

The Competency Workstream Update

MDIC Case for Quality

26 October 2016

Whitepapers have been developed for **Management Review** and **Understanding the Cost of Poor Quality**.

We like these topics because either one alone can help to improve Quality, and they can start at opposite ends of an organization.

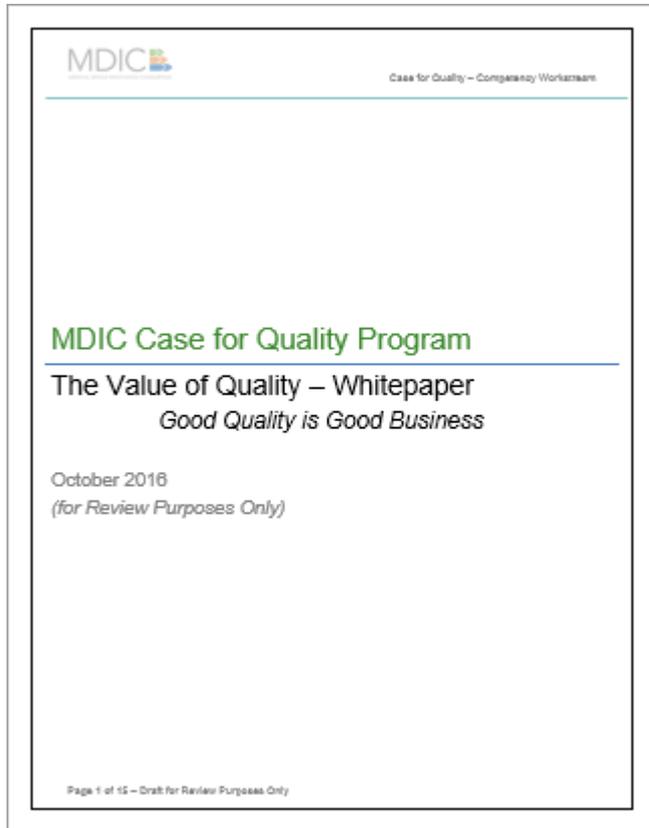
Management Review allows C-Suite to better understand what is going on inside of their organization, and in fact, the recent update to ISO13485 has additional emphasis on Management Review.

Understanding the **Value of Quality** (VoQ) can help front-line managers understand where their costs truly are, and can highlight areas for Quality investments.

Because there is so much existing literature about VoQ, much of our focus has been on that topic.

The Value of Quality

Objective: To provide industry with a common, comprehensive playbook for measuring and monitoring quality costs and investments to provide a foundation for quality improvement.



Audience:

The target audience includes the C-Suite, to get buy-in and drive a strategic view of quality, and the action-taker, who needs to improve quality and/or reduce costs

Intended outcome:

- Broad understanding of the importance that Quality has to every stakeholder group, inside and outside the company
- Ability to quantify and communicate the hidden CoPQ
- Ability to communicate a vision regarding the benefits of good Quality

Content:

The paper includes

- Purpose and principles of measuring cost of poor quality and value of quality
- Recommended metrics and dashboard
- Approaches for implementing a Cost of Poor Quality / Value of Quality program

Cost of Poor Quality Metrics

The initial work was to define the Costs of Poor Quality for manufacturers and for other stakeholders impacted by manufacturing quality issues

Approach:

- Representatives from manufacturers, providers and the FDA identified cost drivers
- Costs were prioritized to identify the metrics for inclusion in the MDIC CoPQ dashboard
- Benefits of Good Quality metrics were identified however it was determined that challenges related to data collection precluded reliable reporting
- Investment in Good Quality metrics were identified and included separately in the dashboard

Manufacturers

Category	Cost or cost driver	Feasibility	Impact	Description
Recalls	Plant Recall Costs (Plant mfg. related Recalls)	1.0	1.0	The costs of Plant investigation and changes made attributable to defective product or installation
Recalls	Non-plant Recall Costs	1.0	1.0	The costs of GBU investigation (not related to a Plant) and changes made attributable to defective product or installation - i.e. Design issue
Recalls	Customer service Recall Costs (Labor)	1.0	1.0	Customer service Recall labor costs associated with contacting customers and making arrangements for returns - Effectiveness checks
Recalls	Field-related recall costs	1.0	1.0	Labor time material

Providers

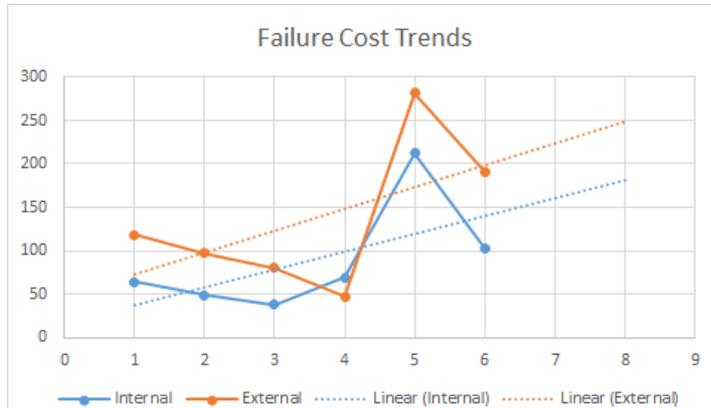
Category	Cost or cost driver	Source	Feasibility	Frequency	Impact	Description
Remediation	Consulting costs - temp					
Rework	Retraining time and expense	Compliance	Failure to comply with widely accepted standards - incompatibility			
Recalls	Extra procedures for imp	Compliance	Seizure			
Complaints	Cost to investigate com	Compliance	Injunction			

FDA

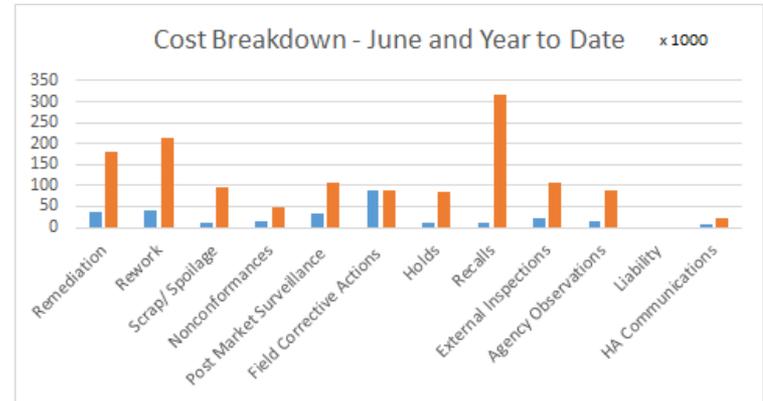
Category	Cost or cost driver	Feasibility	Impact	Description
Distribution	Inventory expired / sent to	Health impact	Patient wellness - safety and effectiveness	
Holds	QA Holds at the DC's (L	Health impact	Patient inconvenience	
Rework	Scrap of obsolete materia	Income loss	When device off line - cancelled procedures	
Rework	Scrap of expired materia	Income loss	Patients move to other facility	
Complaints	Time to file MDRs/MDV	Income loss	Loss of income for procedure	
Rework	Rework and Sorting (La	Income loss	Lack of availability - orders filled on-time	
Rework	Additional Sampling and	Income loss	Patients prefer other devices - loss of market share	
Rework	address quality issues fo	Income loss	Clinicians prefer other devices - loss of market share	
Rework	Scrap in excess of Stand	Income loss	OAI - can't get export certificate / import alert	
	plant)	Insurance	Related impact to premiums	
		Insurance	Risk management payments	
		Insurance	Large providers self-insure up to a threshold, purchase secondary coverage and tertiary coverage	
		Insurance	Malpractice companies would likely reduce premiums for cooperation in quality improvement	
Inspection	Costs related to inspection findings	3	1	
Follow-up	Compliance follow-up	3	1	
Corrective Action	Training related to quality issues	3	1	
Concept of appraisal costs	Highest value to the patient	3	1	
Follow-up	Additional burden related to consent decree	1	2	hours related to compliance follow-ups may be born by device manufacturer
Corrective Action	Hours spent on recall related activity	1	2	
Recall	Hours spent on recall-related activity	1	2	
Inspection	WL / UL Response	2	2	
Inspection	Increased inspection frequency	3	2	
Inspection	Increased inspection durations	3	2	
Follow-up	Follow-up to inspection findings	3	2	

The Value of Quality Dashboard

The VoQ Dashboard provides select views for leadership and quality professionals: CoPQ informs leadership of failure costs to inform improvement efforts - investment in quality measures help quality professionals optimize quality spend



Cost Trends



Cost Breakdown



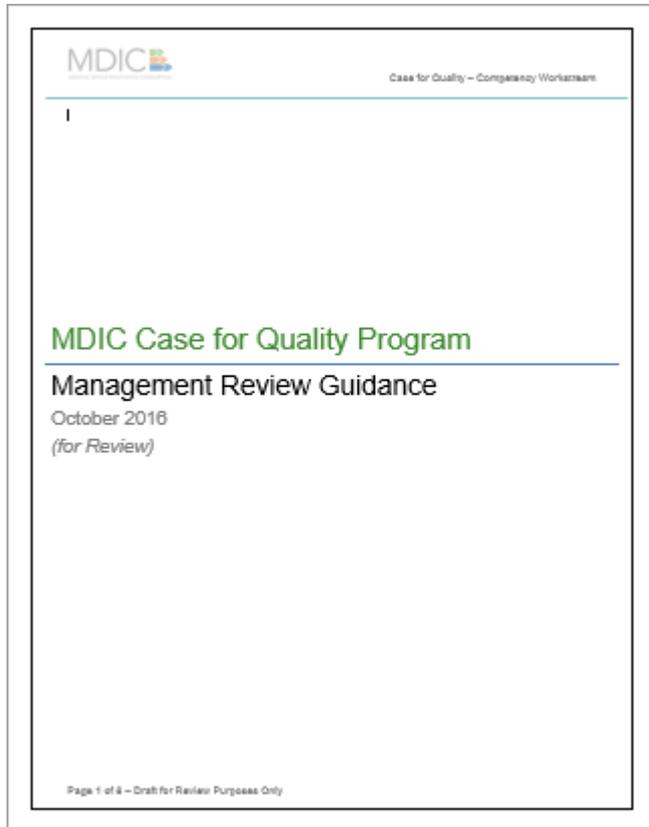
Cost of Poor Quality (COPQ)

Cost Category	Full Year 1					Full Year 2					Full Year 3					Total - Three Year Summary
	Q1	Q2	Q3	Q4	Total - Year 1	Q1	Q2	Q3	Q4	Total - Year 2	Q1	Q2	Q3	Q4	Total - Year 3	
Controversial Costs	\$ 28.0	\$ -	\$ -	\$ -	\$ 28.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 28.0
Inclusion of overhead on top of direct costs	\$ 28.0	\$ -	\$ -	\$ -	\$ 28.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 28.0
Internal Failure Costs	\$ 50.0	\$ -	\$ -	\$ -	\$ 50.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 50.0
Remediation	\$ 50.0	\$ -	\$ -	\$ -	\$ 50.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 50.0
Rework	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Scrap/ Spoilage	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Nonconformances (NCR, CAPA, SCAR)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
External Failure Costs	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Post Market Surveillance (Complaints)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Field Corrective Actions (FCA)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Holdes	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Recalls	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
External Inspections/Audits	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Agency Observations /wL	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Liability	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
FDA/MOH Communications	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Opportunity Costs	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Cost of regaining lost customers (measureable campaigns)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Lost sales what could be regained	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Summary																
Controversial Costs	\$ 28.0	\$ -	\$ -	\$ -	\$ 28.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 28.0
Internal Failure Cost	\$ 78.0	\$ -	\$ -	\$ -	\$ 78.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 78.0
External Failure Cost	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Opportunity Costs	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Cost of Poor Quality (VOPQ)	\$ 78.0	\$ -	\$ -	\$ -	\$ 78.0	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 78.0				

Management Review

The second topic selected as part of the competency initiative was Management Review. The primary deliverable is a Management Review Guidance document.

Objective: To provide industry with a template and guidance for conducting effective Management Review.



Approach:

The team collected samples of management review charters, reports and SOPs. The samples were analyzed and leading practice gleaned to form the basis of the guidance document.

Content:

The guidance document provides

- Background on Management Review
- An outline for the Management Review process
- Examples of Management Review tools
- Advice for getting started



Future Thoughts

The VoQ White Paper, the VoQ Dashboard and the Management Review Guidance document are in draft form. They have been written or developed and are ready for review beyond the original Competency Team. Our request is that group agree to undertake this review and provide comments.

A strong theme in many of our discussions has been making these concepts as clear and adoptable as possible.

The VoQ dashboard is quite comprehensive and has a number of nifty features – this also means that some people may be intimidated by the complexity of it all.

One suggestion is to make a Powerpoint plus an instructional video showing how to use the VoQ dashboard tool.