

CDRH's Case for Quality and CMMI

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Agenda



CMMI Performance Solutions Overview



CDRH's Case for Quality Voluntary Improvement Program

CMMI Performance Solutions Ecosystem Overview



The CMMI Has Evolved Significantly Recently – It is Not Your Father's CMMI



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The Global Impact of CMMI



10K+

ORGANIZATIONS



12

NATIONAL GOVERNMENTS



106

COUNTRIES



10

LANGUAGES



424

PARTNERS



4,075

APPRAISALS in 2021

Who Uses CMMI?

Many of the World's Most Respected Organizations Use CMMI



Why Use the CMMI?

- The Capability Maturity Model Integration (CMMI)[®] is a proven set of **global best practices** that **drives business performance** through building and benchmarking key capabilities.
- CMMI best practices **focus on what needs to be done** to improve performance and align operations to business goals.
- Standardized performance **benchmarking and measurement to compare capabilities across organizations**

Why Build Capability? Knowing Your Key Capabilities Creates New Value.

CMMI001V2 © 2021 ISACA

When an organization's distinctive capabilities are clearly defined, everything and everyone within the organization begins to positively reinforce each other to improve performance. The business takes on new life as people know and focus on putting standard processes in place to strengthen their key capabilities, and the result is:

- Increased customer satisfaction
- Increased probability of capturing new and repeat business
- Increased profit through improved quality and less rework
- Increased productivity
- Decreased risks

How Capable is your Organization?

According to McKinsey & Company, capability is: **"anything an organization does well that drives meaningful business results."** All organizations have capabilities. What many don't have is a process by which they can measure their different capabilities against best practices and pinpoint which ones are driving higher performance.



Source: CMMI Institute, "Assess Your Organizational Capability Study," 2015.

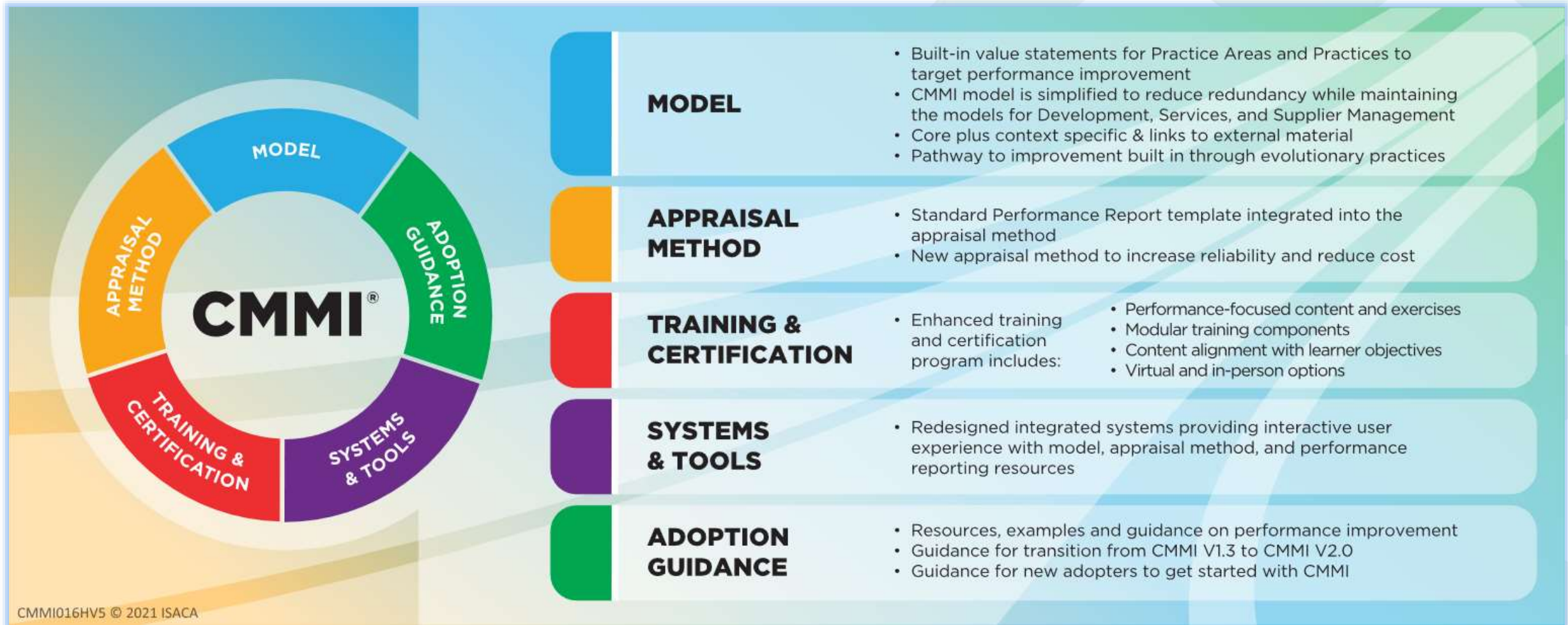
The Benefits of Building Capability



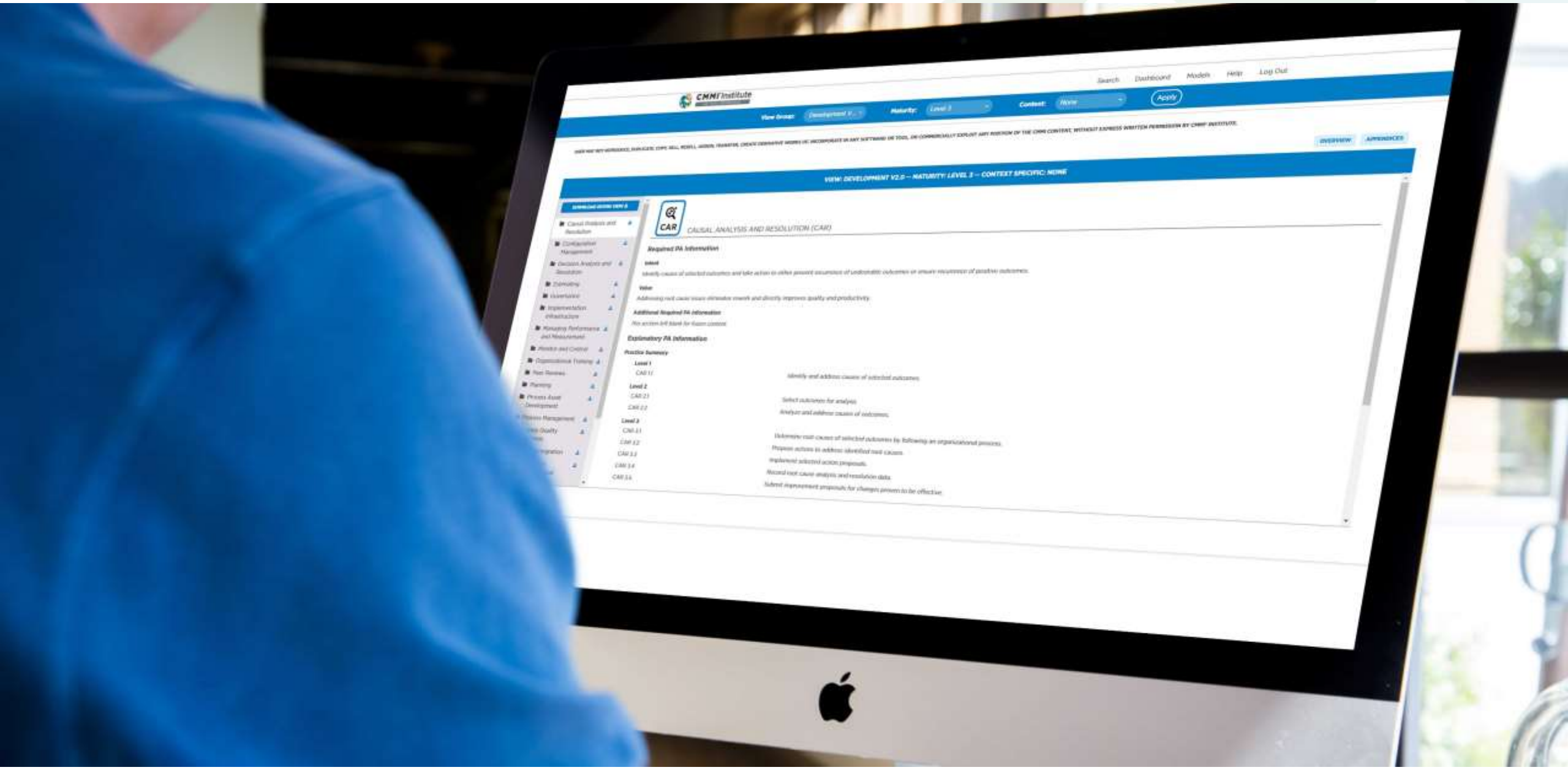
CMMI001V2

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CMMI Product Suite & Ecosystem Overview



CMMI Model Content Shift to Digital Experience



CMMI Capability Areas

CMMI is a broad, but integrated framework, covering many key capabilities across multiple industries and domains.

- The CMMI Model covers 11 major Capability Areas with 29 Practice Areas and enables integration with other standards and frameworks, such as ISO, COBIT, NIST, ITIL, etc.
- CMMI-Development is by far the most widely adopted domain, followed by CMMI-Services
- CMMI-Security/Safety is the latest in new domain/capability areas
- Releasing in 2022: CMMI-Data Management and DevSecOps, CMMI-People and Organizational Behavior



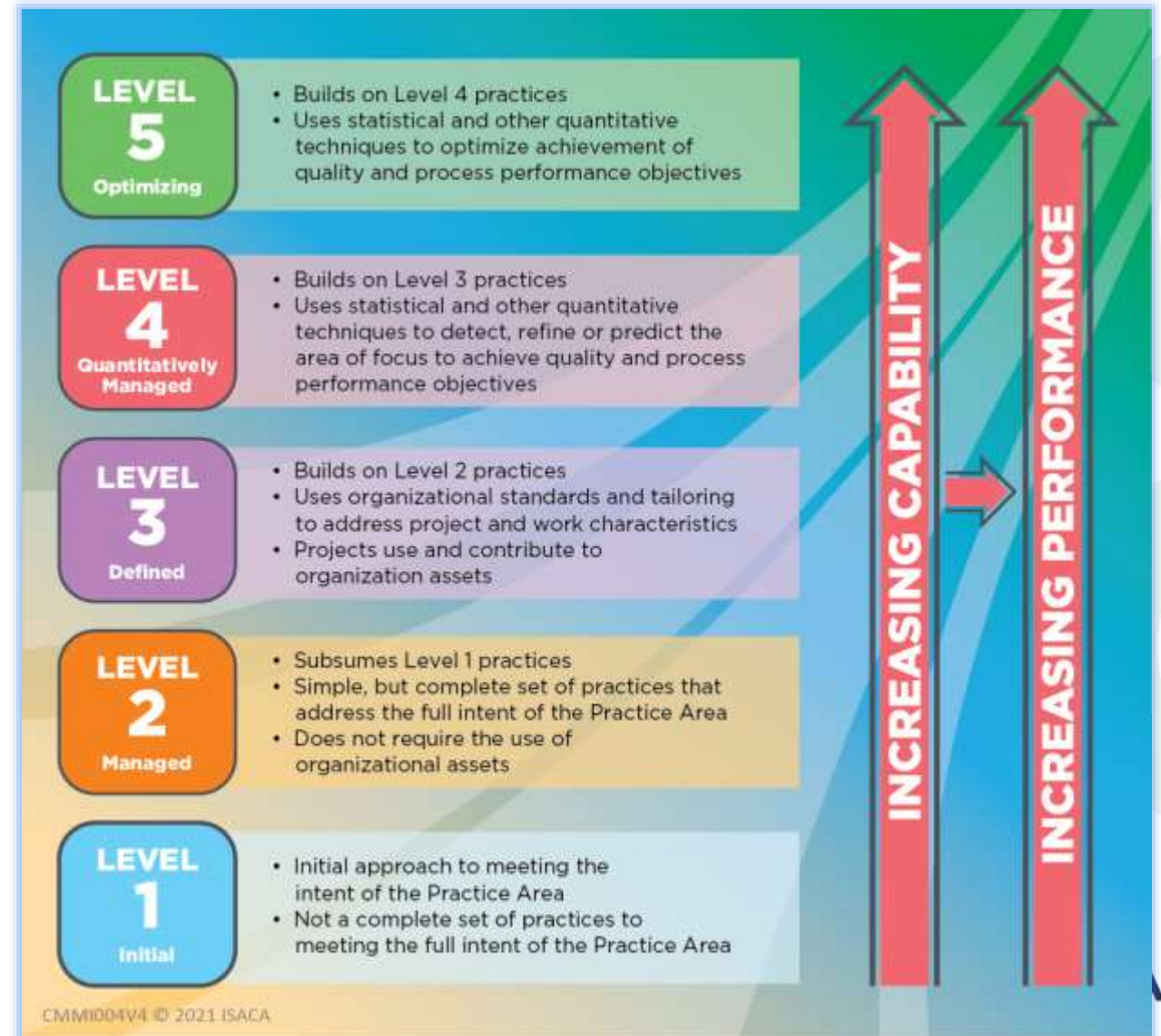
CMMI Architecture Enables Flexible, Continuous Improvement

Organizations can *select and focus on their unique business challenges*



Categories are logical groups or views of related **Capability Areas** that address common problems encountered by businesses when producing or delivering solutions.

Practice Group Levels provide a *clear capability path to performance and quality outcomes*



CMMI Shift to Continual Quality and Performance Improvement vs. Compliance

A compliance-only focus typically assumes that quality and performance is a guaranteed outcome – this is typically NOT true. **Compliance must always be coupled with performance.**

Innovation, Quality, and Performance Improvement Requires Discipline. Each aspect must be counterbalanced by tougher behavior that's less fun...rigorous discipline, a high level of individual accountability, and strong leadership.

From: *The Hard Truth About Innovative Cultures*, Pisano, Gary, Harvard Business Review, Issue 97, Jan/Feb, 2019

Tendency to inflexibility puts long-term change, innovation and improvement at risk

Tendency to become additional level of administrative overhead without clear value to performance or bottom line

Fosters lasting organizational innovation, agility, and performance improvement

Objective data related to business performance improvement

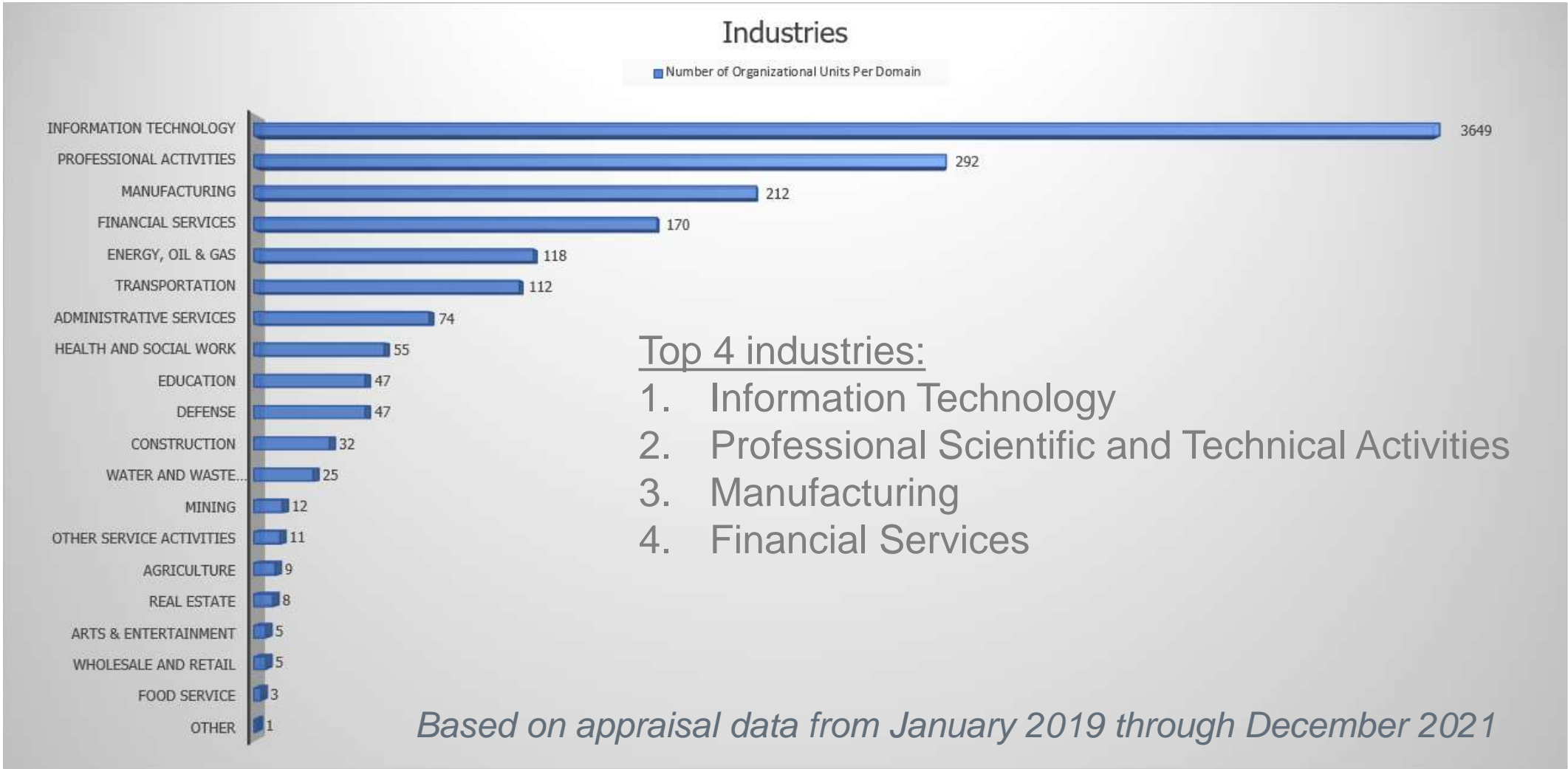
Qualitative as well as quantitative indicators

Compliance

Performance

Focus of Approach

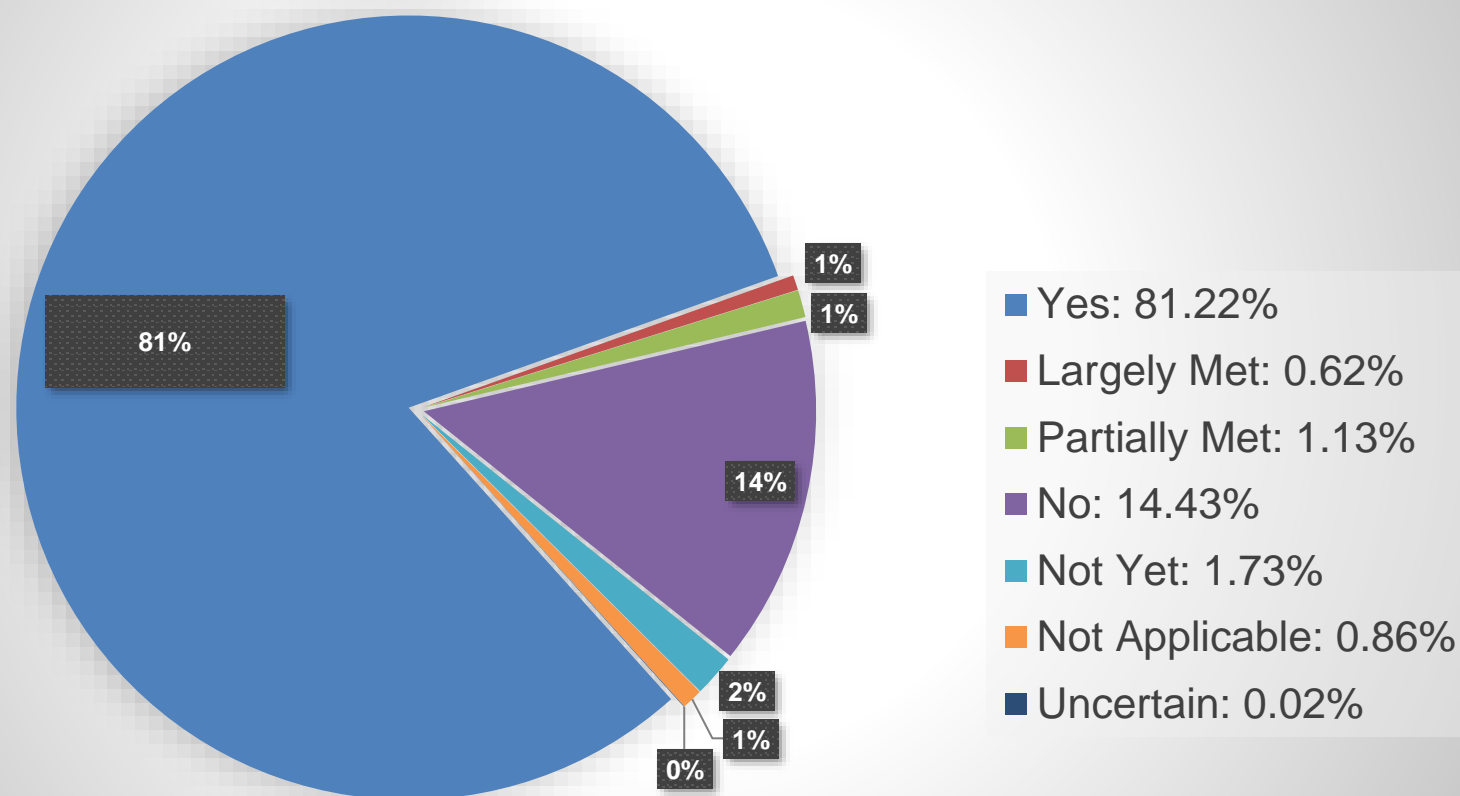
CMMI Industries



CMMI Performance Objectives - 1

*Based on appraisal data from
January 2019 through
December 2021*

Measurement and Performance Objective or QPPO Achieved



Definitions

Yes: Objective fully met

Largely Met: More than half of the criteria was met

Partially Met: Less than half of the criteria was met

No: Objective was not met

Not Yet: At the time of the appraisal, the objective had not been met, but was on target to be met

Not Applicable: Objective was not applicable for the appraisal

Uncertain: Ability to meet the objective was unable to be determined

CDRH's Case For Quality Voluntary Improvement Program



CASE FOR QUALITY VOLUNTARY IMPROVEMENT PROGRAM - HISTORY

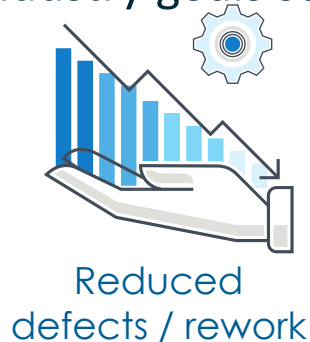
- 2011** [Dr. Jeff Shuren discusses](#) launch of Case for Quality in response to findings from [FDA study](#)
- 2014** [MDIC](#) joins the Case for Quality - [Video Overview of the Case for Quality](#)
- 2015** Formation of Maturity Model Working Group
- 2015** [Deloitte White Paper](#) - selection of [CMMI](#)
- 2016** Proof of Concept Pilots - [Outcomes](#)
- 2017** MDIC Working Groups developed pilot outline
- 2018** Launched [Case for Quality Pilot](#)
- 2021** Pilot transitioned to a formal program by the Case for Quality and is here to stay!



WHAT IS THIS PROGRAM?

The **Case for Quality Voluntary Improvement Program (CfQ VIP or VIP)** is a **collaborative initiative** between FDA CDRH, MDIC, ISACA, and the medical device industry. This Program was developed with the intention to **elevate medical device stakeholders from the established standard of regulatory compliance to advancing medical device quality and safety through sustained and predictive practices** that achieve better patient outcomes.

VIP leverages the Medical Device Discovery Appraisal Program (MDDAP), which is a **tailored version of the ISACA CMMI framework**, as a model and appraisal method by which medical device organizations can measure their capability to manufacture high quality devices. **FDA CDRH has adjusted the engagement activities** and submission requirements for VIP participants in recognition of completing this independent assessment and committing to continuous improvement in an effort to support their individual improvement journeys and reach industry goals such as:



A culture of quality - across the organization.

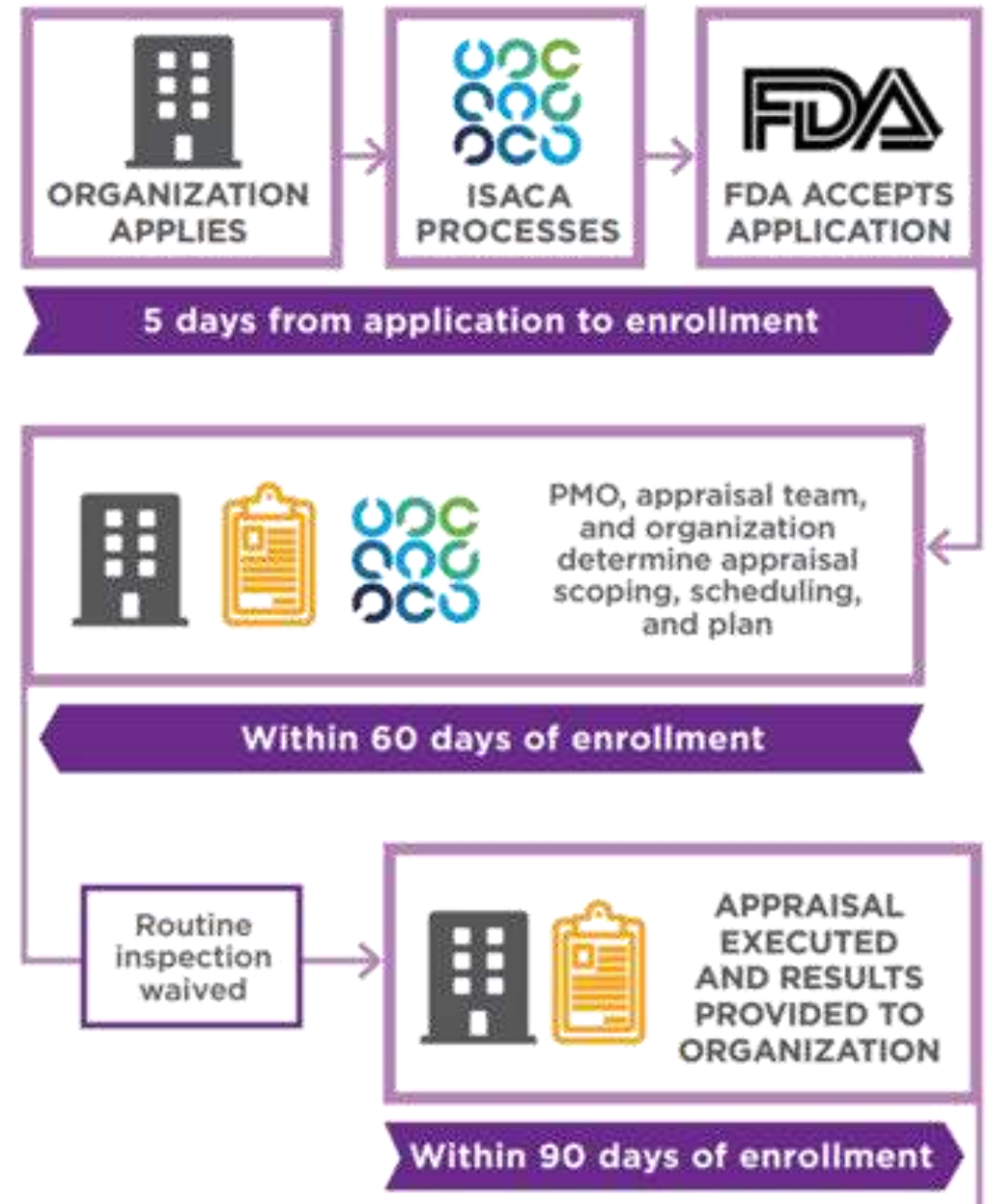
Compliance is important, but not enough. How do we build a culture of quality?

Medical device organizations that market devices in the US and have no Official Actions Indicated are eligible to apply for VIP

Site plans and completes third-party MDDAP appraisal that leverages the ISACA CMMI framework to assess the facility's capability to manufacture high-quality devices

To reduce disruption and burden to innovative changes:

- Forgo surveillance inspection
- Forgo risk-based inspections
- Forgo post-approval inspections



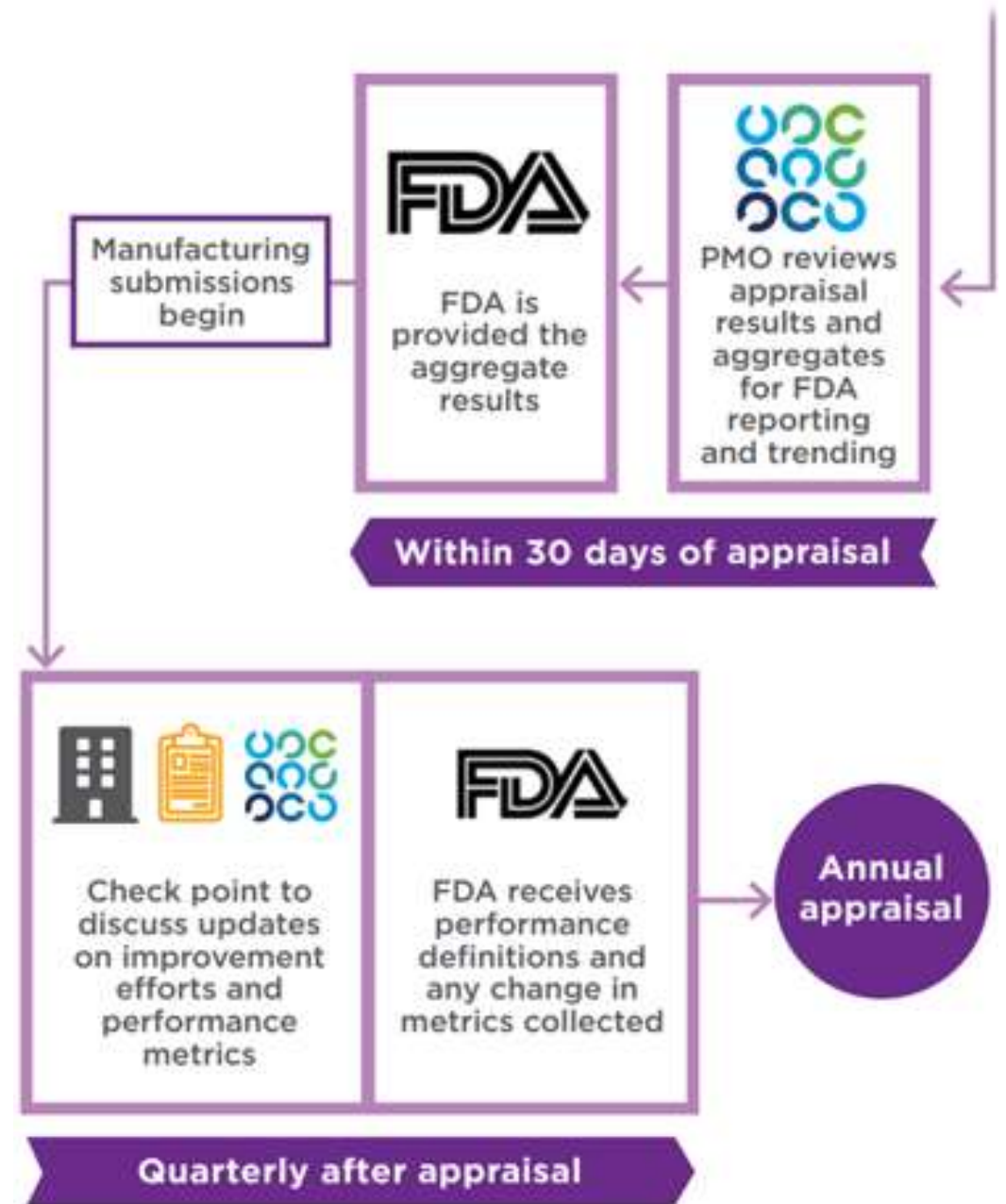
Compliance is important, but not enough. How do we build a culture of quality?

The appraisal (approach and method) undergoes quality review, and, upon approval, high-level results are submitted to FDA

Facility completes quarterly check points with Appraiser to discuss progress and submit performance metrics

To reduce disruption and burden to innovative changes:

- Manufacturing change notice submissions *streamlined & accelerated, 10 business days*
- Manufacturing site transfers *streamlined & accelerated, 25 business days*
- Original PMA manufacturing module *streamlined, waiver of preapproval inspection*

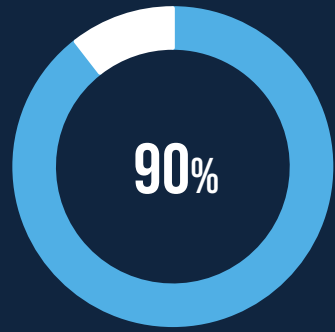


WHO IS INVOLVED?

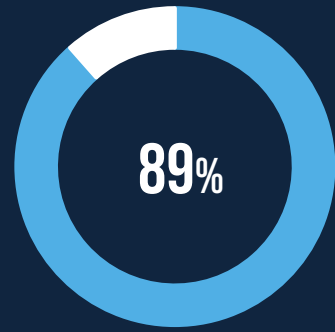
Group	Responsibilities (all provide input and feedback to VIP)
MDIC Board	Has fiduciary responsibilities for MDIC
CfQ Steering Committee	Provides direction for Case for Quality and alignment of all the Case for Quality initiatives
VIP Governing Committee	Provides strategic leadership for VIP, reviews VIP Working Group recommendations, includes membership by FDA, MDIC, and medical device industry members, as well as advisors from ISACA and MDDAP Appraisers
VIP Working Groups	Authorized to investigate specific program topics and make recommendations to the VIP Governing Committee
FDA	Supports and authorizes regulatory opportunities, reviews data analysis and trending, verifies participant eligibility
MDIC	Convener of Case for Quality activities, facilitates CfQ Steering Committee and VIP Governing Committee, coordinates CfQ Forums and webinars, and supports stakeholder involvement
Device Manufacturers	Engages in appraisal planning activities and the appraisal itself, drives improvements within organization based on opportunities identified in appraisal, participates in checkpoints to report progress, and submits performance metrics
MDDAP Appraisers	Conducts planning and appraisal activities year over year, provides results to participants and PMO, executes check points quarterly (at minimum) and submits reports and performance metrics to PMO
ISACA	Program Management Office for VIP, provides CMMI® model and framework, manages enrollment/de-enrollment, provides training and guidance for appraisers, assures consistency in service and quality of appraisals and appraisers, collects appraisal and performance data for analysis and trending, provides de-identified and/or aggregate data analysis to VIP stakeholders, facilitates VIP Working Groups, connects new participants to participant Mentors, and adjusts approach based on feedback from VIP stakeholders

Program Effectiveness – 2021 Survey Results

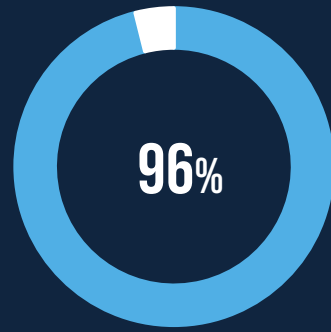
(305 respondents)



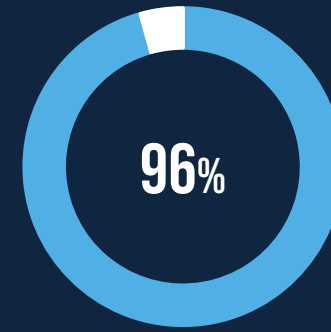
Had a positive
experience with
appraisal
activities



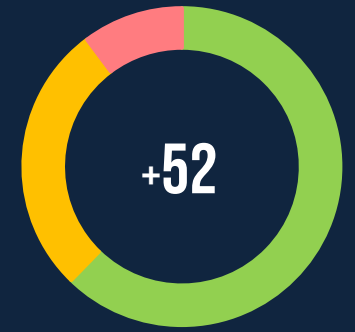
Believe the
appraisal
identified
opportunities
to improve
product quality



Saw no conflict
between
compliance and
the appraisal
activities



Believed the
appraisal
provided
broader value
add



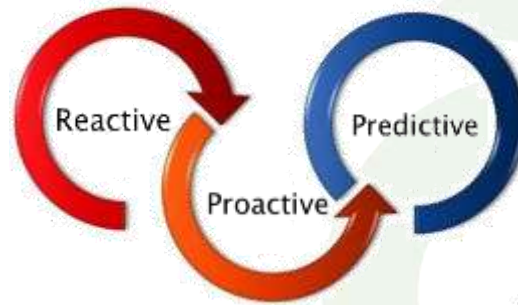
Net Promoter
Score

Range:
-100 to +100

Program Effectiveness – Survey Themes in Product Quality



- **Better knowledge** of what product quality is and how to produce it with new ideas & perspectives
- **Common language** across teams, improved communication
- **Standardized reporting** metrics, better understanding of measurement systems, tracking mechanisms supporting accountability
- **Better sharing** of information across R&D, Operations, and QA/RA
- **Better access** between departments, getting the right people together
- **Aligned objectives** as a company
- **Predictable communication** pathway for escalations for faster resolution of needs

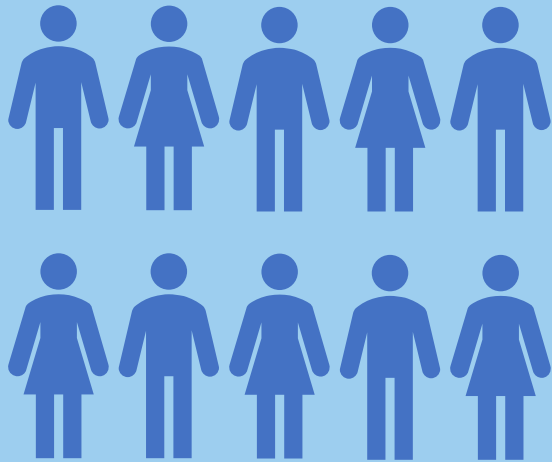


- Pathway towards **anticipating and preventing delays** and nonconforming products
- **Making corrections before** errors become nonconformity
- **Earlier identification** of potential issues, taking action before impact
- **Increased rigor and predictability** in new product development
- **Improved risk mitigation** of nonconforming products, process control, and supply chain
- **Increased rigor** around training and understanding processes
- **Agility** in decision making

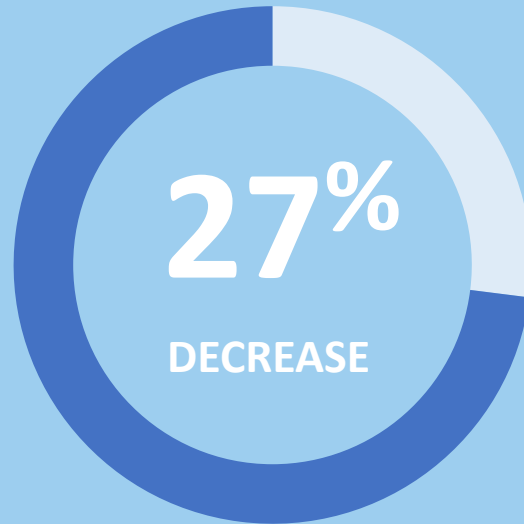
- Focused on **continuous improvement** culture
- From **start-up culture** to **mature company**
- Greater sense of **direction**
- Pursuit of **systemic changes** rather than just addressing problem at hand
- Tackling projects with **lasting benefits**
- Shift **from tactical to strategic** thinking
- Focused **quality culture**
- Increased **customer satisfaction**
- Looking at **holistic view** of organization
- Recognition **we all contribute** to quality



PROGRAM EFFECTIVENESS – REPORTED VALUE IN PROGRAM



10 FTEs reallocated to
higher value operations



In Complaint
Closure Time



Patients received faster,
life-saving treatment

Program Effectiveness – Case Study: Building Capability w/ CMMI

↑ **62% daily production**

↑ **quality culture**

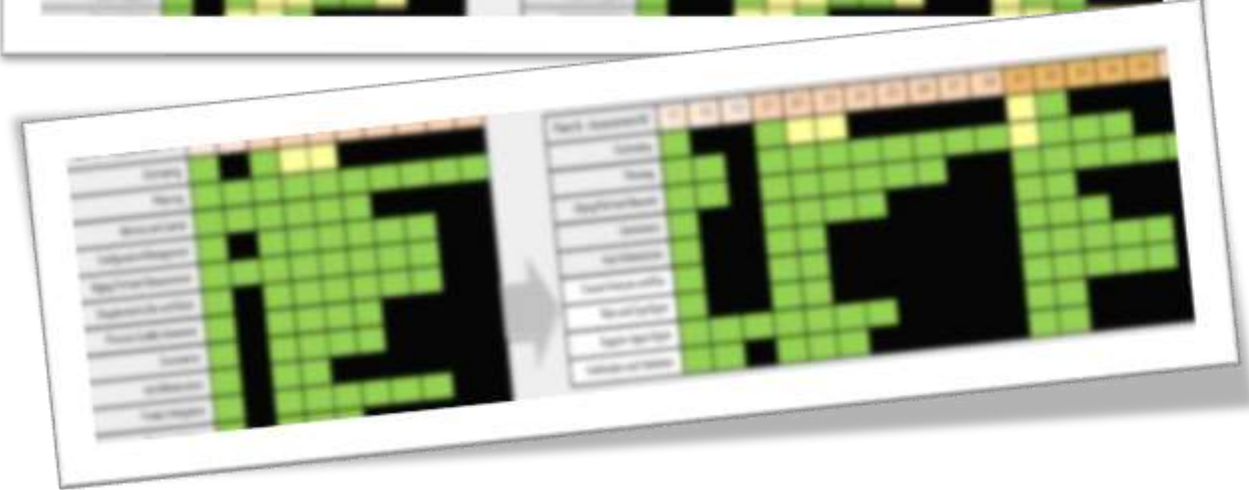
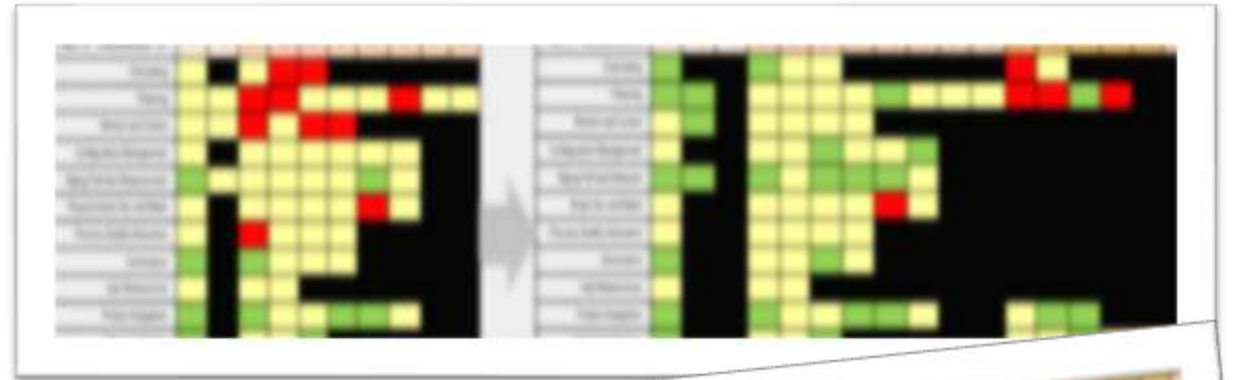
86 → **00 open headcount**

10% → **3% turnover**

30d → **3d root cause**

↓ **complaint reduction**

485 → **24 CIPM (complaint incidents per million)**



Elevating Industry: Appraisal Data - Industry Reports



Welcome, User

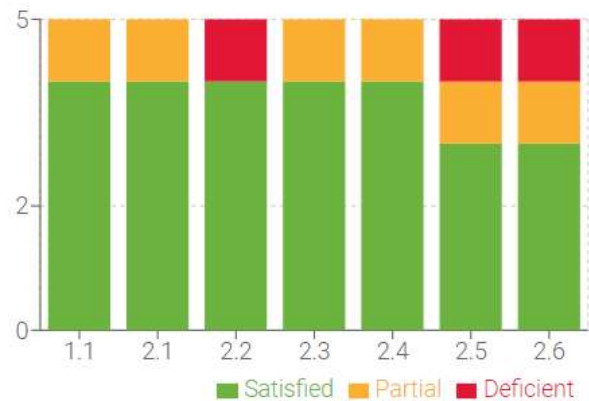
- Data Reports
- Industry Reports
- Organization Reports
- Resources

Data Reports > Industry Reports > Baseline

Table 1 [Configuration Management, PGL 2, Year 1]

Practice Characterization

Displays the cumulative industry characterizations for each practice in the selected PA and PGL.



- Aggregate Percentage

Displays the distribution of results (in quintiles) for the Aggregate Percentage of the selected PA and PGL.

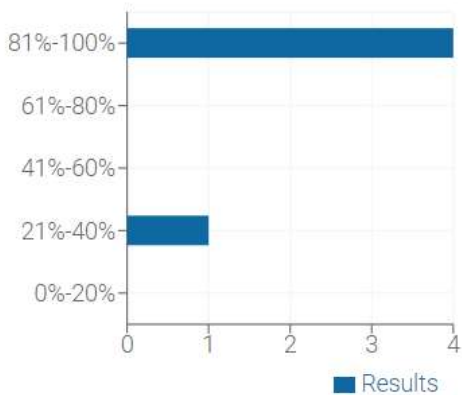
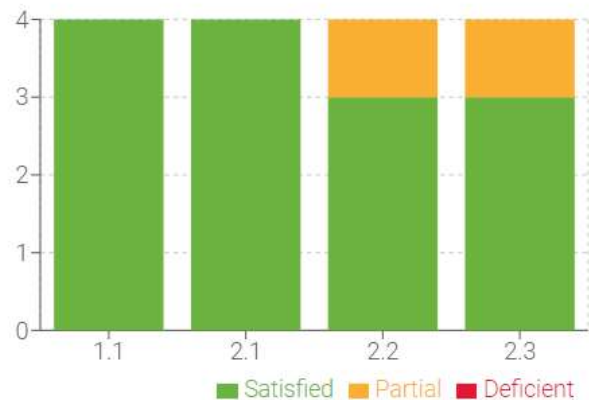
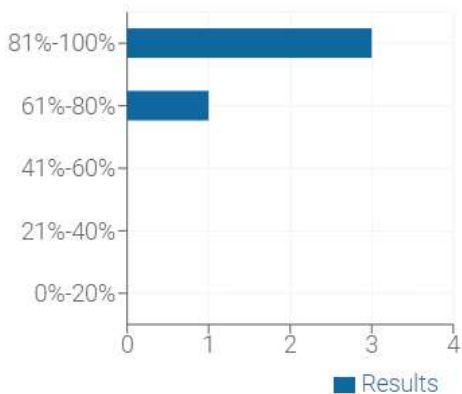


Table 2 [Estimating, PGL 2, Year 1]

Practice Characterization



+ Aggregate Percentage



Download Report

Select a practice for more information.

Elevating Industry: Performance Data – Organization Reports



Welcome, Marlene

Data Reports

Resources

User Management Log Out

Data Reports > Organization Reports > Actual Performance Report

Download Report

Detailed Appraisal Report

Aggregate Appraisal Report

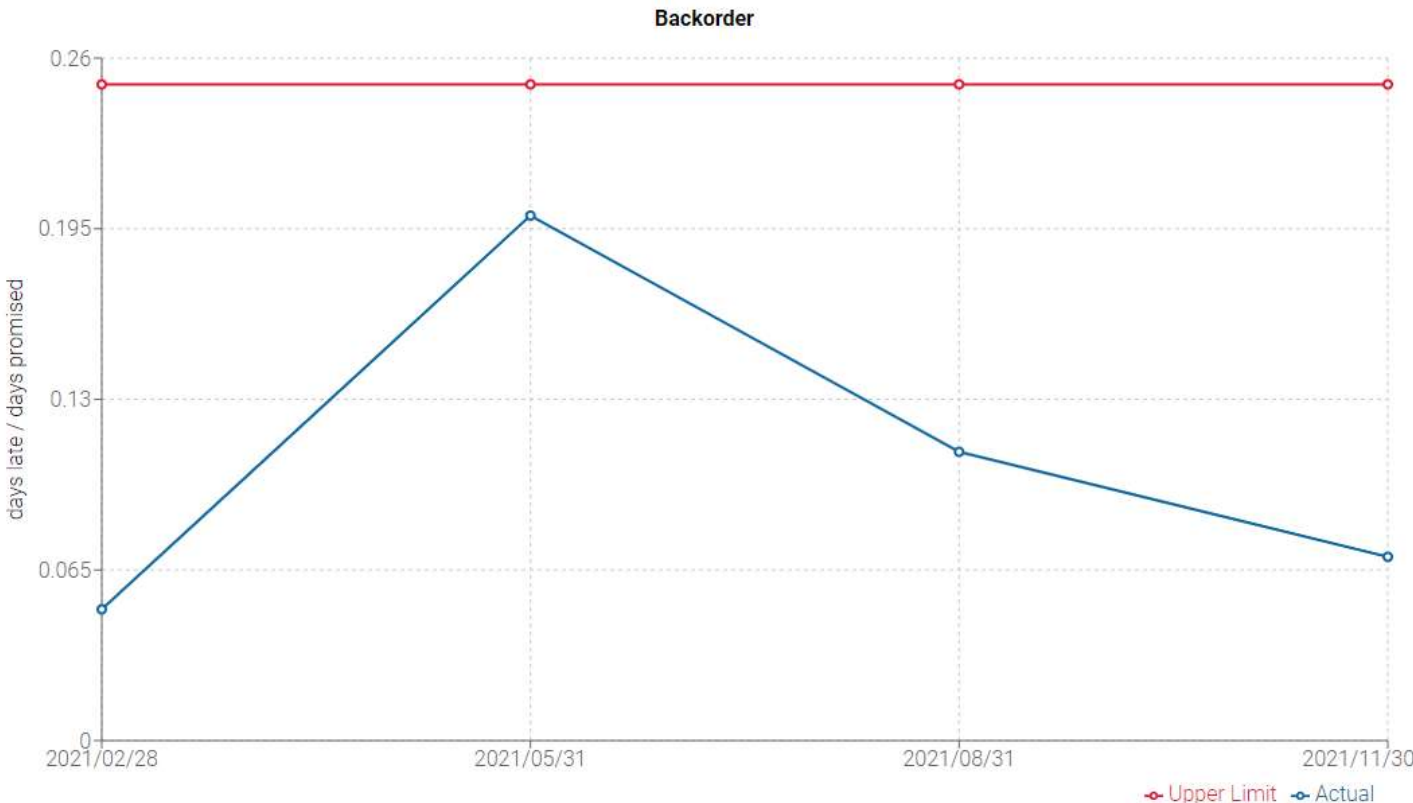
Actual Performance Report

Delta Performance Report

Actual Performance Report

Performance Report metrics represented graphically over all time, including actuals and targets.

Select a graph title or submission date (x-axis) for more info.



Recap: The Value of CMMI



Improve Quality, Performance and Business Outcomes

Business goals are tied directly to operations in order to drive measurable improved performance against time, quality, budget, customer satisfaction and other key drivers throughout the supply chain.



Agile Resiliency and Scalability for Any Industry

Direct guidance on how to build and improve other critical capabilities to enable innovation and scalability for supply chain management, product development, service operations, data management and more.



Increase Value of Benchmarking

The performance-orientated appraisal methods improves reliability and consistency of benchmarks and performance results while reducing preparation time and lifecycle costs.



Accelerate Supply Chain Management Capability and Performance

Online access and adoption guidance makes straightforward best practices easily accessible to systematically build critical capabilities, improve their performance and achieve benefits for the entire supply chain.

Thank you!

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