MDIC Case for Quality Program

Maturity Model Research Report

June 2015

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1.0   Introduction

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. MDIC conducted a project sponsored by the Food and Drug Administration (FDA) to conduct research concerning the use of maturity models in other industries. Although there are explicit regulations globally for medical devices and diagnostics, there is no recognized quality system maturity model. The objective of this research was to gain an understanding of various maturity models and how they have been implemented and leveraged within other industries. This information will be helpful to devise a plan for the potential development of a maturity model for use by both industry partners and regulators in the Medical Device industry.

2.0   Executive Summary

One of the primary objectives of a maturity model is to help organizations assess operations consistently and reproducibly. The outputs of the maturity assessments allow for the development of strategies that can lead to improved operations and quality – either product, service, or both. MDIC members, including industry and FDA, are pursuing the development of a quality system maturity model which will facilitate consistent, effective communication and assist in the prioritization of quality issues.

In order to leverage established maturity models and identify learnings from past implementations across industries, recognized maturity models were researched for fit and purpose. Research on the maturity models was conducted through literature review, interviews with subject matter advisors, industry benchmarking, and regulator interviews. Initial research was conducted on publically available sources to identify published maturity models.

Twenty-two models across seven industries were examined to identify potential maturity models for analysis.
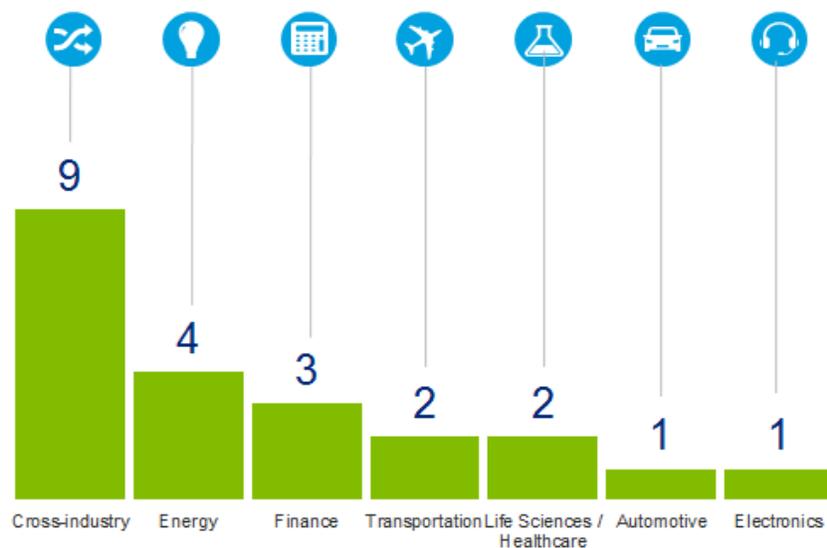

Figure 2.1: Distribution of Maturity Models Researched by Industry

A fit analysis was conducted on the maturity models identified from the literature review to determine a subset of models for evaluation. Five models were identified for further study:

Maturity Model	Function	Industry	Level of Fit
Capability Maturity Model Integration v1.3	Product Development	All	●
Global Aviation Safety Roadmap	Safety Management	Transportation	●
Electricity Subsector Cybersecurity CMM v1.1	Cybersecurity	Energy	◑
Privacy Maturity Model	Privacy	All	◑
Procurement Maturity Model	Procurement	All	◑

● Very Good Fit   ◑ Good Fit   ◔ Weak Fit

Table 2.2: Models Identified for Further Study

Capability Maturity Model Integration (CMMI) is a process model that provides a definition of what an organization should do to promote behaviors that lead to improved performance. With five "Maturity Levels" and three "Capability Levels," the CMMI defines the important elements that are required to build products, or provide services, and summarizes them in a model. Capability Levels refer to an organization's process improvement relative to a specific area, while maturity levels refer to an organization's overall process improvement. The three capability levels are directly related to the first three levels of maturity (Initial, Managed, and Defined), and applied to a specific process area.

The Global Aviation Safety Roadmap defines twelve specific focus areas and related objectives that have been accepted by industry as essential to the enhancement of safety levels within global commercial aviation. The roadmap defines specific practices that can enable organizations to address and correct the deficiencies outlined by the focus area.

The Electricity Subsector Cybersecurity CMM (ES-C2M2) provides a mechanism that helps organizations evaluate, prioritize, and improve cybersecurity capabilities. The model is a common set of industry-vetted cybersecurity practices, grouped into ten domains and arranged according to maturity level.

The AICPA/CICA Privacy Maturity Model (PMM) is based on Generally Accepted Privacy Principles and the Capability Maturity Model (CMM). The PMM provides entities an effective means of assessing their privacy program against a recognized maturity model and has the added advantage of identifying the next steps required to move the privacy program in a positive direction.

The Procurement Maturity Model is a self-assessment tool which can be used by procurement departments working with or focusing on efficiency and their level of maturity within different areas of procurement.

A benchmarking survey and interview guide were developed to gather information on the use and implementation of maturity models across various industries. Responses were supplemented by interviews conducted with survey respondents, subject matter advisors and regulators within respective industries. 210 professionals were contacted from 130 companies across multiple industries, company sizes, and geographies. Responses (n=37) were collated and analyzed to identify trends across the implementation and use of maturity models. A number of potential respondents provided feedback that they did not use maturity models and therefore were not able to participate in the survey.

Research indicates that the CMMI model was the most commonly implemented model. In the literature research, it was identified that other models that focused on different processes and industries leveraged the CMMI model as well. One such model, Test Maturity Model Integration (TMMI), was also commonly used. Of the companies that participated in the Maturity Model Benchmarking survey, 76% used the CMMI model, 16% used the TMMI model, and 8% used another model or maturity tool (Figure 2.3)**.** Therefore, in aggregate, 92% of the companies that responded used maturity models that were based off of CMMI principles.
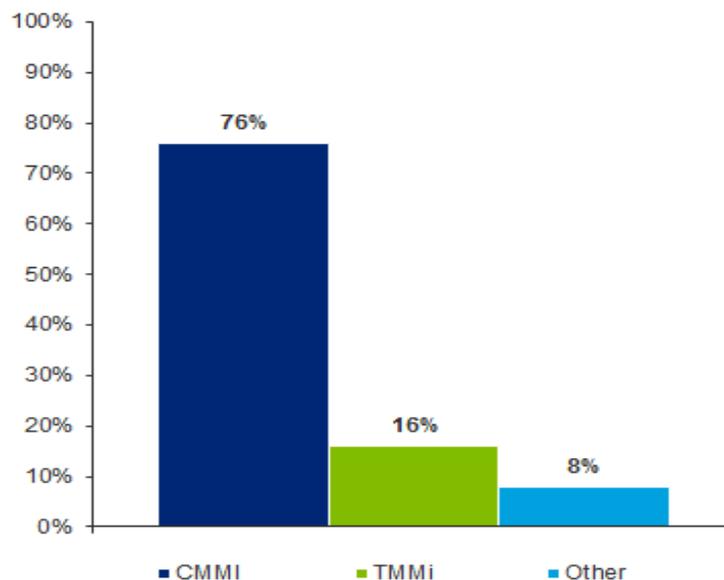

Figure 2.3: Distribution of Maturity Models Used to Conduct Maturity Assessment

Recommendations

It is recommended that CMMI be leveraged as the basis for the development of a quality system maturity model for Medical Devices. CMMI has been successfully implemented in multiple regulated industries and includes a significant number of elements that are applicable to Medical Devices. Other industries have attempted to develop and implement maturity models with their regulatory counterparts with limited success. Developers should focus on maintaining transparent and collaborative communications between regulators and industry when defining leading practices and maturity benchmarks. The published maturity model should be concise, relatively simple to understand, and easy to implement. Examples were identified of maturity models where complexity increased the level of difficulty to efficiently and effectively perform assessments and the implementation and use of the model became cost prohibitive. The quality system maturity model for medical devices should be lean and efficient with the ability to be implemented at medical device companies of various size, organizational and geographic structure, and product portfolio.

CMMI is a model that warrants further consideration for the development of a quality maturity model for the medical device industry based on:

- globally recognized across multiple industries;

- well-established (20+ years) with demonstrated success;

- governed and maintained by an independent authority that also performs the assessments;

- well-defined and holistic in terms of people, process, and technology;

- flexibility across companies of various size, organizational and geographic structure, and product portfolio;

- ease to update with regulatory changes;

Specifically, the CMMI model:

- contains requirements for a formal decision analysis process that could help medical device designers to gather facts and data, analyze alternatives, make decisions, and record this decision data;

- compliments medical device standards by focusing on process performance and closed loop improvement;

- places importance and recognition on the institutionalization of process performance and continuous improvement within organizations;

- facilitates prioritization of processes to address the most critical processes with the highest maturity levels, which may be applicable to medical device classification levels;

- facilitates ease of adoption and maturity progress which can lead to process standardization across various organizational levels increasing efficiency and consistency;

- encourages sharing of lessons learned and celebrates successes, which fosters a culture of quality and improvement;

Efforts will need to be taken by MDIC to develop the inputs for the CMMI maturity levels that will allow for consistent, repeatable cross-industry implementation. Consistent maturity definitions, required evidence, and associated quantifiable measures and metrics will facilitate implementation across the medical device industry. Collaboration and alignment between regulators and industry on leading practices, assessments and benchmarking thresholds including metrics, should be a focus of the development. A project management program and clear governance structure should be devised to facilitate implementation and track success. Communications and change management should support the implementation throughout the initial implementation and on-going communications and lessons learned should be distributed.

3.0   High Level Research Approach

Research was conducted through four main sources: literature review, subject matter advisor interviews, industry benchmarking (via survey), survey participants and regulator interviews. Literature research was conducted to identify published maturity models within various industries. A maturity model fit analysis was performed against the identified models from the literature research. This analysis determined a subset of five models that warranted further evaluation. Subsequently, a survey was developed and distributed to organizations cross-industry to obtain specific information concerning the use and value of these five maturity models. Qualitative interviews with regulators, subject matter advisors within respective industries, and survey participants were conducted to gather information on the implementation and use of these maturity models across industries.
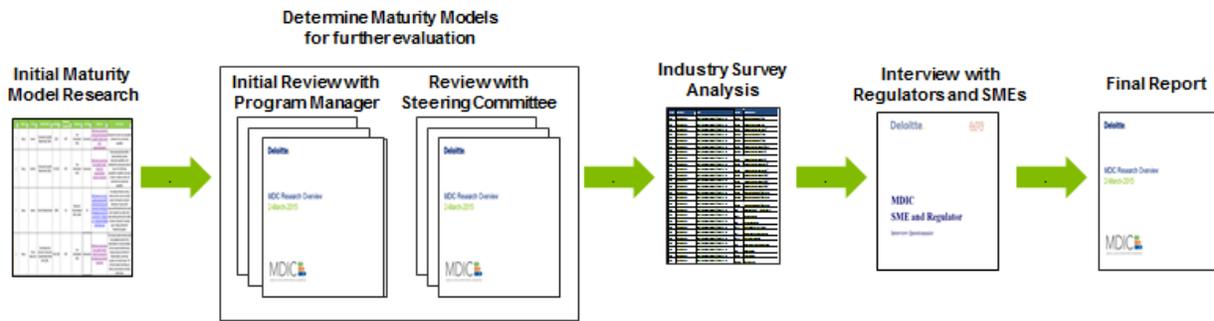

Figure 3.1: High Level Research Approach

4.0   Literature Research and Fit Analysis

The purpose of the literature research and fit analysis was to identify published, relevant maturity models and evaluate each model's potential for conducting further study against criteria agreed upon by the MDIC Steering Committee.

4.1 Models Researched and Industry Distribution

Twenty-two models across seven industries were examined to identify potential maturity models for analysis. Information sources used were publically available sources, government websites, and university research. The initial screening criteria used to select models for further evaluation is listed below:

- How long the model has been established

- How widely the model has been accepted

- Recognition by regulators
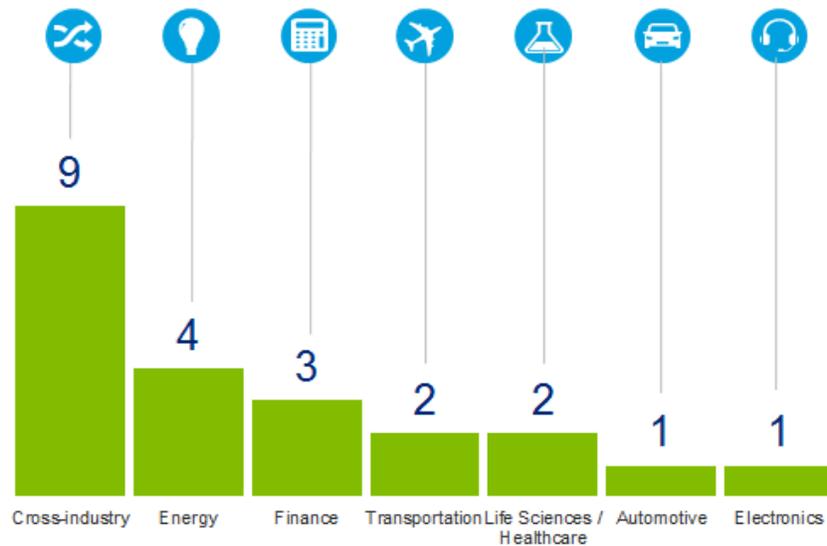
- Implementation by industry

- Complexity

Figure 4.1.1: Distribution of Maturity Models Researched by Industry

4.2 Fit Analysis

In order to develop a rational list of models, criteria were applied to determine each model's potential fit for the medical device industry. A qualitative fit analysis was conducted to evaluate the degree of fit for each model.

Fit levels and criteria are listed below:

Very good fit

- Holistic - including people, process, and technology
- Ease to update with regulatory change
- Applicability to the Medical Device Industry
- Training methods incorporated into model
- Well-defined content
- Tools created for implementation
- Recognition by industry / regulators
- Provides next steps / actionable items
- Ability to handle diverse product portfolio
- Agility with size of business

Good fit

- Contains elements of people, process, and technology
- Established model
- Defines specific components
- Some applicability to Medical Device Industry

Weak fit

- Does not easily apply to Medical Device Industry
- Model is not widely implemented
- Specific components not well defined
- Does not provide next steps / actionable items

Five models were determined to be either a "Very Good" or "Good" Fit potentially for the medical device industry (see table below). Other models that were determined to be a weak fit were not included for further evaluation. Summary information concerning these models is listed in the appendix.

Maturity Model	Function	Industry	Year Created	Level of Fit
Capability Maturity Model Integration v1.3	Product Development	All	2010 Built off CMM (1990)	●
Global Aviation Safety Roadmap	Safety Management	Transportation	2011	●
Electricity Subsector Cybersecurity CMM v1.1	Cybersecurity	Energy	2012	◐
Privacy Maturity Model	Privacy	All	2011	◐
Procurement Maturity Model	Procurement	All	2014	◐

● Very Good Fit ◐ Good Fit ◔ Weak Fit

Table 4.2.1: Models Identified for Further Study

4.3 Maturity Models Selected for Further Evaluation

Three major areas were examined for the five models selected: background information, specific components, and relevancy. This section presents the detailed information of each model.

4.3.1 Capability Maturity Model Integration (CMMI) v1.3

Maturity Level	Characteristic
Level 5: Optimizing	• Focus on process improvement
Level 4: Quantitatively Managed	• Processes measured and controlled
Level 3: Defined	• Processes characterized for the organization and are proactive
Level 2: Managed	• Processes characterized for projects and is often reactive
Level 1: Initial	• Processes unpredictable poorly controlled and reactive

Table 4.3.1.1: Characteristics of the CMMI Maturity Levels 1-5
(Reference: http://www.sei.cmu.edu)

Background Information

Capability Maturity Model Integration (CMMI) is a process model that provides a definition of what an organization should do to promote behaviors that lead to improved performance. With five "Maturity Levels" and three "Capability Levels," the CMMI defines the important elements that are required to build products, or provide services, and summarizes them in a model. Capability levels refer to an organization's process improvement relative to a specific area, while maturity levels refer to an organization's overall process improvement. The three capability levels are directly related to the first three levels of maturity (Initial, Managed, and Defined).

- The Capability Maturity Model Integration v1.3 was developed in 2010 by the Software Engineering Institute at Carnegie Mellon (based upon the original CMM model developed in 1990)

- The model aims to provide guidance for developing or improving processes that meet the business goals of an organization

- Five levels of maturity:

  o **Level 1-Initial:** The process is characterized as ad hoc, inconsistent, and occasionally even chaotic. Defined processes and standard practices to the extent that they exist are summarily abandoned during a crisis. Success depends on individual effort, talent, and heroics. The heroes, of course, eventually move on to other projects or organizations, taking their knowledge with them.

  o **Level 2-Repeatable:** Basic and consistent project management processes are established to track cost, schedule, and functionality. The process discipline is in place to repeat earlier successes on projects with similar applications. However, the discipline and process while established varies from project to project. Program management is a characteristic of a level two organization.

  o **Level 3-Defined:** The process for both management and engineering activities is documented, standardized, and integrated into a standard process for the entire organization. All projects use an approved, tailored version of the organizations standard process for developing and maintaining . Consistent practices across the organization minimize the learning curve for people moving to new teams and projects.

  o **Level 4-Managed:** Detailed measurements of software process and product quality collected throughout the organization drive strategic analysis. Both the software process and products are quantitatively understood and controlled.

  o **Level 5-Optimizing:** The key characteristic is continuous, pro-active process improvement, enabled by quantitative analysis of the process and by piloting innovative ideas and technologies. In other words, continuous improvement becomes institutionalized into the development process.

Key Components

- Model incorporates twenty-two process areas that list and describe the aspects of the product development that are to be covered by the organizational processes.

- Capability Levels refer to an organization's process improvement relative to a specific area, while maturity levels refers to an organization's overall process improvement. The three capability levels are directly related to the first three levels of maturity (Initial, Managed, and Defined), but a applied to a specific process area.

- The core process areas include:

  - Causal Analysis and Resolution
  - Configuration and Management
  - Decision Analysis and Resolution
  - Integrated Project Management
  - Measurement and Analysis
  - Organizational Process Definition
  - Organizational Process Focus
  - Organizational Performance Management
  - Organizational Process Performance

  - Organizational Training
  - Project Monitoring and Control
  - Project Planning
  - Process and Product Quality Assurance
  - Quantitative Project Management
  - Requirements Management
  - Risk Management
  - Supplier Agreement Management

Relevancy

- Established model that is recognized by industry and regulators

- Well-defined content

- Can be applied to the medical device industry

- Ease to incorporate changing regulatory requirements into model

- Provides working examples

- Includes actionable items and next steps

- Ability to handle diverse product portfolio

- Agility with size of business

- Focus on people and culture

Application to the Medical Device Industry

- CMMI Risk Management process addresses "project" risks and not safety risks; however, it can be modified to include safety risk management practices which follow a similar methodology. In several instances in other industries, lead appraisers have required that safety risk management practices be incorporated into the model.

- CMMI contains requirements for a formal decision analysis process that could help medical device designers to gather facts and data, analyze alternatives, make decisions, and record this decision data.

- **CMMI for Development** compliments medical device standards by focusing on process performance and closed loop improvement. There are placeholders for regulatory requirements such as Design Controls, Production and Process Controls, etc.

- **CMMI for Acquisition** provides insight into purchasing and supply, which link into medical devices quality system components including purchasing controls.

- **CMMI for Services** supports information on how services are provided and received, both internally and externally.

- The combination of development, acquisition, and services maturity frameworks or "constellations" together provide for more complete coverage of the medical device lifecycle.

- CMMI places importance and recognition on the institutionalization of process performance and continuous improvement within organizations.

- CMMI facilitates prioritization of processes to address the most critical processes with the highest maturity levels, which may be applicable to medical device classification levels.

- CMMI provides flexibility to develop and incorporate metrics to support each level and capability.

- Model adoption and maturity progress can lead to process standardization across various organizational levels increasing efficiency and consistency.

- Implementation of CMMI facilitates sharing of lessons learned and celebrates successes, which fosters a culture of quality and improvement.

4.3.2   Global Aviation Roadmap

Maturity Level	Characteristic
Level 4: Highly Evolved	• The operator/service provider compliance is established through internal and external assessments/audits • A system is in place to assess compliance on a continuous basis and corrective actions are taken promptly whenever appropriate • Staff are aware of the regulatory requirements and are actively encouraged to apply the requirements
Level 3: Evolving Changes in Work	• The operator/service provider complies with most applicable regulatory requirement and lapses in compliance do not affect safety critical areas • The operator/service providers does not have an effective system to ensure its continuous compliance with regulatory requirements
Level 2: Areas Identified for Improvement	• Compliance with regulatory requirements • The operator/service provider does not have a system to ensure its regulatory compliance • Lapses in compliance exist and may affect safety critical areas
Level 1: Developing	• Major lapses in regulatory compliance exist • Willful non-compliance with regulatory requirement in the frequent

Table 4.3.2.1: Characteristics of Global Aviation Roadmap Maturity Levels 1-4
(*Reference: http://flightsafety.org*)

Background Information

The Global Aviation Safety Roadmap defines twelve specific focus areas and related objectives that have been accepted by industry as essential to the enhancement of safety levels within global commercial aviation. The roadmap defines specific practices which will enable industry to address and correct the deficiencies outlined by the focus area. The objective of the roadmap is to provide common framework for assessing twelve focus areas that are vital to the enhancement of safety levels within global commercial aviation. In 2011, the Global Aviation Safety Roadmap was developed in collaboration between industry and regulators including:

- Airports Council International (ACI)
- Airbus
- Boeing
- Civil Air and Navigation Services Organization (CASNO)
- Flight Safety Foundation
- International Air Transport Association (IATA)

Key Components

- Inconsistent Implementation of International Standards
- Inconsistent Regulatory Oversight
- Impediments to Reporting Errors and Incidents
- Ineffective Incident and Accident Investigation
- Inconsistent Coordination of Regional Programs
- Coordination of Regional Programs
- Impediments to Reporting and Analyzing Errors and Accidents
- Inconsistent Use of Safety Management System
- Inconsistent Compliance with Regulatory Requirements
- Inconsistent Adoption of Industry Best Practices
- Non-alignment of Industry Safety Standards
- Qualified Personnel
- Gaps in Use of Technology to Enhance Safety

Relevancy

- Based on established model (Capability Maturity Model)
- Created in collaboration with industry and regulators
- Well defined components
- Based on regulatory requirements
- Agility with size of business

4.3.3   Electric Subsector Cybersecurity CMM V1/1

Maturity Level	Characteristic
Level 3: MIL3	• Monitoring requirements are based on the risk to the function • Monitoring is integrated with other business and security processes • Continuous monitoring is performed across the operational environment to identify anomalous activity • Risk register (RM-2) content is used to identify indicators of anomalous activity • Alarms and alerts are configured according to indicators of anomalous activity
Level 2: MIL 2	• Monitoring and analysis requirements have been defined for the function and address timely review of event data • Alarms and alerts are configured to aid in the identification of cybersecurity events (IR-1b) • Indicators of anomalous activity have been defined and are monitored across the operational environment • Monitoring activities are aligned with the function's threat profile (TVM-1d)
Level 1: MIL 1	• Cybersecurity monitoring activities are performed • Operational environments are monitored for anomalous behavior that may indicate a cybersecurity event

Table 4.3.3.1: Characteristics of the Electricity Subsector Cybersecurity CMM (ES-C2M2) Maturity Levels MIL1-3

Background Information

The Electricity Subsector Cybersecurity CMM (ES-C2M2) provides a mechanism that helps organizations evaluate, prioritize, and improve cybersecurity capabilities. The model is a common set of industry-vetted cybersecurity practices, grouped into ten domains and arranged according to maturity level.

The Electricity Subsector Cybersecurity CMM v1.1 is built upon existing efforts, models, and cybersecurity leading practices and is aligned with the White House's 2010 Cyberspace Policy Review, the Department of Energy (DOE) Roadmap to Achieve Energy Delivery Systems Cybersecurity, the Energy Sector-Specific Plan, and the Industrial Control Systems Joint Working Group's (ICSJWG) Cross-Sector Roadmap for Cybersecurity of Control Systems. The goal of the model is to enable organizations to evaluate cybersecurity capabilities consistently, communicate capabilities levels in meaningful terms, and prioritize cybersecurity investments

Key Components

- The model is broken into ten domains, where each domain is a logical grouping of cybersecurity practices. The domains include:
  o Risk Management
  o Asset, Change, and Confirmation Management
  o Identity and Access Management
  o Threat and Vulnerability Management
  o Situational Awareness
  o Information Sharing and Communication
  o Event and Incident Response, Continuity of Operations
  o Supply Chain and External Dependencies Management
  o Workforce Management
  o Cybersecurity Program Management

Relevancy

- Based on established model and leading practices
- Provides actionable items
- Includes tools to implement
- Based off of regulatory requirements
- Built in collaboration with the industry and regulators

4.3.4   Privacy Maturity Model

Maturity Level	Characteristic
Level 5: Optimized	• Management monitors compliance with policies and procedures concerning personal information. Issues of non-compliance are identified and remedial action taken to ensure compliance in a timely fashion
Level 4: Managed	• Compliance with privacy policies is monitored and the results of such monitoring are used to reinforce key privacy messages
Level 3: Defined	• Policies are defined for notice, choice, consent, collection, quality, and monitoring/reinforcement
Level 2: Repeatable	• Privacy policies exist but may not be complete, and are not fully documented
Level 1: Ad Hoc	• Some aspects of privacy policy exist informally

Table 4.3.4.1: Characteristic of Privacy Maturity Model Level 1-5
(Reference: http://www.kscpa.org)

Background Information

The AICPA/CICA Privacy Maturity Model (PMM) is based on Generally Accepted Privacy Principles and the Capability Maturity Model (CMM). The PMM provides entities an effective means of assessing their privacy program against a recognized maturity model and has the added advantage of identifying the next steps required to move the privacy program ahead. The Privacy Maturity Model (PMM) was developed in 2011 by the American Institute of Certified Public Accountants and Canadian Institute of Chartered Accounts. The model aims to assist organizations in strengthening their privacy policies, procedures, and practice.

Key Components

- Model incorporates the ten Generally Accepted Privacy Principles (GAPP) including:
    - Management
    - Notice
    - Choice and Consent
    - Collection
    - Use, retention and disposal
    - Access
    - Disclosure to third parties
    - Security for privacy
    - Quality
    - Monitoring and enforcement
- Model is built off of the Capability Maturity Model, which was established over 20 years ago

Relevancy

- Based on established model (Capability Maturity Model)
- Identifies next steps required to move privacy program ahead
- Can measure progress against both internal and external benchmarks
- Can measure the progress of a specific project and the entity's overall privacy initiatives
- Based regulated requirements
- Agility with size of business

4.3.5   Procurement Maturity Model

Maturity Level	Characteristic
Level 5: Optimized	• Management is focusing on achievement best practice through continuous optimization and reporting
Level 4: Managed	• Organizational responsibilities are placed vision and vision, goals are defined by management
Level 3: Documented	• Processes are defined / confirmed as standards and are documented
Level 2: Repeatable	• Uniform processes based on practical experience emerge. Acknowledgement of the need for improvements
Level 1: Ad Hoc	• Unmanaged without a defined goal or strategy. Everybody has his own approach towards processes and practices

Table 4.3.5.1: Characteristics of Procurement Maturity Model Level 1-5
(Reference: http://implementconsultinggroup.com)

Background Information

The Procurement Maturity Model is a self-assessment tool that can be used by procurement departments working with or focusing on efficiency and their level of maturity within different areas of procurement. The Procurement Maturity Model was developed in 2014 by Implement Consulting. The model focuses on assessing eight focus areas of an organizations procurement department.

Key Components

- The model is based off the established Capability Maturity Model
- The eight core dimensions that the model evaluates are:
    - Sourcing
    - Strategy
    - Organization
    - Procure-to-pay
    - Reporting and documentation
    - System Support
    - Supplier relationship management
    - Change and effect

Relevancy

- Built off of established Capability Maturity Model (CMM)
- Provides tools to implement model
- Provides working examples
- Develops next steps
- Well defined with content
- Provides industry benchmarks
- Holistic across people process and technology
- Ability to handle diverse product portfolio

5.0 Maturity Model Benchmarking Analysis and Recommendations

5.1 Approach and Industry Breakdown

Building off of the literature research, the benchmarking survey was developed and focused on evaluating the landscape of maturity models used cross-industry. The purpose of the survey was to understand the key components that encompass maturity models, the historical use of maturity models, the effectiveness of maturity models post implementation, and other assessment tools used to measure maturity.

The survey was distributed to 200 potential respondents at 130 companies in a variety of industries including Aerospace, Automotive, Consulting, Electronics, Finance, Technology, and Transportation. The four industries that had the highest participation were Technology, Aerospace, Consulting and Automotive at participation rates of 31%, 28%, 19%, and 11% respectively (Figure 5.1.1). A total of 37 survey responses were analyzed. Responses were gathered from companies of varying size, as determined by revenues. Of the companies that participated in the survey, 35% had revenues less than $1 billion per year, 24% had revenues between $1 billion – $10 billion per year, and 41% had revenues greater than $10 billion per year (Figure 5.1.2).
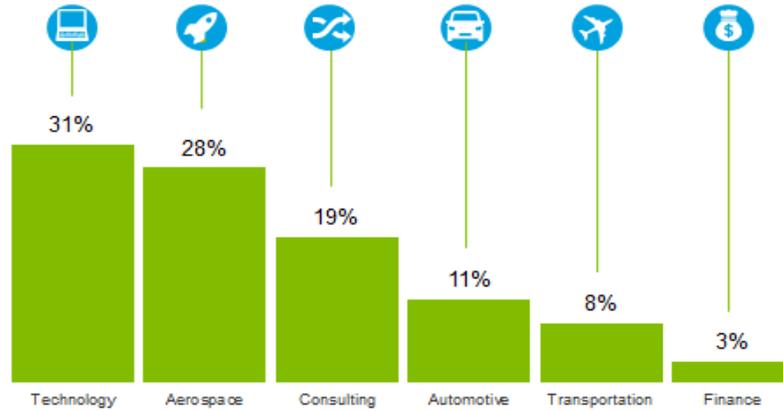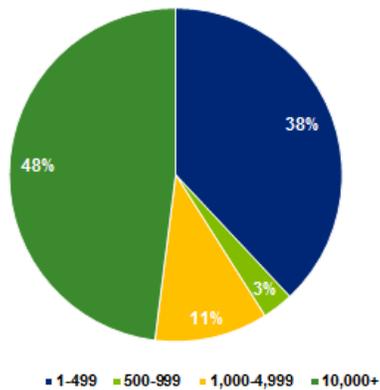
Figure 5.1.1: Distribution of Companies that Participated in the Survey by Industry

Distribution of Organization Participation in Maturity Model Benchmarking Survey by Number of Employees

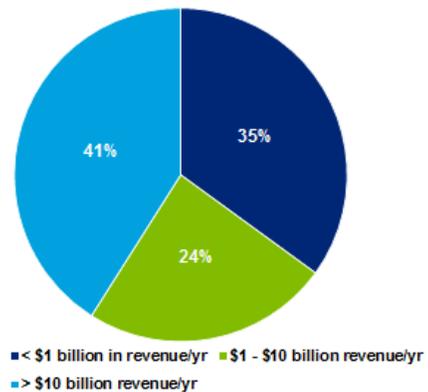**Distribution of Organization Participation in Maturity Model Benchmarking Survey by Revenue per Year**


**Figure 5.1.2:** Distribution of Companies that Participated in the Survey by Revenue per Year

5.2 Analysis of Benchmarking

Approximately 81% of the companies surveyed reported that they have conducted a maturity model self-assessment. These companies reported both their overall maturity level and their quality maturity level. The distribution of self-reported overall maturity classification is as follows: 12% Level 1- Initial, 14% Level 2- Managed, 60% Level 3- Defined, 4% Level 4- Quantitatively, 10% Level 5- Optimizing. The distribution of self-reported quality maturity classification is as follows: 7% Level 1, 82% Level 3, and 11% Level 5. A majority of companies reported a Level 3 classification for both their overall maturity and their quality maturity. Level 3 maturity classification indicates that an organization has well defined processes and their processes documented and standardized.
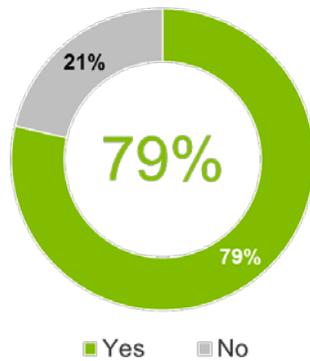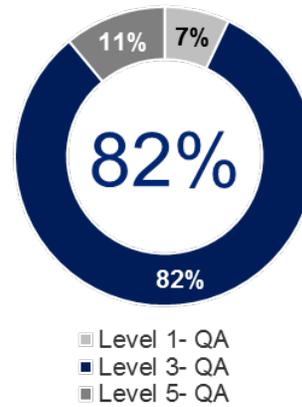
Conducted Maturity Model Assessment?

19%

81%

81%

- Yes
- No
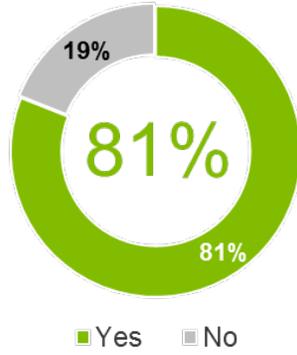
Planning on Conducting Maturity Assessment?
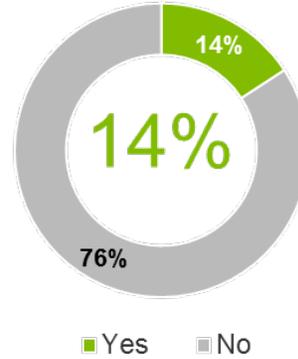
14%

14%

76%

- Yes
- No

Have you used a maturity model to assess your Quality?

21%

79%

79%

- Yes
- No

Self Reported Quality Maturity Assessment

11% 7%

82%

82%

- Level 1- QA
- Level 3- QA
- Level 5- QA

Self Reported Overall Maturity Assessment

10% 12%

4%

14%

60%

60%

- Level 1
- Level 2
- Level 3
- Level 4
- Level 5
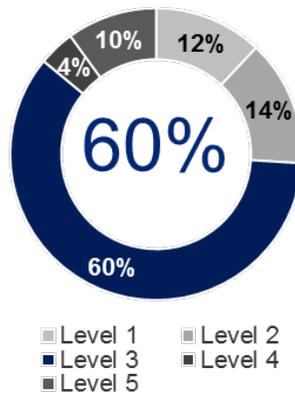
Has your organization communicated your maturity assessment with regulators?

28%

28%

72%

■ Yes   ■ No
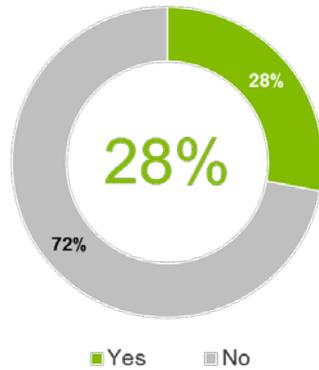
Has a regulator asked for your maturity assessment?

31%

31%

69%

■ Yes   ■ No
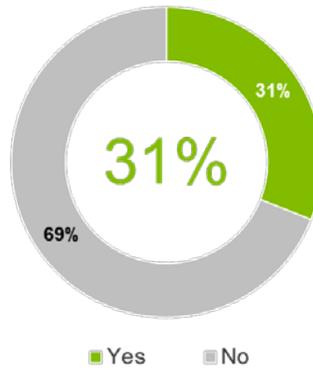
How long as your organization been implementing a maturity model?

45%

7%

17%

10%

45%

21%

■ 0-1   ■ 1-2 years
■ 2-5 years   ■ 5-10 years
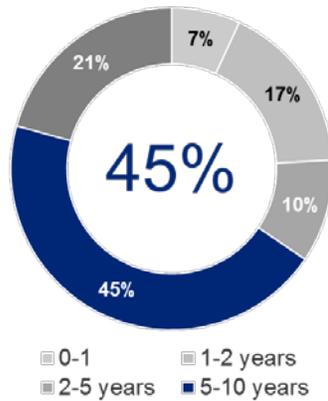
Has your organization been able to realize strategic goals by implementing a maturity model?

88%

12%

88%

■ Yes   ■ No
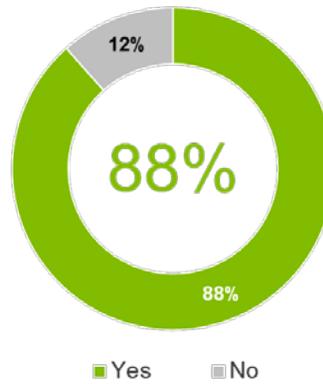
Has your organization used any tools to benchmark your maturity model?

39%

39%

61%

■ Yes   ■ No
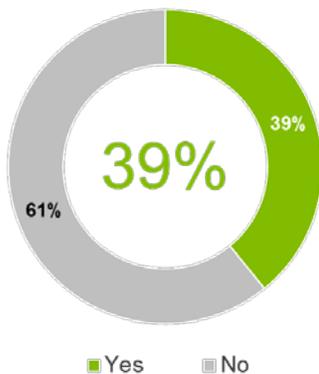
Are you aware of any common metrics associated with your industry for maturity?

43%

43%

57%

■ Yes   ■ No

Figure 5.2.1: Distribution of Use of Maturity Model Information

Maturity models are often used in parallel with benchmarking to assess processes and determine maturity (Figure 5.2.2). Research indicates that the CMMI model was the most commonly implemented model. In the literature research, it was identified that other models that focused on different processes and industries lever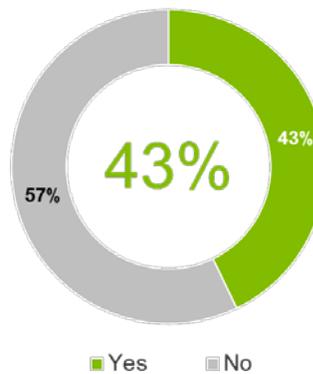aged the CMMI model as well. One such model, Test Maturity Model Integration (TMMI), was also commonly used. Of the companies that participated in the Maturity Model Benchmarking survey, 76% used the CMMI model, 16% used the TMMI model, and 8% used another model or maturity tool (Figure 5.2.3). Therefore, in aggregate, 92% of the companies that responded used maturity models that were based off of CMMI principles.
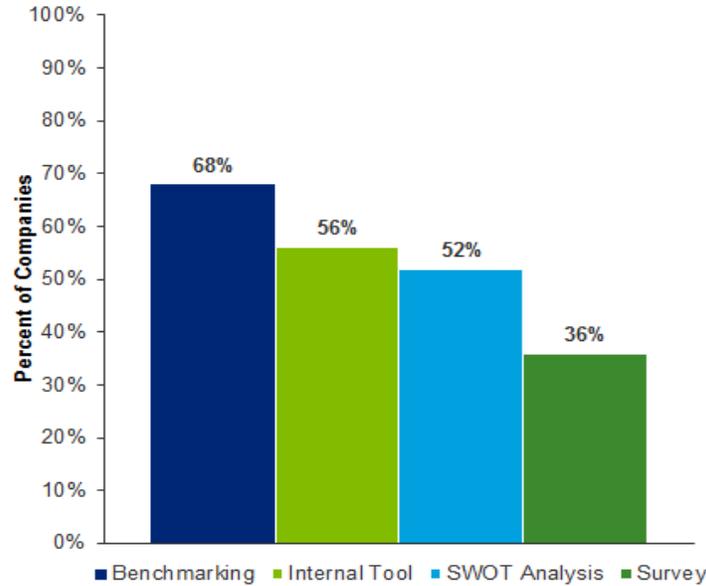

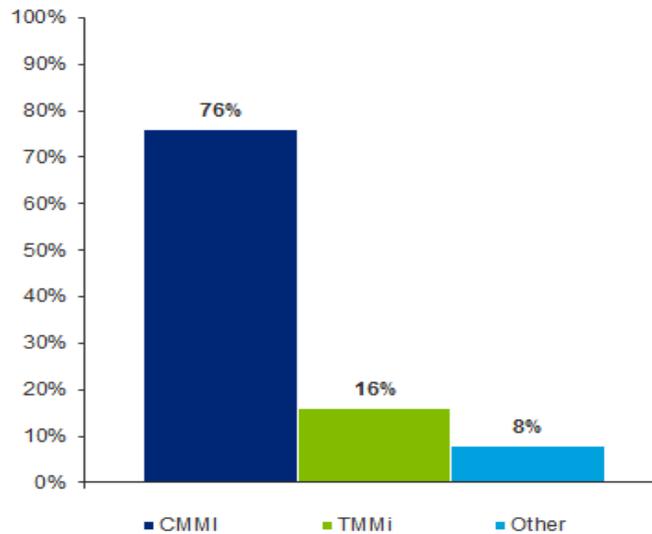**Figure 5.2.2:** Distribution of Other Tools used for Maturity Assessment

Figure 5.2.3: Distribution Maturity Models Used to Conduct Maturity Assessment

One of the goals of the survey was to determine the core process areas that companies focus on cross-industry. As shown in Figure 5.2.4, the top seven process areas were Quality, Management, Risk Management, Operations, Reporting and Documentation, Strategy, and Sourcing. It is interesting to note that a limited number of companies focused on Safety Management and Regulatory Compliance. With respect to these two core process areas, interviews discussed the challenges and limited effectiveness resulting from limited communication between industry and regulators. The results of the survey identified only 27.5% of survey participants have communicated their maturity assessment with regulators. Moreover, only 12% of the companies surveyed targeted their maturity assessment for regulators (Figure 5.2.5). The majority of the companies targeted their maturity models for IT and Leadership.

Process Area	Yes	No
Quality	87%	13%
Management	78%	22%
Risk Management	70%	30%
Operations	52%	48%
Procurement	50%	50%
Reporting Documentation	50%	50%
Strategy	45%	55%
Sourcing	42%	58%
Reg & Comp	28%	72%
Supply Chain	25%	75%
Security and Privacy	18%	82%
Safety Management	14%	86%
Cybersecurity	10%	90%
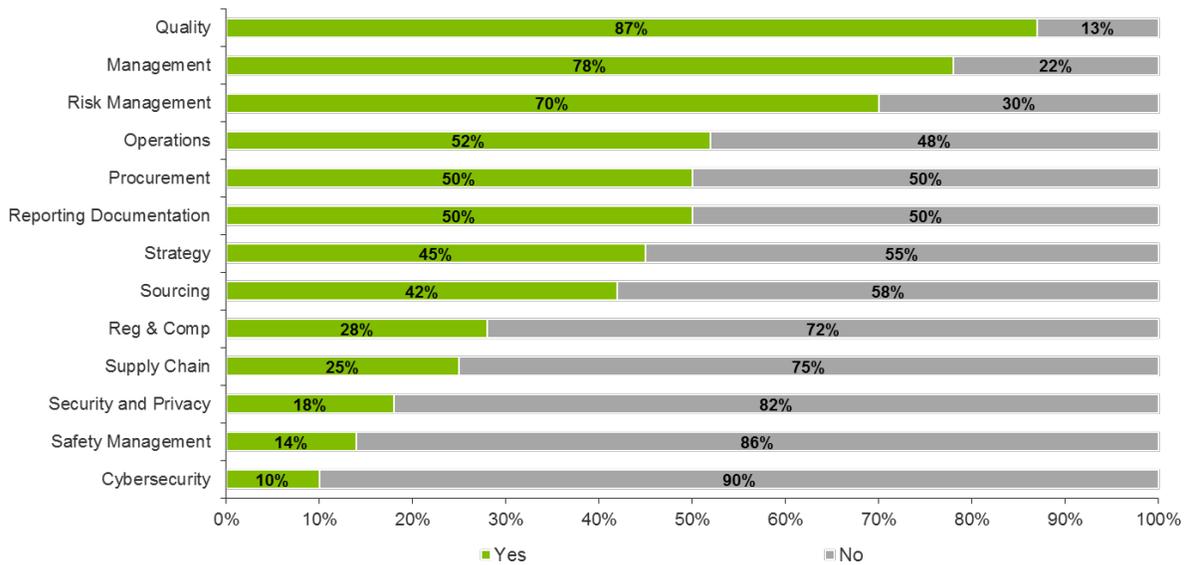
Figure 5.2.4: Distribution of Maturity Model Process Area Included in Maturity Models

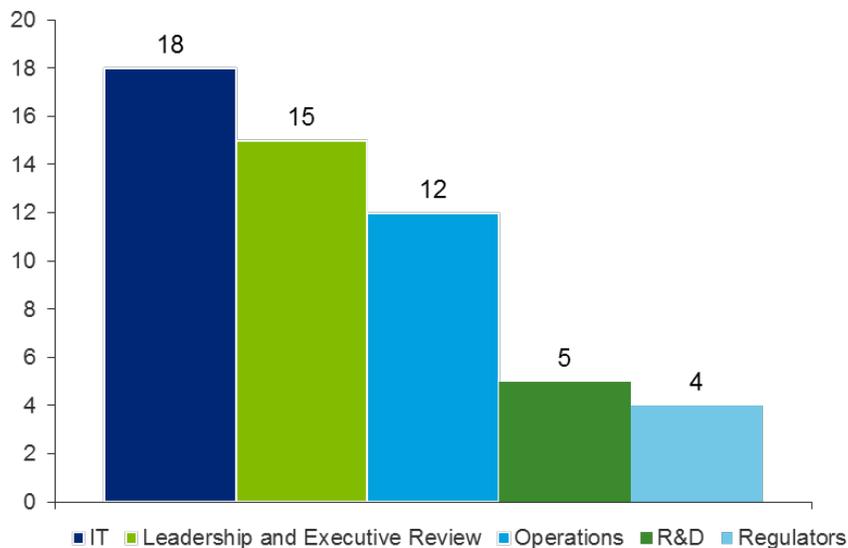| Function	Value
IT	18
Leadership and Executive Review	15
Operations	12
R&D	5
Regulators	4

Figure 5.2.5: Distribution of the Communication of Maturity Models by Function

5.3 Summary

Based on the literature research, survey analysis, and the interviews conducted with subject matter advisors, CMMI is a model that warrants further consideration for the development of a quality system maturity model for the medical device industry based on:

- globally recognized across multiple industries;

- well-established (20+ years) with demonstrated success;

- governed and maintained by an independent authority that also performs the assessments;

- well-defined and holistic in terms of people, process, and technology;

- flexibility across companies of various size, organizational and geographic structure, and product portfolio;

- ease to update with regulatory changes;

Specifically, the CMMI model:

- contains requirements for a formal decision analysis process that could help medical device designers to gather facts and data, analyze alternatives, make decisions, and record this decision data;

- compliments medical device standards by focusing on process performance and closed loop improvement;

- places importance and recognition on the institutionalization of process performance and continuous improvement within organizations;

- facilitates prioritization of processes to address the most critical processes with the highest maturity levels, which may be applicable to medical device classification levels;

- facilitates ease of adoption and maturity progress which can lead to process standardization across various organizational levels increasing efficiency and consistency;

- encourages sharing of lessons learned and celebrates successes, which fosters a culture of quality and improvement;

Quality System Maturity Models in Use Today

The research including survey benchmarking responses and interviews indicate that CMMI is the most widely used model cross-industry. In aggregate, 92% of the companies that participated in the benchmarking survey used the CMMI model or maturity models built from CMMI. This model is also the most commonly used for Quality purposes. Based upon interviews with a significant number of subject matter advisors who lead CMMI development and implementations, it is suggested that a quality maturity model for the medical device industry should be built from a combination of three frameworks or "*constellations*" for development, services, and acquisition:

- ***CMMI for Development*** broadly focuses on product development

- ***CMMI for Services*** focuses on service establishment and delivery

- ***CMMI for Acquisition*** focuses on the procurement process

Regulator Use

Based upon the research, some regulators leverage Maturity Model information to provide inputs for assessments. However, the degree to which they use them varies and they do not communicate with industry. Interviews with subject matter advisors in the transportation industry indicated that prior attempts at developing and implementing a maturity model that could be leveraged by both industry and regulators failed; largely due to lack of transparency and communication between regulators and industry. It is recommended that a collaborative approach be adopted between regulators and industry in determining leading practices and maturity benchmarks including transparent and consistent communication. It is also recommended that the development and implementation of a maturity model that would be used across both industry and regulators be simplified to allow for streamlined assessments and focused areas of effort.

Use and Maintenance of Maturity Models

The process by which maturity models are populated and maintained varies across users. Groups who have successfully developed maturity model programs, recommended that a project management office be implemented. Clear activities should be planned to advance toward the next maturity level and status reporting used to continuously document the process and provide evidence. It is recommended that internal and external assessors leverage information provided in the status reporting to assess progress.

Additionally, the maturity model should be fit-for-purpose and streamlined. There are examples of existing maturity models that have been built off of CMMI that have gotten too complex and cost prohibitive to implement. The quality maturity model for medical devices should be lean and efficient with the ability to be implemented at medical device companies of various size, organizational and geographic structure, and product portfolio.

Effectiveness

Effectiveness of the maturity model implementation is tracked by each company. Metrics are dependent on the strategy and goals associated with the use of the maturity model. Elements that were consistently tracked were time in use and progress in addition to marked improvement in quality over time, including demonstrated ability to follow SOPs and reduction in internal and external findings.

Benefits and Risks of Maturity Models

Successful implementation of maturity models allows for the users to align on leading practices and determine actionable steps to increase their maturity. Those interviewed mentioned that it allows for transparency and full understanding of their capabilities. It also enables repeatable, consistent assessments that track progress over time.

Those interviewed cited that the biggest risk to implementing a maturity model was the overall change management associated with implementation. Often the organization is reticent to the implementation - changing the way progress is driven and quality is tracked is difficult to achieve. It is necessary to have leadership buy-in, support, and involvement in the implementation. The presence of a maturity model does not facilitate implementation. A structured and managed project related to the implementation of a maturity model is critical to successful implementation. This includes a project plan and change management framework that allows for understanding of processes, communications with those impacted, and tracking of implementation progress.

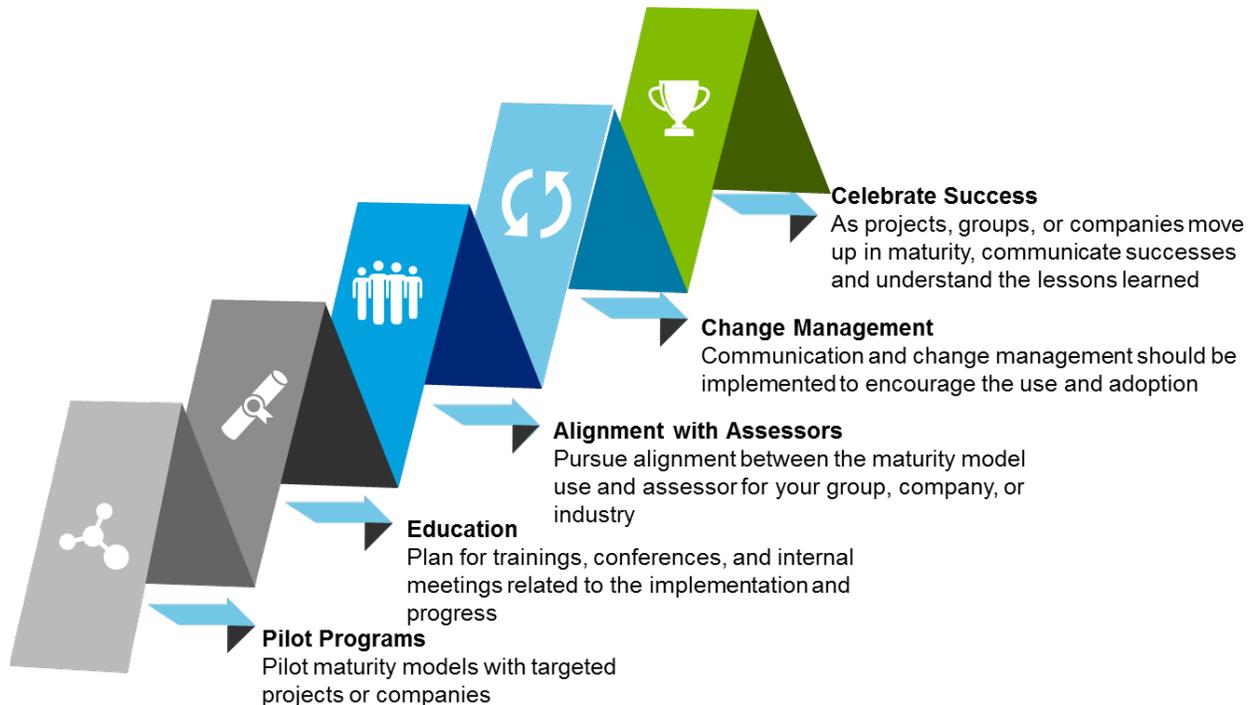Some techniques for facilitating successful implementation include:

Celebrate Success
As projects, groups, or companies move up in maturity, communicate successes and understand the lessons learned

Change Management
Communication and change management should be implemented to encourage the use and adoption

Alignment with Assessors
Pursue alignment between the maturity model use and assessor for your group, company, or industry

Education
Plan for trainings, conferences, and internal meetings related to the implementation and progress

Pilot Programs
Pilot maturity models with targeted projects or companies

Figure 5.3.1: Successful Implementation Techniques

Efforts will need to be taken by MDIC to develop the inputs for the CMMI maturity levels that will allow for consistent, repeatable cross-industry implementation. Consistent maturity definitions, required evidence, and associated quantifiable measures and metrics will facilitate implementation across the medical device industry. Collaboration and alignment between regulators and industry on leading practices, assessments and benchmarking thresholds including metrics, should be a focus of the development. A project management program and clear governance structure should be devised to facilitate implementation and track success. Communications and change management should support the implementation throughout the initial implementation and on-going communications and lessons learned should be distributed.

6.0 Appendix

6.1 Additional Models

Maturity Model	Function	Industry	Year Created	Description	Reasons Classified as Weak Fit
Cybersecurity Maturity Model	Cybersecurity	Energy	2012	Designed to be used by any organization to enhance its own cybersecurity capabilities.	• Does not provide next steps • Not easily applied to Medical Device Industry
Capability Maturity Model for Scientific Data Management	Data Management	All	2010	The CMM describes key process areas and practices necessary for effective SDM. The CMM further characterizes organizations by the level of maturity of these processes, meaning the organizational capability to reliably perform the processes.	• Model narrow in scope • Not easily applied to the Medical Device Industry • Not holistic in terms of people process and technology
CMM for Supply Chain Management	Supply Chain	All	N/A	Analyze the relationship between supply chain management process maturity and performance, and provides a supply chain management process maturity model for enhanced supply chain performance.	• Does not provide next steps • Components not well defined • Not widely accepted • No implemented examples • Does not provide next steps
Continuity of Care Maturity Model	Management	Life Sciences / Healthcare	2014	Continuity of Care Maturity Model aims to represent the levels of integrated care required to coordinate care across multi-disciplinary teams in various healthcare settings and has been developed to complement HIMSS' Electronic Medical Record Adoption Models (EMRAM) for the acute and primary sectors.	• Model not widely accepted • Components not well defined
Electronic Healthcare Maturity Model	Regulation	Life Sciences / Healthcare	2008	The eHMM illustrates a transformation of the healthcare enterprise electronic process from an immature level to a national state.	• Content not well defined • Narrow in scope • Not widely adopted

Maturity Model	Function	Industry	Year Created	Description	Reasons Classified as Weak Fit
Electronics Capability Maturity Model	Operations	Electronics	2007	This model defines key practices that can be used to assess whether an organization has the ability to design, develop and manufacture reliable electronic products.	• Model not holistic in terms of people process and technology • Does not provide next steps
Financial Management Maturity Mode	Operations	Finance	2013	IT financial management maturity model will help identify the current stage of maturity, establish a goal for improvement, and identify which practices to target for improvement activities; decisions will help develop a company-specific roadmap to develop IT processes, focused on accounting, charging, and budgeting.	• Components not well defined • Narrow in scope • Not easily applied to Medical Device Industry
IBM Data Governance Council Maturity Model	Data Governance	All	2007	The Data Governance Council Maturity Model measures data governance competencies of organizations based on the 11 domains of data governance maturity, such as organizational awareness and risk lifecycle management.	• Content is not well defined • Does not provide working examples
Information Governance Maturity Model	Operations	Finance	2007	The IGM model can be used by an organization both to understand where they currently are, and to identify reasonable next steps by which a company can gradually, incrementally, and reliably achieve the level of information governance maturity they desire.	• Not holistic in terms of people process and technology • Does not provide next steps
Maturity Model for Enterprise Content Management	Management	All	2011	The exponential growth and diversity of content are causing organizations to adopt enterprise content management; can help assess how to raise their organization's capabilities to achieve business goals.	• Components not well defined • Not easily applied to the Medical Device Industry • Does not include next steps

Maturity Model	Function	Industry	Year Created	Description	Reasons Classified as Weak Fit
Maturity Model for the Internationalization of Customer Care in the Automotive Industry	Customer Care	Automotive	2009	This model evaluates the use of maturity models within an organization to support the internationalization of global customer care standards, best practices, and guidelines that enable a globally consistent customer care service quality.	• Not easily applied to medical device industry • Does not include regulatory requirements
National Initiative for Cybersecurity Education CMM	Cybersecurity	All	2014	Facilitates the application of leading practice elements of workforce planning in analyzing their cybersecurity workforce requirements and needs.	• Model not widely implemented • Components not well defined • Does not provide next steps
Oil and Natural Gas Subsector Cybersecurity Capability Maturity Model (ONG-C2M2).	Cybersecurity	Energy	2010	The ONG-C2M2 provides a mechanism that helps organizations evaluate, prioritize, and improve cybersecurity capabilities; consists of a common set of industry-vetted cybersecurity practices, grouped into ten domains and arranged according to maturity level.	• Does not provide next steps • Not easily applied to Medical Device Industry • Does not focus on people and process
Quality Maturity Model	Quality	All	2014	The QMM looks at 7 elements including: management of organization, environment sensing, learning organization, attitude to change, attitude to quality leadership, investment to staff, and alignment.	• Components not well defined • Does not include next steps • Not widely accepted
Railway Management Maturity Model (RM3)	Safety Management	Transportation	2011	The model provides a consistent way of evaluating the management arrangements required by the Railways and other Guided Transport Systems (Safety) Regulations 2006 (ROGS) and the Management (Health and Safety at Work) Regulations 1999.	• Model narrow in scope • Not easily applied to the Medical Device Industry • Not holistic in terms of people process and technology

Maturity Model	Function	Industry	Year Created	Description	Reasons Classified as Weak Fit
Smart Grid Maturity Model	Infrastructure	Energy	2009	Value Management Maturity Model (VM3) is a structured plan of maturity and performance growth for businesses. It proposes five levels of maturity and each level has its own criteria or attributes to be achieved before progressing to a higher level. Data is collected through questionnaire surveys to organizations that have implemented VM methodology.	• Content not well defined • Narrow in scope • Does not include regulatory framework
Value Management Maturity Model	Planning / Accounting	All	2014	The focus of the VRMMM is to provide third party risk managers with a tool they can use to evaluate their program against a comprehensive set of best practices. Using governance as the foundational element, the model identifies the framework elements critical to a successful program.	• Not easily applied to the Medical Device Industry • Components not well defined • Does not include next steps
Vendor Risk Management Maturity Model	Risk Management	Finance	2014	The model provides a consistent way of evaluating the management arrangements required by the Railways and other Guided Transport Systems (Safety) Regulations 2006 (ROGS) and the Management (Health and Safety at Work) Regulations 1999.	• Components not well defined • Model not widely implemented • Does not provide next steps
Regulatory Change Management Maturity Model	Change Management	All	2015	A maturity model to measure regulatory change management programs to support an efficient, effective and agile process.	• Relatively new concept, not widely implemented • Does not provide systematic approach for execution

6.2 Survey Questions

1. What is your role in your organization?
   a. Engineering
   b. Management
   c. Operations
   d. R&D
   e. Regulatory
   f. Quality
   g. Other: _____

2. What is your organization's annual revenue (USD)?
   a. < 100 Million
   b. 100 Million – 499 Million
   c. 500 Million – 999 Million
   d. 1 Billion – 1.99 Billion
   e. 2 Billion – 4.99 Billion
   f. 5 Billion – 9.99 Billion
   g. More than 10 Billion

3. What is your organization's primary industry?
   a. Aerospace
   b. Automotive
   c. Electronics
   d. Energy
   e. Life Sciences
   f. Transportation
   g. Other:_____

4. How many people are employed in your entire organization? (smaller categories
   a. 1-499
   b. 500-999
   c. 1000-4999
   d. 5000-9999
   e. 10000+

5. Has your organization conducted a maturity model self-assessment?
   a. Yes
   b. No

6. If no, is your organization planning on using a maturity model?
   a. Yes
   b. No

7. If planning on using a maturity model, when will this occur?
   a. < 1 year
   b. 1-2 years
   c. 2-4 years
   d. 4-8 years
   e. > 8 years

8. If yes, which maturity model has your organization used?
   a. Capability Maturity Model Integration v1.3
   b. Global Aviation Safety Roadmap
   c. Electricity Subsector Cybersecurity CMM v1.1
   d. Privacy Maturity Model
   e. Procurement Maturity Model
   f. Other_____

9. Has your organization communicated your Maturity Model assessment with regulators?
   a. Yes
   b. No

10. Has a regulator ever asked about using a maturity model or considered using a maturity model?
   a. Yes
   b. No

11. Are there are any other tools your organization uses to assess maturity?
   a. Benchmarking
   b. Internal Tool
   c. SWOT Analysis
   d. Survey
   e. Other:_____

12. Which of the following categories do you have in your maturity model [Select all that apply]?
   a. Management
   b. Quality
   c. Procurement
   d. Supply Chain
   e. Operations
   f. Risk Management
   g. Cybersecurity
   h. Regulatory Compliance
   i. Safety Management
   j. Security and Privacy
   k. Reporting and Documentation
   l. Sourcing
   m. Strategy

13. Who was the maturity model used for [Select all that apply]?
    a. Regulators
    b. Operations
    c. Leadership and Executive Review
    d. R&D
    e. IT
    f. Other:_____

14. How long has your organization been implementing maturity models?
    a. <1 year
    b. 1-2 years
    c. 2-4 years
    d. 5-10 years
    e. More than 10 years

15. Has your organization been able to realize your strategic goals implementing maturity models?
    a. Yes
    b. No

16. If you were to classify the overall current maturity of your organization, what would you classify it as?
    a. Initial- Processes unpredictable, poorly controlled, and reactive
    b. Managed- Processes characterized for projects and is often reactive
    c. Defined- Processes characterized for the organization and is proactive
    d. Quantitatively Managed- Processes measured and controlled
    e. Optimizing- Focus on process improvement
    f. Other: _____

17. Have you and your organization used any tools to benchmark the maturity model?

18. Are you aware of any commonly known, industry specific metrics to measure maturity?

19. Have you used a maturity model to assess your Quality?
    a. Yes
    b. No

20. If yes, what would you classify your Quality Maturity as?
    a. Level 1- QA processes implemented in ad hoc manner
    b. Level 2- QA process characterized for supporting project management processes and is localized
    c. Level 3- QA process characterized for the organization and is aligned to the overall SDLC
    d. Level 4- QA process is measured and controlled
    e. Level 5- QA process focused on continuous improvement

6.3 Use of Benchmarking Information

All information obtained during the survey and interview process was taken "as is" and was not confirmed or validated by Deloitte & Touche LLP (D&T). Deloitte & Touche LLP makes no representation or warranty to the accuracy of the information. In addition, the discussion and examples presented in this paper are for educational purposes. They are not to be viewed as an authoritative statement by D&T on the quality and/or appropriateness of an individual company's practices or an indicator of "better" practices from one company relative to another.