MDIC Case for Quality Program

Management Review Guidance

November 2016

(for Review)

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1.0. Introduction

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 perform an effective Quality Management Review was identified as a key competency, providing leadership-level insight into a company's quality health and key issues.

The purpose of this white paper is to provide a path to an effective quality management review – how to justify the resource and time investment, examples and guidance on what constitutes an effective management review, where and who provides the information, who is involved it collecting and the information, what capabilities should these resources have and how to get started.

Through the use of examples and specific guidance, as well as the combined experience of the members of the authoring team, this paper will clarify and explain the steps to implementing and executing an effective management review process.

Conducting an effective management review has benefits outside of simply managing the quality aspects of a company. It is tied to bottom line costs (either actual or avoided). Ignoring the messages contained in a thorough quality management review results in "leaving money on the table." Making the case for the magnitude of impact across the business is critical to ensuring the right level of participation from leadership and senior management.

2.0. Background

The Medical Device Innovation Consortium (MDIC), through its public-private partnership with FDA and other stakeholders, aims to advance regulatory science in the medical device industry through development of methods, tools, and resources used in managing the total product life cycle of a medical device. The FDA has partnered with Industry to advance the *Case for Quality* (CfQ). The Medical Device Innovation Consortium is managing the FDA sponsored project which is comprised of four 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 intent is to create a Quality Management Review process and template that 1) reflects the industry's leading practices while at the same time is 2) relatively easy to implement. The two are not necessarily mutually exclusive.

Once the competency team decided on Management Review as one of two high-impact topics within the competency workstream, the first step was to collect samples of management review artifacts from team members' companies as well as other sources. Examples included Management Review SOPs, Charters, sample presentations, meeting minutes templates, a sample agenda, a list of metrics and responses to our Management Review questionnaire.

These artifacts were examined to identify leading Management Review practice in terms of governance, process, tools and metrics. The output is this guidance document which includes descriptions and examples of assets that can be leveraged by med tech companies to implement their own Management Review capability.

This version represents the initial draft guidance document. It is expected that this will be assessed and vetted by the broader MDIC Case for Quality community prior to general release.

3.0. Objectives

From a business perspective, the desired outcome is improved quality that leads to both superior business performance for manufacturers and health care providers, and optimal safety for patients. Key learning objectives for this guidance include:

- Develop a broad understanding of the importance of Management Review
- Understand how to establish and perform effective Management Reviews
- Understand roles and responsibilities in the management review process
- Identify the capabilities required to collect and present information
- Understand the connection between good management review and good business practices

Stakeholders

The intended audience includes diverse stakeholder groups, with different objectives for each group:

- C-Suite
  - Better understanding of the link between quality outcomes and business results
  - Clear understanding of what to expect from an effective review and expectations for participation
- Quality Management
  - Ability to apply leading practice to implement and conduct management reviews
  - Ability to communicate quality performance to all parts of the organization
  - Identify approaches for escelation of issues through the organization
  - Understanding of various levels of reviews within the organization
  - Understanding what auditors may look for (Management review procedures, minutes, agendas, sign in sheets, ETC.)
- People developing Management Review materials
  - Understanding of process for collecting and presenting metrics and information
  - Guidance on what to include and how to present
  - How to tie to business results and quality outcomes

4.0. Value Proposition – Impact of Quality

The fundamental issue is that management is often unaware of the true impact of quality on their business. Even if they do have visibility to yield rates, throughput and customer satisfaction, there is no clear connection to the broader ecosystem in terms of financial or patient health and safety impact. And while line managers and operators may have access to quality metrics, management needs to be aware of these metrics to drive changes needed to improve quality and business performance.

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.

Impact on Manufacturers

The impacts of poor quality are far-reaching. Internal failure costs, those contained within the manufacturer's environment, include: 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, disposal of defective products, analysis of the cause of defects in production, re-entering data because of keying errors, debugging software errors, redesigns, and re-do's (engineering, tooling, programming, gauges).

External failure costs, those associated with products that left the manufacturing environment, include: 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, and lost sales arising from a reputation for poor quality.

Impact on Providers

Manufacturing quality was found to have 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.

Impact on Health Authorities

Over a recent three-year period, the FDA 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, the 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.

5.0. The Challenge

Conducting a regularly scheduled, effective management review is a critical component of a healthy Quality system, yet is difficult to get right.

- There never seems to be enough time between reviews to effectively assemble content for the review, to conduct the review and act on the issues
- There is often disagreement on exactly what elements should be covered in the review
- The rationale for "escalation' of issues through the organization to the executive level is unclear (firms with multiple sites may have site-level reviews more frequently, where leadership will have visibility to more detailed information)
- Blurred lines between business reviews which generally do not focus on quality issues and quality reviews which may involve many of the same members but focus specifically on quality issues and performance

The quality and effectiveness of quality management reviews varies widely across the medtech industry. The management review is a key component of the Quality Management System (QMS), yet there has been limited health authority guidance on the structure, format and content regarding an acceptable management review[1]. Lack of an effective management review puts patient health and safety at risk as well as creating a compliance risk for the company.

The connection between the overall Value of Quality (VoQ) and Management review is strong but may not be clearly called out, which can result in negative financial impacts. As companies embrace the maturity model approach to their quality system, regular, frequent and effective management reviews will be critical to a firm's ability to assess its current state, and development plans to reduce eliminate and prevent quality related risk in their processes and products.

6.0. A Vision for Industry

To address the challenges, the team identified a set of leading practices to aid in the desired outcomes. It is not necessary that all the following suggestions be incorporated. Rather, it is possible to choose the ones that makes the most sense for a given company's environment, challenges and available tools.

Recommended guidelines for an effective management review include:

- Involvement and buy in from senior management
- Regular scheduled time devoted specifically to review of quality metrics
- A clear, coherent set of metrics, with a key for interpretation (don't make the audience guess the story)
- A focus on visual methods of representing the data (heat maps, speedometers, etc.) for the high level summary story, with detailed data supporting the conclusions lying behind the summaries

[1] See ISO 13485 MR guidance

- Rules for escalation to executive leadership
- Action item tracking with clear ownership, due dates, and follow-up
- Uniform standards for metrics – agreed upon definitions, common interpretations, aligned "action levels"

One critical element for a successful review is dependable metrics availability. This can be accomplished by manual means, but without systems support (programs and appropriate data architecture), such metrics will be time-consuming and tedious to collect, as well as subject to error. Investing in standard business automation (such as ERP and MES systems), as well as automating common Quality functions (such as CAPA, complaints, training) will greatly ease the effort involved in management review, as well as making it timely enough to allow reaction. By enabling timely metrics collection, such systems allow almost real time monitoring of quality system changes and improvements, with equally quick readjustment if needed.

7.0. The Management Review Process

The Management Review process is a consistent, periodic review of quality metrics and the quality management system as a whole. Management review includes the following components:

- **Governance model** – including charter, to define roles, responsibilities and accountability
- **Process Model** – a detailed, documented periodic management review process
- **Scope** – specific quality metrics to be reviewed as well as the overall performance of the QMS
- **Output** – documentation and actions that come out of the management review

7.1. Governance

The roles, responsibilities and accountability for performing the Management Review and taking follow-up action is typically defined in the Quality Management Review Charter, examples of which appear in Section 7.1.

7.2. The Quality Management Review Process

The QMR Process can be defined in the QMR Charter, or in a separate SOP or process map. The process should define for each step, the responsible and accountable parties as well as the inputs and outputs of the process steps. RACI (responsible, accountable, consulted and informed) and SIPOC (source, input, process, output, customer) tables are helpful in clarifying process fundamentals. A sample process map appears in Section 7.2.

7.3. Frequency

The frequency of Management Reviews is not mandated, however the norm, based upon our research, appears to be quarterly. For one company, reviews happen quarterly at the site, region, and executive level. They cascade information, therefore the Executive review is often 45 days after the close of the quarter. The company is looking to shorten that duration.

At another company, the Executive Management Review (EMR) happens two times per year, a mid-year and an end-of-year review. In addition, the Quality Review Board reviews data monthly on behalf of EMR. The data reviewed by the Quality Review Board is similar to that eventually seen by the EMR.

7.4. Participants

The Executive management review is intended for executive management – i.e., Vice President level and up. Director-level positions are invited members and are generally in attendance, if not presenting at EMR. The Quality Review Board that meets monthly consists of supervisor, manager, director-level positions.

Another company defined participation in the following table:

Review Level	Required	Optional
Executive	CEO, Global Business Head(s), VP Global Quality, Chief Scientific Officer, CVP Manufacturing, VP Global Pharmacovigilance	CFO, CIO, CVP Human Resources, Head of Global Compliance, VP Global R&D, Corporate Counsel, Corporate MR Process Owner, Regional VPs and/or Data Owners as appropriate
Region & Global Business	Regional/Global Business Operations Head, Regional/Global Business Quality Head	Regional/Global Business Lead(s), Regional/Global Business Head IT, Regional/Global Business Head Finance, Corporate MR Process Owner, Data Owners as appropriate
Manufacturing Site	Site Manufacturing Head, Site Quality Head	Site Management Team, Site Quality Management Team, Corporate MR Process Owner, Data Owners

7.5. The Agenda

The agenda varies somewhat from company to company. The table below shows topics common to most companies.

The scope of the discussion will vary depending on how well we are doing and what is driving a metric to be off-target. It is not uncommon for the conversation to go very deep into exactly what is being done to bring the measures back on track. Resources (whether we have enough or they need to be shifted) are always a part of each of the conversations.

Common Quality Management Review Topics
Follow-up actions from previous Management Reviews
Any escalation(s) from any Operational Structures
Quality Policy
Quality Objectives Quarterly Results
Suitability, adequacy and effectiveness of the QMS
QMS Audits
Results of audits and inspections
Applicable new or revised regulatory requirements
Other changes that could affect the quality management system
Review of changes to voluntary standards (ANSI, ASTM, etc.)
Complaints
Pharmacovigilance, safety statistics

Preventive and corrective actions - CAPA Metrics
Process performance and product conformity
New key issues requiring oversight
Product field actions
Manufacturing Sites Performance
Conclusion/Recommendations for improvement
Customer feedback
Supplier performance management
Training
Changes in market needs

The table below shows additional management review topics that were reported by some companies.

Other Management Review Topics
Resources requirements / organizational structure
Local improvement projects
Customer Engagement
Local QMS Improvements
Recon/Robotics Integration
Change Management
MDR/MDV
Regulatory Actions and Product Holds
Resource Requirements
Product performance trends
Manufacturing statistics
Out-of-specification (OOS) test results
Documentation errors by type (part of Lot Release statistics)
On time delivery performance
Validation activities and statistics
Stability testing statistics
Risk management issues
Summaries
Process control trends
Root cause trends
Quality Manual
Returned product rates
Environment health and safety

7.6. The Metrics: What's Reported

It addition to the topics listed above, companies may report metrics as part of a Management Review dashboard. Some of the metrics identified include:

- **Performance trends (improvements, deterioration) of processes against established benchmarks or baselines. When baselines are exceeded, we analyze the root causes.**
- **Quality costs associated with deviations, nonconforming product and complaints**
- **Quality costs associated with improvements**
- **Potential impacts to business of changes in market needs, standards or regulations**
- **Workman's compensation costs and causes and targeted improvements**
- **Results of audits and inspections**
  - Observations (severity/repetitiveness)
  - Responses (timeliness/adequacy)
- **Pharmacovigilance**
  - Reporting timeliness
  - Product Safety
- **Preventive and corrective actions**
  - WIP, Timeliness, Effectiveness
- **Process performance and product conformity**
  - i.e. Complaints, MDR, FAR, Field Actions, Supplier Quality
    - Records, Incidents, WIP, Timeliness, Effectiveness
  - Product performance trends

Some suggestions for identifying, capturing and reporting Quality Management Review Metrics:

- Don't expect to find "perfect" metrics – start where you are and refine as needed
- Take action on lagging metrics – if it is important enough to collect, it is important enough to act on
- Don't allow sites to "game the system" – stay aware of this possibility and encourage sites to remember the goal is to actually improve the quality (impossible to measure precisely) with an inexact proxy (metrics)

8.0. Examples – Management Review Tools

8.1. The Charter

There is no standard format for a charter, though there are typical contents:

- **Purpose** – Define scope and objectives for the charter
- **Definitions** – Provide definitions for terms and acronyms
- **Policy** – Define the guiding principles, frequency, content and other aspects of the management review
- **Participants** – List the roles (not individuals) who must participate and those that are optional
- **Roles and Responsibilities** – define which role within the management review is responsible for what inputs, actions, deliverables and follow-up
- **Outputs** – define the specific outputs of management review meetings (minutes, reports, actions, etc.)

A sample charter appears below:

SAMPLE

1.0 Purpose

1.1 The purpose of this Quality Policy is to define the process for periodic Management Reviews at Company Pharmaceutical, Inc. (Company).

2.0 Definitions

Management Review:	Management Review is the evaluation of the quality system by management to determine its effectiveness, suitability and future direction. The review includes assessment of the conclusions of periodic reviews of process performance and product quality and of the pharmaceutical quality system.
Quality System:	Aggregate of the organizational activities, incentives, plans, policies, procedures, processes, resources, responsibilities and the infrastructure required in formulating and implementing a total quality management approach.
Senior Management:	Person(s) who direct and control a company or site at the highest levels with the authority and responsibility to mobilize resources with the company.

3.0 POLICY

3.1 Management Review

3.1.1 The Quality Assurance Unit and Company Senior Management Team will routinely perform a "Management Review", wherein they will:

- Examine the quality system and determine if the conditions set by company policies and standards are being met to develop action plans when necessary.
- Utilize the management review to evaluate effectiveness of the quality systems and to foster a culture of continuous improvement.
- Discuss whether the quality system may need to be modified due to changes that have taken or are expected to take place in the organization, facilities, staffing, equipment, activities or workload.

SAMPLE

3.2.1 The Management Review will take place at least two times per year to facilitate review of the Company Quality System and discuss internal and external factors that can have an impact on the Quality System. Examples of discussion topics may include, but are not limited to:

- Quality Objectives/Key Performance Indicators/Trends
- Product Quality Complaints
- Corrective and Preventive Action
- Regulatory Inspections and Findings
- Recalls/Field Recovery
- Review of Quality Policies

- Change Management
  - Internal and External Audits
  - Feedback Relative to Outsourced Activities
  - Training
  - Resources, including personnel, facility, equipment and materials.

3.2 Escalation

3.2.1 An escalation to Management will occur when:

- After working through the approved Quality System processes and procedures, Management feedback and/or intervention are required to resolve an issue related to the Quality System.
- There is tangible impact to the Company Quality System and/or patient safety.
- Discuss whether the Quality System may need to be modified due to changes that have taken place (or are expected to take place) in the organization, facilities, staffing, equipment, activities and/or workload.

3.2.2 Escalation topics can be addressed during periodic meetings; however, high risk issues, including but not limited to patient safety concerns will be escalated immediately for Management Review.

3.3 Management Review Structure

3.3.1 The Management Review process will be coordinated by the Quality Assurance Unit.

3.3.2 All meetings will utilize agendas and minutes to document occurrence, topics, attendance and decisions.

Charter Appendix I Minimum Management Review Inputs

Management Review Agenda Items (Note: The presentation order of the agenda items is at the discretion of the Management Representative.)	**Division Input**	**Local Site Input**
Review status of action items from previous Management Review	X	X
Results of audits (Regulatory Agencies, Notified Body, Internal)	X	X
Status of preventive and corrective actions (CAPA & NCR) - Including minimum KPI monitoring as listed in D00075-1	X	X

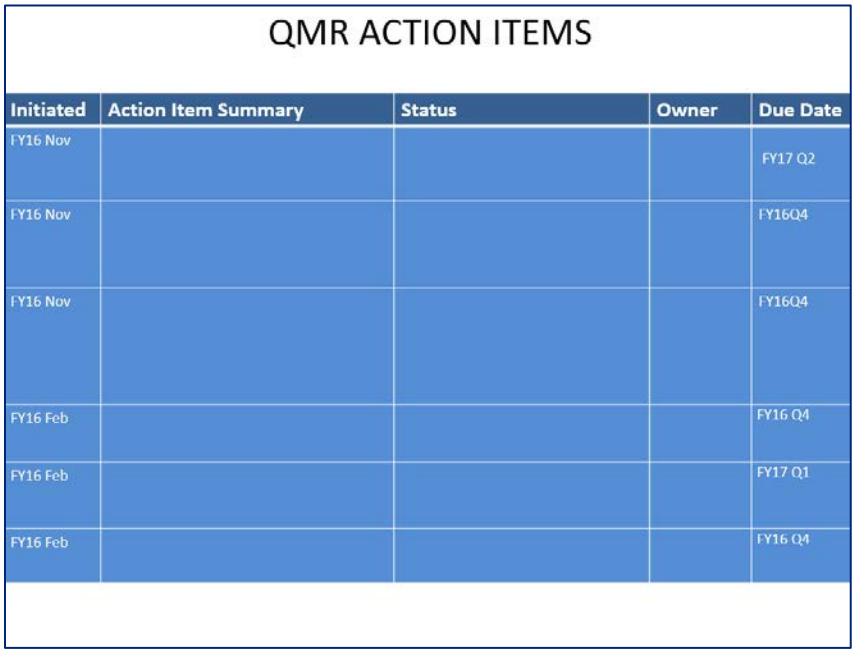
Customer feedback (Post market surveillance, complaints, MDR, MDV), - Including minimum KPI monitoring as listed in D00075-1	X	
Product field actions - Including minimum KPI monitoring as listed in D00075-1	X	X
Supplier performance management (including supplier audits and product non-conformity)	X	X
Review of regulations / standards for changes that can impact the QMS (Including all regulations and standards listed in QM01) Regulatory Affairs to provide input as required	X	X
Review of changes to voluntary standards (ANSI, ASTM, etc.)	X	X
Review of all other changes that can impact the QMS (as applicable)	X	X
Resources requirements / organizational structure	X	X
Suitability, adequacy and effectiveness of the QMS	X	X
Process performance and product conformity - process operations metrics (scrap, rework, quality awareness test, manufacturing loss/ cost of quality, etc.)	X	X
Quality plan progress review and recommendations for improvement	X	X
Training	X	X
Local improvement projects	X	X
New key issues requiring oversight	X	X
Quality policy review/suitability	X	X
Recommendations for improvement	X	X
Customer Engagement	X	

SAMPLE

8.2. Dashboards

Some examples of Management Review dashboards include:

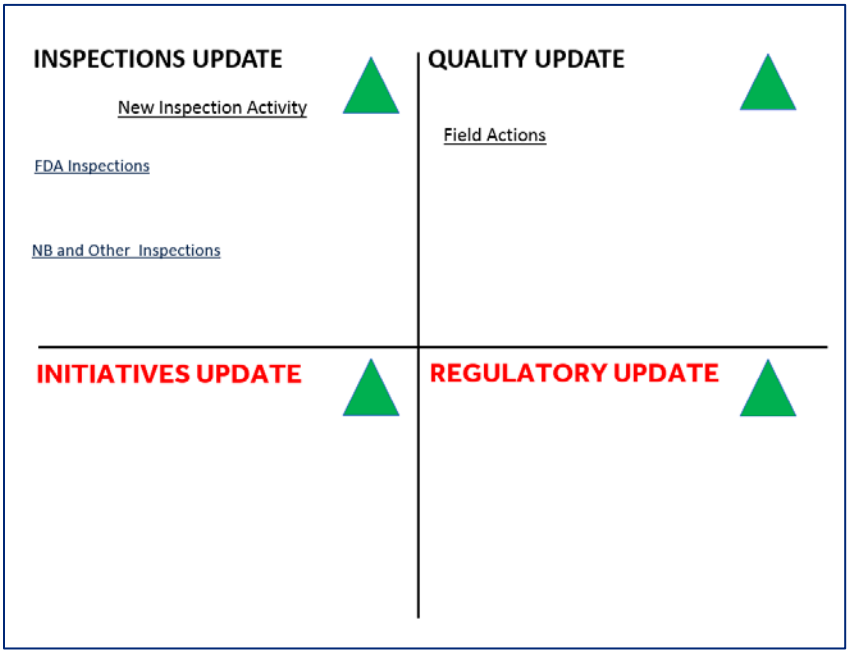
- Action items from previous Quality Management Review meeting



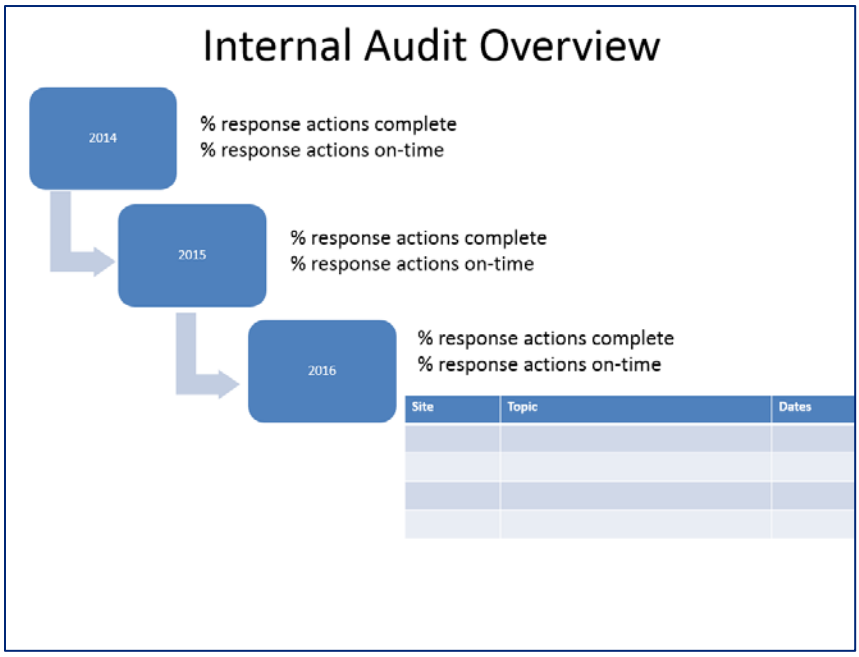
QMR ACTION ITEMS

Initiated	Action Item Summary	Status	Owner	Due Date
FY16 Nov				FY17 Q2
FY16 Nov				FY16Q4
FY16 Nov				FY16Q4
FY16 Feb				FY16 Q4
FY16 Feb				FY17 Q1
FY16 Feb				FY16 Q4

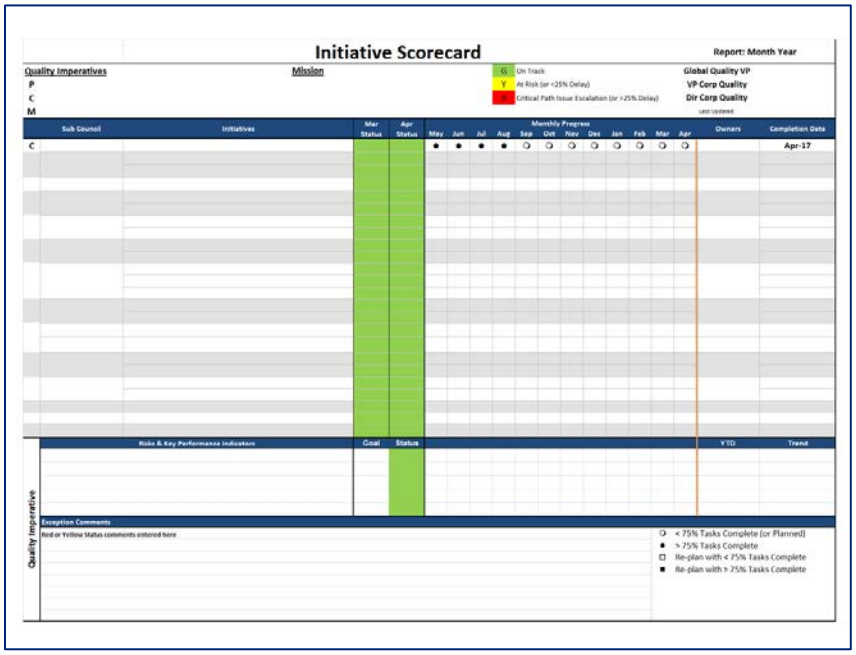
- Update and status on specific topics (inspections, quality metrics, initiatives and regulatory activities)



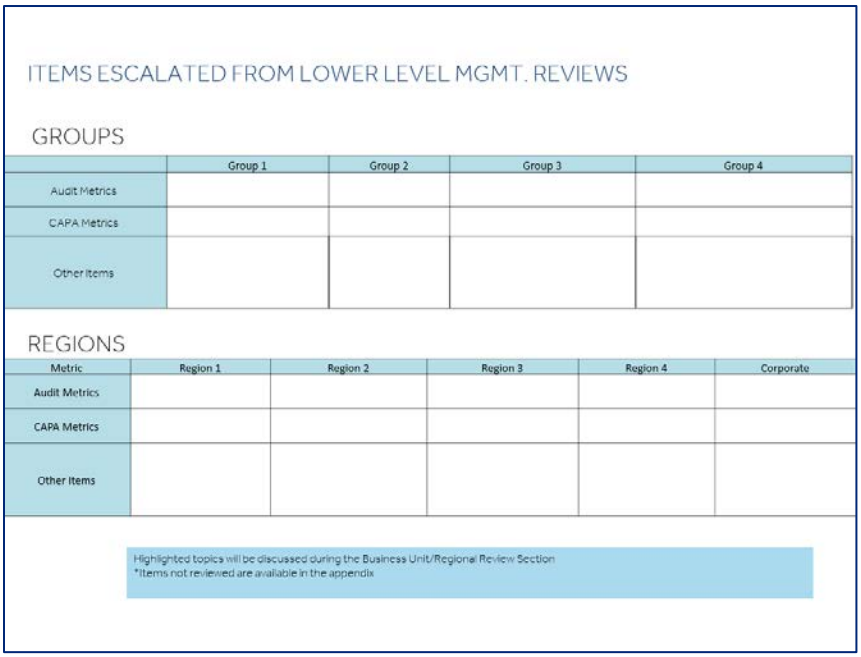
- Internal audit performance



- Update and status on specific quality initiatives



- Escelation report



ITEMS ESCALATED FROM LOWER LEVEL MGMT. REVIEWS

GROUPS

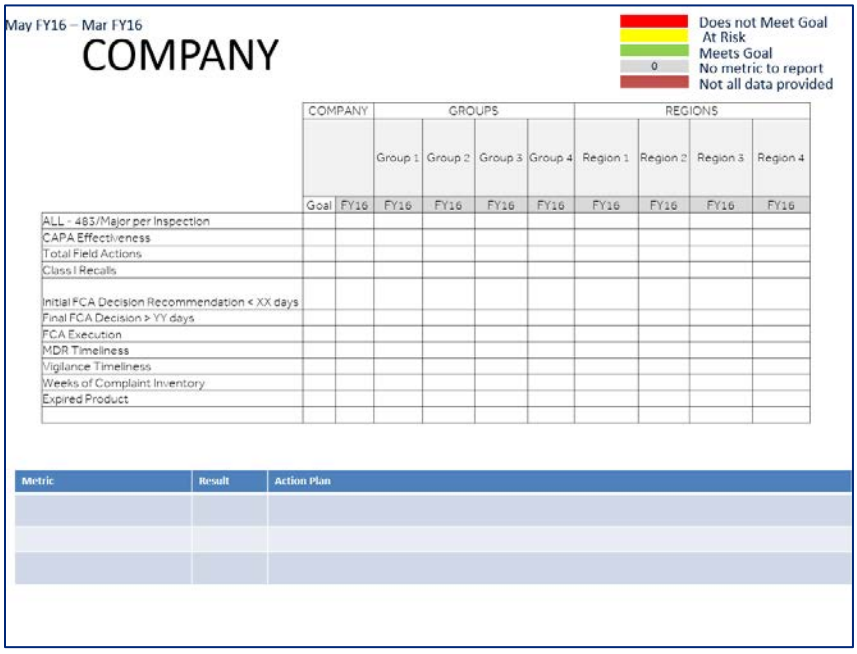
	Group 1	Group 2	Group 3	Group 4
Audit Metrics				
CAPA Metrics				
Other Items				

REGIONS

Metric	Region 1	Region 2	Region 3	Region 4	Corporate
Audit Metrics					
CAPA Metrics					
Other Items					

Highlighted topics will be discussed during the Business Unit/Regional Review Section
*Items not reviewed are available in the appendix

- Quality scorecard



May FY16 – Mar FY16

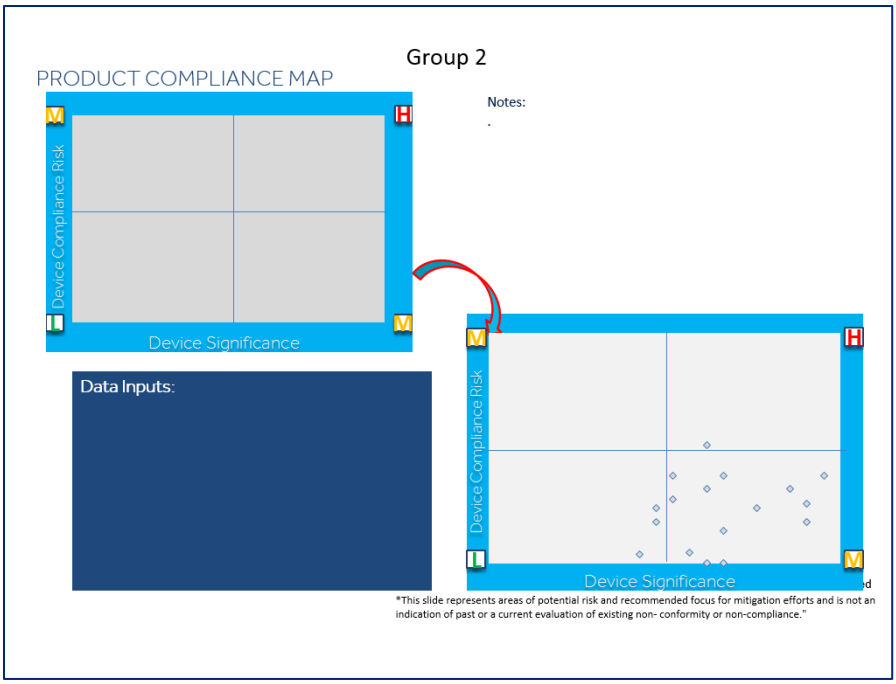
COMPANY

Does not Meet Goal
At Risk
Meets Goal
0 No metric to report
Not all data provided

	COMPANY		GROUPS				REGIONS			
			Group 1	Group 2	Group 3	Group 4	Region 1	Region 2	Region 3	Region 4
	Goal	FY16	FY16	FY16	FY16	FY16	FY16	FY16	FY16	FY16
ALL - 483/Major per Inspection										
CAPA Effectiveness										
Total Field Actions										
Class I Recalls										
Initial FCA Decision Recommendation < XX days										
Final FCA Decision > YY days										
FCA Execution										
MDR Timeliness										
Vigilance Timeliness										
Weeks of Complaint Inventory										
Expired Product										

Metric	Result	Action Plan

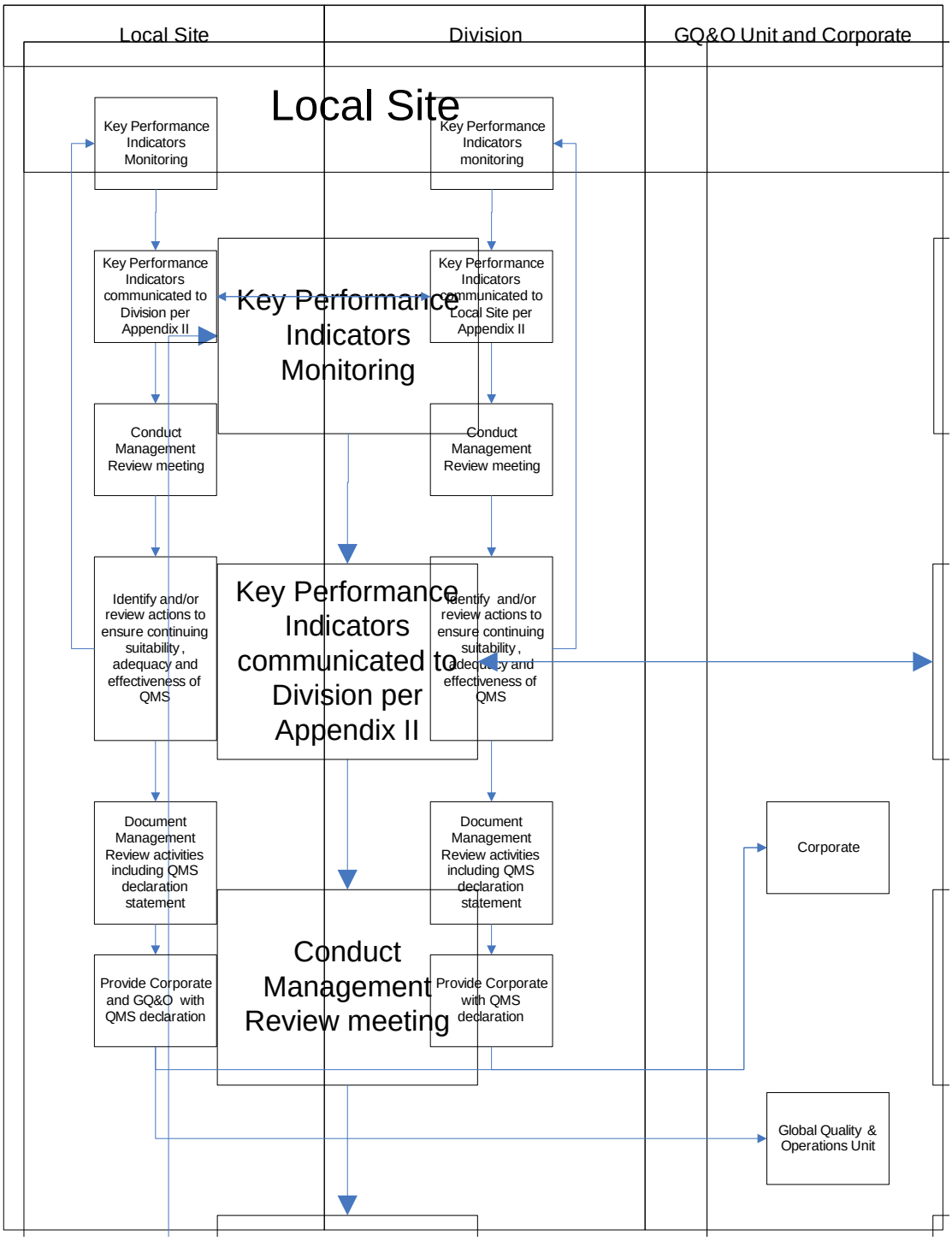
- Data visualization (in this case, a risk assessment)



8.3. Process

Process samples include a process map and an example of RACI and SIPOC matricies:

- Example Management Review process flow



- Sample RACI and SIPOC matrices are illustrated in an instructions page for an Adverse Event / Product Quality Complaint reconciliation process

This document includes RACIs and SIPOCs for the AE/PC/MI Reconciliation process outlined in the embedded process map

RACI - Sample

Send Case to PV and QS				
Stakeholder	**Responsible**	**Accountable**	**Consulted**	**Informed**
Call Center	✓			
Medical Information		✓		✓
Pharmacovigilance		✓		✓
Quality Systems		✓		✓
SRT				

Each RACI describes responsibility, accountability, consulted and informed for each box in the process map. This document represents an initial draft. The core team will walk through the process to address issues such as the role of the call center in the reconciliation process.

SIPOC - Sample

Source	Input	Process	Output	Customer
Reporter	Report / inquiry	Record data	Report	Team
Patient	Medical Inquirey	Enter data	Data in IRMS	MI
Provider	Product Complaint			PV
Multiple sources	Adverse Event			QS
	Other Complaint			

Note: Some ADRs/AEs May come from sources outside the Call Center pathway

SIPOCs identify the inputs and outputs of a process step. In many cases, outputs are addressed in the next process step. In these cases, the output boxes are left empty. The core team will determine the desired approach (specific or generic).

9.0. Getting Started – Implementing Effective Management Review

9.1. Building Demand

The first step is to raise awareness of the need for a formal quality management review process. Exposing senior leadership to the Case for Quality and the risks and rewards related to quality by translating quality issues into financial terms is often helpful. One resource is the Value of Quality whitepaper which was also developed by the Compency team.

9.2. Building the Quality Management Review Structure

Once there is organizational will to initiaite the quality management review process, you and your team can lay the groundwork. This includes developing the charter, defining the metrics and the data collection and reporting process, and building the templates for reporting quality performance withing the management review meetings. Also consider ongoing communications and training as needed to support accurate and timely execution of tasks.

9.3. Pilot

Even the most carefully designed process needs to be tested. Some companies perform a dry run: a test of the end-to-end process, collecting dummy metrics, creating a strawman report and conducting an abbreviated test meeting with all participants to verify that the process will run smoothly and produce the desired outcome.

Others jump right in, spending the time to collect metrics, run analysis and create the management review presentation or dashboard. In such cases, timelines are usually stretched as companies work out the bugs. In either approach, the team must collect feedback and make updates to the process and the metrics as needed to that management reviews become efficient and highly productive.

Regardless of what approach you take, as you build the team, empower them to think outside the normal lines of functions and expense reporting.

10.0. You'll Know You've Arrived

Companies that have implemented effective management review processes demonstrate the following evidence of success:

- Regularly held management reviews
- Regular participation of senior management
- Action items are tracked and followed up on
- Negative trends identified proactively, and appropriate actions identified and taken to address them
- Strong tie-in with KPIs in management reviews and corporate level Goals and objectives
- Balanced metrics scorecard including leading and lagging indicators, costs incurred as well as costs avoided, company-wide scope
- Reduced costs of poor quality, continuous favorable trending of costs and returns on investments