MDIC Case for Quality Program

Value of Quality – Whitepaper

Good Quality is Good Business

November 2016

(for Review)

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1.0. Introduction

Are you looking to achieve new levels of efficiency? Reduce costs related to poor quality? Develop a reputation for quality and reliability? If so, this paper is written for you.

Since 2011, the FDA's Center for Devices and Radiological Health (CDRH) has been developing the *Case for Quality*, a program to shift the industry mindset from one of compliance to one of continuous improvement. CDRH has partnered with the Medical Device Innovation Consortium (MDIC) and the medtech industry to pursue the Case for Quality. Being able to understand and leverage CoPQ was identified as a key competency, providing insight to drive competitive advantage and top line and bottom line performance.

The ideas discussed in this paper are not new, they have been around for decades. However, for a variety of reasons, industry has been slow to be adopt them. Discussions with industry's quality leaders suggests that there are several barriers:

- **Low quality transparency**, driven by a lack of information for consumers and decision-makers around comparative quality
- **Increasing complexity** of medical devices and usage environments straining the current quality system infrastructure, and
- A perception that the **regulatory framework is misaligned with assurance of quality outcomes**.

Many within the medtech industry are comfortable with where their organizations are now. People believe that compliance to the regulations are all that is needed to participate in the marketplace. But that is changing. The days of allowing poor quality products into the market are gone. New companies, smarter companies, are adopting these Quality techniques from other industries, and are moving the paradigm from "Compliance Implies Quality" to "Quality beyond Compliance."

Customers are driving this change. Healthcare Providers are more and more measuring quality, and are seeing the value of quality. This drives higher expectations and a lower tolerance for poor or "baseline" quality products. The provider industry is moving from a reactive mode for quality issues to a proactive mode, and manufacturers will need to adapt.

2.0. Background

The FDA launched the Case for Quality in 2011 following an in-depth review of device quality data and feedback from both FDA and industry stakeholders. The FDA's analysis flagged manufacturing quality risks and showed that firms that manage those risks by driving quality organization-wide are more productive, with fewer complaints and investigations per batch, and often with smaller quality organizations with lower quality-related costs than their competitors. In other words, investing in quality pays. Firms with an established quality culture are able to use increased capacity resulting from avoidance of quality failures to accelerate device design, innovation, and market introduction.

The Case for Quality represents a major initiative to engage the medical technology industry and the FDA in collaboration to focus manufacturers and regulators on the design and manufacturing elements that have the

greatest impact on improving product quality and patient safety. MDIC is coordinating the work of four Case for Quality working groups: Maturity Model, Metrics, Product Quality Outcomes Analytics, and Competency.

This paper is a result of work completed by the Competency working group. The Competency team first built a competency model representing the broader healthcare ecosystem: manufacturers, regulators, providers, payers and patients. Key quality-related competencies were then identified and mapped to 44 stakeholder sub-groups resulting in some 1,200 combinations. Each subgroup was assigned a target competency level for each competency as well as assessed on the current level. A gap assessment and prioritization identified two related competencies: Conducting an Effective Quality Management Review and Understanding Cost of Poor Quality.

The team surveyed manufacturers, regulators and providers to identify cost drivers and establish a set of common metrics that would help industry to measure the cost of quality and develop a business case for quality improvement efforts.

3.0. Intended Audience

The impact of poor quality affects a broad range of stakeholders: manufacturers, providers, payers and patients. Within manufacturing, these costs include the cost of scrap or rework, warranty costs, complaint handling costs, loss of goodwill. Costs of poor quality extend beyond the organization. For example, recalls represent an additional burden on Regulators (additional oversight) and Providers (loss of use, missed procedures), not to mention Patients (loss of access to care).

While the impact of poor quality is broad, the focus for this paper is the medical device industry, specifically executive leadership (the C-suite) and quality professionals.

For the C-Suite, this paper presents the business case for including the Value of Quality as a core management tool. We hope that this paper increases your interest in the topic, and that you will support a pilot project that applies these techniques to your organization.

The other audience for this paper is anyone who has been tasked with either improving quality or reducing costs. You may be someone in a Design Assurance role during product development, a senior manager on a manufacturing line, or a frontline manager at a customer call-center. The ideas and advice in this paper are universally applicable and are easily tailored to individual products, brands, divisions, or entire companies in a scalable fashion.

4.0. A Vision for Industry

A significant amount of research already exists regarding the “Cost of Quality” or “the Cost of Poor Quality.” This paper is intended to build upon that existing body of knowledge and provide a framework for identifying the commercial upside that exists beyond mere reduction of waste. This can be measured in terms of competitive advantage, customer loyalty, and perhaps, a reduced inspection burden for those companies that build credibility with regulatory authorities given the move towards a risk-based approach to inspections.

The return on investment in quality may take time to materialize, although there are scenarios where the benefits might be immediate (such as when actions are necessary to gain license approval or avoid a costly recall).

Measuring, reporting and acting upon financial measures of quality will help manufacturers prioritize investment in quality programs and distinguish themselves with customers and shareholders alike.

5.0. Impact of Poor Quality

As part of the process of developing guidance for measuring Cost of Poor Quality, the MDIC Case for Quality team surveyed representatives from device manufacturers, service providers and the FDA. The impacts of poor quality are far-reaching.

5.1. Impact of Poor Quality on Manufacturers

Costs can be categorized as **internal failure costs**, those that are contained within the manufacturing ecosystem such as scrap rates and rework, and **external failure costs**, those that are related to failures occurring outside the manufacturing environment such as warranty claims and complaints. Both cost the organization resources, time and money. A list of these costs prioritized by the authoring team is included below, and the complete list is included in Appendix A.

Internal Failure Costs	Net cost of scrap
	Net cost of spoilage
	Rework labor and overhead
	Re-inspection of reworked products
	Retesting of reworked products
	Downtime caused by quality problems (CAPAs, Complaints, NCRs)
	Disposal of defective products
	Analysis of the cause of defects in production
	Re-entering data because of keying errors
	Debugging software errors
	Redesigns
	Re-do's: Engineering, Tooling, Programming, Gauges
External Failure Costs	Cost of field servicing and handling complaints
	Warranty repairs and replacements
	Repairs and replacements beyond the warranty period
	Product recalls
	Liability arising from defective products
	Returns and allowances arising from quality problems
	Lost sales arising from a reputation for poor quality.

5.2. Impact of Poor Quality on Health Care Providers

Though typically not part of a manufacturer's quality dashboard, product quality has a significant impact on providers. While it's impractical for manufacturers to track the impact on providers, it's important to be aware of the types and magnitude of the impact. Costs fall into a range of categories, including tangible costs such as inventory service and replacement, recall management, rework and retraining as well as the even greater intangibles such as income loss, lost productivity, insurance, legal and malpractice costs.

It's not hard to imagine a hospital's Value Analysis Committee (VAC) looking at device quality as a key purchase criterion. Discussions with hospital system administrators indicate that device reliability (or lack thereof) can have profound cost implications, including income loss related to missed procedures, service costs, costs related to having to repeat procedures, and in some cases, legal fees. The American Hospital Association has indicated that with the product Unique Device Identifier (UDI) included in the clinical data sets, hospitals will be able to easily identify which devices are performing well and which might drive snowballing costs.

A list of provider costs is included in Appendix B.

5.3. Impact of Poor Quality on Health Authorities and Regulators

Over the last three fiscal years, the Agency has seen an increasing amount of medical device recalls, from 1065 devices in FY13 to 2850 devices in FY15. Over the last two fiscal years, FY14-FY15, FDA's field organization has expended approximately 28,000 hours in monitoring medical device recalls. These hours do not reflect the time spent by CDRH in the final classification and press release editing, which is substantial. These hours could be better spent on investigating high risk firms, training, collaboration and responding to various public health emergencies.

Strikingly, in FT14-15, the Agency's field staff has expended close to 36,000 hours on "Compliance follow up" inspections and sample analysis both domestically and internationally. Compliance follow up inspections represent repeat inspections at firms to confirm corrections to prior violations. If firms concentrated on quality beyond compliance, many of these repeat inspections can be avoided saving time for both the government and industry.

A list of costs for Health Authorities and Regulators can be found in Appendix C.

6.0. Industry's Challenge

However, these costs are often hard to measure, and therefore often invisible. These costs may be absorbed as "overhead" such as a call center that is needed to handle customer questions. Initiatives to reduce call center cost are often focused on more efficient complaint routing or relocation of the call center to an inexpensive labor market. Rarely do organizations look to design improvements as the primary way to reduce those costs which have become accepted as normal costs of doing business. They fade into the background.

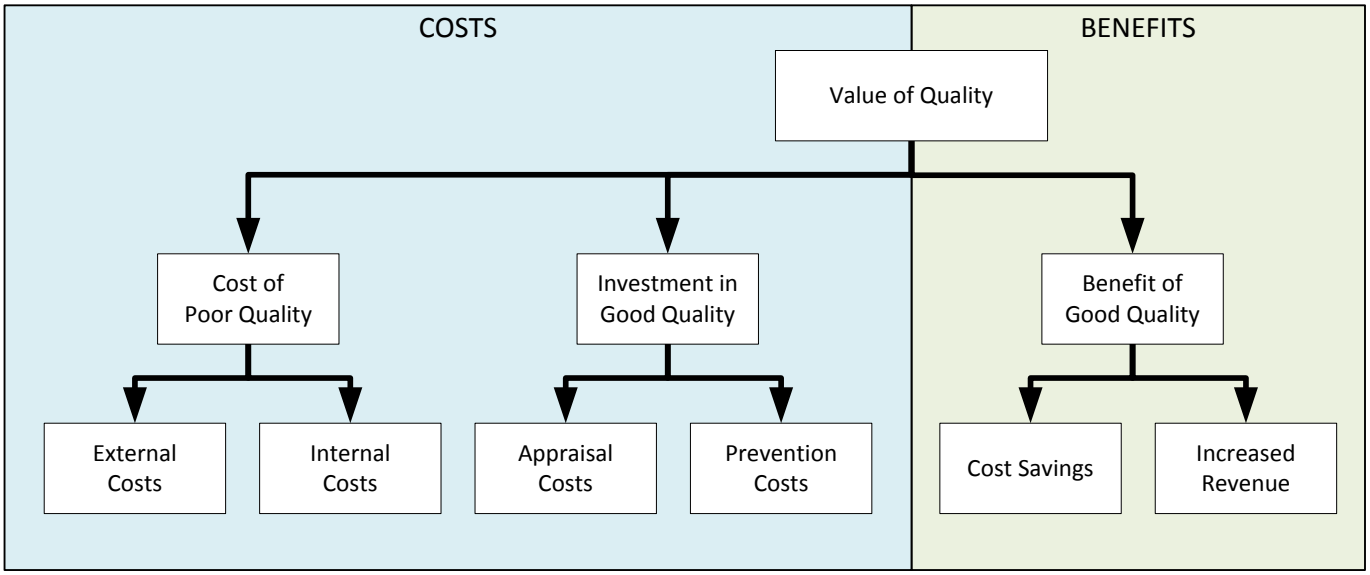
Another issue is the compounding of costs. Poor quality can create a financial chain reaction that quickly explodes to harrowing dimensions – take for example the plight of a life sciences company that failed to detect contaminants in their product. Improved process monitoring would have eliminated the quality issue from the

start. Improved product inspection would have limited the financial impact to losing the batch. However, failure to detect the issue resulted in release of product to the market. When the defect was discovered, a complaint was filed. The company's slow response ultimately led to a large, expensive recall effort, shutdown of the production line for an extended period, loss of revenue, a warning letter and increased, ongoing oversight.

A clear understanding of the potential impact might have led to increased vigilance. However, the ability to capture and report quality metrics assumes access to data.

Cost of Quality data would be ideally collected automatically, real-time through integration of manufacturing and financial systems to a quality performance database. The reality is that if data is collected at all, it is manually reported from a variety of systems and put into a PowerPoint presentation for a quarterly management review. The authors believe that most companies simply do not collect Cost of Quality data.

7.0. The Value of Quality Framework



The Cost of Quality is the aggregation of the traditional Costs of Poor Quality and Investment in Good Quality. The Value of Quality reflects both quality Costs and Benefits.

Companies need to be careful how they use the framework, as there may be a tendency to find a "break-even" point, where the Cost of Poor Quality meets the Investment in good quality. Though industry may have a long way to improve before that point is reached, there are two points to consider.

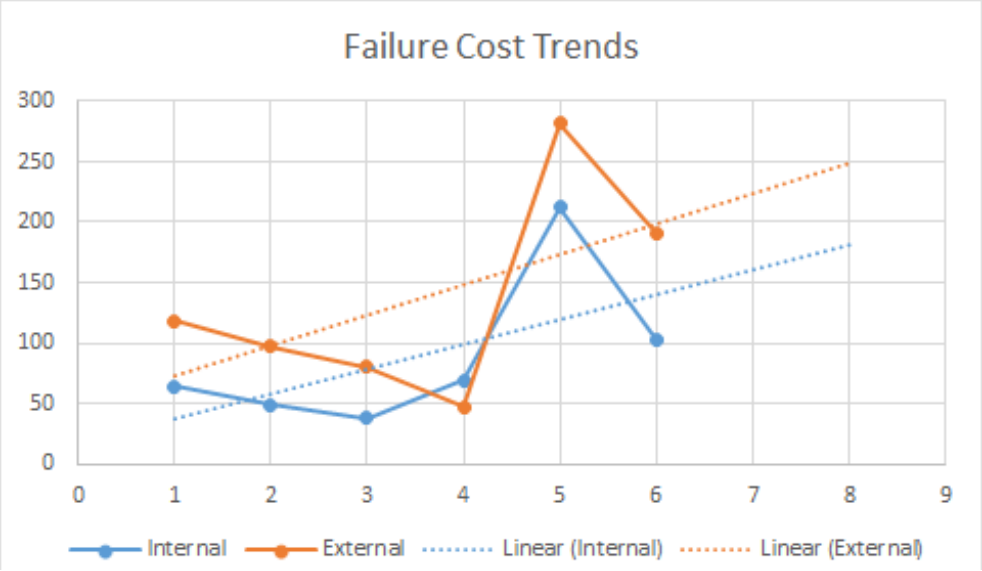
- First, because many device manufacturers are in the business of saving lives, the tolerance for failure is zero. The concepts of "good enough" or "acceptable failure rate" do not apply to many of the industry's products.
- Second, measuring quality investments will likely be easier than capturing the costs of quality failures, so the investments will likely appear greater than they actually are in proportion the costs.

7.1. The Value of Quality Dashboard

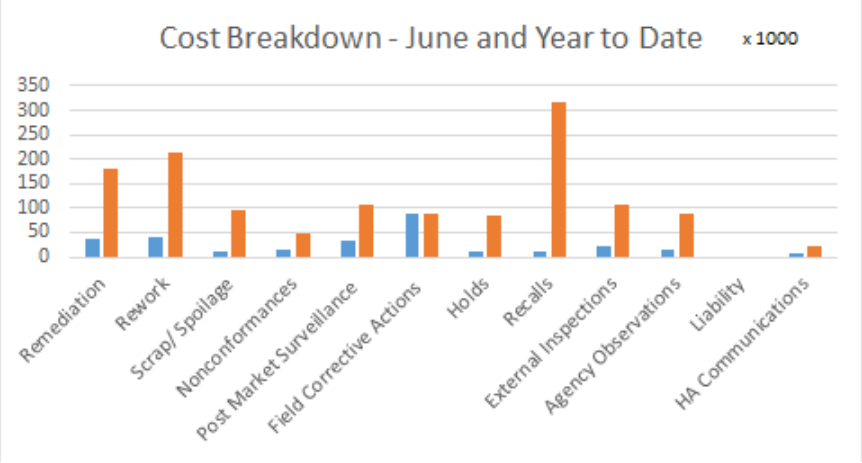
Perhaps the best way to present the Value of Quality is through a dashboard. The Dashboard can take many forms: a spreadsheet, a PowerPoint deck, or a hand-out during a Quality Management Review meeting. Some leading companies have developed intranet sites that display quality metrics in "real-time".

One company, a leading furniture manufacturer, developed a single quality metric expressed as a percentage. When works log onto their computers, the current value is displayed. If it is below the threshold (97%), management takes immediate action. Employees can also research the underlying performance metrics by "drilling down" to isolate the area where quality is below expectations. The dashboard is fed by the global finance, manufacturing and warehouse systems, so the data is always up-to-date.

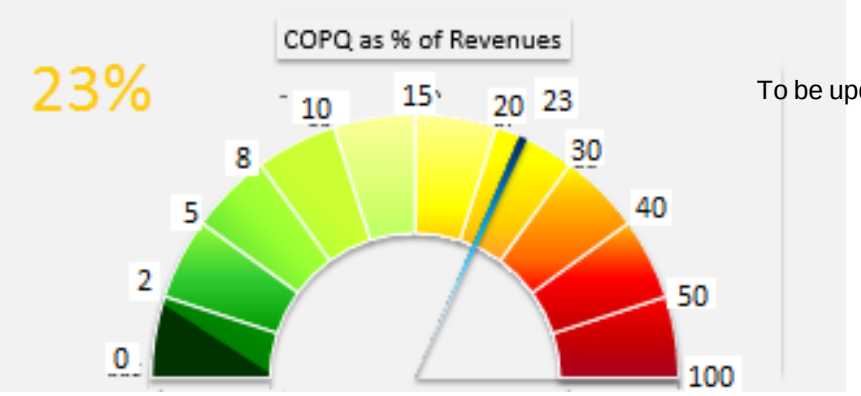
The Dashboard template developed as part of this initiative is Excel-based. It allows users to update definitions and input their own data to achieve a baseline Quality report.



Monthly tracking and trending of internal and external costs of poor quality



Breakdown by cost category



To be updated

Real-time instrumentation

8.0. How it Works

Measuring and reporting the financial impact of good or poor helps prioritize issues and supports development of a business case for investing in good quality. Implementation of a Value of Quality program starts with a top-down directive to measure and act upon quality metrics. A Value of Quality metrics framework with common definitions of cost drivers and measures of benefit must be established. A reporting framework is developed so that quality performance can be communicated with common understanding. And a governance mechanism for evaluating and acting upon quality signals must be implemented.

What follows is the proposed framework for implementing a Value of Quality capability. This paper describes the metrics and their definitions. A companion *Value of Quality* Dashboard has been developed, as well as guidance on Quality Management Review, to accompany this paper. Together, these tools can be used to support:

- Periodic performance analysis
- Effective Quality Management Review
- Continual improvement
- Ongoing awareness of quality

The framework was developed by representatives from the medical device industry.

8.1. Capturing metrics values

There are multiple ways in which the metrics values can be determined. Some larger companies will be in a position to perform a periodic "pull" of information from existing IT systems maintained by the Quality and Financial organizations. In other cases, data may need to be manually collected. The costs and related data can be maintained in a database dedicated to Value of Quality. In this way, costs across multiple products can be compared, as well as cost trends over time.

One challenge to be prepared for is that of it is difficult to capture the costs due to a lack of infrastructure. If something isn't already being measured by the existing infrastructure, it may be difficult to determine the costs. For example, a manufacturing facility may have a team of Quality Inspectors that support product A and product

B, and therefore the labor costs of those QIs are captured as a single "QI Cost Center." The infrastructure may not tell you how much of their time is spent on A and how much on B. In this case, additional work is needed to determine the costs of specific products.

Another challenge is understanding how to separate quality-related costs from normal operating costs. For example, is pest control simply an overhead cost, or is it something related to the quality of the manufacturing operation itself?

Additionally, there are some costs that are the result of chronically poor quality. Examples include multiple field-actions, increased regulatory scrutiny, the loss of customer goodwill, etc. These costs are not easily captured and are not universally applicable, but these are real costs and show how sustained poor quality has a compounding effect on product costs.

8.2. Leveraging Value of Quality

Companies capture metrics for many reasons. Historical metrics provide a performance baseline. Tracked over time, they provide trending information and can identify opportunities for corrective action to improve performance. Other metrics can be used to monitor market conditions and predict demand or regulatory requirements. Still other metrics, combined with advanced analytics, can be used to proactively explore opportunities for transformational changes or improvements.

The Value of Quality metrics measure three distinct areas and must therefore be applied appropriately.

Cost of Poor Quality

Cost of Poor Quality was used early-on by Dr. Joseph Juran to highlight the impact of poor quality on the bottom line to senior leadership. It was the foundation of the business case for quality improvement. With improved data collection and reporting capability, cost of poor quality metrics are used by managers and leadership today to continuously inform quality performance and identify areas where corrective or preventative action can be taken. Studying CoPQ trends can help drive quality improvement projects. And in our industry, where quality can have direct impact on patient health and safety, companies can work closely with health care providers to drive productive investment in product innovation.

CoPQ metrics should be a component of periodic Management Review, either as part of an overall Management Review, or as part of a dedicated Quality Management Review. Senior leadership should understand the quality of its products as well as the financial impact of poor quality. The topic of Management Review is discussed in another MDIC Case for Quality paper.

Some companies have developed Quality dashboards that report on a range of quality metrics, Cost of Poor Quality among them. In one company, metrics are served to the company intranet home page. Employee can click on the "rolled-up" metric and drill down to explore the contributing metrics. Such practice drives quality awareness as well as accountability since there is great transparency behind the overall quality score.

The Cost of Poor Quality should be shared with everyone who is responsible for designing, manufacturing and distributing medical devices. However, the primary audience is likely senior leadership who can immediately internalize the meaning of financial impact and translate that into an enterprise desire to improve quality and reduce those costs.

Investment in Good Quality

While the Cost of Poor Quality should be directed towards senior leadership, investment in good quality should be top of mind within the Quality organization. Quality professionals should be focusing not only on continuous improvement, but looking deeper to understand what investments provide the most benefit for the resources invested. Spending on inefficient quality measures will quickly reduce senior leadership's eagerness to invest in quality.

By monitoring quality investment costs at a granular level, and measuring the related benefit to the company, to providers and patients, will provide the best input for targeting investment in quality.

Benefits of Good Quality

Ideally, all stakeholders would be interested in the size and scale of the returns on investment in good quality. Unfortunately, the benefits of good quality are rarely measured, in part because measurement is so difficult, in part because you can't measure what doesn't happen (adverse quality events). Establishing an accurate estimate the economic impact of good quality is next to impossible.

That said, the benefits of good quality can be profound, and can be expressed in terms of improved customer loyalty, improved patient recovery times, reduced inspection burden, and increased sales volume to name a few. Causality is difficult to establish, so accuracy remains elusive.

It is for this reason that looking at the Value of Quality in terms of Return on Investment (RIO) is greatly misleading. It is relatively simple to capture and report the failure costs. And equally simple to capture the investment in the Quality Management System. The returns are unquantifiable, so it might appear that the investments far outweigh the benefits.

Companies can try to track improvements in sales, customer loyalty, and reduced costs of poor quality (such as recall costs). Identifying those benefits directly related to quality may be difficult. It may be worthwhile to allocate these wins across multiple investments. The gains are not limited to reducing failure costs.

8.3. Maintaining Value of Quality

An effective quality program requires more than reporting metrics, including a strong push from leadership at the start. Continued focus is needed, keeping the conversation about the value of quality and its impact within the company, and across the broader heath care ecosystem. In our industry, good quality has meaning far beyond quarterly profits. It translates directly to the health and safety of patients.

9.0. Making Value of Quality Happen

9.1. Communication

The first step is to raise awareness among key stakeholders that costs of poor quality are real, measureable and correctable. A cross-functional team will provide the most value and encourage organization-wide support and implementation. Once an initial tally of costs is conducted, senior leaders will likely want to verify and explore more deeply. Data will likely come from multiple sources – manufacturing sites, service centers, and finance. So it may take some time to round up initial figures. Until there is confidence in the data, it will make sense to

keep the Cost of Quality output as a separate, standalone report, so it doesn't get prematurely mixed in with "official" reports. This is often implemented as a pilot for a set period of time; this allows for easier modification as the project unfolds.

Once leadership is aware of the magnitude of the Costs (some companies report costs of quality as high as 30% of revenues), there will likely be sufficient interest to pursue a dedicated Value of Quality initiative. At this point, it can be treated as any significant, leadership-led initiative.

9.2. Design

Once there is sufficient awareness and motivation behind the Value of Quality initiative, the project team will need to follow a disciplined approach to develop the capability. These initiatives impact people (there is a large cultural element), processes (both for collecting and reporting the metrics and for making quality improvements based upon the metrics) and technology (though metrics can be collected manually, it's far more efficient to automate collection and reporting).

Design of the program is key. A common project framework is "Plan Do Check Act". Planning, including detailed design of the communications plan, governance model, metrics definition and the eventual Value of Quality Report is key. It's best to developing the model in a collaborative way given that there will be many groups participating.

9.3. Building the Infrastructure

By "infrastructure", we mean all the structures that will support a high-profile quality initiative. This includes developing the process and ideally, the technology to capture the metrics, building the dashboard to report the metrics, and the governance structure to take the output of the report and drive meaningful improvement. Build the team, empower them to think outside the normal lines of functions and expense reporting.

9.4. Implementation

How you implement Value of Quality will depend upon your company. Many companies implement high-impact projects by running a pilot with a controlled population (representing a product or a division) in an effort to increase likelihood of success and generate favorable feedback. The initial implementation can be highly manual, with automated collection of data coming at a later time.

9.5. Lessons Learned

Common traps to avoid (pursuit of everything vs. vital few, hard to measure items, information overload, failure to sustain) 6/16 – don't sink an infinite amount of resources in this; be selective for a few items. It's tough work to develop a company model, requiring collaboration across functional lines and the willingness to look at costs in a way that drives product quality improvements and support competitive advantage.

Can leverage savings from first project to finance additional projects. Need to customize approach. Recognize that this CoPQ initiative will be competing with other initiatives – this is not the only value proposition. Need to speak stakeholders' language. Also it is sometimes easy to rationalize the interpretation of data instead of seeing it as a "call to action"

Success will look like:

- Proactive investments are well-accepted and reactive costs have fallen (they may never be zero).
- Leadership thoughtfully considers what the data is saying, defining root causes and making course corrections as needed.
- Investments in quality are seen as important as the technology platform, marketing costs, selling costs, etc.

10.0. Appendix

10.1. Appendix A – Cost of Quality Metrics for Manufacturers

The metrics are divided into two groups: Cost of Poor Quality and Investment in Good Quality. The metrics reflected in the dashboard are listed below:

Costs of Poor Quality (failure costs) – full list of identified costs with prioritization score (1 = high)

Category	Cost or cost driver	Feasibility	Impact
Recalls	Plant Recall Costs (Plant mfg. related Recalls)	**1.0**	**1.0**
Recalls	Non-plant Recall Costs	**1.0**	**1.0**
Recalls	Customer service Recall Costs (Labor)	**1.0**	**1.0**
Recalls	Field-related recall costs	**1.0**	**1.0**
Remediation	Consulting costs - temps, etc.	**1.0**	**1.0**
Rework	Retraining time and expense	**1.0**	**1.0**
Recalls	Extra procedures for implanted devices	**3.0**	**1.0**
Complaints	Cost to investigate complaints	**1.0**	**1.3**
Distribution	Inventory expired / sent to scrap	**1.0**	**1.3**
Holds	QA Holds at the DC's (Labor and Freight)	**1.0**	**1.3**
Rework	Scrap of obsolete materials	**1.0**	**1.3**
Rework	Scrap of expired materials	**1.0**	**1.3**
Complaints	Time to file MDRs/MDVs	**1.0**	**1.5**
Rework	Rework and Sorting (Labor and Material by plant)	**1.0**	**1.7**
Rework	Additional Sampling and Re-inspection cost	**1.0**	**1.7**
Rework	Scrap in excess of Standard (Labor and Material)	**1.0**	**1.7**
Opportunity costs	Revenue lost due to design flaws	**3.0**	**1.7**
Opportunity Costs	Market Share	**3.0**	**1.7**
Opportunity Costs	Loss of income (general)	**3.0**	**1.7**
Opportunity Costs	Cost of regaining lost customers	**3.0**	**1.7**
Opportunity Costs	Lost sales	**3.0**	**1.7**
Opportunity Costs	Lost shareholder value (market cap)	**3.0**	**1.7**
Opportunity Costs	Company brand perception	**3.0**	**1.7**
Rework	Equipment Repair and Maintenance	**1.0**	**2.0**
Corrective Action	Cost of root cause analysis	**2.0**	**2.0**
Redress and Shipping	Redress at DC's (Labor and Material by DC)	**2.0**	**2.0**
Rework	Cleanup work (extra documentation, etc.)	**2.0**	**2.0**
Time to Market	Cycle times for PMA submission development	**2.0**	**2.0**
Time to Market	Review period times for PMA submissions	**2.0**	**2.0**
Time to Market	Development cycle times related to rework	**2.0**	**2.0**

Deviation	Fail to execute a procedure accurately	**2.5**	**2.0**
Opportunity Costs	Inability to gain new customers	**3.0**	**2.0**
Oversight costs	Increased scrutiny, inspection burden	**3.0**	**2.0**
Preventive costs	Quality programs e.g. six sigma	**3.0**	**2.0**
Recalls	3rd Party distributor costs	**3.0**	**2.0**
Rework	Redesign of hardware or software	**2.0**	**2.5**
Observations	Costs related to HA findings - fines, re-inspection	**2.5**	**2.5**
Deviation	Inconsistency in the output of operations performed	**3.0**	**2.5**
Redress and Shipping	Inbound Shipping Cost (including Freight and T&E)	**2.0**	**2.7**
Redress and Shipping	Supplier Shipping Cost	**2.0**	**2.7**
Rework	Time required for additional audits	**2.0**	**3.0**
Rework	Time required to process nonconformance report	**2.0**	**3.0**
Rework	Revalidation of Process	**2.0**	**3.0**
Corrective Action	Cost of submitting changes	**2.5**	**3.0**
HR Costs	Field sales force retraining	**3.0**	**3.0**

Investments in Good Quality

Prevention Costs	Systems development
	Quality engineering (Design Change/Controls & Redesigns)
	Quality Management Reviews (Risk Management)
	Complaint trending
	statistical process control
	Supervision of prevention activities
	Quality data gathering, analysis, and reporting
	Quality improvement projects
	Technical support provided to suppliers
	Audits of the effectiveness of the quality system
	KPI's, Standard Work
	Quality, operations design
Appraisal Costs	Test and inspection of incoming materials
	Test and inspection of in-process goods
	Final product testing and inspection
	Supplies used in testing and inspection
	Supervision of testing and inspection activities
	Depreciation of test equipment
	Maintenance of test equipment
	Plant utilities in the inspection area
	Field testing and appraisal at customer site

10.2. Appendix B – Cost of Quality Metrics for Providers

Income loss	Lack of availability - orders filled on-time
	Patients prefer other devices - loss of market share
	Clinicians prefer other devices - loss of market share
	OAI - can't get export certificate / import alert
Insurance	Related impact to premiums
	Risk management payments
	Large providers self-insure up to a threshold, purchase secondary coverage and tertiary coverage
	Malpractice companies would likely reduce premiums for cooperation in quality improvement
Intangible	Emotional stress
Inventory Costs	Extra device units (standby)
	Spare parts inventory
	Storage & inventory costs - process impact
Legal	Physician review can cause Dr. to close doors to accomplish task
Lost Productivity	Repeated use errors / human factors problems
Malpractice Award	Damages (actual costs, related costs, lost wages); actuary-based ongoing losses (salary to age ??); actuary-based predictive cost of care; modifications to home/vehicle; mortality; punitive (can provoke class-action)
Opportunity cost	Fewer patients served
Publicity	Public reporting of a quality event can cause substantial loss of revenue in all venues
Recalls	Extra procedures for implanted devices
	Products non-saleable during remediation
Remediation	Consultants
Residual Impact	Despite successful resolution of a suit, additional impacts may be provoked if JC, CMS, states investigate
Retooling	Swap out entire device line
	Discontinuing and transfer from poor choice suppliers
Time out of service	Loss of productivity
	Allocated costs to plant, personnel
Training	Training - technique, raise awareness, retraining on new equipment
	Reactive costs vs. preventive costs

10.3. Appendix C – Cost of Quality Metrics for Health Authorities

Concept of appraisal costs	Highest value to the patient
Corrective Action	Training related to quality issues
	Hours spent on recall related activity
Follow-up	Compliance follow-up
	Additional burden related to consent decree
	Follow-up to inspection findings
Inspection	Costs related to inspection findings
	WL / UL Response
	Increased inspection frequency
	Increased inspection durations
Recall	Hours spent on recall-related activity