

Quality Management Maturity (QMM) Case Study: MSD

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MSD



PDA Aseptic Processing of Biopharmaceuticals Conference 2024

CONNECTING
PEOPLE
AND
SCIENCE
REGULATION®

Agenda:

Cost of Quality

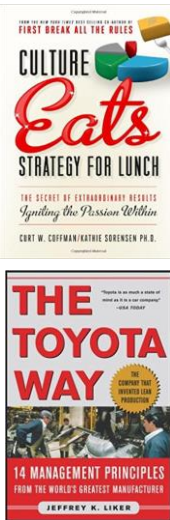
MSD QMM Journey

QMM Qualitative Assessment Overview

QMM Quantitative Assessment Overview

Conclusions

Business focus shift from "Strategy" to "Culture" due to positive indicators



Companies with extremely healthy cultures are

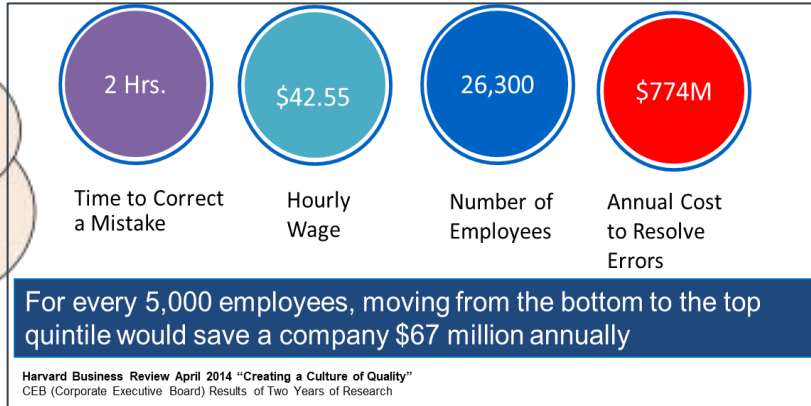
1.5X

more likely to report average revenue growth over 15% for the past three years

Public companies with extremely healthy cultures are nearly

2.5X

more likely to report significant stock price increases over the past year.



Our findings on increased retention show that the average S&P 500 company would see a savings of \$156M in turnover costs annually if employees were to describe its culture as healthy.¹

\$156M

From Grant Thornton 2019: Return on Culture

Companies ranked in the top 20% in terms of quality culture reported 46% fewer mistakes in their daily work resulting in a saving of \$67M per 5K employees

From Harvard Business Review April 2014: Creating a Culture of Quality. Ashwin Srinivasan & Bryan Kurey CEB

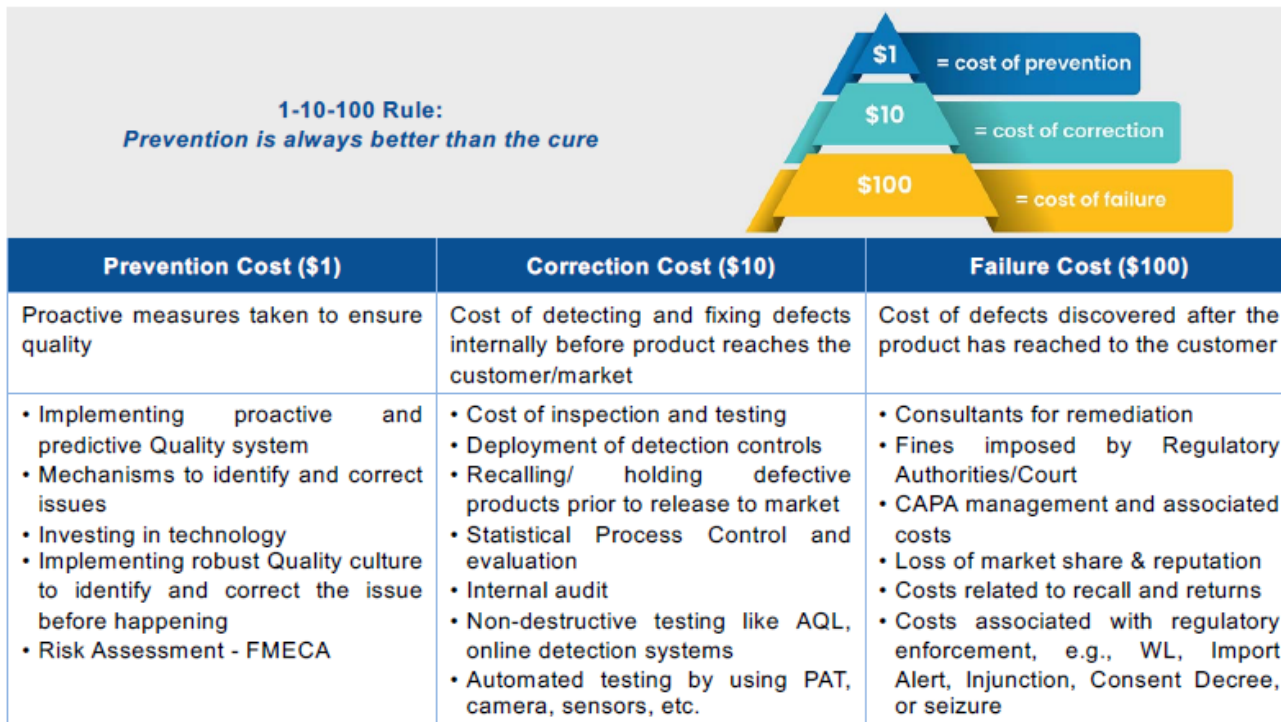
Self-described **world-class* organizations** are more apt to increase investment in quality, with **66%** of those organizations planning to **increase investment in quality programs** in the next 18 months.

<http://asq.org/culture-of-quality/>

Since the launch of our Quality Driven Management program in 2008 ... we have been able to achieve **hundreds of millions of dollars of cost savings.**

—FedEx

Why should we Care about QMM ? Cost of Reactive vs Proactive Quality



* Graphic presented during PDA 2024 Supply Chain Resilience & Quality Management Maturity Conference (09/19/2024): "Investing in Quality," Sun Pharma.

Reactive Quality Cost in Terms of Enforcement Actions

- Hypothetical-Five inspection observations citing the following subsystems:
 - Complaint Handling and MDR Reportability
 - CAPA
 - Design Controls
 - Process Validation
 - Internal Audit
- 6-month remediation plan (**TOTAL COST: \$1,526,000**)
 - Salary costs (~\$280,000+)
 - Ex-FDA Consultants (~\$120,000+)
 - Product recalls – 3 lots / approx. 350 units @ \$1,800 each (\$630,000)
 - Finished goods scrap – 1 lot / 120 units @ \$1,800 each (\$216,000)
 - New production equipment + process validation package (\$180,000)
 - New CAPA software module (\$100,000 to implement + \$50,000 annually)



MSD QMM Implementation Strategy

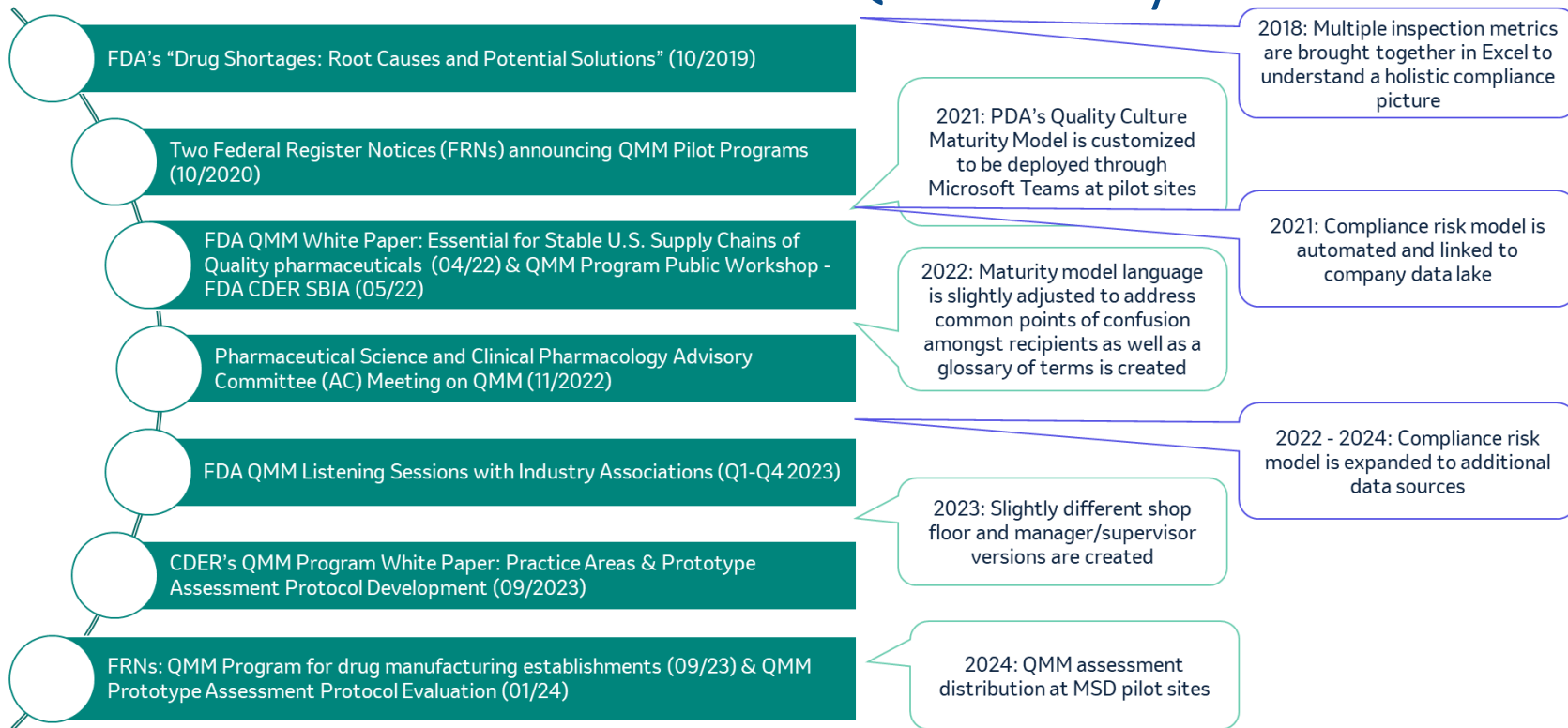
Qualitative Assessment

- Based upon the Parenteral Drug Association's (PDA) **Quality Culture** Maturity Model
- Customized for shop floor and managers / supervisors
- Output summarized in an interactive dashboard

Quantitative Assessment

- Leveraged our company data lake to access Quality Council **metrics** as well as other data sources
- Created a quantitative risk level per site with ability to narrow down to individual **metrics**
- Output summarized in an interactive dashboard

FDA's and MSD's QMM History



Foundation of Qualitative QMM Assessment

MSD Qualitative Model
(aligned with PDA Quality Culture Maturity Model)*

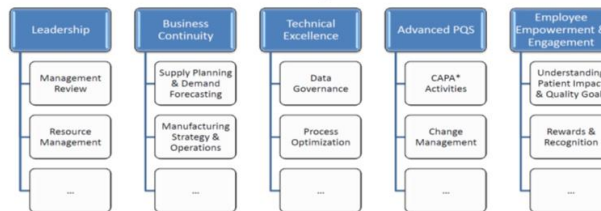
Category	Attributes	Elements	
Employee Ownership and Engagement	Understanding Quality Goals	Impact on Product Quality Patient Impact	
	Staff Empowerment and Engagement	Process Ownership and Engagement	
		QMS Processes	
Continuous Improvement	CAPA Robustness	Root Cause Human Error	
	Clear Quality Objectives and Targets	Continuous Improvement	
		Utilization of New Technologies	Manufacturing Technologies
Technical Excellence	Maturity of Systems	Training Business Conduct Quality Risk Management	
		Leadership Commitment	Accountability and Quality Planning Safety Program Rewards & Recognition Feedback & Staff Development
			Communication & Collaboration
Quality Communications	Quality Communications		
Management Review and Metrics	Management Reviews Metrics		
Internal Stakeholder Feedback	Internal Stakeholder Feedback Quality Culture Survey		

*Reach out to PDA Training (training@pda.org) for more information on the Quality Culture Maturity Model training program

Evolution of FDA model: Practice Areas and Elements

Prototype of Protocol: Examples of Assessment Practice Areas

Practice Areas will be assessed according to a defined rubric.



*CAPA – Corrective Action and Preventive Action

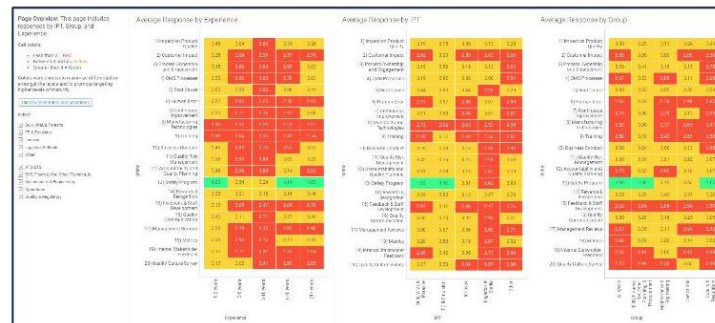
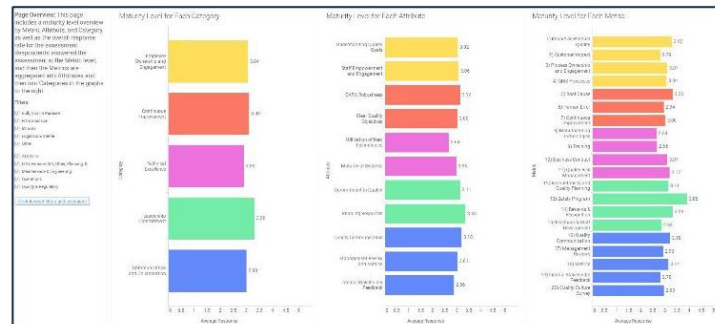
Five QMM Practice Areas



*Top graphic presented during GMP by the Sea (08/15/2023); *Realizing Supply Chain Resiliency through a Commitment to Quality* U.S. FDA, Slide 11. Bottom graphic presented during PDA 2024 Supply Chain Resiliency & Quality Management Maturity Conference (09/19/24); *An Overview of CDER's QMM Program,* U.S. FDA, Slide 20.

QMM Qualitative Assessment Details

- Dashboards are created for each site
- Individual metrics can be aggregated to the Attribute and then the Category level for better action targeting
- Data can analyze data by:
 - IPT/End-to-End
 - Functional Area
 - Length of service
- Optional comments are collected per question for additional insight and provided via Excel

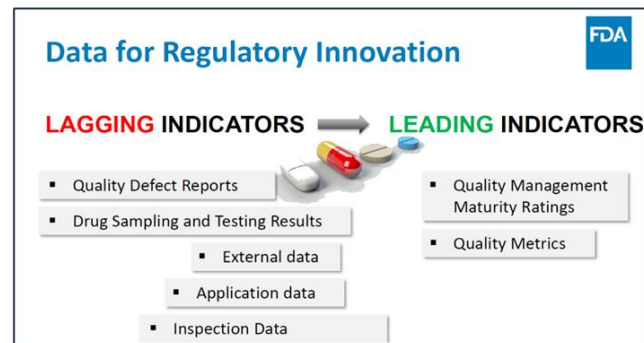


QMM Qualitative Assessment Output and Next Steps

- After completing the assessment, sites will:
 1. Identify opportunity areas using the dashboard
 2. Determine whether the trend is for the entire site, or a sub-section of the site
 3. Develop an action plan that is embedded in the site's governance structure (e.g., Hoshin planning process)
- Example: A site reviewed their assessment data for individual laboratories. Example actions:
 - Continuous Improvement: Installed a six sigma “model area” with redesigned tier process to improve problem escalation
 - Manufacturing Equipment: Implemented improvements to the asset reliability program regarding laboratory equipment
 - Feedback and Staff Development: Implemented a new GEMBA process to ensure better adherence to shop floor presence commitments

Wait, What about Quality Metrics? QM ≠ QMM but QM informs QMM

- FDA has long shown an interest in broader utilization of QM, QMM is part of this evolution
- Industry's early focus on QMM has been on the assessment of quality culture, but this is not the complete picture
- The best approach will be a combination of qualitative and quantitative strategies

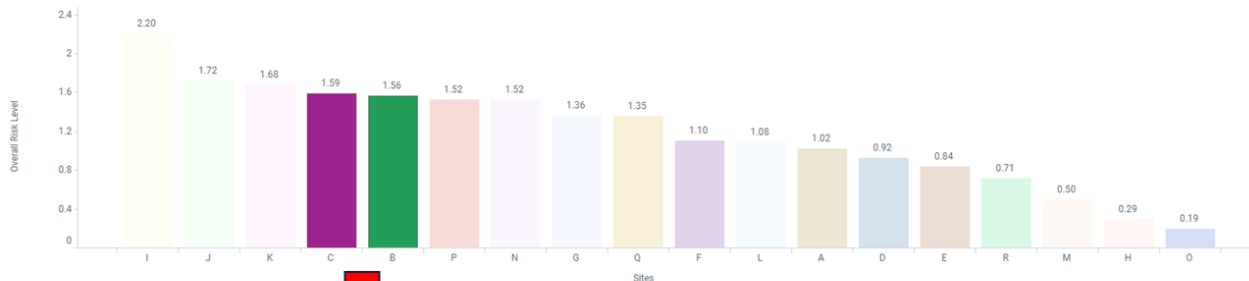


*Graphic presented during FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee Meeting (11/2/22): Slides 27 and 28. <https://www.fda.gov/media/162821/download>.

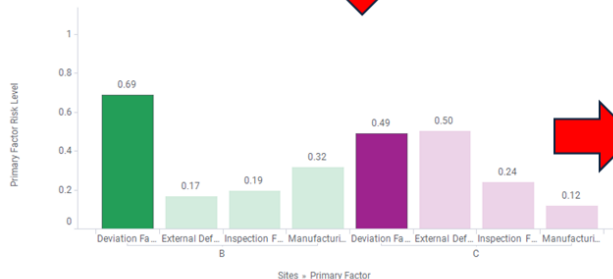
QMM Quantitative Assessment Overview

- Focuses on the proactive signals from QM
- An interactive dashboard displays a manufacturing site's compliance risk versus impact
- No manual calculations are required for the model to function
- Impact is viewable through multiple views that provide different methods of segregation depending on the audience

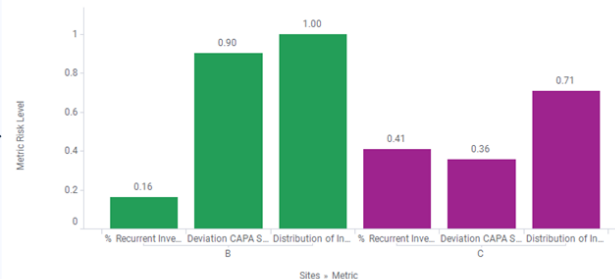
DRAFT Risk Level per Site - For testing purposes only



Primary Factor Risk Level per Site



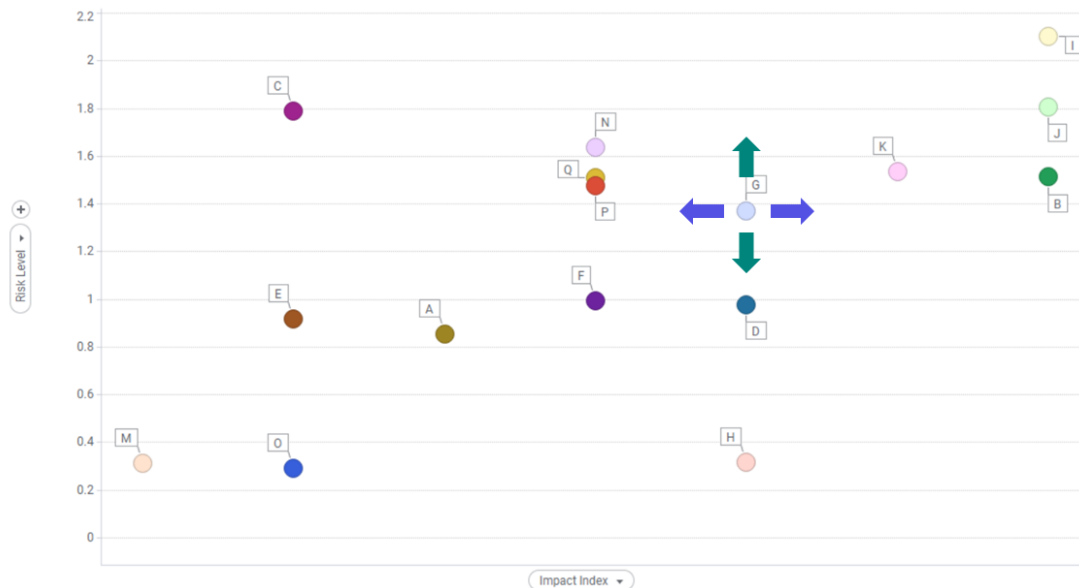
Metric Risk Level per Site



QMM Quantitative Assessment Overview (continued)

The view at right shows how relative risk can change

- Overall risk can go up or down the y-axis as inputs are mitigated or new risks emerge
- An impact score on the x-axis helps prioritize constrained resources across the network

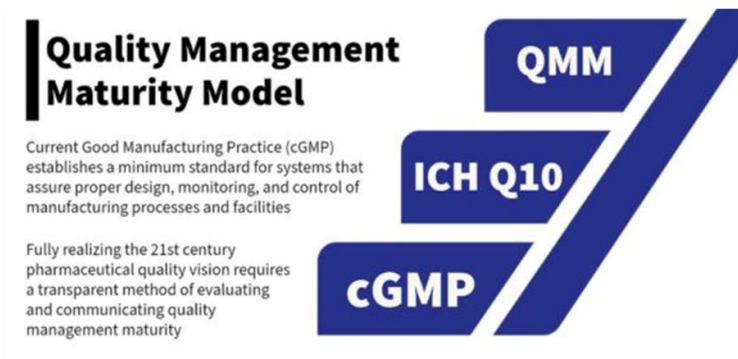


QMM Quantitative Assessment Factors

- An overall risk score is a culmination of four factors:
 - 1. Inspection Factor:** Incorporates measures on health authority observation quantities, global auditing outcomes, overdue and extended CAPAs
 - 2. Manufacturing Factor:** Incorporates measures on calibration and maintenance, batch release, batch acceptance, and invalidated OOS
 - 3. External Defects Factor:** Incorporates measures such as BPDRs, FARs, complaints, and recalls
 - 4. Deviation Factor:** Incorporates measures such as CAPA strength and recurrent investigation rate
- Once a factor is highlighted for review, explore further with advanced analytical tools in alignment with FDA's QMM umbrella

Conclusions:

- Companies should NOT invest in Quality Culture because it is a U.S. FDA initiative but rather because it's the RIGHT thing to do.
- Establishing proactive qualitative and quantitative measures to identify Quality compliance issues will save company resources in the long term.
- QMM is a tool used to measure a company's Quality Culture.



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Acknowledgements:

Adam Caruso

Thank You!