



CLOSED-LOOP QUALITY MANAGEMENT: CONNECTING THE VALUE CHAIN



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Executive Summary

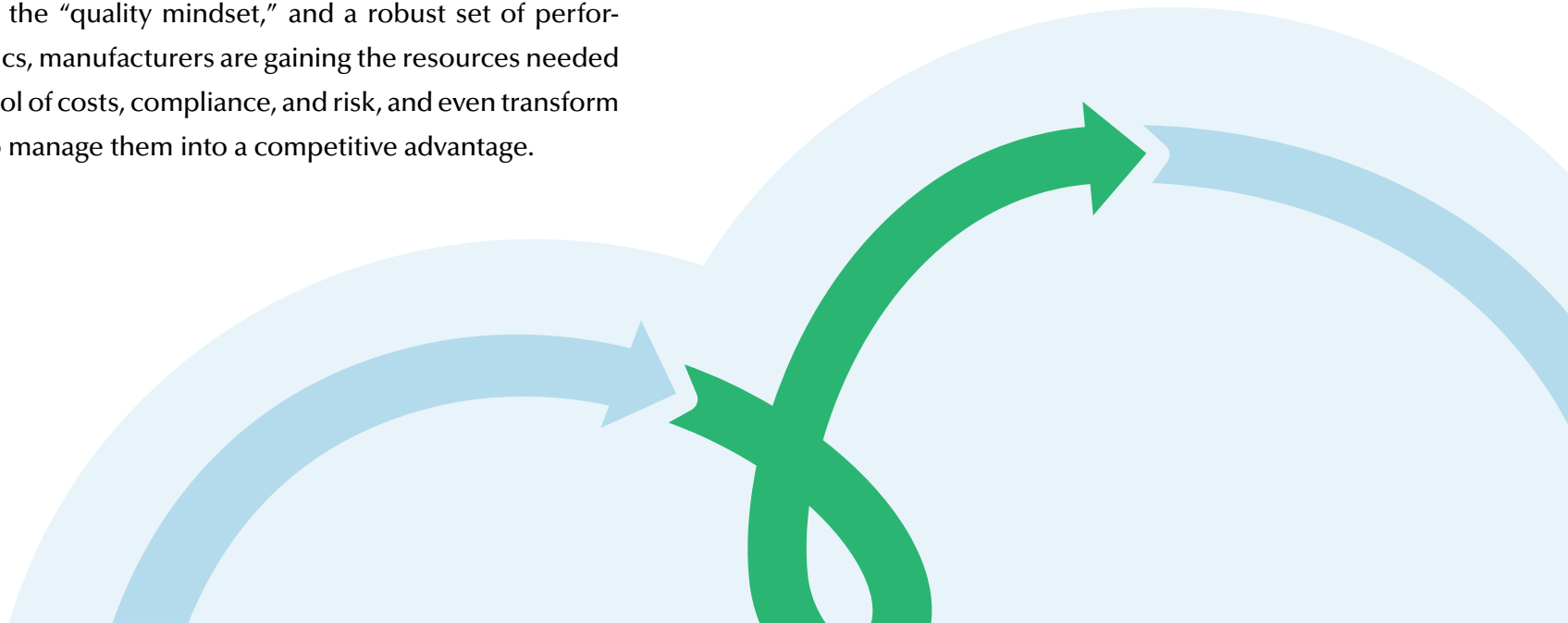
Executive Summary

Manufacturers are under more pressure to improve costs, meet compliance, and mitigate risks than ever before. Because quality is at the core of nearly all business activities, organizations are increasing focus on it to assuage these pressures. However, many are finding that traditional approaches to quality are falling short. Quality management in 2014 must extend far beyond the manufacturing environment. And today's prevalence of disparate solutions and strategies is not providing the visibility or level of interaction across the value chain required to maintain competitiveness in the global market.

Leading organizations are leaving outdated technologies and strategies behind, taking a closed-loop approach that connects quality from design and procurement up through manufacturing, distribution and service. With the support of next-generation technology like Enterprise Quality Management Software (EQMS), streamlined and standardized business processes, a culture with the "quality mindset," and a robust set of performance metrics, manufacturers are gaining the resources needed to take control of costs, compliance, and risk, and even transform the ability to manage them into a competitive advantage.

In addition to addressing the challenges manufacturers are facing today with quality management and providing an overview of closed-loop quality management, this eBook focuses on what is required to achieve and maintain market-leadership now and into the coming years. Specifically, it covers:

- An overview of LNS Research's 2012-2014 Quality Management research findings
- How manufacturers should view the value chain in 2014
- Building closed-loop quality management processes
- How EQMS supports closed-loop quality management processes
- The quantified benefits of closed-loop quality management
- Actionable recommendations for manufacturers





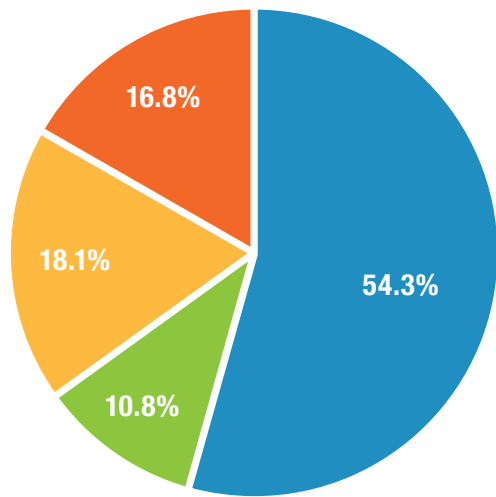
SECTION 1

Understanding the Data Used in This eBook

The LNS Quality Management Survey

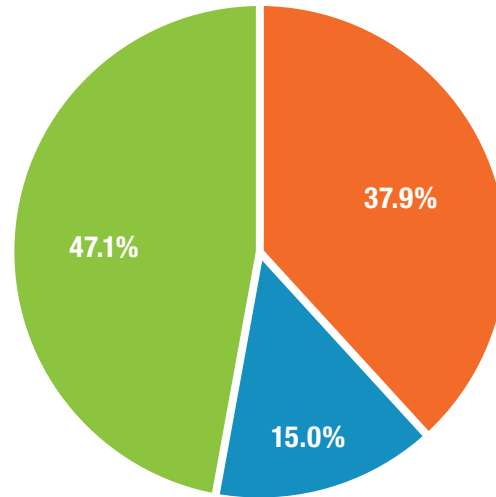
Before getting into closed-loop quality, it is important to set the stage for the supporting data used throughout this eBook. The 2013-2014 LNS Research Quality Management Survey has been completed by over 500 executives and other senior leaders, coming from a variety of company sizes and geographies across a range of industries. The survey questions drill down into the challenges and opportunities that companies face, strategic objectives data, and the most important goals currently being pursued around quality.

54.3% of companies were from discrete manufacturing industries, with the remainder coming from F&B/CPG, life sciences, and process manufacturing. Just over half were from North America, followed by just under a quarter from Europe. Almost half, 47.1%, were from small companies, with 37.9% from large companies and the remainder from mid-sized companies. Because LNS Research surveys remain open continuously, this eBook will use data dating back to 2012 in some cases for comparison, which includes another 400+ respondents.



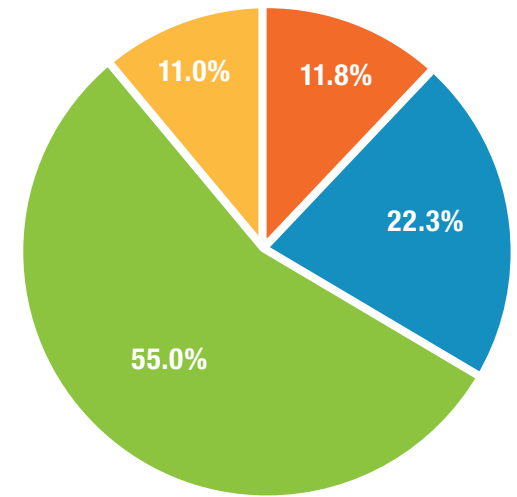
COLOR BY INDUSTRY

- Discrete Man
- F&B / CPG
- Life Sciences
- Process Man



COLOR BY COMPANY REVENUE

- Large: \$1BB+
- Medium: \$250MM - \$1BB
- Small: \$0 - \$250MM



COLOR BY HQ LOCATION

- Asia / Pacific
- Europe
- North America
- Rest of the World



SECTION 2

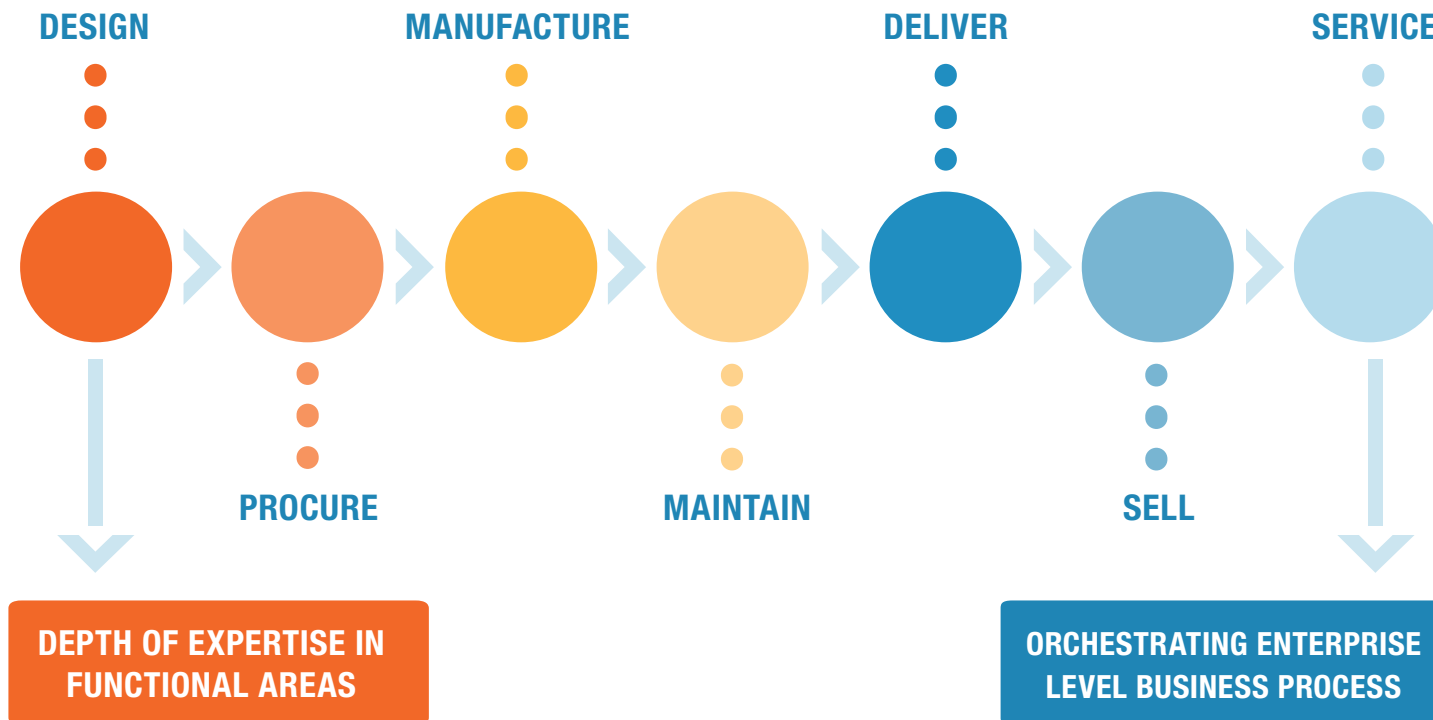
Quality Across the Value Chain

Quality Across the Value Chain

One of the most misunderstood aspects of quality management is that it is a responsibility solely of the “quality department.” This outdated way of thinking is actually surfacing as many companies’ greatest challenge today. In reality, manufacturing in 2014 requires employees across the value chain to consider quality their responsibility—whether in a quality-specific function or not—because quality does, in fact, play a critical role in each different functional area. There is data to prove it.

Closed-loop quality is about elevating the role of quality

management across the value chain. With next-generation technology and robust business processes, it supports an employee mindset that actions not only impact quality in their respective value chain node—design, procurement, operations, service, etc.—but also as what they produce moves downstream. This section will look into each of these different value chain nodes, discuss the role of quality in each area of the value chain, and the types of data being generated to support closed-loop quality management.



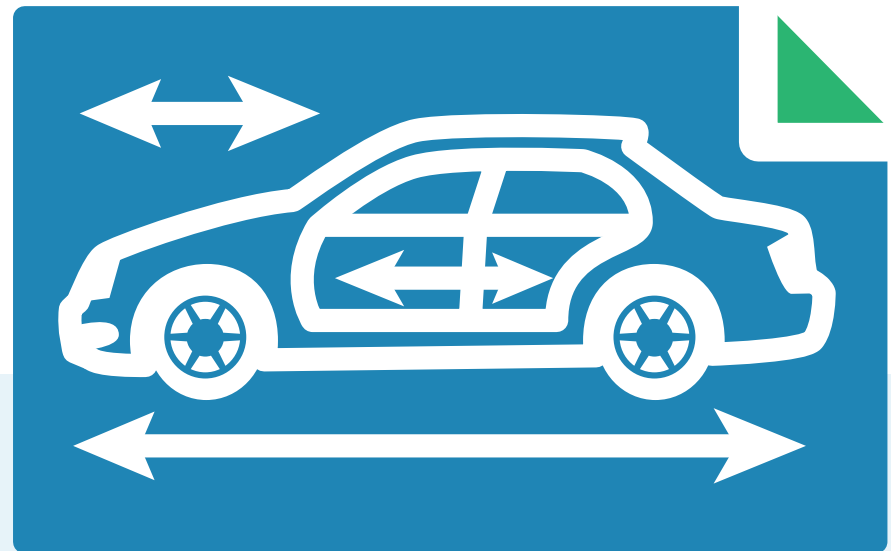
Design

Product design is crucial for downstream process and product quality. A faulty design can result in internal quality failures in the manufacturing environment and beyond. And, as seen in many of the high-profile automotive safety recalls, faulty design can also result in external quality failures that have catastrophic impacts to reputation and overall business performance. Market leaders are designing for quality and manufacturability, which makes the data generated during this process vital to downstream activities. Critical quality information is generated here, including:

- Quality inspection plans
- Quality testing plans
- Failure modes and effects analysis

However, companies cannot stop at just sending quality design information downstream. Closing the loop on quality is all about sending information back to R&D and engineering from other stages in the value chain for continuous improvement on future product iterations. Often this information includes but is not limited to:

- As-built data
- As-maintained data
- As-manufactured data



Suppliers

Unfortunately, some organizations consider activities in the supplier network to be entirely independent from manufacturing activities. As companies continue to outsource manufacturing, any weathered manufacturing professional knows that ultimate success is dependent on establishing visibility and control into suppliers that are at the same level as if operations were not outsourced at all.

Like OEMs, most suppliers already have some forms of solutions for monitoring, recording, and analyzing quality data, as well as continuous improvement tools like corrective and preventive actions (CAPA) for resolving quality non-conformances. The types of data being captured here are:

- Real-time quality process performance data
- Non-Conformance/Corrective and Preventive Action (NC/CAPA)
- Final test data
- Inspection data
- Audit results
- EH&S performance data

However, the challenge is that most suppliers today do not have an efficient or formalized process for sharing and collaborating with trading partners around this information.

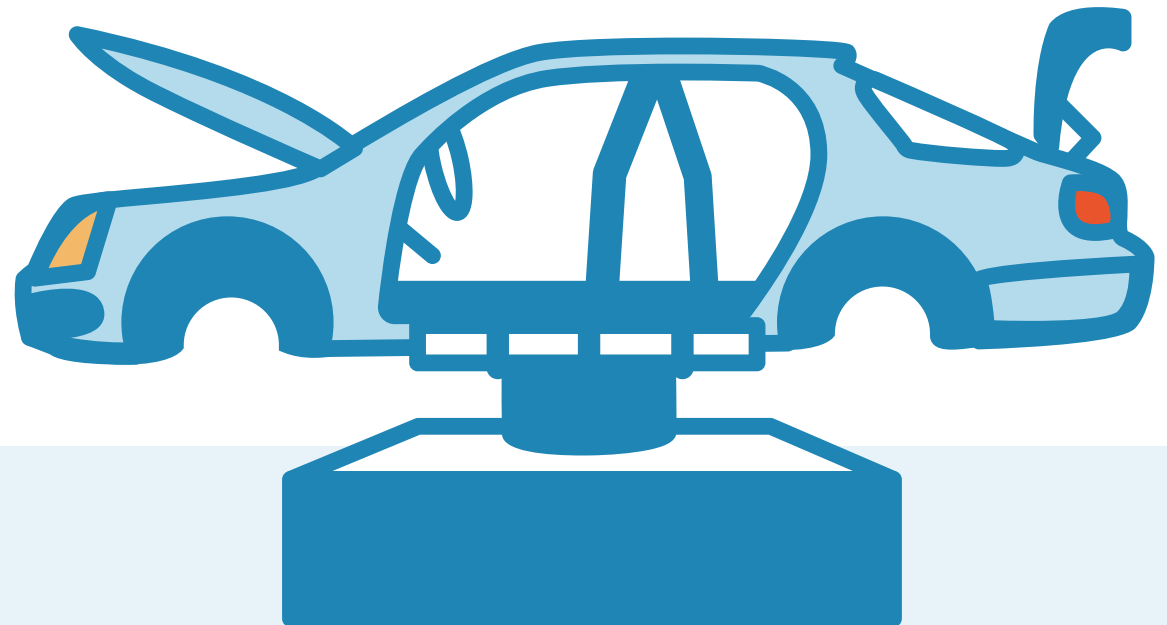


Operations

When professionals envision quality in its most traditional sense, they think of it in the manufacturing environment and optimizing the process with tools like Statistical Process Control (SPC). This is because, in many cases, quality non-conformances can be most easily traced back to where a product was built, rather than where it was designed, or from where the parts or components were sourced. Within the manufacturing environment, where there are so many different moving parts, multitudes of quality data are being generated. This data includes:

- NC/CAPA
- Receiving inspection
- Traceability
- Statistical Process Control
- HACCP
- In-line testing
- At-line testing

However, this information cannot exist in a silo if closed-loop quality processes are to be established. All too often companies will look at this information without considering similar errors or systems in the field or at suppliers. This can create repeated efforts in identifying root cause analyses for events that may have a similar cause but are identified in different areas of the value chain. In closed-loop quality processes all of these information sources must be managed in a central system that is accessible across the enterprise.



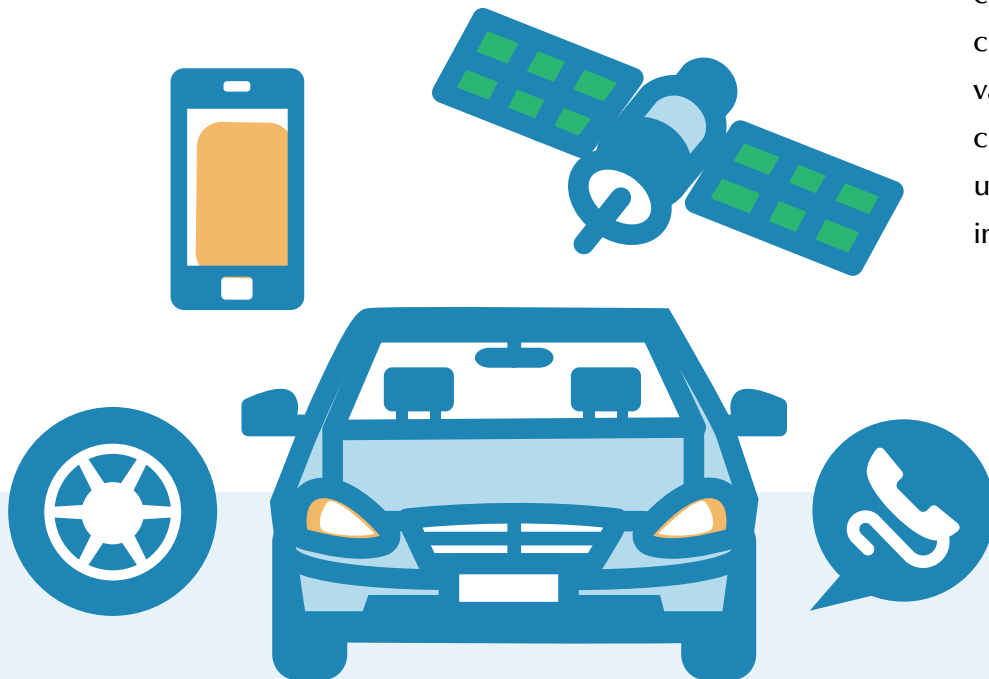
Service

Once a product leaves the manufacturing environment, a whole new set of quality performance data begins growing as it moves downstream and ultimately reaches the end of the product lifecycle. In addition to traditional forms of quality data sources in the service stage—such as customer complaints, field failures, and warranty information—new forms of data are surfacing with the widespread use of social media and other online outlets. Many companies are already using these data sources in conjunction with technologies like social media analytics and sentiment analysis to improve the customer experience and interact more with customers, but few are

using them to drive quality improvements. Data sources coming from this area of the value chain include:

- Social media complaints (Twitter, Facebook, etc.)
- Product review forum complaints
- Formal customer complaints and feedback data
- Warranty claims
- Service data
- Field failures

Once in the arena of service, this is the last stage of the value chain and often where companies most intimately interact with customers. It is also the last mile and most critical area of the value chain for creating closed-loop quality. To truly create closed-loop quality it is critical for this data to be pushed back upstream through formalized processes to ensure continuous improvement.





SECTION 3

Building Closed-Loop Quality Management Processes

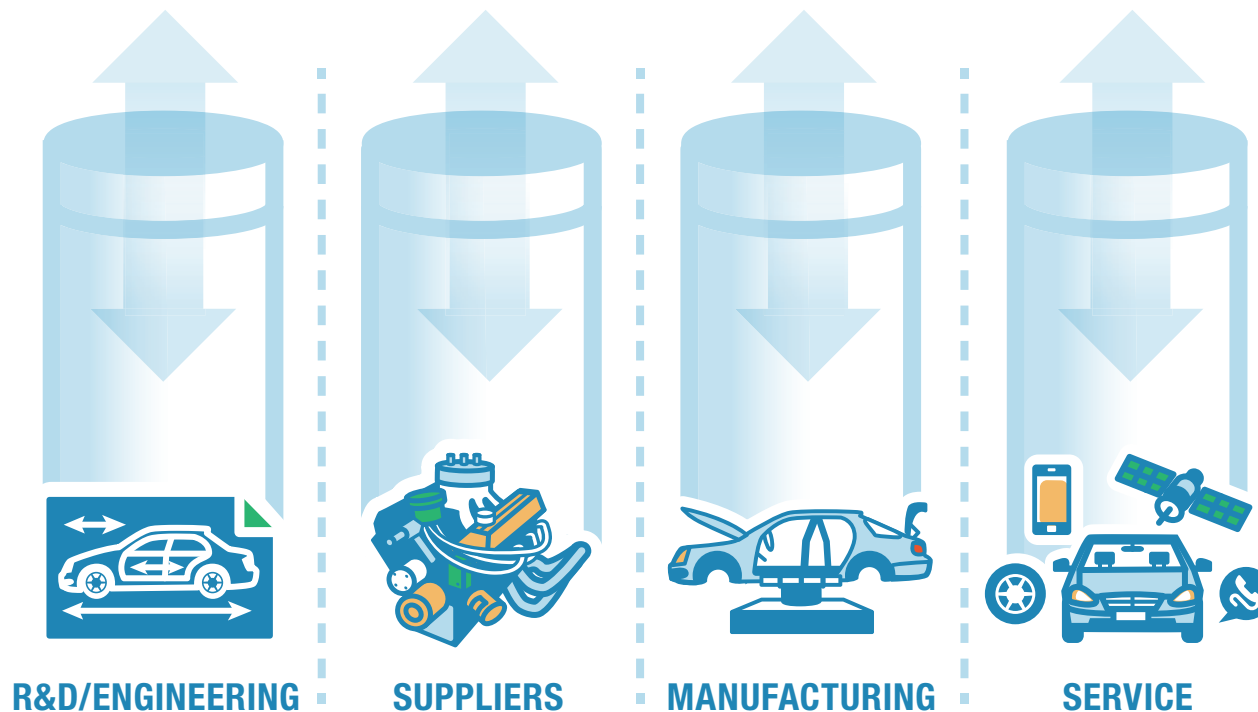
The Current State of Affairs

The previous section discusses different forms of quality management activities and data coming from across the value chain. Despite the fact that quality information in one area of the value chain may be critical information for professionals in another area, in many organizations this connection is never made. LNS Research's recent survey revealed that 78% of companies exist in a state of quality management disconnect. This means professionals are dealing with a variety of fractured data sources and systems for managing quality, making integration between them an unrealistic goal without the use of significant resources.

The result tends to look like what is visualized below—quality management silos across the value chain. Finding the

culprit or culprits of this disconnect may be challenging, since every organization is unique, but there are several identified by research:

- Shortsighted IT strategies
- Past technological limitations
- Reliance on homegrown solutions
- Lack of communication at the enterprise level
- Complex organizational structures (conglomerates)
- Different forms of IT from M&A activities

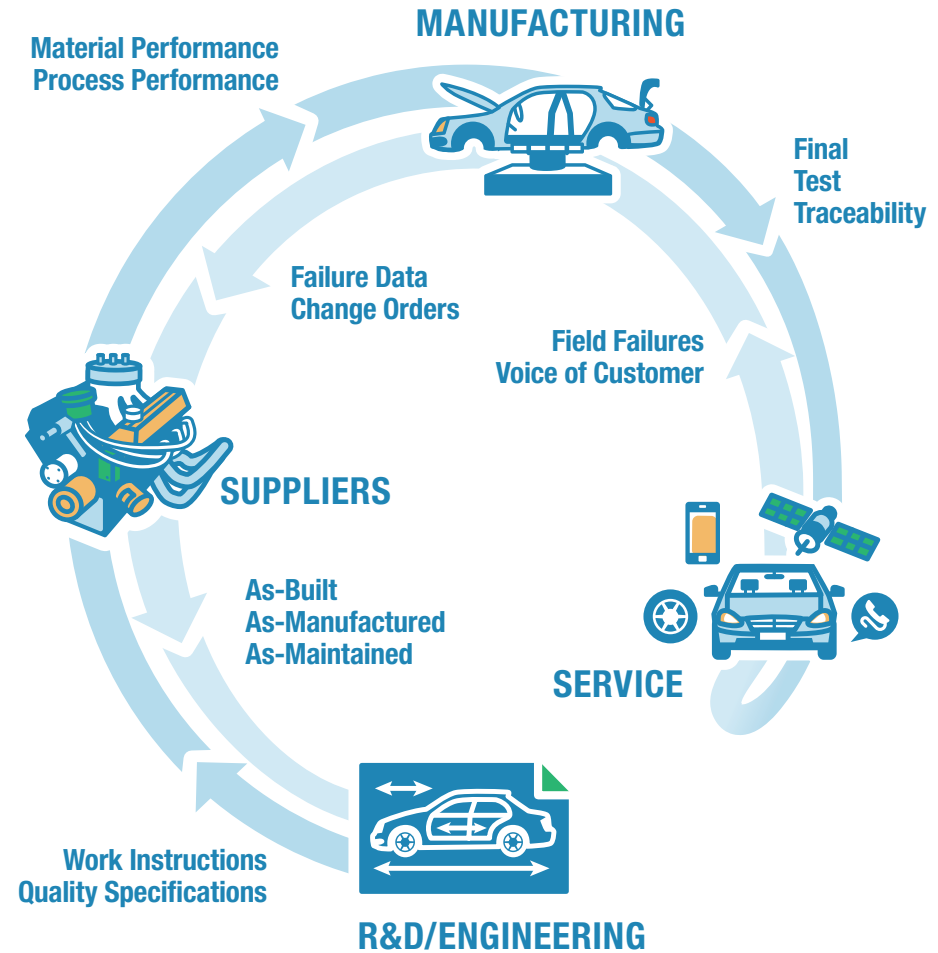


78%
of the 900+ companies surveyed reported quality management disconnect.

Breaking Down Closed-Loop Quality Management

As a term used by many manufacturing professionals over the past few years—one that’s gaining notoriety—closed-loop quality management is a concept that should be fully dissected to be fully understood. It refers to the bi-directional connection of people, processes, and data across the value chain. Market leaders are following this strategy to create feedback loops between different functional areas with the end-goal of ensuring process and product quality as early as possible.

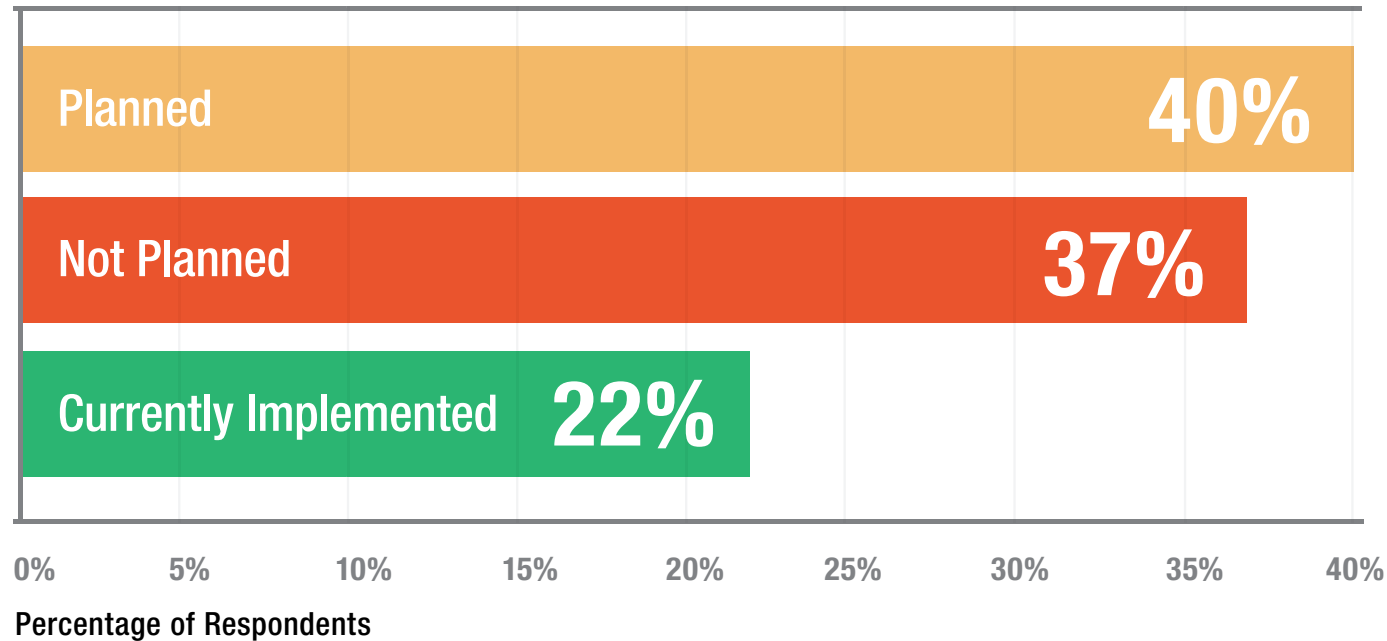
As shown in the automotive example to the right, these feedback loops typically pass performance data back upstream. These are the types of data discussed in the previous section. For instance, field failures submitted by customers to service centers may be shared with continuous improvement professionals in the manufacturing environment. These professionals may analyze this data to identify the source of failures and take the steps to avoid it, ultimately correcting the failure internally and reducing the (potentially significant) downstream impact. This is just one use case, but there are many across the value chain.



Why Focus on Closed-Loop Quality Management Today?

Across discrete, batch, and process manufacturing industries, LNS Research is seeing and hearing about the adoption of closed-loop quality management processes. The data below supports this. While less than a quarter of manufacturers surveyed had closed-loop quality processes established in 2013, 40% were in the planning stages of an adoption. This means 40% of manufacturing organizations are currently developing a strategy for interconnecting people, processes, and data from one node in the value chain to another.

Closed-Loop Quality Processes Established



Creating Closed-Loop Quality Processes

Closed-loop quality management is about enabling communication and collaboration. As has been stated, for most organizations, quality efforts and data exist in silos. It is not uncommon for manufacturing, design, and other functions to have individual quality management systems. However, many organizations are starting to work to connect quality across the value chain, even with manual efforts. At the most rudimentary levels, companies are sharing quality performance data via a combination of spreadsheets and email or with some form of enterprise content management solution.

While this may not be the most efficient method for sharing data and interacting with value chain counterparts, it is a positive step in the right direction and an indicator that companies are thinking about quality in the broader context. More mature organizations are working to take advantage of existing—typically homegrown—quality management solutions. These companies generally have to undertake significant investment for integration as well as system maintenance once a process is established. Today, however, advancements in quality management technology—namely with EQMS—are enabling the types of next-generation closed-looped processes many professionals could have only dreamed of a decade ago.

WAYS TO ENABLE DATA SHARING AND COLLABORATION:

- Spreadsheets and email/enterprise content management
- Shared database
- Homegrown system integration
- Document management solution
- Enterprise Quality Management Software



SECTION 4

Supporting Closed-Loop Quality with EQMS

What Is EQMS?

The last section discussed how less than a decade ago, the resources required to actually create closed-loop processes were not readily available. Doing so generally meant significant time and capital investments, and even harder to rationalize business cases. Consequently, such investments tended to find themselves pushed down on the list of executive priorities. Today, however, advancements to EQMS have made closed-loop processes not only justifiable, but also an enabler for achieving a level of world-class quality needed for maintaining competitiveness in the modern global economy.

EQMS centralizes, standardizes, and streamlines end-to-end business processes and quality data. It acts as a common platform for cross-functional communication and collaboration by bringing together people, processes, and technology from across the value chain. By automating traditionally manual quality processes with EQMS, companies are able to better manage operational risk, work together to resolve quality issues with root cause analyses on nonconformances, attain better visibility into supplier activities, and more.

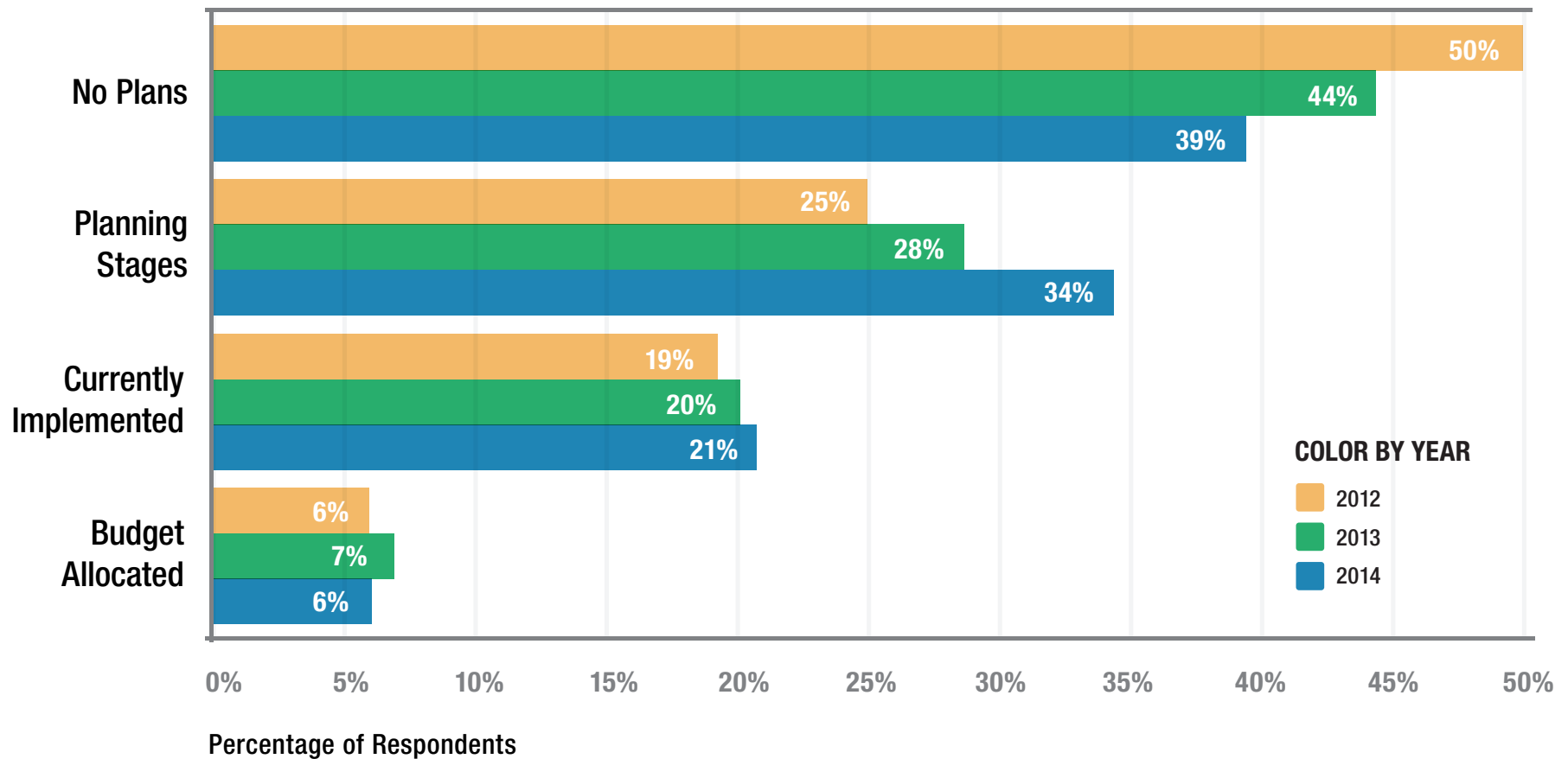
EQMS acts as a common platform for cross-functional communication and collaboration by bringing together people, processes, and technology from across the value chain.

EQMS Adoption: 2012-2014

EQMS adoption has been on the rise in the past several years, and there are some impressive numbers to support that claim. As shown, planned adoptions have risen from 25% in 2012 to 34% in the first half of 2014. Organizations reporting an EQMS implementation have risen from 19% to 21% from

2012 to 2014. And, standing out the most, companies with no plans for an EQMS implementation have dropped from 50% to 39%. As the software market only matures, LNS Research expects to see these numbers continue to move in favor of EQMS implementations.

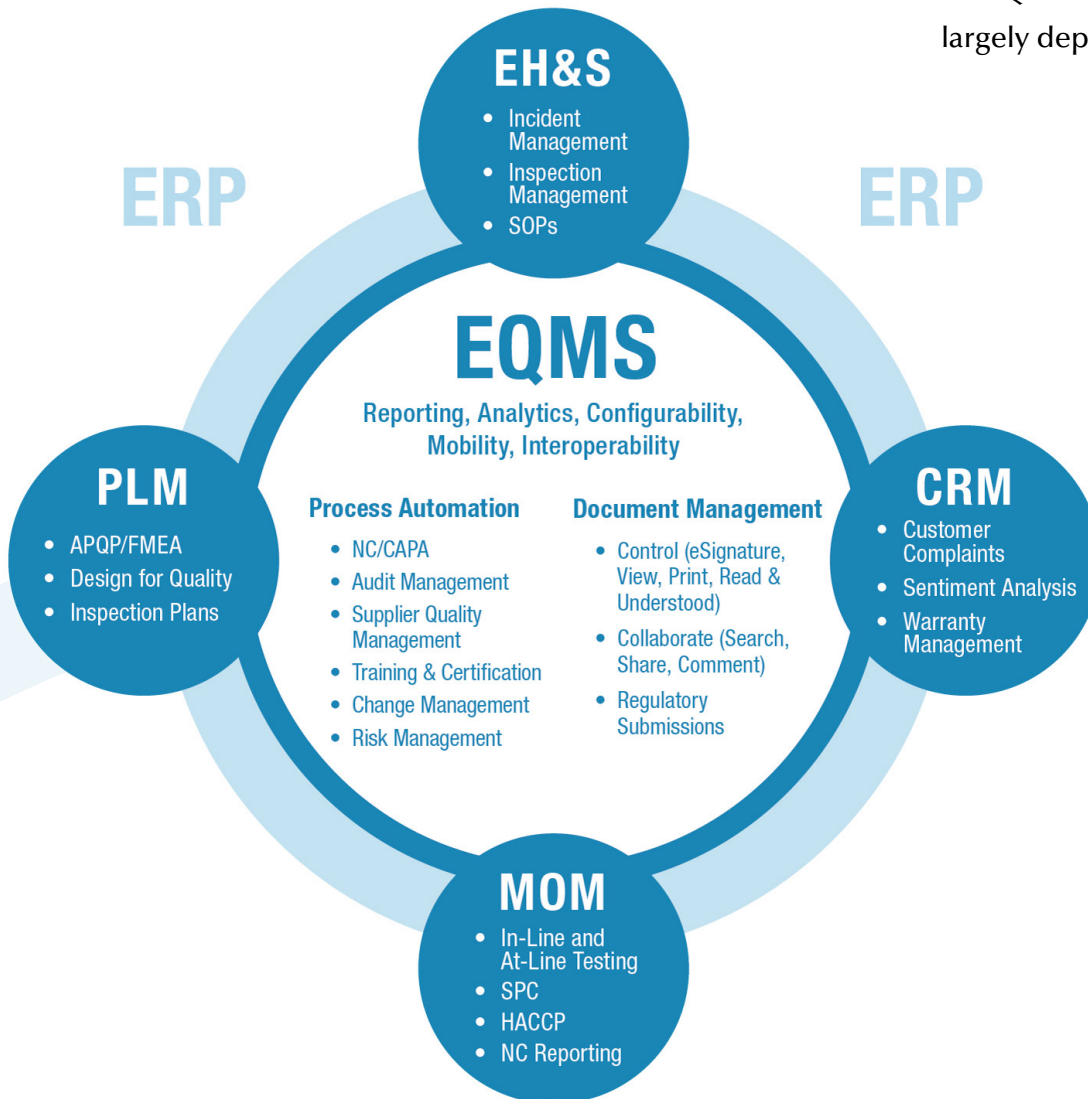
EQMS Implementation



EQMS as a Quality Hub

Depicted in the figure below, EQMS acts as a hub for quality processes and data between traditionally disparate systems, including Environment, Health, and Safety (EH&S), Product Lifecycle Management (PLM), Customer Relationship Management (CRM), and Manufacturing Operations Management (MOM).

It integrates with these systems as well as the broader ERP IT backbone. Generally, large companies today will have an ERP, one or two of the other platforms mentioned, and perhaps an EQMS. The portfolio of software and processes may vary, largely dependent upon the needs of the organization.

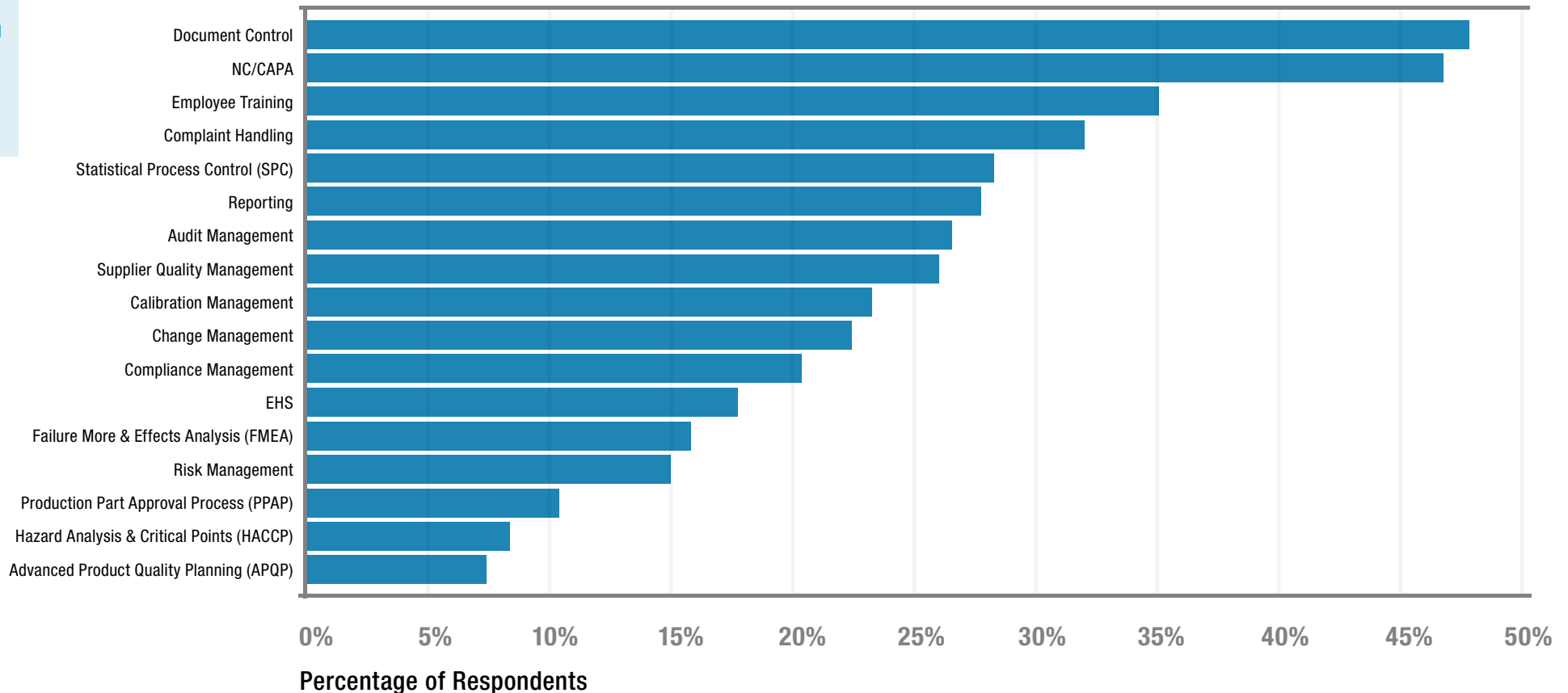


Adoption of Functionality

When examining the top reasons why companies have implemented EQMS, the largest responses are around integrating disparate legacy systems and processes such as document control and establishing a formal process for identifying NC/CAPA. According to the survey, companies have implemented these solutions around NC/CAPA and document control to address the most immediate pain points being experienced.

As the EQMS market matures, LNS Research expects less adopted functionalities such as compliance management and risk management to gain momentum. In the past several years, although document management and NC/CAPA have stayed strong on the top of this list, less-adopted functionalities like SPC and reporting have been moving closer to the top.

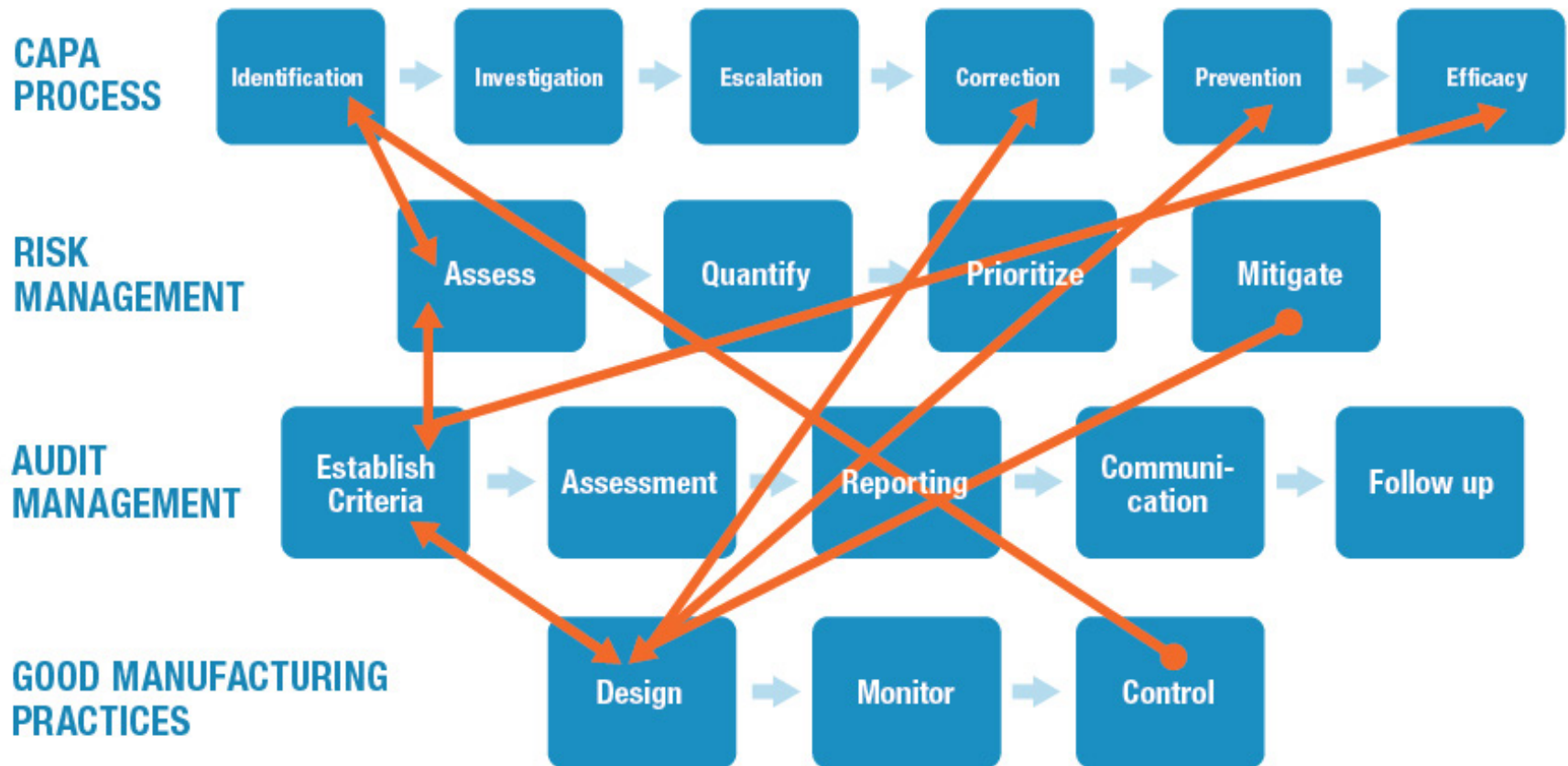
EQMS Functionality



Interconnecting Quality Processes

Adoption percentages are relatively low when looking at EQMS functionalities like audit management, risk management, compliance management, and others. In neglecting some of these functionalities, businesses are leaving important value behind, as most of these processes are connected with one

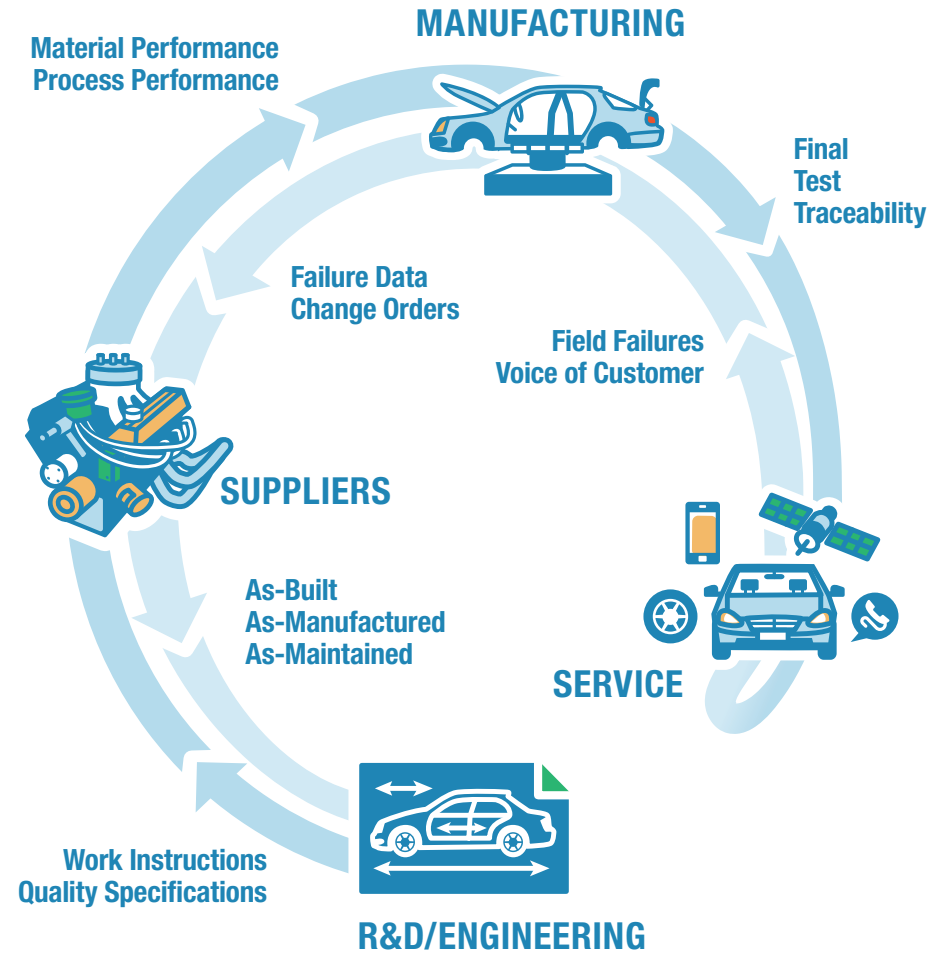
another in some way. Risk and CAPA processes, for example, should be connected, as in many instances risk tools could be beneficial in determining which CAPA processes to prioritize. Viewed holistically, these processes can drive significantly more value for companies.



Developing Closed-Loop Processes with EQMS

The automation and standardization of traditionally manual and disparate quality management processes are proving to be enormously useful across enterprises. As shown in the previous slide, companies are taking advantage of EQMS to drive next-generation improvements between complementary quality processes like NC/CAPA, risk management, and Good Manufacturing Practices (GMP).

But today's most innovative and quality-minded market leaders are taking EQMS a step further, using it to develop closed-loop quality processes. By interconnecting key data sources and systems, EQMS can actually streamline the delivery of quality performance data and open up portals for collaboration between functional units. This eliminates the need for manual interaction and compounds the impact of the connections shown in the graphic.





SECTION 5

Quantifying the Benefits

Quantifying the Benefits

By cross-analyzing survey respondents reporting the establishment of closed-loop quality processes with different performance metrics, the true impact of closed-loop quality management can be quantified. Across three key performance indicators—OEE, On-Time and Complete Shipments, and Successful New Product Introductions—companies with closed-loop quality processes established displayed impressive performance in comparison to those without closed-loop quality processes established.

These metrics are important, since they each encompass many different variables around quality and operations. For a large organization, improvements are particularly notable, as a percentage point difference could have considerable impacts (up to millions of dollars) on costs. It could also mean the difference between being the first to market with a new product, maintaining reputation as a supplier, winning additional contracts, or passing an audit. Closed-loop quality introduces new ways to strategically and sustainably improve these KPIs over time.

	CLOSED-LOOP QUALITY PROCESSES IN PLACE	ALL OTHERS
Median Overall Equipment Effectiveness	87%	80%
Median On-Time and Complete Shipments	95%	92%
Median Successful New Product Introductions	85%	76%

Benefits in Engineering

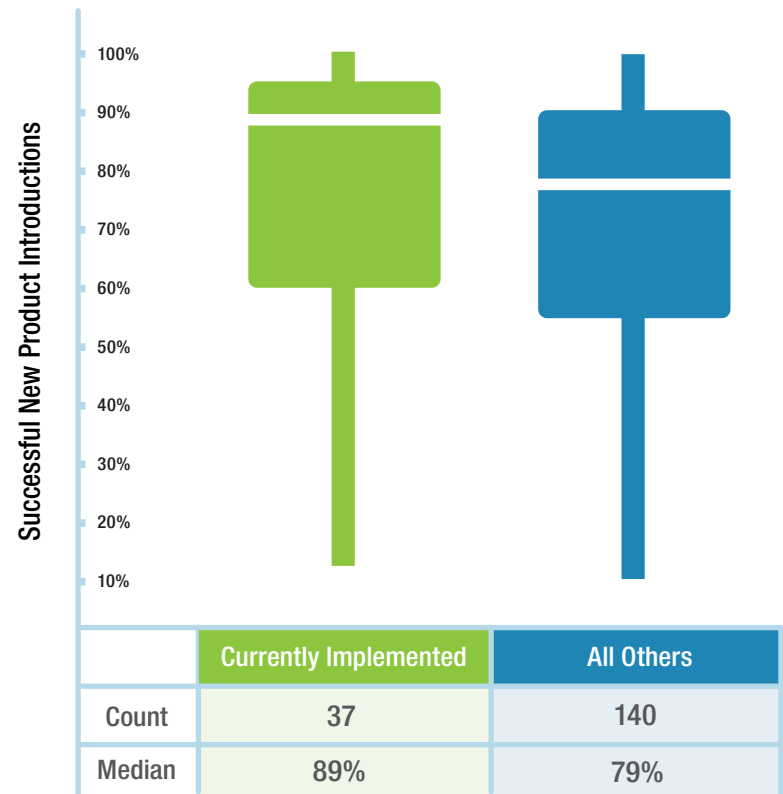
Diving deeper into closed-loop quality management, data from the quality management survey can be used to look at the impact of enablers of closed-loop quality on performance. For instance, as shown to the right, companies with real-time visibility of quality metrics in engineering reported a 10% higher median rate of successful new product introductions. Visibility into as-built, as-maintained, and testing data can be inspected and given feedback on by professionals downstream to improve quality earlier in the design process.

Real-time visibility into engineering quality performance translates into a

12.7%

higher rate of successful new product introductions

Real-Time Visibility of Quality Metrics in Engineering

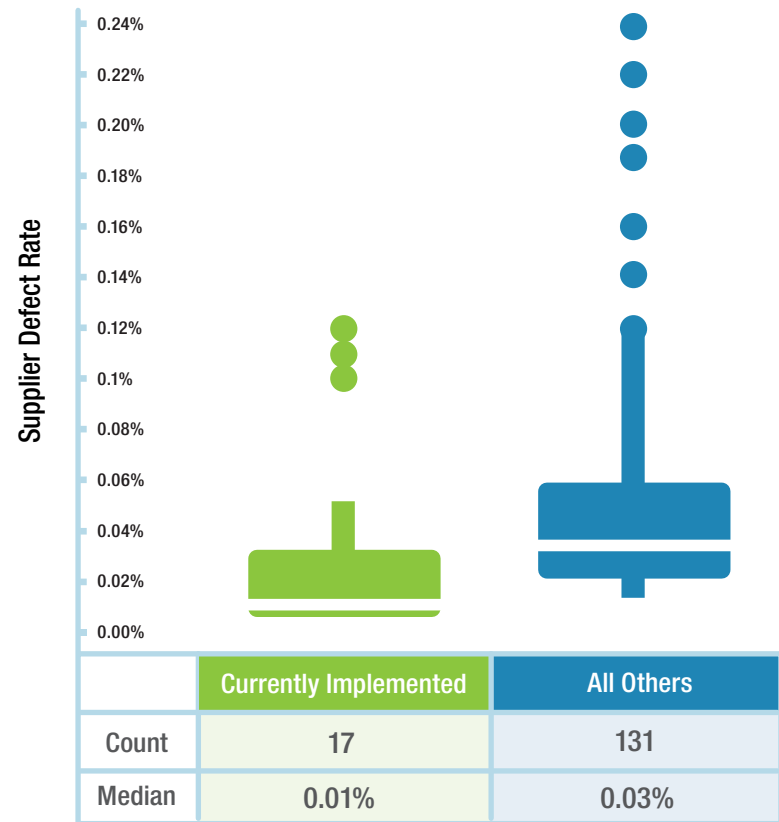


Benefits in Supplier

Organizations with the ability to automatically collect supplier quality data through a Web-based portal reported a supplier defect rate of 0.01% versus 0.03% for those without the ability. This comes with little surprise, as improved visibility into supplier quality benefits both manufacturing and engineering. On one side, manufacturers can monitor and even influence quality before products get shipped. On the other side, engineering can tune things like quality specifications based on supplier performance.

A **67% LOWER** median supplier defect rate could very well attribute to
AVOIDING A MAJOR PRODUCT RECALL

Supplier Quality Data Collected Automatically Through Web-Based Portal



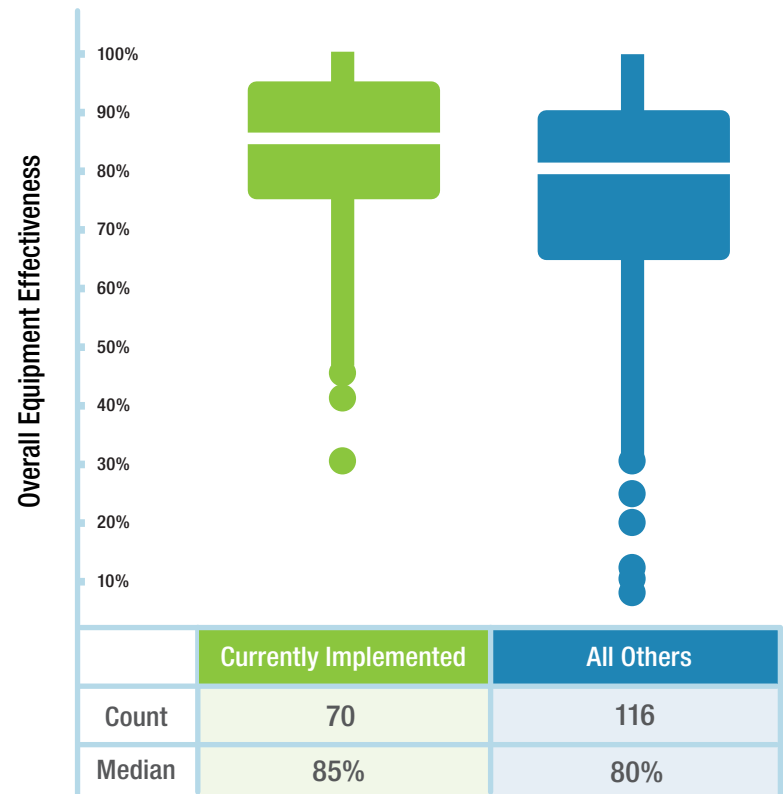
Benefits in Manufacturing

Reporting a higher median OEE—85% versus 80%—companies with real-time visibility of quality metrics in manufacturing have a better handle on the KPI’s core components: availability, quality, and efficiency. Quality management technology like SPC is driving this, and this performance data can be used by continuous improvement professionals in the manufacturing environment to identify performance correlations across different plants in real-time. It can also be viewed historically to identify performance correlations across the value chain.

The establishment of real-time visibility of quality metrics in manufacturing drives a higher OEE by

6.25%

Real-Time Visibility of Quality Metrics in Manufacturing



Benefits in Service

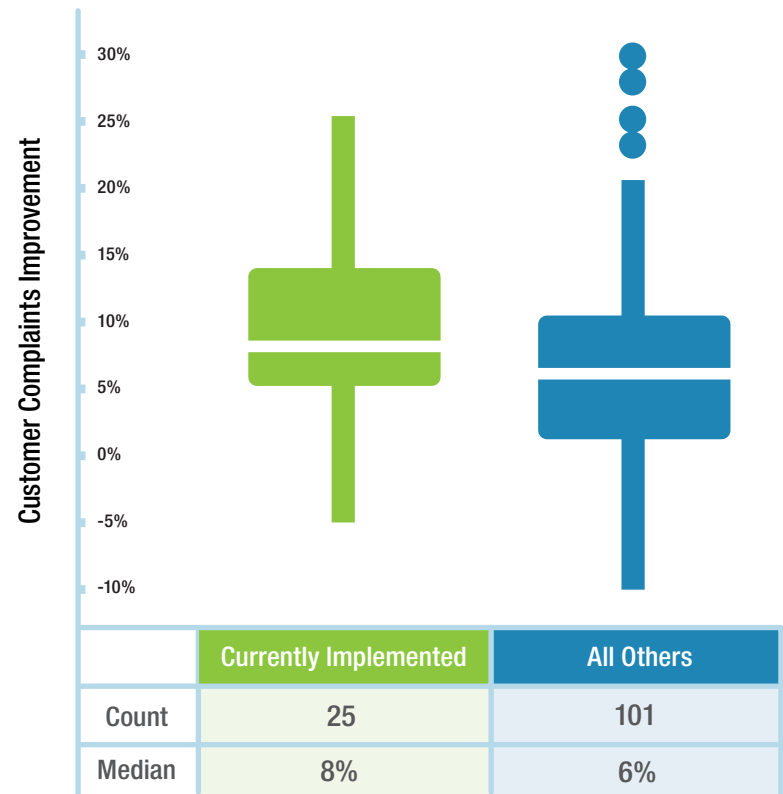
Companies with real-time visibility of quality metrics in customer service reported a 33% higher improvement in customer complaints. Although the use of this type of service data for driving upstream quality improvements is relatively new, many companies are starting to identify use cases for it and put it into action. Streamlining CRM data on customer complaints into consumable reports for engineering and manufacturing will likely become more common in the coming years with closed-loop quality awareness and new solutions on the rise.

Real-time visibility of quality metrics in customer service helped drive a

33% HIGHER IMPROVEMENT

in customer complaints

Real-Time Visibility of Quality Metrics in Customer Service





SECTION 6

Moving Toward a Closed-Loop Environment

Take Action Now

The benefits of closed-loop quality management are clear; however, there are still many different approaches manufacturers are taking to achieve them. Companies need to invest in people, process, and technology excellence in each area of the value chain, including engineering, suppliers, manufacturing, and service. However, this is not enough. Integrating key enterprise software systems and data sources across the value chain with EQMS is becoming an increasingly common method for this. Advancements to EQMS have made it readily available for organizations across industries, company sizes, and geographies. It has become easier to implement and integrate, and a more viable option for organizations with less budget for quality management.

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