Accelerate Sustainable Capability (ASC) Pilot Study: Pilot Site Playbook

A Report of the Case for Quality Collaborative Community of the Medical Device Innovation Consortium (MDIC)

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GLOSSARY

- **Action Plan** – The manufacturing site's plan to address the FDA observations/violations, CMMI appraisal gaps, and incorporate Residual Risk Assessment.
- **Broad Agency Announcement (BAA)** – The BAA outlines research areas of interest that will help fulfill the FDA requirements to utilize capabilities for state-of-the-art advancement and achieve improvements in technology, materials, processes, methods, devices, or techniques in specific topics.
- **Compliance Dossier** – Document which lists the compliance gaps, the processes impacted by any enforcement action, and the progress of actions to address these gaps.
- **CMMI** – Capability Maturity Model Integration, is a framework that includes a set of proven best practices grouped into practice areas, as well as a method by which to appraise an organizational unit (project, department, facility, organization, etc.) against any subset of these best practices.
- **ISACA** – Information Systems Audit and Control Association, is the nonprofit organization that owns the IP for the CMMI (model and appraisal method). Manages the quality control of appraisals and appraisers (training, certification, auditing).
- **Appraisal** – An examination of one or more organizational processes by a trained team of appraisers using CMMI as the basis for determining strengths, gaps, and opportunities.
- **Appraiser** – An individual trained in the CMMI framework to understand the model
- **Practice Area (PA)** – A collection of similar practices that together achieve the defined intent, value, and required information described in that practice area.
- **MDIC (Medical Device Innovation Consortium)** – is the first-ever public-private partnership created with the sole objective of advancing medical device regulatory science for patient benefit.
- **Residual Risk Assessment** – product-specific assessment utilizing the residual risk assessment tool developed by Mgmt-Ctrl, Inc. The residual risk assessment measures the 'state of the art benefit' of patient safety to provide an indication if the device poses "an unreasonable risk of substantial harm to the public health."
- **Manufacturer** – Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

PILOT STUDY PURPOSE

The objective of this pilot study is to leverage a quality system maturity and integration approach to provide manufacturers with systemic insight that may improve the effectiveness of the quality system; focus and accelerate improvement efforts to reach a state of sustainable compliance faster; structure systems for continuous improvement; identify objective performance metrics, and develop reports that may provide the agency with the information it needs to oversee product safety throughout the pilot process.
To encourage manufacturers to enroll and participate, this pilot study will cover the costs of the activities listed and defined in this playbook.

PILOT STUDY SCOPE

This pilot study is run and facilitated by MDIC. Once enrolled, the pilot will run at a site for approximately **18 months.**

- The pilot study consists of the initial appraisal, residual risk analysis, action plan, quarterly checkpoints, and performance metrics. The organization may choose to continue to fund follow-up appraisals because they see the value.
- All pilot sites must have an established Quality Management System (QMS) (see 21 CFR Part 820).

INITIAL PILOT STUDY ACTIVITIES

The following section outlines the initial Pilot Study Activities and their purpose.

Residual Risk Assessment:

A product focused risk assessment* will be conducted, of currently marketed products, utilizing the Mgmt-Ctrl, Inc. residual risk assessment tool (Product Specific Assessment).
Publicly available market data will be used to create and compare the overall residual risk experienced with a specific medical device against the risk that is typically found inherent with the use of competitively marketed devices.

- Note: This risk assessment is conducted as part of the ASC pilot to monitor patient safety for the duration of the pilot study. This information will additionally be shared with the pilot study participants for the purpose of providing actionable insights as input into their post-market risk assessment process.

The following steps will be used for each pilot participant:

1. On boarding call will be conducted by Mgmt-Ctrl with each participant, for purposes of transparency, and to provide an understanding of the residual risk assessment process used in support of the pilot study.
    - Mgmt-Ctrl will explain the residual risk report including the value and potential utilization of the initial and the subsequent reports, along with next steps the participating site should take to address failure modes with an *'indication of concern'.*
    - The participating site should describe how the relevant data is reported, with respect to the products associated with site being assessed, to ensure reporting accuracy for the site. (i.e. reporting site may be used as an identifier for reporting for multiple manufacturing sites for a particular product code; or other issues that may reduce specificity for the site being assessed.)
2. The manufacturing site will provide its address to Mgmt-Ctrl: Participating Manufacturers Name /City (Note: City is a key identifier in the MAUDE database.).
3. Mgmt-Ctrl will send the list of current ProCodes associated with the site address.
4. In a timely manner (e.g. 1-2 weeks), the site is to confirm which ProCodes are manufactured at their site, and, where differences exist, the site should document where those products are manufactured, if not at their site.
5. Mgmt-Ctrl will use this documented list as input to the residual risk assessment to exclude any products that are *Not Applicable* to the participating site.
6. Mgmt-Ctrl will only report on confirmed ProCodes.
7. Mgmt-Ctrl will provide a Statistical Indication Report using MAUDE data that contains within it a residual risk assessment heatmap which provides an 'indication' of products that raise to a 'level of concern' using the process provided by Mgmt-Ctrl. (See Figure 1).
8. In addition to the MAUDE data considered as part of the evaluation.
    - If the manufacturer has residual risk analysis data available. The manufacturer may choose to run their own internally established analysis process in parallel.
        - The use of the assessment tool from Mgmt-Ctrl would still be required to provide a consistent process to monitor patient safety across all participant sites.
        - The site's data will look different as their data analysis methodology is unique to their organization.

- The site is encouraged to reach out to Mgmt-Ctrl for additional information about the tool and how to further interpret the results.

- FDA is learning about the tool and how it will benefit the participating sites to drive focus on improvement. As such, the participating manufacturers may choose to share the baseline Residual Risk Assessment with FDA. A detailed report will be provided to the site for any product that is currently indicated to be of concern (Red = Level 3 = > 3 risk indicators = Indication of Concern) (See Figure 2 below).
  - The residual risk analysis provides an *'indication'* only. It cannot and does not, by itself, support a finding or conclusion that a ProCode product group is *'bad'* or harmful. Such a conclusion can only occur through post-market risk assessment activity.
  - It should be understood that an *'indication of concern'* and/or similar terms, inclusive of colors that appear to connote a heightened level of concern were only utilized to communicate differentiation within the residual risk analysis.
  - A site, on its own or in collaboration with Mgmt-Ctrl (Optional, fees not covered by pilot), can leverage risk assessment methods, market share and complaint data to confirm an identified Level of Concern.
  - The participating site is not expected to validate the data in comparison to their own internally derived analysis process, as it is understood that the two processes are not equal.
  - The information is being provided as an additional external signal to better understand site product risk and for the provision of actionable insights as input into the participants post-market risk assessment process. Participants should consider the 'indication of concern' as a signal and utilize their internal risk-assessment process to confirm whether:
    1) it is not a true signal considering the market share and internal information available.
    2) It is a true signal. The failure mode is within established action limits; therefore, no action necessary.
    3) It is a true signal; however, actions are already underway to address the confirmed risk or action will be initiated as a result.

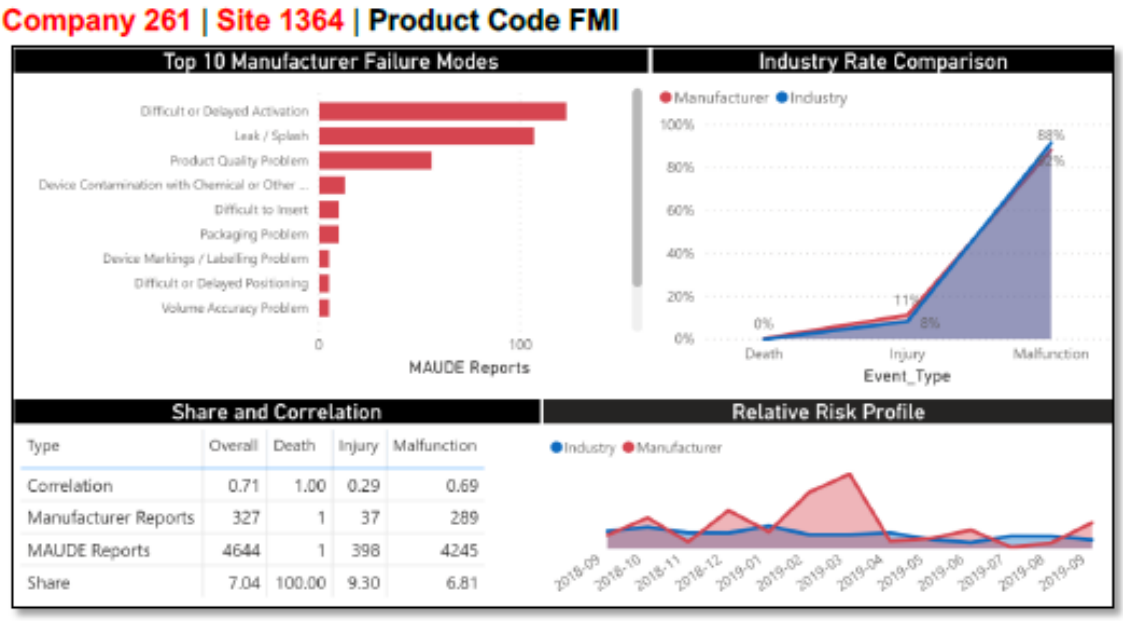
4) Indications eliminated as a 'level of concern' should be documented within the action plan regarding why no further action is needed.

- It is recommended that, as a part of the action plan, the manufacturer conducts an evaluation to reconsider the risk control measures associated with a device that has a confirmed 'Level of Concern'.
    - If safety-related issues demonstrating a 'Level of Concern' are observed within the residual risk assessment results, the manufacturer will be asked to engage with the Agency to define a remediation plan. *[Remediation plan could include any combination of responses to the residual risk assessment, from a correction of inaccurate data, an improved risk control measure, etc.]* The remediation plan should be incorporated into the manufacturer's action plan developed to address identified pilot results (e.g. CMMI, Compliance Residual Risk).
- Mgmt-Ctrl, Inc. services are optionally available in support of internal risk assessment/response efforts. If requested, the cost for this support would be the responsibility of the manufacturer.
- Note: FDA does not intend to use this assessment as a benchmarking tool between manufacturers. The goal of this pilot is to provide an environment where transparency is encouraged.

9. The heatmap will be shared with the CMMI Appraisers. Products that demonstrate a 'Level of Concern' will be considered as an input to the CMMI appraisal scoping activity.

Figure 1: Heatmap Example

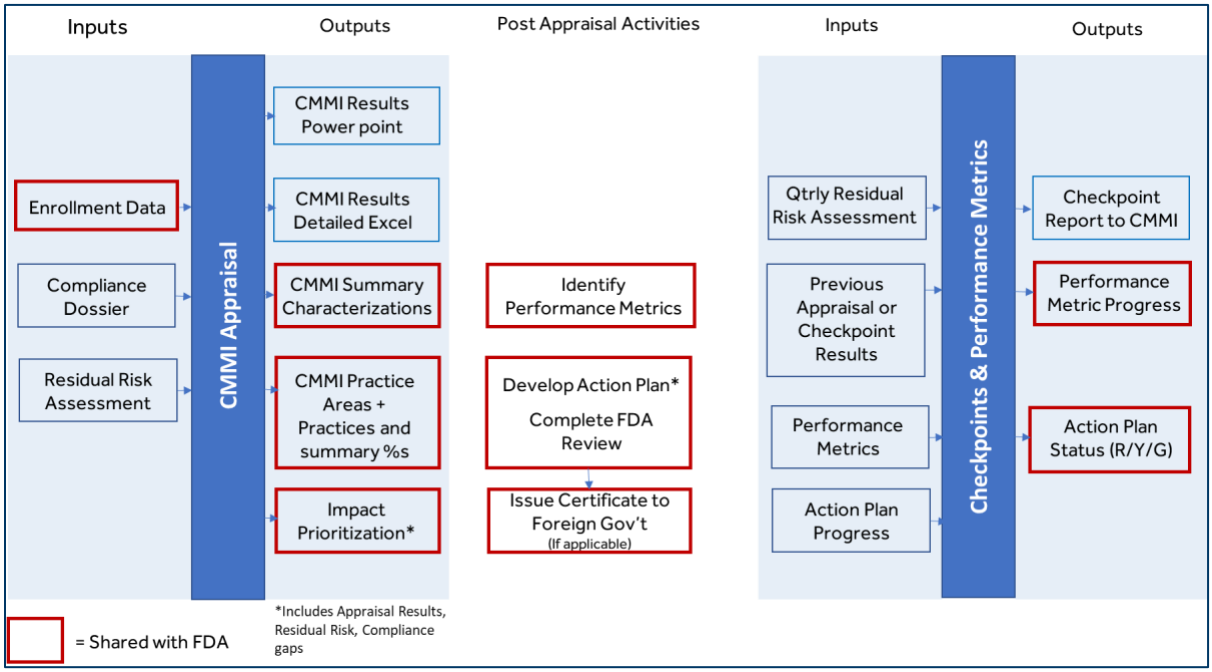
Figure 2: Risk Indicators Example



CMMI Appraisal:

Manufacturers enrolled in the ASC pilot will engage with the CMMI appraisers through the appraisal process, impact prioritization process, action plan development and subsequent quarterly checkpoints/performance metric submission. See Figure 3 for a visual depiction of Inputs/Outputs described within the next two sections of the Playbook.

Figure 3: CMMI Appraisal and Checkpoint Inputs and Outputs



ISACA will target completion of the appraisal within 90 days after enrollment (or as soon as possible due to the pandemic).

Appraisal Planning:

- **Leadership involvement:** CEO or leadership communications to participants is important. This enables participants to see their leadership's alignment with the intent of program and to hear their support for transparency during interviews to enable the identification of opportunities for improvement.
- **Mentoring:** If site has sibling sites enrolled in VIP, recommend seeking guidance from their first-hand experience; otherwise, ISACA can coordinate mentorship from an

industry peer (e.g., inviting a leader from a VIP site or an ASC pilot site to speak at one of the kick-off meetings)

- **Internal ATM:** If a site or site's organization has a trained Internal ATM, consider adding to appraisal team
    - Use of Internal ATM's is recommended, but at the discretion of the Lead Appraiser and ISACA. The Internal ATM should not be within the same reporting structure to ensure there is not a perceived conflict of interest.
- ISACA will introduce Manufacturer to the Lead Appraiser at least 6-8 weeks prior to the Appraisal to provide adequate time for Appraisal planning.
    - Manufacturer will complete a standard Compliance Dossier as an input to CMMI Appraisal planning. The site will send the Compliance Dossier to ISACA, who will share it with the Appraisal team. FDA will not be sent the final version of the Compliance Dossier (See Table 1).
        - Compliance Dossier template can be requested from MDIC or ISACA.
        - Questions about the Compliance Dossier can be directed to your Lead Appraiser (Please cc: ISACA).
- Manufacturer's residual risk heatmap will be an input to CMMI Appraisal planning (See above).

Appraisal duration:

- 5 days is the target for the appraisal team's time on site, with additional time for planning and post-appraisal activities as needed.

Appraisal Practice Areas (Potential):

CMMI Practice Areas					
Core		**Optional**			
CM	*Configuration Management*	**PQA**	*Process Quality Assurance*	**MC**	*Monitor & Control*
GOV	*Governance*	**PI**	*Product Integration*	**OT**	*Organizational Training*
II	*Implementation Infrastructure*	**SAM**	*Supplier Agreement Management*	**PR**	*Peer Reviews*
MPM	*Managing Performance & Measurement*	**TS**	*Technical Solutions*	**PAD**	*Process Asset Development*
RDM	*Requirements Development & Management*	**V&V**	*Verification & Validation*	**PCM**	*Process Management*
RSK	*Risk & Opportunity Management*	**IRP**	*Incident Resolution & Prevention*	**CONT**	*Continuity*
PLAN	*Planning*	**DAR**	*Decision Analysis & Resolution*	**SDM**	*Service Delivery Management*
CAR	*Causal Analysis & Resolution*	**EST**	*Estimating*	**STSM**	*Strategic Service Management*
				SSS	*Supplier Source Selection*

- CMMI model criteria tailoring process**:**
    1. **Core PAs** are required.
    2. **Optional PAs** are selected to include appraisal inputs while optimizing the value provided to the site. Optional PAs will be determined during scoping conversations between the Lead Appraiser and site sponsor.
    3. **All scoped PAs** must be evaluated to at least a **Practice Group Level 2**.
    4. **ASC Appraisal Rationale template** must be completed by the Lead Appraiser to provide rationale for PAs selected.
        - ASC Appraisal Rationale template must be sent to CaseForQuality@fda.hhs.gov by the Lead Appraiser and uploaded to the ISACA ASC sharepoint site.
        - ASC Appraisal Rationale template will be reviewed, and feedback provided by FDA, within 3 business days.
- Each Appraisal will require an Objective Evidence review. The following are options for consideration. The Lead Appraiser will work with the Manufacturer to identify what will be included in the Appraisal.
    - Tour

- Observing Meetings
- Metrics Data
- Systems/Demos
- Interview
- Artifact (e.g., documents, spreadsheets, power points, pdf, work boards, etc.)
- Compliance Dossier

Appraisal Engagement:

- ISACA or MDIC will be able to stop the appraisal or other activities at any time in the pilot study process if there is a lack of pilot participant transparency, engagement, or confidentiality. The pilot escalation process defined below should be followed when escalating concerns or issues.
    - Pilot Escalation Process Guidelines:

        1. If any collaborator (e.g. enrolled manufacturer/ appraiser/ISACA/MDIC) has a concern, they will address issues directly with the concerning party by communicating the concern and requesting a change. If concerns are not resolved in a timely manner, this could be a cause for escalation.
        2. The concerned collaborator should escalate to the appropriate group for review. The Lead Appraiser will escalate to ISACA and the manufacturer will escalate to MDIC (CfQ Program Director). In both cases, ISACA and MDIC will escalate to MDIC, FDA CfQ Staff, ISACA for review.

Appraisal Schedule:

The CMMI Appraisals are managed per schedule that is documented within the Appraisal Plan. The Appraisal Plan will include the following elements at a minimum:

1. Objective Evidence Reviews
2. Appraisal Kick-off meeting
3. Site Tours
4. Practice Area Interviews
5. Validation Sessions
6. Executive Report-out
7. Final Site-wide Appraisal Report-out
8. On-site Retrospective

9. Quarterly Appraisal Checkpoints

- A Site should prioritize these activities:
    - Have a 10-min buffer for the Site Coordinator to gather and ready participants prior to the start of each session (virtually or onsite)
    - These meetings should not overlap other critical meetings.

Appraisal Outputs and Information Sharing:

A sub-set of the CMMI Appraisal results will be shared with FDA.

- The appraisal information tab of the Appraisal heatmap (e.g., site location, appraisal team, appraisal dates)
- Summary percentages and practice statements for each PA will be sent to FDA (See Figure 1 below)
    - Note: To better understand the gaps, FDA will leverage the impact prioritization and action plan to gain visibility of the site's intent to do the right thing and remediate the issues/gaps identified.
    - Note: It must be understood that a 'Deficient' score might not have as big an impact, thus not requiring action. "Scores" are simply an indication of whether an organization is meeting the intent of a given practice area in the CMMI model; however, it does not include a weight to determine impact or priority.

Figure 4: % Practice Area (PA) Characterization Example

84%	Configuration Management		78%	Governance
CM 1.1	Perform version control.		GOV 1.1	Senior management identifies what is important for doing the work and defines the approach needed to accomplish the objectives of the organization.
CM 2.1	Identify items to be placed under configuration management.		GOV 2.1	Senior management defines, keeps updated, and communicates organizational directives for process implementation and improvement based on organization needs and objectives.
CM 2.2	Develop, keep updated, and use a configuration and change management system.		GOV 2.2	Senior management ensures resources and training are provided for developing, supporting, performing, improving, and evaluating adherence to expected processes.
CM 2.3	Develop or release baselines for internal use or for delivery to the customer.		GOV 2.3	Senior management identifies their information needs, and uses the collected information to provide governance and oversight of effective process implementation and improvement.
CM 2.4	Manage changes to the items under configuration management.		GOV 2.4	Senior management holds people accountable for adhering to organization directives and achieving process implementation and improvement objectives.
CM 2.5	Develop, keep updated, and use records describing items under configuration management.		GOV 3.1	Senior management ensures that measures supporting objectives throughout the organization are collected, analyzed, and used.
CM 2.6	Perform configuration audits to maintain the integrity of configuration baselines, changes, and content of the configuration management system.		GOV 3.2	Senior management ensures that competencies and processes are aligned with the objectives of the organization.

Action Plan Development:

The Site action plan needs to incorporate remediation gaps the participating manufacturer is going to close based on assessments completed; FDA inspection (as applicable), CMMI Appraisal, Residual Risk Assessment.

- **Required domains of knowledge:**
  - CMMI Appraisal: The site will have an opportunity to discuss results with the lead appraiser.
  - Residual Risk Assessment: The site will have an opportunity to discuss the results with Mgmt-Ctrl.
  - FDA inspection observations, if applicable: The site should have the expertise to provide input to this plan. If FDA is needed, the site can opt-in or out to have FDA as a part of the impact prioritization discussion and action plan development. This engagement will be with FDA CfQ team members and Office of Health Technology (OHT) reviewers, and ORA.
- **Required Action Plan Elements (Format can vary):**
  - Prioritization and impact analysis: Appraisers will work with the participating manufacturer to arrive at the impact and subsequent prioritization of each individual 'result' line item.
    - These line items will be grouped into projects by the site (see below).
    - Projects will be prioritized based on a combination of these 'impacts'.
    - This impact analysis will be started during the appraisal and finished before the 1st checkpoint. (the participating manufacture must have the subsequent action plan complete before the 1st checkpoint.)
  - Selected Improvement Actions: (Minimum Requirements)
    - The manufacture will have the responsibility to understand/translate which CMMI Appraisal gaps will have an impact on the speed of closure and sustainability of compliance observations and/or violations.
    - The manufacturer will also have the responsibility to understand/translate potential improvements in response to the residual risk assessment data.
      - Products with confirmed Levels of Concern are inputs to the action plan.

- Note: In the pilot, we are not looking at residual risk indicators. This is just an additional input we are providing to help inform their action plan. The pilot is not looking for compliance/gaps against the ISO 14971 / TR 24971 / ISO 13485's regulations/standards.

- Both CMMI Appraisal gaps & the Residual Risk tool together help an organization focus their efforts on which actions would have a bigger impact on the organization and compliance gap closures.
- An organization does not have to respond to all red indicators/appraisal gaps. An organization should take all the data provided by the pilot to create an improvement action plan.
- For non-self-identifying sites, manufacturers are encouraged to also submit a response to the FDA 483 or Warning Letter/Untitled Letter to the Agency as they typically would. Engagement provides the manufacturer an opportunity to update the Agency on their compliance journey, corrective action plan, and progress.
    - The owner, operator, or agent in charge of a device establishment may submit a request for nonbinding feedback to FDA regarding actions the firm has proposed to take to address certain kinds of inspectional observations that have been documented on an FDA 483 and issued to the firm upon completion of an inspection of the firm's establishment. For more information about the non-binding feedback process, refer to non-binding feedback.
    - The MDIC ASC pilot working group will monitor the manufacturer's response decision if, when, and at what frequency they engage with the Agency throughout the pilot process.

- Documented Action Plan (Criteria):
    - All results from pilot activities (e.g., compliance gaps, residual risk results, appraisal results)
        - Identify projects the organization will be completing.
        - Identify/map how projects will resolve the prioritized gaps/results.
            - One project can address multiple results.

- Multiple projects can address a single result.
- Include a high-level rationale for pilot gaps/results that will not be addressed as a part of the action plan – compliance gaps must be addressed.

- Project milestones.
- Progress to milestones.
- Red/Yellow/Green status.
- Sample Template is available (Optional)
  - How this information is reported may be variable depending on the preferences/existing templates of the site.

Certificate to Foreign Governments (CFGs)	Following the development of the action plan, the participating manufacturer may request a Certificate to Foreign Governments (CFGs) consistent with the Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices. If the participants request a CFG, they are encouraged to engage with the CDRH's Case for Quality team caseforquality@fda.hhs.gov and the Exports Team within CDRH's Office of Regulatory Programs (ORP), Division of Establishment Support using exportcert@cdrh.fda.gov.

ONGOING PILOT STUDY ACTIVITIES

The following section outlines the Pilot Study Activities that will continue at a defined cadence after the CMMI Appraisal is complete.

Quarterly Checkpoints:

Pilot Site progress will be monitored quarterly at checkpoints with the Lead Appraiser.

- Quarterly Checkpoint Elements:
  1. **What has changed since the previous checkpoint** that could impact the business, and/or the way work is done.
  2. **Residual risk assessment results**
     - Mgmt-Ctrl will make the risk assessment available to the Lead Appraiser and the manufacturer once data comes available from FDA.

- The report may or may not be available for discussion at each checkpoint.

- The intent of seeing quarterly residual risk trends is to facilitate vigilance activity during the pilot and to help identify which improvement actions could potentially have an impact on product safety. Negative trends should be evaluated to ensure control.
    - Note: This is a lagging indicator and changes might not be seen at the next checkpoint.
    - Note: It is recognized that trends may be negative during the transition, but the goal is for the manufacturer to have early visibility to the cause to allow steps to be taken if needed.
    - Note: Although the detailed Residual Risk Assessment results will not be shared with FDA, Mgmt-Ctrl will calculate and communicate to FDA any shifts in results from quarter to quarter.
        - The Residual Risk Assessment utilizes multiple statistical indications, in aggregate, to determine the baseline status. These same statistical indications are comparatively utilized, in aggregate, to detect when a negative shift may have occurred that is of statistical significance.
        - When a shift of the statistical *'indications of concern'* has been observed, a statistical significance calculator is utilized to determine the value of the comparative error, difference, and the significance of that shift for any given sample size and percentage response.
        - When a shift of the statistical *'indications of concern'* has been determined to be of significance, the FDA will be notified of this outcome.
        - The site will be copied on any communication to FDA.
- After Mgmt-Ctrl works with the manufacturer to map products to the appropriate product codes during the initial assessment, a residual risk assessment can be quickly refreshed without additional input from the manufacture.

3. **Action Plan Status** (R/Y/G) and any plan deviations.

- The action plan must be ready by the 1st checkpoint.
- The action plan will be finalized after including any input provided at the 1st checkpoint.
- The site will submit the finalized action plan to the Lead Appraiser for submission to ISACA who will send to the FDA Case for Quality team.
- The FDA Case for Quality team will connect with the appropriate internal Agency reviewers. At its discretion, FDA may provide input into the action plan to ensure compliance observations and/or violations are addressed.
- The site will start tracking against the action plan in the 2nd checkpoint.

4. **Performance Metrics** within the categories of safety, effectiveness, availability, reliability, patient satisfaction, and usability.
    - The specific metrics are to be identified by the site. (A template will be provided.)
    - The introduction of performance metrics will be included in the action planning meetings. Performance metrics should be included as a part of the action plan at the first checkpoint, and the resulting metrics data included in all checkpoints thereafter.
    - The manufacturing site will provide 2 quarters of historical information at the 1st checkpoint, if available.
    - A recommendation is to capture the data monthly if the organization is capable.

- Expected Checkpoint Timing:
    - Quarterly is the minimum required frequency. May meet as frequently as desired by participants.
        - Assumption: 3-6 hours in total. This could consist of 1-3 different 2-hour meetings. It can be broken up any way the site would like.
    - The site is to measure the actual checkpoint time required during the pilot (Variation is expected).
- Expected Checkpoint Format:
    - It will be a remote/online activity.
- Checkpoint Outputs and Information Sharing (See Table 1 below):
    - Shared with FDA:

- After 1st Checkpoint Only - Action Plan will be shared (including impact prioritization).
    - At its discretion, FDA may provide input into the action plan to ensure compliance observations and/or violations are addressed
- Action Plan status will be shared (as measured against the initial action plan - red/yellow/green).
- Performance Metrics progress will be shared.

- Shared with CMMI:
    - Checkpoint Report will be shared. This report documents the conversation between the site and CMMI).
    - Residual Risk Assessment results will be shared.

Documents shared with MDIC, CMMI, and FDA:

Table 1: CMMI Appraisal and Checkpoint Information Flow Summary

Activity	Creator			Output	Receiver			
	Site	CMMI Appraisers	Ctrl-Mgmt		Site	ISACA	MDIC[1]	FDA
Compliance Dossier	Y	N	N	Identified compliance concerns and Performance Report Metrics	Y	Y	N	N
CMMI Appraisal	Y	Y	N	PA Percentage Scores	Y	Y	Y	Y
CMMI Appraisal	Y	Y	N	All In Scope Practice Statements	Y	Y	Y	Y
CMMI Appraisal	Y	Y	N	PA Excel Workbook	Y	Y	Y	N
CMMI Appraisal	Y	Y	N	Appraisal Results Presentation	Y	Y	Y	N
CMMI Appraisal	Y	Y	N	Opportunity Statements	Y	Y	Y	N
Check Point	Y	Y	N	Impact Prioritization	Y	Y	Y	N
Check Point	Y	Y	N	Action Plan	Y	Y	Y	Y
Check Point	Y	Y	N	Action Plan Status	Y	Y	Y	Y
Check Point	Y	Y	N	Performance Metrics	Y	Y	Y	Y[4]
Check Point	Y	Y	N	Check Point Report	Y	Y	Y	N
Residual Risk	Y	N	Y	Risk Analysis	Y	Y[2]	Y	N[3]

1 – MDIC will only receive access to de-identified data and some of this data will only be provided upon request. MDIC will not store any of the data.
2 – CMMI Lead Appraiser will also receive the report.
3 – The manufacturer could choose to share the baseline report with FDA. (FDA intent is to learn about the tool, not to take action in response to it.)
4 – FDA will receive Performance Metric definitions and progress (i.e., delta from the previous quarter)

Lessons Learned Data Collection:

Information will be collected from the participating manufacturer at different times throughout the Piot Study. The collected information will cover all aspects of the pilot through the use of interviews, surveys, and/or other data collection tools. It is important that identified stakeholders are transparent, engaged, and timely with their responses as this will be used to shape the current pilot and future direction of the program. Data will be protected as outlined in the Confidentiality Controls section of this Playbook.

FDA INSPECTION

During the pilot study, the FDA intends to forgo planned routine inspections for participating manufacturers; however, the agency intends to continue to conduct "for cause" inspections in response to safety signals, Class I recalls or Allegations of Regulatory Misconduct of such manufacturers as necessary and appropriate.

FDA intends to confirm the adequacy of the corrective actions taken to address the previously cited 21 CFR 820 observations and/or violations through a follow-up inspection, as they normally would, for those participating manufacturers that have an open advisory action (i.e., Warning Letter, Untitled letter) or regulatory meeting. FDA intends to conduct this inspection after the MDIC ASC Pilot Study activities have been completed or when the participating manufacture informs the agency of their readiness to close out the advisory action (i.e., WL, UL) or regulatory meeting.

If the follow-up inspection observes major deficiencies as noted in section A,1 of part V, regulatory/administrative follow up of "Compliance Program Guidance Manual; Inspection of Medical Device Manufacturers" FDA intends to follow the traditional (normal) established process to engage with the manufacturer.

The MDIC ASC working group will engage with the manufacturer to learn more about what could have been done better as part of the pilot and whether there is a need to add additional PA's into the appraisal process or engage differently with the manufacturers.

PILOT STUDY CLOSE OUT ACTIONS

<u>At the Final ASC Checkpoint,</u> time will be allocated to pilot close out actions:

1. Completion of lessons learned to capture:
    - What was beneficial to the site.
    - What was Not beneficial to the site.
    - If the ASC pilot study supported faster and/or more sustainable closure of compliance gaps
        - If yes, how did it support closure.
        - If no, why did it not support closure.
2. Discussion of the site's improvement goals moving forward.
3. Discussion of post-pilot options available to support a site's improvement goals (See table below).

Post Pilot Options
All Sites may consider 1 or more of the following options as appropriate: • Sites are strongly encouraged to complete their Action Plan as defined (if items are still open at end of pilot) • Sites can voluntarily apply to VIP after enrollment criteria is met. • Sites can voluntarily execute a follow-up Appraisal and/or Checkpoints outside ASC pilot or VIP (site responsible for cost of additional engagements as agreed upon with their Lead Appraiser) • Sites can end the pilot without further engagement, following the post-pilot survey. **Sites with an Open Advisory Action:** • FDA intends to confirm the adequacy of the corrective actions taken to address the previously cited 21 CFR 820 observations (noted on FDA 483) and/or violations through a follow-up inspection, as they normally would, for those participating manufacturers that have an open advisory action (i.e. Warning Letter, Untitled letter) or regulatory meeting. FDA intends to conduct this inspection after the MDIC ASC Pilot Study activities have been completed or when the participating manufacture informs the agency of their readiness to close out the advisory action (i.e., Warning Letter, Untitled Letter) or regulatory meeting.

CONFIDENTIALITY CONTROLS

Pilot sites must reach out to the appropriate contact listed below as soon as possible to ensure the necessary master service agreements and confidentiality controls are in place to support the pilot.

MDIC:

This is an MDIC-led pilot and the information provided to MDIC is protected through confidentiality and non-disclosure agreements established between MDIC and the manufacturer. All materials received by MDIC during this Pilot Study will be handled in accordance with confidentiality and non-disclosure agreements executed between MDIC and consistent with MDIC's policy for the protection against disclosure of non-public information. Manufacturers should mark materials as confidential or as containing confidential commercial information or trade secrets to help identify and communicate that the materials may contain information that should not be disclosed. Initially, MDIC will have access to de-identified data from ISACA and Mgmt-Ctrl, and should there be a need for them to have access to more detailed site data sets this can be requested and the needed CDA activities completed. This allows MDIC access to as much data as needed for the report but prevents the need for confidentiality agreements should that level of data not be necessary. MDIC will execute confidentiality and service agreements with both ISACA and Mgmt-Ctrl.
(MDIC Contact: Desiree Steele - dsteele@mdic.org)

ISACA:

ISACA has been contracted by MDIC to deliver services in this Pilot Study. Any and all information collected is protected through the confidentiality section of the Master Services Agreements (to include a statement of work) established between ISACA and the pilot participants and as defined by the Method Definition Document for all CMMI appraisals. From time to time, ISACA will be required to make a subset of information available to MDIC and FDA, but this will never include trade secrets, intellectual property, or other confidential company or product information. Information shared with MDIC and FDA may include, but is not limited to: a subset of appraisal results (individual and aggregate views), demographic data (company size, location, device class), performance report data (if not shared directly by participants), lessons learned, and program success metrics (adoption, effectiveness, etc.).
(ISACA Contact: Kim Kaplan - kkaplan@cmmiinstitute.com)

Mgmt-Ctrl (MC):

Mgmt-Ctrl has been contracted by MDIC to deliver services in this Pilot Study. Any and all information collected is protected through the confidentiality section of the confidentiality and service agreements (to include a statement of work) established between Mgmt-Ctrl and the pilot participants. From time to time, Mgmt-Ctrl will be required to make a subset of information available to MDIC and FDA, but this will never include trade secrets, intellectual property, or other confidential company or product information. Information shared with MDIC and FDA may include, but is not limited to Residual Risk Report (4 indicators) and the heat map. **(Mgmt-Ctrl Contact: Larry Mager - larry@mgmt-ctrl.com)**

FDA:

All materials received by FDA during this Pilot Study will be handled consistent with all applicable protections, procedures, and legal requirements that protect against disclosure of non-public information (See e.g., 21 U.S.C. §§ 331(j) and 360j(c), 18 U.S.C. § 1905, and 21 C.F.R. Part 20). This includes protection of information considered to be trade secret and confidential commercial information ("CCI") as those terms are defined in 21 C.F.R. § 20.61. The protection of this information is of the utmost importance to the Agency. Like all information shared with FDA, information shared throughout the pilot is subject to the Freedom of Information Act ("FOIA") (5 U.S.C. § 552). Processing of FOIA requests will not differ from FDA's typical FOIA process. FDA reviews all responsive records prior to release to redact information pursuant to FOIA and its regulations in 21 C.F.R. part 20. Participant should mark materials as confidential or as containing CCI or trade secret to help flag that the materials may contain information that should not be disclosed.

RULES OF ENGAGEMENT ON SAFETY ISSUES

- The manufacturer understands that they are responsible for complying with all applicable laws and regulations, including the Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations (e.g., 21 CFR 803, 806, 807, 820, etc.), before, during, and after their participation in the pilot.
- MDIC may remove a participant manufacturer from the pilot, as described in the CMMI Appraisal and Quarterly Checkpoints document. After removal from the pilot, the manufacturer would engage with the Agency utilizing the traditional (normal) process established.

- As required by 21 CFR 806, the manufacturer understands that they are responsible for reporting certain actions concerning device corrections and removals throughout the pilot study. In addition, manufacturers may send a courtesy notification to the Case for Quality Staff at Caseforquality@fda.hhs.gov regarding issues in their products, signals, or recalls. FDA (CfQ Staff, OHTs and ORA) intends to proactively engage and interact with the manufacturer to mitigate risks to health posed by the device, unless the issue involves Allegations of Regulatory Misconduct. FDA intends to follow its current defined process to follow up on allegations of regulatory misconduct.
- FDA is a regulatory agency with an established mandate to protect the public health. The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. A manufacturer's participation in this pilot program does not prevent FDA from citing particular inspectional observations during inspections or otherwise taking regulatory action when appropriate.
- As required by 21 CFR part 803, the manufacturer understands that they are responsible for reporting deaths and serious injuries that a device has or may have caused or contributed to the pilot study. In addition, the manufacturer may also send a courtesy notice to the Case for Quality Staff at Caseforquality@fda.hhs.gov. FDA (CfQ Staff, OHT and ORA) intends to work interactively with the manufacturer to address any issues noted.

CONTACTS

Organization	Contacts
MDIC	– Desiree Steele, MDIC Case for Quality Program Manager (dsteele@mdic.org) – Joe Sapiente, MDIC Case for Quality Associate VP (jsapiente@mdic.org)
ISACA	– Kim Kaplan, ISACA CMMI Program Manager (KKaplan@isaca.org)
CMMI Lead Appraiser	– Becky Fitzgerald, Principal Two Harbors Consulting (becky.fitzgerald@twohc.com)
Mgmt-Ctrl	– Larry Mager, Principle at Mgmt Ctrl (larry@mgmt-ctrl.com)
FDA Case for Quality	– Bleta Vuniqi, Case for Quality Team Leader at FDA (Bleta.Vuniqi@fda.hhs.gov) – Case for Quality mailbox, (caseforquality@fda.hhs.gov)

FAQs

This section provides answers to the most frequently asked questions.

How is this pilot different than an audit?	The intent of the pilot study is to evaluate the effectiveness of an established maturity model at enabling the closure of compliance concerns; faster and more sustainably, while structuring internal systems for continuous improvement. The intent of the Appraisal is not to identify compliance gaps, but to help inform how previously identified compliance concerns might be addressed efficiently and for long term effectiveness. Trained and experienced appraisers first seek to understand how an organization functions by talking to those who do the work. This evidence is then evaluated against a proven set of industry best practices to identify opportunities for improvement. Site leaders are empowered to prioritize the opportunities that most align to their business objectives. Quarterly check points enable the organization to track progress and receive guidance on improvement projects. It is not possible to 'pass' or 'fail' an appraisal. In fact, a site will gain the most from the pilot if it approaches the appraisal with a mind-set focused on identifying opportunities to improve. As organizations are very experienced with audits, this shift can feel uncomfortable, until they have completed their first appraisal. Pilot sites are encouraged to reach out to Joe Sapiente at jsapiente@mdic.org. at MDIC to answer questions they may have about the pilot or request to be connected with another industry site to hear about their experience in the pilot.
What are the pilot eligibility considerations?	• Domestic or Outside the U.S. Manufactures marketing devices in the U.S. • Must have an established QMS in accordance with 21 CFR Part 820. • Manufactures meeting the following test case scenarios:

	– **2+ Voluntary Self-Reporting Manufacturers*** –The manufacturer is self-identifying major deficiencies with the Quality System regulation as defined in the Compliance Program 7382.845. – **2+ Manufacturers* that received an FDA 483 during a recent inspection** – The manufacturer has major deficiencies with the Quality System regulation as defined in the Compliance Program 7382.845 observed during an inspection; with no advisory action by FDA (e.g. WL, UL) or Regulatory Meeting as defined in Chapters 4 and 10 of the Regulatory Procedures Manual. – **2+ Manufacturers* where Agency has issued an Advisory Action or Requested a Regulatory Meeting** – Manufacturer with open Warning Letter, Untitled Letter, or Regulatory Meeting as defined in Chapters 4 and 10 of the Regulatory Procedures Manual. Note: Sites with a Consent Decree are not eligible for this pilot study. • See 820.3(o) for definition of a manufacturer
How do I apply?	Go to the Medical Device Innovation Consortium (MDIC) website. Link: https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/
Will the status of my enrollment be made public?	A Site's enrollment will be kept confidential unless it provides permission for its participation in the pilot study to be made public. This option must be selected on the application form linked to the MDIC Site.
What happens if my site is not accepted into the pilot?	MDIC will notify the Site that it was not accepted. It is recommended that applicants should continue engaging as they normally would with the Agency.
What happens if I can't meet the pilot study	There is an escalation process built into the pilot process. The Site would notify the MDIC Case for Quality Program Manager (dsteele@mdic.org) that it cannot meet the expectations. If no path forward can be identified, the

expectations after I've enrolled?	Site will be removed from the pilot, and engagement with the Agency will follow its normal process.
What is the expected investment by my Site once enrolled? (Time, Effort, Cost)	There is an expectation that the Site will engage fully in the pilot study, this includes the CMMI appraisal, residual risk analysis, action plan, quarterly checkpoints, performance metrics, and FDA follow-up inspection (if applicable). • CMMI must be used for the Appraisal and Mgmt-Ctrl must be used for the residual risk assessment tool. Additionally, regular lessons learned sessions, participant surveys, and pilot study data collection activities will be completed with the Site The Site will be enrolled in the pilot study for approximately 18 months after application approval. • Specific sites could take longer to close compliance gaps and /or improvements identified as a part of this pilot. However, pilot data collection will end after 18 months. The on-site CMMI Appraisal is typically 5 days, with additional time required for planning and post-appraisal activities as needed. • Appraisal Planning Activities could require 3-5 days for a small number of site resources. A Site does not have to respond to all identified CMMI and/or Residual Risk tool gaps. It should take all the data provided by the pilot to create an improvement action plan in a way that positively impacts the closure of their compliance gaps and the sustainability of impacted processes. The cost of the pilot is covered by MDIC. If the Site decides to further engage with Mgmt-Ctrl beyond the residual risk assessment tool or enrolls in a follow-up CMMI appraisal, the Site must cover the cost of this additional work.

What are the benefits of enrollment?	MDIC will cover the costs of the CMMI Appraisal and other activities conducted under the pilot. This includes the development of an action plan that is agreed upon with FDA, and that is intended to address any FDA inspectional observations, concerns communicated in FDA advisory actions, CMMI appraisal gaps, and residual risk assessment concerns. During the pilot study, the FDA intends to forgo planned routine inspections for participating manufacturers; however, the agency intends to continue to conduct "for cause" inspections of such manufacturers as necessary and appropriate. Participants will have the opportunity to complete the improvements to product quality and safety as specified on their action plan. Additionally, the participating manufacturer may request a Certificate to Foreign Governments (CFG), if needed. The participating manufacturer may request a Certificate to Foreign Governments (CFGs) consistent with the Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices. If the participants request a CFG, they are encouraged to engage with the CDRH's Case for Quality team caseforquality@fda.hhs.gov and the Exports Team within CDRH's Office of Regulatory Programs (ORP), Division of Establishment Support using exportcert@cdrh.fda.gov.
Who were the stakeholders involved in defining the pilot study?	The pilot study process was intentionally defined in partnership with both ISACA (i.e., representatives of the Appraiser community) and FDA. Industry, Mgmt-Ctrl, ISACA, CDRH, ORA, MDIC
How will my Site's information be used from the	The purpose of this pilot study is to evaluate the effectiveness of the CMMI Appraisal model and the Mgmt-Ctrl residual risk tool at aiding a site in its journey towards compliance and a culture of continuous improvement.

Appraisal and Residual Risk tool?	Information shared with CMMI Appraisers and Mgmt-Ctrl would remain confidential as maintained by formal agreements with the site.
How will pilot participation impact FDA inspections?	During the pilot study, the FDA intends to forgo planned routine inspections for participating manufacturers; however, the agency intends to continue to conduct "for cause" inspections in response to safety signals, Class I recalls or Allegations of Regulatory Misconduct of such manufacturers as necessary and appropriate. FDA intends to confirm the adequacy of the corrective actions taken to address the previously cited 21 CFR 820 observations and/or violations through a follow-up inspection, as they normally would, for those participating manufacturers that have an open advisory action (i.e. Warning Letter, Untitled letter) or regulatory meeting. FDA intends to conduct this inspection after the MDIC ASC Pilot Study activities have been completed or when the participating manufacture informs the agency of their readiness to closeout the advisory action (i.e. WL, UL) or regulatory meeting. If the follow-up inspection observes major deficiencies as noted in section A,1 of part V, regulatory/administrative follow up of "Compliance Program Guidance Manual; Inspection of Medical Device Manufacturers" FDA intends to follow the traditional (normal) established process to engage with the manufacturer. The MDIC ASC working group will engage with the manufacturer to learn more about what could have been done better as part of the pilot and whether there is a need to add additional PA's into the appraisal process or engage differently with the manufacturers.
When can my Site enroll in the CFQ Voluntary Improvement Program (VIP)	Once a state of compliance has been achieved and the adequacy of the corrective actions is verified through FDA inspection; the Site may seek enrollment into the CfQ VIP program once the program becomes operational, and if the enrollment criteria for the CfQ VIP pilot program have been met.

	• **Enrollment Criteria Link** (ISACA Website): https://cmmiinstitute.com/medicaldevice#MDDAP_Program_Requirements • **Pilot Study Application Link** (MDIC Website): https://mdic.org/project/case-for-quality-accelerate-sustainable-capability-pilot/
How does this connect with other FDA initiatives?	The ASC pilot study is facilitated by MDIC; FDA and other stakeholders are contributors to this MDIC effort. It leverages learnings from the Case for Quality Voluntary Improvement Program (VIP), but it is a separate activity. Enrollment on the ASC pilot is voluntary and would not preclude the site from enrolling in other pilots or programs (e.g., MDSAP).

Contact information

For more information, please contact
Joe Sapiente at jsapiente@mdic.org