associated with late, expedited, or returned shipments should be reflected in supply chain metrics

For many discrete manufacturers, especially large and distributed ones, collecting accurate, standardized, and timely data is a major pain point.
For many discrete manufacturers, especially large and distributed ones, collecting accurate, standardized, and timely data is a major pain point. Following the LNS Research operational excellence model, a strong metrics program requires alignment and then optimization of people, processes, and technology.

**Actionable Recommendations**

The continuously rising need to deliver high quality products and processes in discrete manufacturing places considerable pressure on the design process. The earlier an organization can catch a quality issue, the less it will negatively impact operating margins, reputation, and overall business performance. A CAPA process that closes the loop on quality is instrumental in identifying and resolving quality issues early on as well as for continuously improving quality in engineering and product development.

Organizations should work to align and then optimize people, processes, and technology to take full advantage of a global CAPA deployment. The following are actionable recommendations an executive can take for implementing and utilizing PLM-based CAPA:

- Attain executive backing for the enterprise quality initiative
- Develop a cross-functional team to evaluate the effectiveness of existing quality management systems and processes
- Assess technology architecture and competitive positioning of your company to identify gaps and potential global synergies of extending PLM with CAPA processes
- Establish a formal, standardized, and intuitive CAPA process across the enterprise that requires little to no training and can be adopted by a broad user base
- Develop a CAPA process workflow that enables cross-functional communication and collaboration to close the loop on quality management from engineering to the entire value chain
- Connect quality processes together for improved efficiency, for example change management is an important part of a successful CAPA process
- Develop real-time data acquisition and analytical capabilities
- Focus on measuring and improving metrics related to the CAPA process
- Streamline quality data to the executive dashboard using a unified information management system (EQMS)
- Leverage benchmark data to continuously improve CAPA processes and product quality

Identifying and resolving quality deviations early in the design process, rather than during production, is a critical factor of success and competitive advantage that is differentiating market leaders from the rest of the pack in discrete manufacturing.
LNS Research provides advisory and benchmarking services to help Line-of-Business, IT, and Industrial Automation executives make critical business and operational decisions. LNS research focuses on providing insights into the key business processes, metrics, and technologies adopted in industrial operations.

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