QUALITY MANAGEMENT IN THE BOARD ROOM

Building the Executive Business Case for EQMS

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Executive Overview

Executive Overview

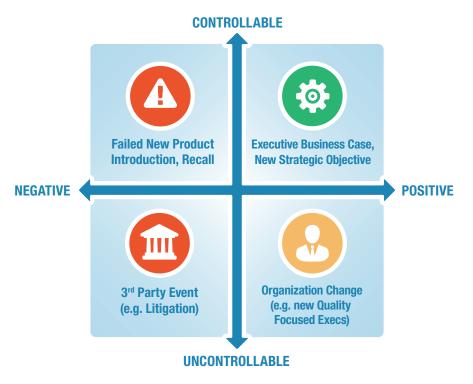
Quality leaders today are facing new challenges and opportunities presented by changing global markets, disruptive technologies, new regulations, and social media. Their quality management maturity has not increased quickly enough to keep pace, largely due to chronic underinvestment. Top executives often do not see as much strategic value in quality management as in sales, engineering, or manufacturing. As consequence, in many organizations quality is a silo and perceived as the "quality police."

When done right, quality extends throughout the enterprise and provides unique value across all functions. However, quality is stuck in a catch-22. It must break out of the silo to achieve its potential value, but the lack of perceived value reduces support from other leaders and top executives. Support from top executives plays a crucial role in the long-term effectiveness of quality, far beyond project funding. Long-term executive sponsorship results in top-down support, executive voice, and sustained resources, which are the three elements that quality needs to thrive. Top down support drives culture change and cross-functional engagement, cross-functional processes, and quality culture from leadership down. Moreover, executive voice is the ability to influence corporate strategy, planning, and operations. Sustained resources are the resources needed to build a long-term roadmap that results in high maturity. Most quality leaders have not been able to garner this level of executive support.

Quality leaders need to gain executive sponsorship and need a *compelling event* to accomplish this goal. A compelling event is a business influence or pressure that forces action or response, with a defined date and business owner. Unfortunately, compelling events

that drive executive sponsorship are often *negative*, such as recalls or regulatory failure, which are extremely damaging to the company, employees, and public. The industry needs *positive* compelling events for executive sponsorship that can be controlled and driven by quality. This positive, controllable, and compelling event is the executive business case, connected to either existing strategic objectives or new strategic objectives such as the Internet of Things (IoT).

COMPELLING EVENTS RESULTING IN EXECUTIVE SPONSORSHIP







Research Demographics

Research Demographics

Before inspecting the business case for Enterprise Quality Management Software (EQMS), it is important to set the stage for the supporting data used throughout this eBook. The LNS Research Quality Management Survey has been completed by over 700 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. There were 54.3% of companies from Discrete Manufacturing industries, with the remainder coming from Food & Beverage/Consumer Packaged Goods, Life Sciences, and Process Manufacturing. Just over half were from North America, followed by just under a quarter from Europe. Almost half, 46.8%, were from small companies, with 38.0% from large companies, and the remainder from mid-sized companies.

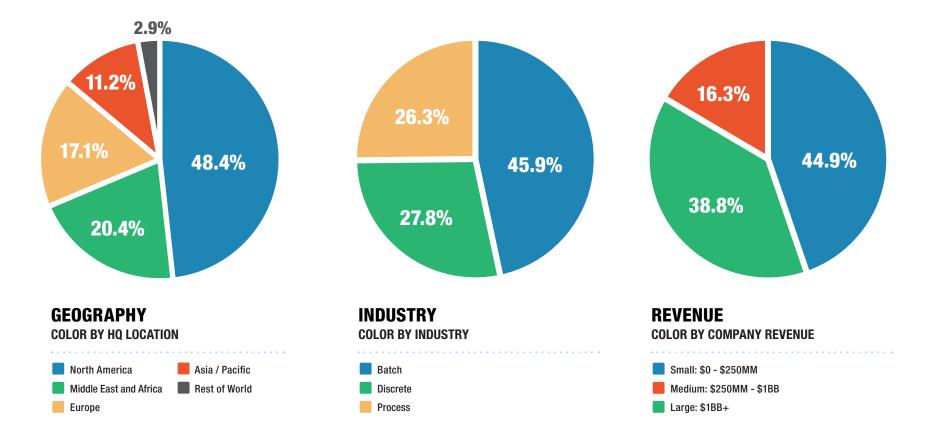


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Quality Maturity and Operational Excellence

Operational Excellence Considerations

LNS Research has long held the stance that the correct way to view quality management is through the lens of Operational Excellence: people, process, and technology. While these are described in detail in other LNS Research publications, it is important to realize that all three of these elements interconnect, and that any change to one element will also impact the other two. Therefore, when quality investment is requested, quality leaders must optimize across these three elements to achieve the maximum impact of the investment. Deploying an EQMS that replicates existing paper-based processes is a missed opportunity. This deployment should be used to enable cross-functional processes and information sharing, and is an event that can take quality out of the silo and increase its cross-functional relevance and strategic value. Organizations must consider the potential impact to not just the Operational Excellence of the quality "department," but rather to quality across the broader enterprise, and drive toward the optimal cross-functional quality Operational Excellence.

When quality achieves executive sponsorship and increases in maturity, it ceases to be a department and becomes a responsibility across all functions. This creates a new role for the quality department as quality *leaders*, not exclusively as quality *do-ers*. Quality leaders must gain and nurture support of top executives but also of the quality team as well.



Quality Maturity and Performance

LNS Research's Quality Maturity Model provides a perspective that connects Operational Excellence with operational and financial performance and the ability to meet market demands. Organizations can use the maturity levels both as a yardstick to measure their current maturity, as well as a method for guiding future investments. Comparing the performance at Level 1 (Ad Hoc) versus Level 5 (Market Leader) provides clear impact of quality maturity.

LNS Research Quality Maturity Model

MARKET LEADER

Ability to define markets, transform business models, and disrupt incumbents

AGILE

Ability to meet and exceed current market demands. Fast follower as markets transform.

PROACTIVE

Ability to meet and exceed current market demands. Potential to meet future market demands.

CONTROLLED

Ability to meet and current market demands. Inability to meet future market demands.

AD HOC

Inability to meet current or future market demands.

Quality Maturity and Performance (Cont.)

As an example, compare Business Process Excellence at Ad Hoc versus Market Leader. While processes are disconnected and disparate at Ad Hoc, at Market Leader the company has harmonized processes across sites, functions, and business units. This common set of processes across the company creates the basis for company-wide continuous improvement, allows many functions to easily engage in quality activities, and enables agility in responding to changes in market, technology, leadership, and regulations.

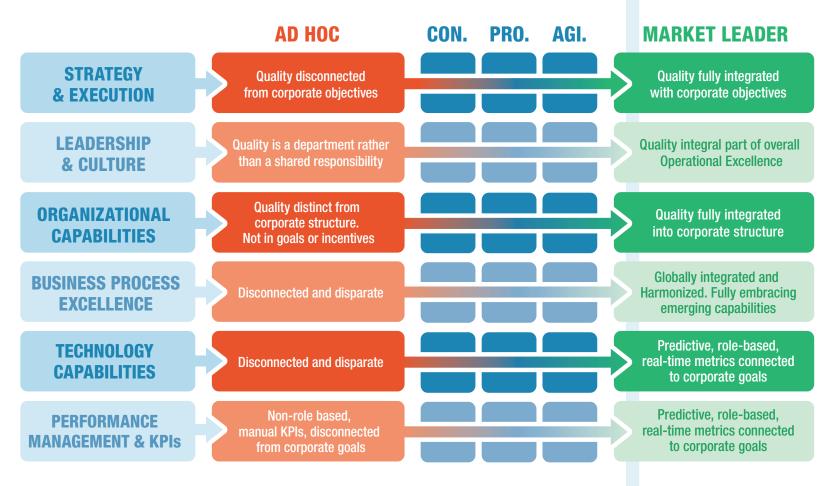


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Industry Challenges

The number one challenge to achieving top quality objectives is "Disparate quality systems and data sources," with 38% respondents across all industries. Top challenges are associated with lack of technology and lack of formal processes, and a full 34% of respondents say that quality is considered to be a department, not a responsibility. These clearly indicate that much of industry has quality maturity of Level 2 or below. This particular mix of challenges also illustrates the chronic underinvestment in quality, as the top two challenges are associated with lack of technology investments.

Top Operational Challenges in Quality Management

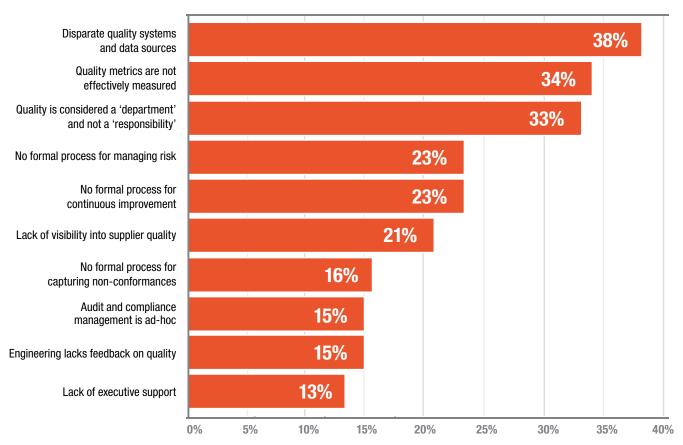


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State of Quality Operational Excellence

An analysis of quality processes automated with software also indicates low maturity and underinvestment. Of all quality processes, NC/CAPA is automated most often at 46%, followed by Document Control at 44%. However, the adoption rate of remaining processes drops off substantially. The median adoption rate for all the automation of all processes surveyed is just 23%.

Many organizations have not yet begun their journey into process automation and, of those that have, most have deployed relatively few processes. Automation and use of software is important for cross-functional engagement to quality processes.

AUTOMATED QUALITY PROCESS ADOPTION has a relatively broad but generally low range from 7% TO 46%

MEDIAN ADOPTION RATE OF AUTOMATED QUALITY PROCESS is still surprisingly low at just 23%

SECTION 3



Quality Maturity, Executive Sponsorship, and the Executive Business Case

Executive Sponsorship Drives Quality Maturity

Executive sponsorship is the single most important correlation to quality maturity. Its criticality is largely because a mature quality organization must operate across functions. Attempting to build this cross-functional alliance bottom up is a challenging and lengthy process, taking years or decades. However, top executives can drive sweeping people, process, and technology changes very quickly and effectively. This is often seen as an executive response in the wake of a negative compelling event.

The data clearly supports this rationale. LNS Research surveys industry on many elements, including whether or not "Quality is

a Top Executive Priority." The adoption rates of 21 quality Operational Excellence best practices (table shown in the appendix) were compared between companies where "Quality is a Top Executive Priority" versus those where it was not. Companies with top quality prioritization were almost 3 times more likely to have adopted any given quality practice. Additionally, these organizations adopted an average of 8.6 quality Operational Excellence best practices, where All Others adopted an average of 2.9 quality best practices.

Clearly, the path to higher Operational Excellence maturity is enabled by—and necessitates—executive sponsorship.

EXECUTIVE SPONSORSHIP



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QUALITY MANAGEMENT

IN THE BOARD ROOM

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Impact of Quality as a Top Executive Priority

Companies with executive priority for quality adopt approximately 2 to 7 times more best practices than other companies. Companies with executive priority for quality adopt approximate-

ly 3 times more best practices on average than other companies.

Average Number of Adopted Quality Management Best Practices

"Quality is an Executive Priority"

2.9 All Others

COMPANIES WITH EXECUTIVE PRIORITY FOR QUALITY, on average, adopt almost **3 TIMES AS MANY** best practices as other companies.

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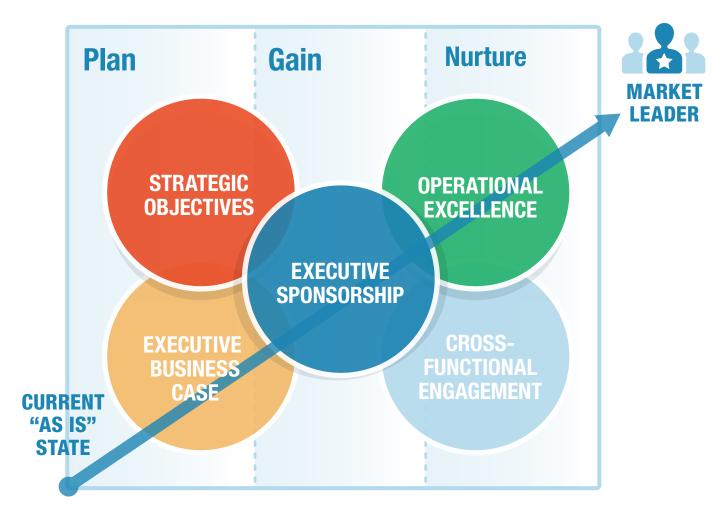
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The Executive Business Case and Quality Maturity

In order to achieve high maturity, quality leaders must plan, gain, and nurture executive sponsorship. Quality leaders must assess their current as-is state and determine an ultimate to-be state of high quality maturity. Leaders plan for executive sponsorship by building an executive business case connected to strategic objectives. They gain executive sponsorship by positioning the executive business case, then nurture the executive sponsorship as the executive drives cross-functional engagement to achieve new levels of Operational Excellence.

The executive business case is critical and sets the quality leader on a path to gain executive sponsorship for quality, driving Operational Excellence and ultimately, high quality maturity.







Building the Executive Business Case

Focus on the Proper Metrics

The executive business case must be supported and justified by the appropriate metrics. Metric selection is critical to gain credibility as well as to measure project success. Often, organizations justify EQMS or similar investments using siloed metrics that are primarily of interest to the quality department, such as number of complaints or non-conformances. These can be translated into financial impacts, but the connection between siloed metrics and corporate finances or value is tenuous.

The five classes of metrics shown are arranged in order of ascending strategic value. Quality leaders looking to improve quality maturity must understand cross-functional Operational Excellence impact and also use the appropriate cross-functional metrics to justify and support the project. However, one challenge faced by quality leaders is evidence-based connection between adopted quality management best practices and non-siloed metrics. This eBook provides supporting evidence in a later section.

Big Data enables a different perspective on metrics. The siloed operational, financial, and value metrics are rearward-looking descriptive analytics. Big Data uses a broad array of real-time and historical data to enable new descriptive analytics as well as new analytical options such as diagnostic, predictive, and prescriptive analytics. Diagnostic analytics are backwards looking and answer the question "Why did it happen?" Predictive analytics are forward-looking and answer "What will happen and when will it happen?" Prescriptive analytics are also forward-looking and answer "What should we do when it happens?" While most often applied to hardware and software, Big Data analytics leverages historical and real time data from many different sources to enable predictive and prescriptive analytics for achieving long-term strategic objectives.



BIG DATA

Leverages real-time data to perform Descriptive, Diagnostic, Predictive, and Prescriptive analytics



VALUE

Metrics that capture positive Value, such as market share, revenue, earnings, revenue/earnings growth, and % successful NPI

FINANCIAL

Metrics that capture financial costs, such as Cost of Poor/Good Quality, Cost of Compliance/Noncompliance



OPERATIONAL

Metrics that capture the performance of operations, such as OEE, TTM, OTD



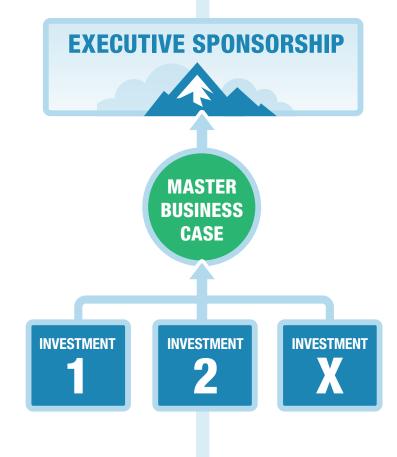
SILOED

Departmental metrics such as # Records, personnel efficiency, # IT systems, adoption

Master and Incremental Business Cases

Quality leaders must be able to identify an ultimate end goal and position both that goal and its value to gain executive sponsorship. That ultimate end goal and value are key components in the master business case, the overarching document that conveys the value of quality management to the organization. The master business case is not focused on a specific investment request or even a series of investment requests. It is separate from requests for investment but, rather, focused on the value of achieving a high level of quality management maturity. A successful master business case will result in executive sponsorship with top-down support, executive voice, and sustained resources.

The master business case is supported and enabled by a number of incremental business cases, which are specific investments. These incremental business cases are tied to the master business case, but can change over time. They should demonstrate progress to the ultimate end goal.



"A SUCCESSFUL MASTER BUSINESS CASE will result in executive sponsorship with top-down support, executive voice, and sustained resources."

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Connecting the Elements of the Executive Business Case

The executive business case framework captures the considerations necessary to build a business case that is a positive, controllable, and compelling event that generates executive sponsorship. Historically, many quality business cases have been singular requests, addressed as objectives most important to the quality department, justified with siloed metrics, and considering a siloed quality-centered operational architecture.

Quality leaders should expand the scope of their business cases to address objectives important to other functions as well as quality, with the collaboration and participation of those other functions. In order to attain executive sponsorship, identify how quality can work with the rest of the organization to address strategic objectives. This view then cascades into a view of Operational Excellence and operational architecture that aligns more closely with "Quality is a responsibility" than "Quality is a department." The supporting business case can leverage many of the standard business case elements, but must also leverage metrics and project value aligned with an executive scope, as well as capture the concept of a business case.

EXECUTIVE SPONSORSHIP OBJECTIVE Cross-Functional Departmental Strategic SCOPE Process Technology People **OPERATIONAL Metrics** (Siloed, Operational, Financial, Value, Big Data) EXCELLENCE L Maturity Level (L1 - L5) QUALITY · COMPLIANCE · EH&S **OPERATIONAL** FINANCE ARCHITECTURE **SCOPE** Supply Chain Verification Distribution Development Support Validation Manufacturing Marketing Sales Service FOCUS (Strategic Objectives, Smart Connected Ops, Op Ex, Op Architecture) **FINANCIALS** (Justification, Ask, LLC, Cost Breakdown Structure, NPV, Alternatives) **RISKS BUSINESS CASE** (Inaction, Delayed Action, Improper Action, Misaligned Action) **BUSINESS CASE SCOPE** (Departmental, Cross-Functional, Executive) **BUSINESS CASE JOURNEY** (Master and Incremental As Is / To Be)

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What Is the Business Case Journey?

The business case journey charts an organization's progress from today's as-is state to the ultimate end goal captured in the master business case. An organization should identify its current as-is state on the business case journey chart by identifying the current quality maturity and moving to the business case journey line. This identifies the as-is business case and objective scope along with as-is justification metrics. Organizations must also identify the ultimate end goal from the master business case on the chart and find the resulting business case scope, objective scope, and justification metrics. Incremental business cases can be charted as well, plotting the course between the initial as-is and the ultimate end goal.

The business case journey chart also identifies a dividing line where quality shifts from being perceived as a cost center to a value center. Top executives view cost centers as requirements that deserve minimum investment, as they do not deliver value. Conversely, value centers receive sustained investment as they drive positive business outcomes.

SSSSS 5 **BUSINESS CASE** JOURNEY **METRICS** 4 **Big Data*** *Big Data Analytics, Diagnostic, Predictive, Prescriptive VALUE CENTER \$\$\$\$\$ Value** COST CENTER 3 **e.g. Revenue and Earnings **Financial** \$\$\$\$\$ 2 **Operational** \$\$\$\$\$ Siloed **CROSS-FUNCTION** DEPARTMENT **EXECUTIVE**

BUSINESS CASE AND OBJECTIVE SCOPE

DPERATIONAL EXCELLENCE MATURITY

\$\$\$\$\$

SECTION 5



From Here to There: The Quality Business Case Journey

Steps to Gain Executive Sponsorship

The frameworks and content provided can be condensed into the six steps needed to gain executive sponsorship. Steps 1 to 3 align with constructing the master business case; Steps 4 and 5 capture the construction of the incremental business cases; and Step 6 is gaining executive sponsorship. The resultant master and incremental business cases are iterative and will change with input from other leaders, executives, and time.

As stated earlier, the ultimate end goal should be connected to strategic objectives and a desired quality maturity level. New strategic objectives can serve as compelling events. As an example, quality improvement is a leading use case for investment in IoT. However, investing in IoT to drive quality improvement should be coupled with broader investment in quality operational architecture, such as EQMS, in order to connect the information from IoT to the quality system of record. In this way, quality is enabling the strategic objective and optimizing Operational Excellence.

When building incremental business cases, quality leaders should drive credibility by delivering maximum value as soon as possible. LNS recommends identifying low hanging fruit while performing the as-is assessment. There are often opportunities to make smaller investments that drive highly visible value, provide short time-tovalue, are simple to deploy, or make measurable progress towards key objectives identified in Step 1. Use these initial successes to nurture executive sponsorship and cross-functional engagement.

| Initial End Goal Identify Impact of end goals on strategic objectives and metrics | Objectives Operational Excellence Operational Architecture Financials and Metrics | Correlate As Is Assessment with Maturity Model LNS's Maturity Model or other | Use Maturity Model and Practices to determine feasible next steps | Determine required metrics, impact of next steps on metrics Identify Business Case Scope Identify Objective Focus Engage Cross- Functional Leaders | Position End Goal, Impact and Business Case Leverage frameworks and statistics to underline need for executive sponsorship |
|--|--|---|--|---|---|
| 1 IDENTIFY END GOAL AND IMPACT | 2 ASSESS "AS IS" STATE | 3 IDENTIFY "AS IS" QUALITY MATURITY | 4 IDENTIFY NEAR TERM INCREMENTS | 5 BUSINESS CASE JOURNEY | 6 EXECUTIVE SPONSOR- SHIP |
| | | | | | |

Evidence of Value

Quality leaders have difficulty connecting quality management best practices and non-siloed metrics. This challenge prevents leaders from building cross-functional business cases based on financial metrics, such as Cost of Quality. It forces departmental business cases based on siloed metrics.

LNS Research performed an analysis to quantify the impact of adopting quality management Operational Excellence best practices. Survey data was analyzed to compare the mean performance of respondents that had adopted the best practice versus those that had not. As an example, those that had implemented "Compliance processes are easily understood and documented" had a mean Supplier Defect Rate that was 34% lower than those that had not implemented this practice. In this manner, 46 best practices and 12 quality metrics were analyzed for a total of 552 data points.

The data below displays representative process and technology practices for each tier of metrics.

| | OpEx | BEST PRACTICE | BENEFITS |
|------------------------|------------|---|--|
| | PROCESS | Compliance processes are easily understood, documented. | 2%↑ FPY, 34%↓ SDR |
| SILOED | TECHNOLOGY | Supplier quality data collected automatically through portal. | 2%↑ FPY, 45%↓ SDR |
| io i | PROCESS | Formal NC/CAPA processes established across company. | 1%↑ 0EE, 8%↑0TD |
| OPERATIONAL | TECHNOLOGY | Automate Production Part Approval Process. | 8%↑ OEE, 7%↑OTD |
| \$ FINANCIAL | PROCESS | Formal audit management processes. | 30% ↓ COPQ-Internal 15% ↓ CoPQ-External 13% ↓ CoGQ-Appraisal 9% ↓ CoGQ-Prevention |
| | TECHNOLOGY | Deploy EQMS. | 27% ↓ COPQ-Internal 10% ↓ CoPQ-External 7% ↓ CoGQ-Appraisal 1% ↓ CoGQ-Prevention |
| | PROCESS | Suppliers are included in design for quality initiatives. | 12% ↑ Successful NPI |
| VALUE | TECHNOLOGY | Deploy EQMS. | 21% ↑ Successful NPI |

METRICS KEY

FPY = First Pass Yield SDR = Supplier Defect Rate OEE = Overall Equipment Effectiveness OTD = On Time Delivery CoPQ = Cost of Poor Quality CoGQ = Cost of Good Quality NPI = New Product Introductions

A Sample Business Case Journey

The frameworks and content provided can be condensed into the six steps needed to gain executive sponsorship. Steps 1 to 3 align with constructing the master business case; Steps 4 and 5 capture the construction of the incremental business cases; and Step 6 is gaining executive sponsorship. The resultant master and incremental business cases are iterative and will change with input from other leaders, executives, and time.

As stated earlier, the ultimate end goal should be connected to strategic objectives and a desired quality maturity level. New strategic objectives can serve as compelling events. As an example, quality improvement is a leading use case for investment in IoT. However, investing in IoT to drive quality improvement should be coupled with broader investment in quality operational architecture, such as EQMS, in order to connect the information from IoT to the quality system of record. In this way, quality is enabling the strategic objective and optimizing Operational Excellence.

IDENTIFY END GOAL AND IMPACT

ASSESS "AS IS" STATE

IDENTIFY "AS IS" QUALITY MATURITY

IDENTIFY NEAR TERM INCREMENTS

> **BUSINESS CASE** JOURNEY

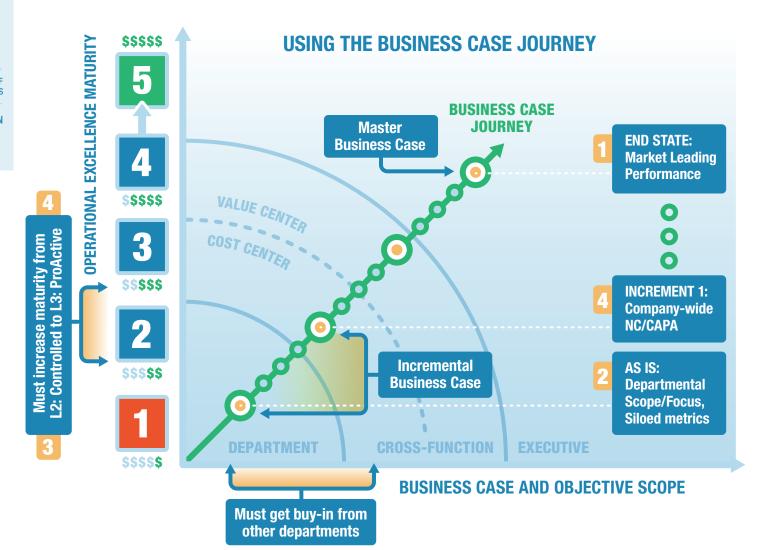
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A Sample Business Case Journey (Cont.)

When building incremental business cases, quality leaders should drive credibility by delivering maximum value as soon as possible. LNS recommends identifying low hanging fruit while performing the as-is assessment. There are often opportunities to make smaller investments that drive highly visible value, provide short time-to-value, are simple to deploy, or make measurable progress towards key objectives identified in Step 1. Use these initial successes to nurture executive sponsorship and cross-functional engagement.







Actionable Recommendations

Summary and Actionable Recommendations

Many quality organizations have low quality maturity, exemplified in part by low levels of software automation. This poor technology landscape is their biggest challenge in achieving their strategic quality objectives. Quality is also seen as a department rather than a responsibility, although it must be deployed across the organization to drive optimum value. Quality leaders need to gain executive sponsorship in order to drive quality maturity and improve operational and financial performance. Executive sponsorship for quality is gained through compelling events, and the executive business case is a positive and controllable compelling event.

Executive business cases must demonstrate alignment to strategic objectives as well as provide a journey from the initial as-is state to an identified ultimate end goal. This is accomplished by using both a master business case as well as many supporting incremental business cases. The master business case is aligned to the strategic objectives and ultimate end goal, and is the tool that will gain executive sponsorship. Many incremental business cases are identified to support the business case journey from the initial as-is to the ultimate end goal. The business case must consider Operational Excellence impacts and quality maturity as well as operational architecture.

The executive business case must also provide proper evidence of value to justify investment and executive sponsorship. Quality leaders must be able to leverage operational, financial, value, and even Big Data metrics to justify and track quality value.

Organizations looking to drive increased maturity should take the following steps:

- Break out of the quality silo by establishing the business case for quality management itself. The business case for quality management is not the prevention of defects, but rather achievement of cross-functional and strategic objectives. The business case should clearly identify the value of quality and support it through carefully chosen metrics, such as those provided by LNS Research.
- Develop many incremental business cases to support the master business case for quality management. These incremental business cases should progressively push quality out of the silo and throughout the organization following a quality maturity model. They will shape a culture of quality and change the role of the quality department.
- Allow other leaders to constructively share ownership. Moving quality management out of the silo transforms the initiative from being a "quality" initiative to a cross-functional or strategic initiative, and other leaders will share ownership to help enable the transformation. This is a natural extension of "Quality is a Responsibility" and is welcome.
- Use the executive business case to gain executive sponsorship. Without executive sponsorship, cross-functional initiatives are often viewed as discretionary and may conflict with the priorities of other functional leaders. The executive sponsor can help overcome these hurdles and other obstacles.

Summary and Actionable Recommendations (Cont.)

- Nurture executive sponsors after gaining sponsorship. Careful-٠ ly select incremental business case opportunities to increase quality maturity, realize short time to value, and be sure to measure success.
- Identify opportunities to leverage technology to support cross-functional and strategic objectives and enable cross-functional pro**cesses.** Proper technology selection criteria should emphasize requirements that elevate quality out of the silo and encourage cross-functional participation. Some recommendations include:
 - Provide a single platform for quality, such as an EQMS with broad process support. Set a goal of simplifying the access to quality data and processes for all stakeholders to drive cross-functional engagement.
 - Focus on using the single platform to enable cross-functional processes. Substantial value is derived through cross-functional process support. Consider selection of an EQMS and deploy company-wide processes such as corrective actions or audits.
 - Connect to other enterprise systems to increase the cross-functional value of quality data and processes. When cross-functional users and leaders perceive value, adoption and participation greatly increases.
 - Engage IT early-and OT leaders if aligning with Digital Transformation objectives-to be sure to get buy-in and guidance on preferences on considerations like Cloud and Analytics. Cloud is a good option in many cases to simplify deployment and prevent roadblocks.

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MANAGEMENT

APPENDIX

Impact of Executive Sponsorship on Quality Maturity

ADOPTION RATE

| Best Practice | With Executive Sponsorship of Quality | All Other Companies |
|--|--|------------------------|
| Ability to identify risk factors across operations. | 30% | 10% |
| Ability to prioritize risk factors across operations. | 22% | 8% |
| Ability to quantify risk factors across operations. | 22% | 8% |
| Ability to track mitigation of risk factors across operations. | 20% | 7% |
| Ability to visualize risk factors across operations. | 19% | 6% |
| Closed-loop processes established to connect quality across design, manufacturing, and suppliers. | 21% | 4% |
| Compliance processes are easily understood and documented. | 43% | 15% |
| Cross-functional teams in place to manage quality across design, manufacturing, and suppliers. | 33% | 9% |
| Formal audit management processes established to understand current compliance status and identify area for improvement. | 45% | 19% |
| Formal NC/CAPA processes established across company. | 36% | 15% |
| Formal risk management framework established. | 34% | 13% |
| Process established to share compliance processes across functional areas. | 33% | 10% |
| Real-time visibility of quality metrics in customer service. | 23% | 8% |
| Real-time visibility of quality metrics in engineering. | 17% | 4% |
| Real-time visibility of quality metrics in manufacturing. | 28% | 9% |
| Real-time visibility of quality metrics in supplier performance. | 21% | 6% |
| Standardized escalation processes exist for supplier quality and non-compliance events. | 27% | 9% |
| Statistical analysis used to monitor and analyze real-time supplier quality data. | 12% | 4% |
| Supplier quality data collected automatically through web-based portal. | 12% | 3% |
| Supplier scorecards established to measure and monitor performance | 26% | 10% |

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