BUILDING A BUSINESS CASE FOR QMS INVESTMENT

Do you have a compelling business case to support your QMS goals?

Honeywell

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MANAGEMENT SUMMARY

1

Life Sciences manufacturers today face enormous challenges in managing quality and compliance.

The expectation on quality teams to add value across the entire business has never been greater, supporting key enterprise-wide initiatives, accelerating product innovation and time-to-market, and delivering a mission-critical cross-functional service.

All quality teams still share the same five common imperatives that they must uphold—patient safety, supply continuity, compliance, product quality and efficacy.

Mode 1 is synonymous with operational stability, predictability, efficiency and incremental continuous improvement. It's often characterized by the need to drive down Total Cost of Quality (TCoQ). Mode 1 is risk averse and focused on prevention. Mode 1 can be viewed as these micro challenges effecting quality.

Mode 2 is exploratory. It is about innovation, speed and big-step changes. It is risk-tolerant and proactive, where fast failure is even allowed. Today's macro industry trends of Digital Transformation and Industry 4.0 epitomize Mode 2.

The right quality management system (QMS) can help quality capitalize on this bimodal challenge and deliver value; as well as help increase an organization's overall agility, scalability and productivity.

However, with many manufacturers focused on managing costs, you need a strong business case to gain buy-in for any QMS investment.

QMS INVESTMENT OPTIONS VS QMS REQUIREMENTS

2

If you're on the team responsible for product quality and regulatory compliance, you might have already decided that your organization needs to invest in its QMS to overcome specific challenges.

But how do you determine the right level of investment?

The necessary investment will depend, first and foremost, on whether you want to expand an existing QMS solution or implement a new one. Each option requires its own evaluation and mapping-to-requirements and will involve additional tasks or components in your business case calculations. In Diagram 1, see sample QMS requirements that can quickly determine initial QMS investment options. With a cloud solution, that scalability is built into the system, and new functionality can be snapped into the system using an API rather than requiring a time-consuming new build.

QMS INVESTMENT OPTIONS	EXPAND AN EXISTING QMS	IMPLEMENT A NEW QMS
QMS Requirements	• New processes • New capabilities • New business group or department • New sites • More users	• Transition from paper or manual systems • Consolidation of multiple disparate systems • Replacement of outdated system • Migation to cloud/digital technology

Diagram 1

ALIGN WITH QUALITY OBJECTIVES AND PRIORITIES

3

When considering QMS investment options, you need to ensure they clearly align with and support your company's quality management objectives.

This is paramount for building a compelling business case for QMS investment. Your quality objectives should underpin all quality management planning, including any QMS projects and initiatives. They should also align with top-level business objectives and support the needs of IT, manufacturing and other departments.

When formulating your objectives, you must consider:

- What are your core quality management needs and goals? (Mode 1)
- Do these quality goals align with broader business challenges?
- How do—or might—future trends, needs or challenges impact and influence your objectives? (Mode 2)

According to an LNS survey[1] of more than 1,300 top executives, siloed quality data and hard-to-integrate systems are the No. 1 operational challenge in quality management. A lack of quality metrics takes the second spot. Low visibility into supplier quality is also among the top 10 concerns. (See Diagram 2).

If, like the LNS survey respondents, your biggest challenge is disparate quality systems and data, then implementing a new QMS can help you consolidate siloed quality systems and data into a single enterprise QMS.

However, if lack of quality metric reporting or supplier quality is your most pressing issue, you might be able to simply expand the capabilities of your existing QMS, so long as it offers that functionality.

BY SOLVING THREE MAJOR PROBLEMS WITH ONE QMS INVESTMENT IN THIS WAY, YOU ALREADY HAVE THE BUILDING BLOCKS OF A COMPELLING BUSINESS CASE.

More significantly though, the right QMS built on a reliable platform, can solve all three of these problems by providing:

1. A single enterprise-wide system that consolidates multiple systems and data sources
2. Reporting and dashboard capabilities that deliver meaningful insights and intelligence
3. Supplier quality management capabilities that extend into your external supply chain

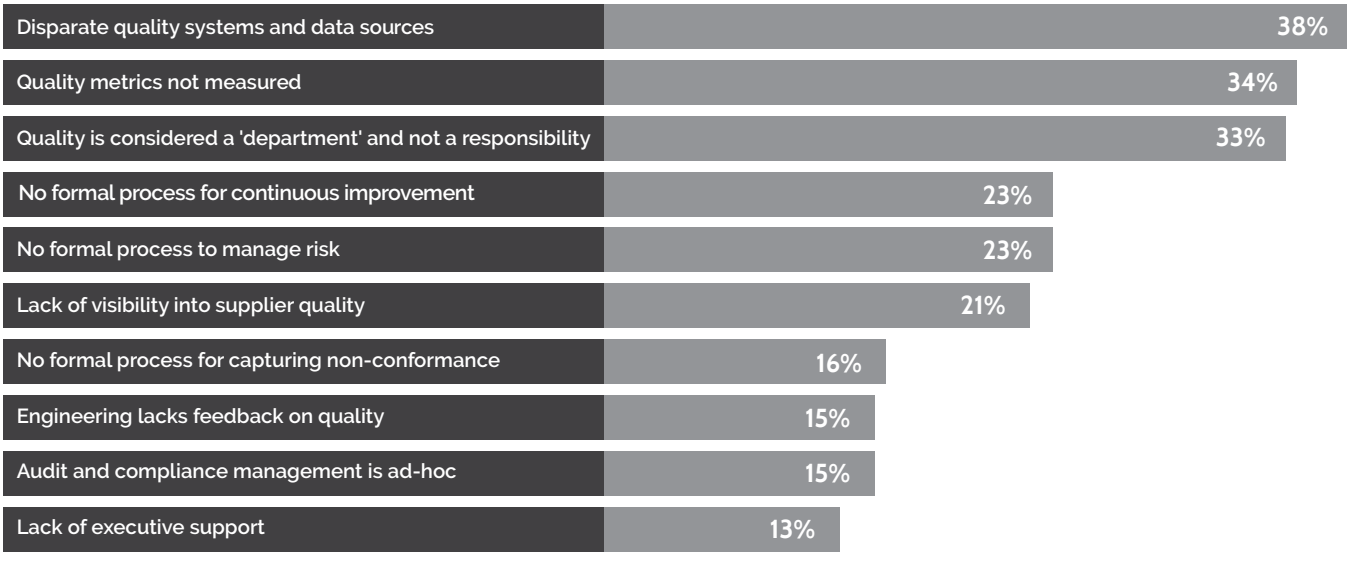

Diagram 2

QMS DEPLOYMENT OPTIONS

4

Traditionally, QMS solutions are focused on managing, tracking and reporting a company's quality management processes.

These include:

- Incident management
- Corrective and preventive actions (CAPAs)
- Audit management
- Complaint handling
- Change control

Advances in technology—and evolving regulatory requirements—drove the adoption of QMS software. Customer needs prompted QMS vendors to add additional capabilities, such as document management and training management (often provided as add-on modules).

A decade ago, QMS software solutions were hosted only on-premises. Since then, increasing access to strong internet connections and advances in technology have led to the development of cloud-based, software-as-a-service (SaaS) QMS solutions. Innovation like this has opened more QMS options than previously available, but which is right for you?

There are typically three main options for QMS deployment:

OPTION 1: Modern on-premises QMS

- Interest in modern features/functions and enhanced user experience
- Need to implement or maintain numerous custom configurations
- Need to maintain onsite storage of quality data
- Limited or unreliable internet access
- No digital or cloud initiatives imposed on the quality group

OPTION 2: Hybrid QMS environment

- Preference to extend existing on-prem QMS investment
- Outsourced manufacturing, or a complex supply chain
- Recent acquisition of a business or product line with independent processes
- Preference to maintain an on-premises QMS at one or more sites, whilst enjoying faster deployment and affordable scalability at other sites
- Need to gain insight into the supply chain without giving suppliers direct access your QMS
- Desire to harmonize Complaints or Intake processes across sites
- Aspiration to implement AI-based automation

OPTION 3: Fully digital cloud

- Internal 'cloud' strategy
- One or more digital transformation champions
- Adopting innovation such as smart sensors and equipment, AI capabilities, etc.
- Greater access to digital documents needed to support a mobile workforce and culture of quality
- Workflow optimization by using pre-validated process configurations
- Advanced reporting and analytics to monitor quality events and metrics

APPLY A QMS DIGITAL MATURITY MODEL

5

Increasing regulatory, industry and customer demands, as well as a global focus on agility and scalability, are driving life science manufacturers to evaluate their overall digital maturity.

Your QMS should be a vital part of your overall digital strategy. As a result, many companies now evaluate their current and future QMS needs against a QMS digital maturity model.

Here is one example of a QMS digital maturity model (Diagram 3). Where are you as a quality organization? And where do you need to be to meet your quality goals?

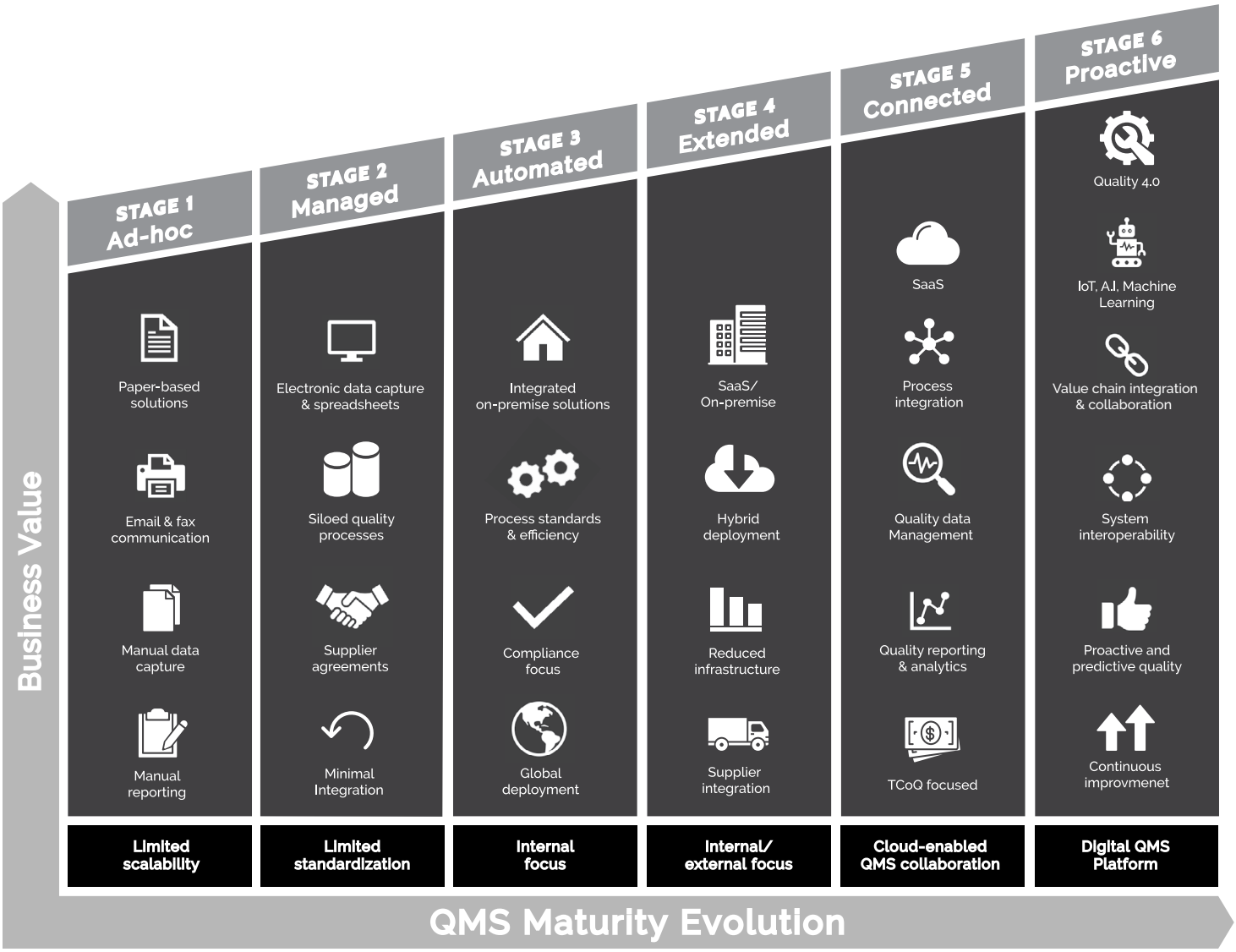

Diagram 3

STAGE 1: AD-HOC

Quality management is comprised of fragmented processes. Data collection is manual, and paper based. Communication is through email and fax. Such an organization doesn't have access to quality data to make actionable business decisions.

STAGE 2: MANAGED

Electronic quality data capture exists, but possibly only in spreadsheets. Quality systems extend to some supplier management functions. No specialized quality management software to aid compliance and increase efficiencies.

STAGE 3: AUTOMATED

On-premises quality management software has been adopted and there is governance for most quality process standards that lead to streamlining of product compliance. Quality data is accessible, but not easily correlated for decision-making.

STAGE 4: EXTENDED

QMS software is a hybrid of on-premises and cloud, benefitting from adding capabilities to your core on-premises QMS via integrated SAAS modules. This can allow for a secure extension of your QMS to suppliers, vendors and 3rd parties, or adding further processes like Complaint Handling, Quality Risk Management, Product Registration Tracking or Supplier Quality Management.

STAGE 5: CONNECTED

Highly intentional and globally harmonized quality management systems, including reporting and analytics for quality data that can lead to business decisions. Processes are integrated with suppliers throughout the value chain.

STAGE 6: PROACTIVE

Best-in-class quality management leveraging the latest Industry 4.0 technology. QMS software is cloud-based and includes elements of IoT and artificial intelligence (machine learning and natural language processing), to make proactive and predictive quality decisions. By connecting quality data and decisions across manufacturing operations and enterprise systems to detect process and product deviations or non-conformances in real-time, organizations stand to improve operational stability, predictability and efficiency. Quality is integrated across the organization as a cultural value, enabling collaboration as a fluid way of working, to achieve positive business and customer outcomes.

A QMS digital maturity model like this will help you determine where you are now and where you need to be – but also more importantly the type and level of QMS investment required to get there.

IDENTIFY KEY STAKEHOLDERS

6

Convincing peers, supervisors and executive management that investment in your QMS is a worthwhile investment can be a challenge with ever-present cost controls.

You must be able to prove significant measurable business value, but it is inevitable you will face competition from other departments, such as Operations and IT, whom must be convinced of the value a QMS provides for them.

When identifying stakeholders, it's important to consider where value will be realized in your organization, beyond your immediate department. Ultimately significant cost savings can reside in functions such as manufacturing or R&D, even though the QMS investment will be owned by the quality function. Essentially any business function or division invested in or potentially saving costs or avoiding costs as a result of such a project, is an important stakeholder group to identify and engage with.

BUILD A STRONG NETWORK OF SUPPORT FOR YOUR BUSINESS CASE PROPOSAL

Within these stakeholder groups be sure to identify the primary stakeholders by role, in the context of your QMS investment business case (Diagram 4):

- The Champion has a personal interest in approving the investment
- The Buyer has discretionary approval to approve the investment
- The IT Partner has a say in any QMS software adoption or expansion
- The Executive must support the QMS throughout

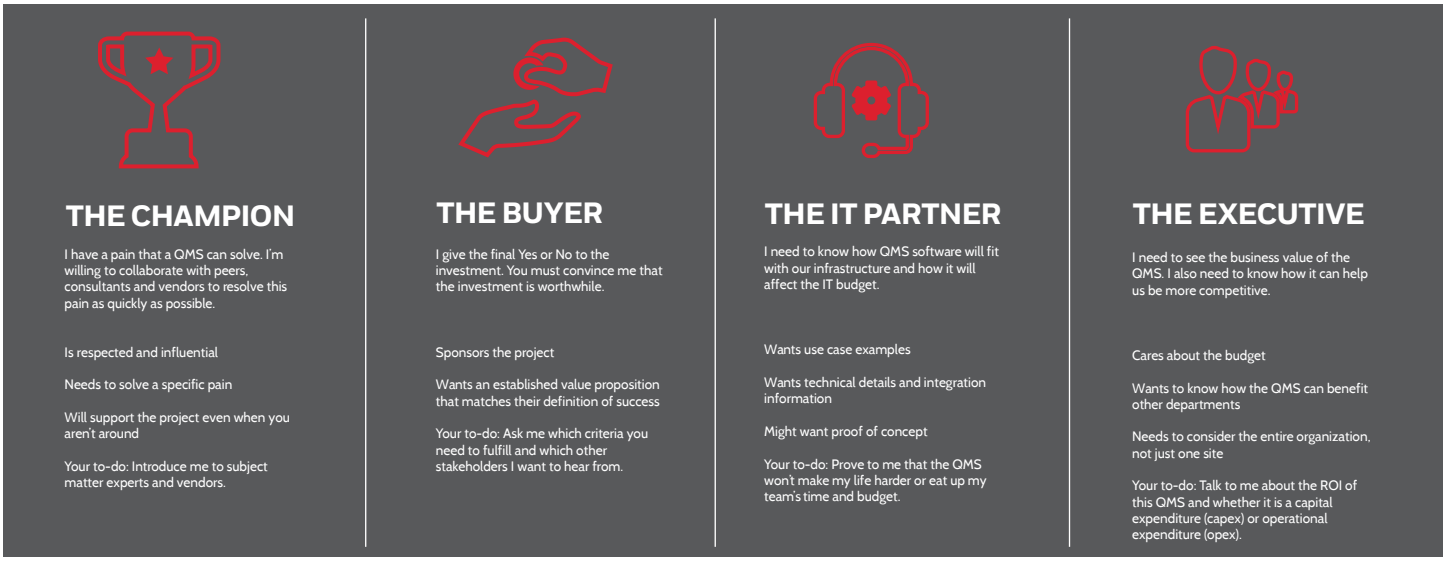

Diagram 4

It is important to build a strong network of support for your business case proposal. Furthermore, the ultimate success of your project, when you move from approval to implementation and launch, will also depend on the work you do up-front, to ensure organizational alignment.

ENSURE A COMPELLING AND COMPETITIVE BUSINESS CASE

7

In any organization, there is always a finite budget, and, as a result, internal competition for funding of key initiatives.

According to Gartner Research[2] (Diagram 5), 'Quality Solutions' are not always considered a leading investment priority. This underscores the importance of tying your QMS investment business case to wider business initiatives and headline company objectives.

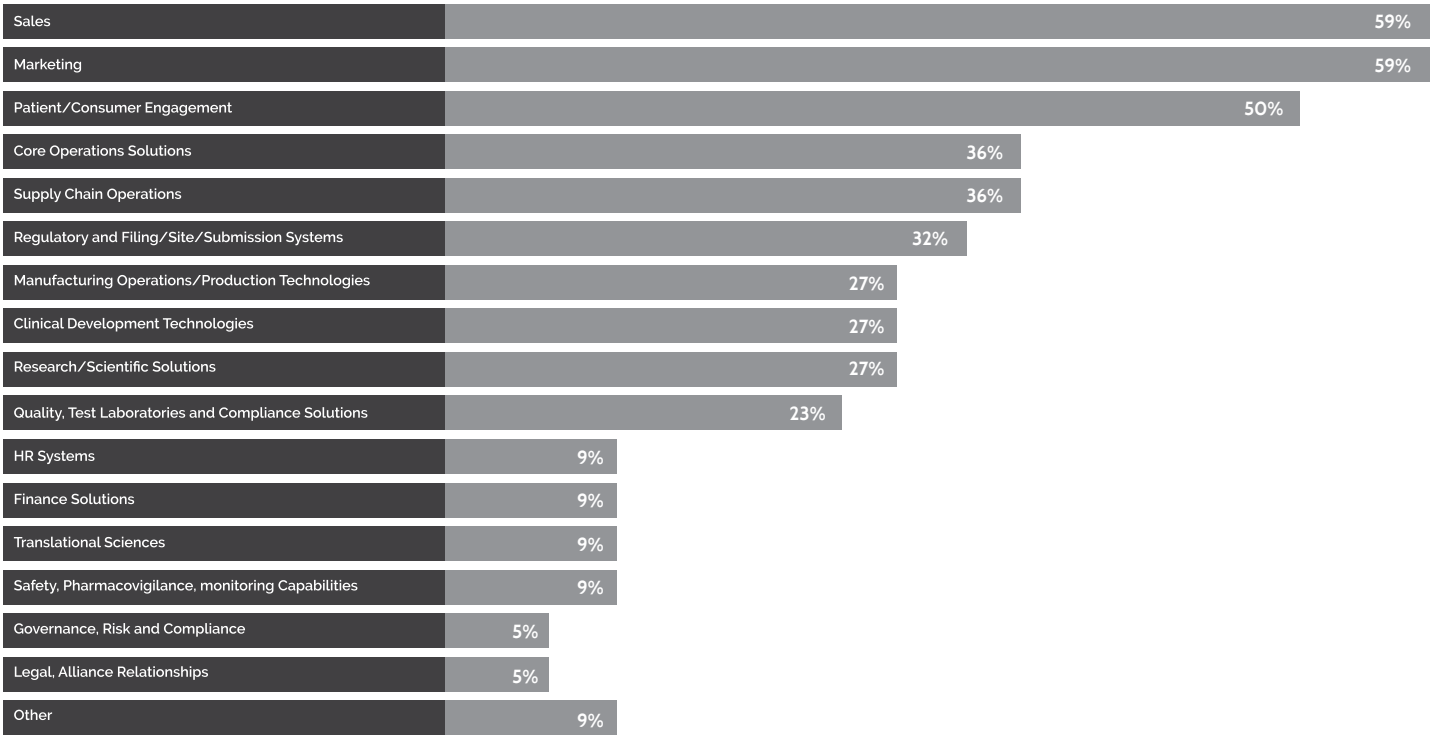

Diagram 5

For example, as more and more companies outsource elements of their supply chain, supplier quality oversight and visibility become even more critical to main product quality consistency, supply chain continuity and protect your brand. Subsequently, any direct alignment to the funding priority of supply chain operations will only help to elevate your QMS business case.

Equally, patient-centricity has become a key industry trend which life science companies are adopting as a primary business objective ('Patient/Consumer Engagement' in Diagram 5). Quality Management is playing a key role in patient-centricity initiatives, often in the management of complaint handling and resolution, another opportunity to align your QMS business case to a top funding priority.

The more funding priorities you can link to your QMS business case, the more competitive and compelling it will be when projects are reviewed internally against other proposals and budgetary requests.

THE IMPORTANCE OF TOTAL COST OF QUALITY (TCOQ)

Regardless of industry, all businesses have top-level objectives relating to both revenue achievement and cost reduction. Furthermore, in the life sciences industry, it's even reasonable to say that, in the past, Quality departments have often been perceived as a necessary cost center, required principally to ensure that mandatory regulatory compliance requirements are fulfilled, to allow a company to operate and sell in a particular market.

Although this perception has changed significantly, with the role and value of quality management being now accepted as broader reaching, it is still critical that Quality leaders continuously monitor and manage the Total Cost of Quality (TCoQ) across the business, and subsequently factor in to any business case for future QMS investment (How will such an investment support lowering the TCoQ?)

In definition, Total Cost of Quality (TCoQ) is a methodology that allows an organization to determine the extent to which its resources are used for quality across the entire company, not just the core Quality function.

"Many organizations will have true quality-related costs as high as 15 to 20 percent of sales revenue, some going as high as 40 percent of total operations. A general rule of thumb is that costs of poor quality in a thriving company will be about 10 to 15 percent of operations." – ASQ

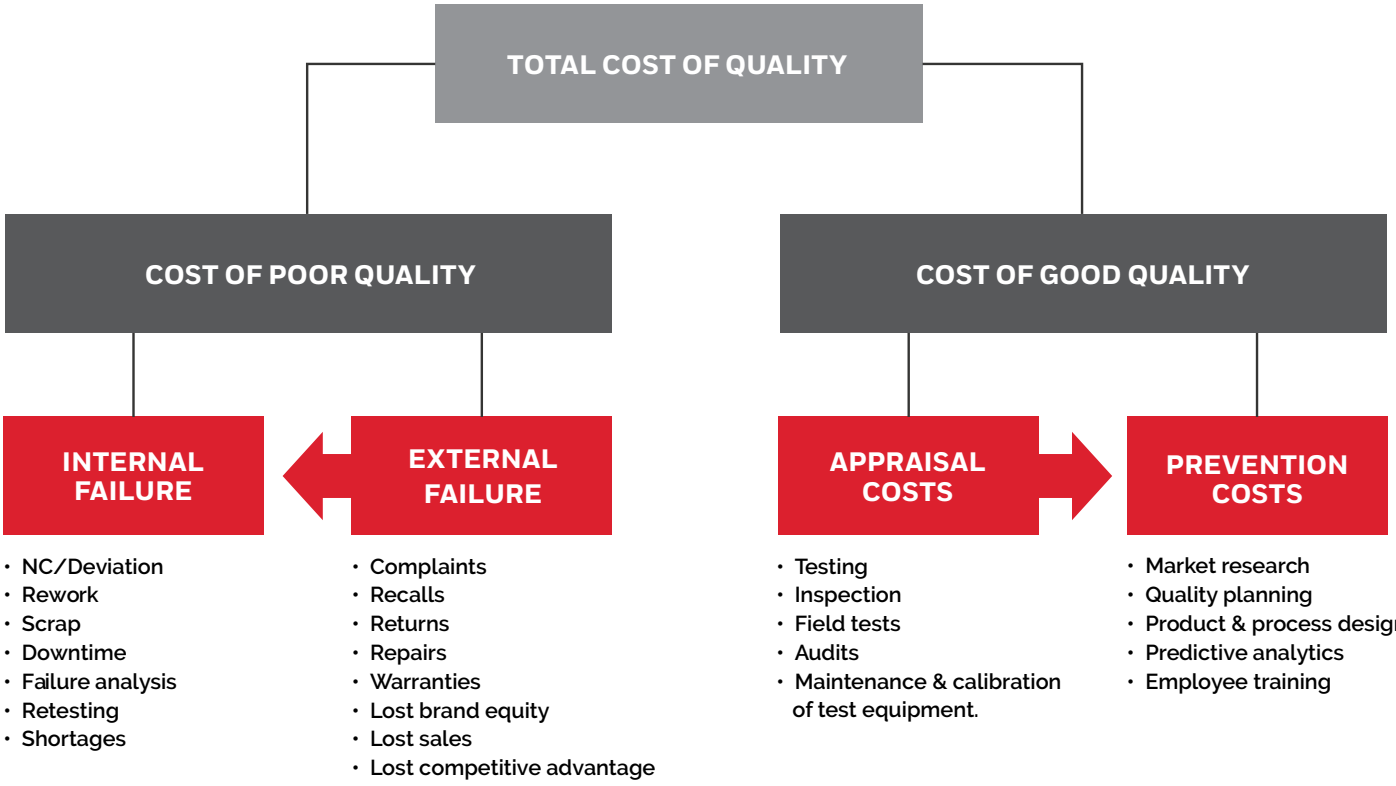

Diagram 6

MEASURE TCOQ

Achieving optimal TCoQ is only possible if you can first measure it. This creates its own set of challenges. Diagram 6 shows one methodology for categorizing quality-related costs, along with examples.

TCoQ can be challenging to measure for numerous reasons. The data you need might not be captured currently, or it may belong to other partners or supply chain partners. In addition, there will undoubtedly be data variability, site to site, region to region, business to business. Worse still, even if the required data is accessible, you might not know how to interpret or analyze the information appropriately.

A KPMG study[3] analyzed three different approaches for calculating the 'cost of quality,' by identifying contributing cost drivers. Whatever your chosen approach, it's important to relate some level 'cost of quality' improvements to your business case for QMS investment.

1 VISIBLE VS HIDDEN

Hidden quality costs can include unnecessary validation as a result of misinterpretation of regulator requirements, longer lead times due to extended holds on supply, or lost revenue opportunity from product recalls.

2 PROACTIVE VS REACTIVE

Understand proactive cost contributors, such as those that support Cost of Good Quality including training, internal audits, and risk assessments. Reactive costs can include field actions, nonconformances and escalations, which according to KPMG analysis can attribute to as much as 40% of overall Quality costs.

3 INSIGHTS VS TRANSACTIONS

This approach looks at Quality costs as either providing real insights or is transactional in nature.

Diagram 7

BUILD YOUR BUSINESS CASE IN 5 STEPS

8

As you read through the following 5 steps, keep in mind that you'll need to tailor them to the needs of your organization.

You might find that you can move quickly through certain steps but need to drill down more deeply into others.

Also, be aware that building a business case is not always a linear process. You might gather all the data you think you need—and then realize that you need different information or that a new stakeholder has entered the picture. Such changes are a normal part of building a business case. External factors will evolve as you move through the process, so be prepared to accommodate such changes and shifts.

STEP 1: UNDERSTAND THE APPROVAL PROCESS

Before building your case, you must understand the process your company uses to evaluate potential investments.

- Meet with your immediate supervisor, someone in the finance department or a person who has led a similar project through the approval process.
- Discuss the specific steps that your company expects, which may differ somewhat from this list.
- Identify key stakeholders whose support you need.

NO BUDGET?

During your due diligence, you might discover that no budget is available for new IT projects currently. Don't be discouraged; you can still assemble your business case, and you'll know which year's budget you'll be aiming for and what your project's time frame will be.

STEP 2: IDENTIFY YOUR CHAMPION AND WIN STAKEHOLDER SUPPORT

To make the case for a QMS investment, you need organizational support. Key internal stakeholders must be involved and invested in the project. Even if the proposed investment project delivers positive improvements, stakeholders might still be unsupportive if they feel it has been forced upon them or they have been inadvertently excluded from the evaluation and decision-making process.

Find Your Champion

You need a partner with both the organizational leverage and the willingness to move the proposal up the hierarchy. Your Champion could be a quality leader, a senior IT manager or even someone in finance. Champions should be involved in financial decision-making about major new projects. They should also have the trust of those at the top. It is also beneficial to have multiple champions where feasible, even if one stands out as a frontrunner with more direct personal interest in your proposal being successful.

Once you identify your project champion, learn about their specific priorities.

For example:

- An IT-based Champion might care most about reducing support and maintenance costs by consolidating infrastructure and reducing the number of systems their department needs to manage
- A finance Champion might care most about the hard costs involved i.e. IT system capital and operational running costs, staffing costs etc., followed by reducing costs around recalls and waste, as well as future-proofing any investments
- A quality Champion should understandably be most closely aligned to your QMS business case and be able to support and articulate a plethora of business benefits and priorities the investment would support. Even so, they will most likely have specific priorities or initiatives they will personally be looking for you to convincingly address in your business case

Do the research. Has a recent issue dominated decision-making in your Champion's department? Is their area of interest or expertise targeting a relevant industry challenge?

Next, determine whether your proposed QMS investment can help to address your Champion's needs. If so, you should emphasize that capability as you present your business case to them. If not, yet you think the Champion's department would benefit directly from the investment in the short or long term, discuss that benefit. Convincing your Champion to back your case is good practice for influencing the other stakeholders you'll need to win over.

Win Over Stakeholders

Hold thoughtful conversations with stakeholders across the various business units that your proposed QMS investment will affect. Ask them about their priorities, what they think needs to be improved and what they would like to see changed. Your willingness to listen, discuss, adjust and make them part of the change process will help you build their support, gain momentum for your ideas at all levels of your company and gauge the extent of your organization's openness to change.

STEP 3: ENGAGE WITH QMS VENDORS

Although vendor selection criteria is formally addressed later in the buying process, it can be advantageous to engage with potential vendors earlier on. Most reputable QMS vendors will naturally have worked on a much high number of QMS projects that they can share their experiences on. Equally they can share info on the various deployment options and capabilities available to meet your business case goals. Engaging with the right vendors in this way will provide you with valuable information and insights to support your business case development.

Furthermore, you will require initial cost estimates to complete the financial elements of the business case; and ultimately demonstrate the monetary value gained from the proposed QMS investment. Ensure all costs are accounted for, whether they be for software and ongoing maintenance or SaaS (Software-as-a Service); as well costs associated with installation, training, upgrades, future expansion plans or anything else that may be relevant.

STEP 4: GATHER SUPPORTING DATA AND SHOW MEASURABLE VALUE

Your business case needs to justify the financial expenditure on your proposed solution. You will need to capture all tangible benefits that the company would achieve, and then place a defensible monetary value on those benefits - in terms of both revenue improvements (where possible) and savings to the organization in a given time period.

Objective	Primary Value Driver	Example Business Benefit Components
Reduce internal costs	Reduce costs from regulatory action	• Reduce recall costs • Reduce inspection costs • Reduce inspection headcount
	Reduce cost of quality processes	• Reduce administration costs • Reduce resourcing requirement from streamlined processes • Reduce complaint volume and handling costs
	Reduce cost of poor product quality	• Reduce scrap costs • Reduce re-work/sort costs • Reduce cost of returns • Reduce warranty claims
Reduce supplier related costs	Reduce cost of managing supplier relationships	• Reduce data re-entry into ERP • Reduce manual tasks by suppliers • Reduce costs of supplier related delays
Increase profitability	Increase operational efficiency	• Reduced hours lost to re-work • Reduced hours lost to manual administration and processes • Reduced hours lost to poor quality • Increase production capacity

Diagram 8

Your research to date should have uncovered the measures and metrics expected for business case approval, but if necessary, ask your Champion to help you gather the resources and information necessary for this task.

Identify Quantifiable Business Benefits

Identify the top three to five quantifiable objectives that the proposed QMS investment will fulfill. Drill down and identify the primary value drivers and their associated business benefits to demonstrate how you are determining the value gained. The table above (Diagram 8) outlines a simplified way of approaching this using a Medical Device company looking to invest in an electronic QMS as an example.

Collect Baseline Metrics

Work with your stakeholders to analyze current processes and cost elements, then identify baseline metrics relating to your proposed value drivers and their business benefit components. Below is a simplified example associated with 'reducing the cost' of the CAPA quality process and listing potential baseline metrics by product.

Primary Value driver: Reduce cost of quality processes

Process = CAPA management

1. Number of product related CAPAs generated each month
2. Cost per hour of staff managing the product's CAPA lifecycle
3. Time expended to complete a product's CAPA lifecycle
4. Number of under-reported or miss-processed CAPAs per month
5. Cost associated with each under-reported or miss-processed CAPA record
6. No of recalls performed as a result of ineffective CAPA process
7. Cost of each recall, associated with ineffective CAPA process

Collecting these metrics will enable you to calculate an approximate Cost of CAPA of Management in the current QMS state.

Incorporate a Current vs Future State Model

Now that you have collected baseline metrics for the current state, you will need to show how the new QMS investment will drive improvements in the form of future state metrics. Since this can be a subjective part of the business case, it's often beneficial to consider two scenarios for identifying improvements to your metrics:

- Conservative - assume that change-management-related inertia will slow the improvements to each process.
- Most Likely - assume that strong sponsorship from the management team will enable the most likely process improvements but factoring in some change management-related pushback.

Continuing with the CAPA Management example used previously, you can now start to tabulate comparative metrics to demonstrate expected improvements from your QMS investment.

DEFINE 'VALUE'?

Value can be difficult to define, but is most commonly categorized into 3 main types:

- Cost savings
- Cost avoidance
- Brand protection

Expand Metrics to Meet Business Case Needs

Baseline and future state metrics can be captured for some or all product lines depending on the depth of business case required. Focusing metrics just on your company's primary products and then providing an extrapolated view for your full product portfolio, based on some key assumptions, could also suffice depending on the level of QMS investment you are looking for and your organizational size, structure and requirements.

The same applies for quality processes in the earlier example; metrics for all or some could be considered in the business case. Either way, prioritize the high value, high impact processes – those whose improvement will deliver the highest cost savings.

Most importantly, always keep your original business case goals in mind when evaluating which metrics to utilize – directly relating them to key company objectives and funding priorities wherever possible.

CAPA Process Metric (per month)	Current	Conservative	Likely
CAPA Investigation (days)	30	20	15
CAPA Execution (days)	25	18	15
No. of Under-reported CAPAs	5	1	0
No. of CAPA Related Recalls	1	0	0
QA FTE (Investigations)	4	3	3
QA FTE (CAPA)	3	2	2

Diagram 9

Develop ROI Data and Monetize the Business Case Benefits

Now that you have collated an expanded set of key metrics to support your business case at various levels, these can be accumulated and mapped to the proposed QMS investment itself, in terms of actual Costs vs Cost Avoidance, to create a more complete ROI (Return-on-Investment) model.

The diagram below illustrates a simplified example of such an ROI model, in the context of a Medical Device organization with a proposed business case to move from a legacy on-premises QMS to a modern digital QMS solution. They have approximately 300 users and manage around 15,000 quality records a year. Their goal is to simplify and standardize their core quality process whilst adding innovative capabilities to improve operational efficiency, reduce costs and enhance quality management oversight and decision making.

The first two tables (diagram 10 & 11) compare the 'hard costs' to run and operate each QMS. Hard costs refer to the visible expenditures on items such as IT systems or staff headcount, which are usually the first to be scrutinized in any business case i.e. where are we making hard cost savings via headcount reduction, technology reduction (hardware, server software, hosting) or by eliminating ongoing software maintenance fees.

In Year 1 you will see there is a negative ROI as expected, due to the initial implementation cost for the new system. Furthermore, when implementing a new system, there is usually an overlap period, whilst you are running both old and new systems in parallel, as you migrate data and users over. As a result, Year 1 'hard costs' will be even higher, and this will need to be factored into your business case. By Year 3 you start to see incremental cost savings when you compare the running costs of your new QMS vs old. However, in this example, these savings alone are not enough to show a positive ROI, simply due to the inflated outlay in Year 1 of potentially running two systems in parallel. Companies will look to minimize this overlap period, and

EXISTING On-premises QMS – 'Hard Costs'

(Assumes initial software and implementation costs have already been recognized/absorbed in a prior period)

Cost	Year 1	Year 2	Year 3	Year 4	Year 5
Maintenance (3% annual increase)	$103,000	$106,090	$109,273	$112,552	$115,929
Internal/External Hosting	$50,000	$50,000	$50,000	$50,000	$50,000
Upgrades	$45,000		$45,000		$45,000
IT Staffing (21% of Maint. /+hosting)	$32,130	$32,779	$33,447	$34,136	$34,845
Total Cost:	$230,130	$188,869	$237,720	$196,688	$245,774

Diagram 10

NEW Digital Cloud-based QMS Solution – 'Hard Costs'

Cost	Year 1	Year 2	Year 3	Year 4	Year 5
Annual Subscription	$200,000	$200,000	$200,000	$200,000	$200,000
Initial implementation	$100,000	-	-	-	-
Total Annual Cost:	$300,000	$200,000	$200,000	$200,000	$200,000

Diagram 11

often account for this period of higher costs in their financial planning.

However, this is where your due diligence, building your business case for QMS investment can really start to make a difference. For the same example, the table below (diagram 12) shows the accumulated value of 'cost avoidance' by implementing a Digital QMS solution to drive quality process optimization whilst additionally capitalizing on its modern capabilities, such as:

• **Mobile enablement** - providing 24/7 access to your QMS. Reducing the costs associated with having no QMS access; when off-site for example, incurring potential late entry of quality events or pertinent quality data.

• **Self-service reporting and analytics** - reducing the time and cost spent relying on specialist resources to produce accurate and meaningful reports, providing quality leaders with true metric-driven management oversight allowing them to make the right decisions faster.

• **AI augmented decisions and triage** – if available, capitalizing on embedded artificial intelligence (AI) capabilities in your QMS can significantly streamline key processes, reduce human error and improve decision making. If applied to Complaint Handling, for example, not only can you achieve significant cost avoidance savings by reducing the time and resources to process and resolve incoming complaints, but also drive a proactive approach to complaint reduction and ultimately product improvement through early identification, tracking and trending of complaint-initiated quality events.

• **Supplier/Vendor Quality Collaboration** – extend your quality processes and standards throughout your external supply chain to reduce the cost of managing supplier, vendor and third-party relationships, and their potential risk to end-product quality.

Such capabilities amongst others will create additional cost avoidance efficiencies and further reduce the cost of poor product quality.

If we look again at the example, by embracing a modern and innovative QMS solution in this way, in Year 1, you already offset the costly challenge of running two QMS solutions in parallel, via cost avoidance: approx. $530K QMS hard costs (combined) vs $707K QMS (new) cost avoidance. By Year 2 you achieve an ROI of almost $700k due to the cost avoidance derived from your new QMS implementation.

In the real world, a company might add and onboard new QMS capabilities in a phased approach, but this simplified example gives a good indication of what is demonstrable with a solid data-driven business case. Equally, you will realistically need to factor in data pertaining to project risks, resourcing requirements and other key factors, depending on what you

Modern Digital Cloud-based QMS Solution – Cost Avoidance

(Assumes 300 users and 15,000 quality records per year)

QMS Value Driver	Year 1	Year 2	Year 3	Year 4	Year 5
Quality Process Optimization	$115,000	$115,000	$115,000	$115,000	$115,000
+ Mobile Enablement	$22,000	$22,000	$22,000	$22,000	$22,000
+ Reporting and Analytics (Self Service)	$95,000	$95,000	$95,000	$95,000	$95,000
+ Embedded AI augmented decisions and triage	$155,000	$155,000	$155,000	$155,000	$155,000
+ Supplier/Vendor Quality Collaboration	$200,000	$200,000	$200,000	$200,000	$200,000
Reduction in Waste/ Rework/Repair/Returns	$120,000	$120,000	$120,000	$120,000	$120,000
Total Annual Savings:	$707,000	$707,000	$707,000	$707,000	$707,000

Diagram 12

uncovered during your internal research on the business case approval process.

STEP 5: COMMUNICATE THE VALUE AND SEEK APPROVAL

Once you have collated all internal requirements, data and metrics you can create your initial business case proposal. This document needs to comprehensively detail your QMS investment business case from start to finish and must be continuously supported by consistent data-driven analysis and insights throughout.

It's important to keep in mind, the action of winning stakeholder support never really finishes, so continue to circle back with key stakeholders communicating your progress and findings, and get their feedback – before, during and after you create your proposal. To be successful, your Champion and key stakeholders need to be supportive of your business case before taking it through the formal submission process. Present your business case proposal, including findings and metrics to your Champion; then allow them, with your help, to use their political leverage to take the initial QMS investment proposal through the approval process.

Your proposal document will most likely need to be distilled into an initial business case presentation. Essentially your Champion will need to sell and justify your business case to the approving stakeholder group, so ensure you arm them with the information needed to present the QMS investment proposal and answer any questions. Focus the presentation on the key concerns and goals of your stakeholders along with management, so that all parties will understand the value and benefits of your proposed QMS investment.

Once you receive initial approval, there will realistically still be changes you need to make and 'gaps' you need to fill in your business case - based on feedback from the approving stakeholder group and/or management team. It is not uncommon to have to produce numerous iterations before getting the formal 'green light' to proceed with your project; and even then, adjustments will need to be made to meet business requirements as the project progresses.

HIDDEN VALUE. BIG IMPACT.

Although hard to measure, the synergistic effect of process optimization, improved visibility and greater accountability on quality management should not be overlooked or undervalued. It can have a substantial impact on a quality leader's ability to improve performance and drive value-add initiatives that contribute to revenue growth and other priority business objectives.

KEY FINANCIAL METRICS

Depending on your organization and the size of QMS investment, you may be required to address specific financial measures in your business case such as:

Payback Period (PP) refers to how many months it takes for the savings from a new technology to equal, and thus pay back, the initial investment and ongoing costs of its implementation.

Return on Investment (ROI) provides a figure for the ratio of savings to the cost of the investment.

Total Cost of Ownership (TCO) refers to the total cost of a process or software implementation over its lifetime, considering both upfront costs and ongoing recurring operating costs.

Net Present Value (NPV) refers to the present value of the project, including initial hardware, software and implementation costs, as well as ongoing recurring operating costs net of quantified benefits, adjusted for the cost of capital. If the NPV is positive, it indicates the project will yield a good investment above the cost of the capital.

Work with your champion and an appropriate representative from the finance team to ensure these measures are calculated accurately and represented most effectively in your business case, if necessary.

ACHIEVE QMS SUCCESS

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As discussed, presenting a successful business case is not a simple or linear process.

But if you follow similar steps to those outlined and keep in mind the importance of people, process and numbers in accomplishing your goals, you'll find that your proposal will be much more effective. Regardless of the timing of its approval, you will have acquired an understanding of your company's structure and processes. And you will have gained allies across the company, enabling you to build a stronger case for future projects or initiatives.

Furthermore the 'business case' represents only a first step in your journey towards achieving your QMS goals. Now you have an initial foundation to support your QMS project you will need to agree and build out your decision criteria for QMS investment and then your subsequent selection criteria for the QMS and QMS vendor itself. In both instances an in-depth understanding and alignment of your business and stakeholder needs and objectives will still be required as you continuously re-visit and develop your business case and project plan.

In the past, QMS solutions have often been viewed as an additional cost that must be incurred to help ensure and maintain compliance. However, if your organization methodically and properly approaches the QMS business case and subsequent steps that follow - ultimately leading to the successful implementation of a modern Digital QMS - it can not only benefit from greater and more efficient compliance, but also a 'quality platform' that drives significant cross-functional value, far exceeding initial ROI expectations.

Sources:

1. LNS Quality Management in the Board Room, 2016

2. Gartner Business Drivers of Technology Decisions for Life Science Organizations, 2020

3. KPMG Quality 2030: Quality Inside, 2019

For more information
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