



MDDAP Appraisal Team Member (ATM) Playbook

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1. Playbook Purpose

Prospective Medical Device Discovery Appraisal Program (MDDAP) Appraisal Team Members (ATMs) have successfully completed the MDDAP Concepts course, passed their end-of-course assessment, and are ready to participate in an appraisal as part of their apprenticeship. This playbook will serve as an easy reference guide for finding answers and explanatory information on key topics.

2. Playbook Scope

This playbook will cover all phases of the appraisal process, including pre- and post-appraisal activities. The focus of this playbook is the activities for which the ATM is explicitly responsible. However, activities executed and coordinated by the Appraisal Team Lead (ATL) are also included, providing insight into how ATM responsibilities fit into the larger appraisal process.

3. Program Background

The US Food and Drug Administration (FDA) launched the Case for Quality (CfQ) to explore new approaches to improving medical device quality and patient safety beyond the established standard of regulatory compliance. The Medical Device Innovation Consortium (MDIC), a nonprofit organization with membership from across the medical device ecosystem, was tasked with managing the CfQ to provide a safe space for industry and agency to work collaboratively on potential solutions.

One of those initiatives involved researching maturity models and leveraging Deloitte to conduct a study of 22 different frameworks, ultimately landing on the Capability Maturity Model Integration (CMMI[®]). This project became the CfQ Voluntary Improvement Program (VIP), which leverages the MDDAP, a tailored version of ISACA's CMMI, as the model and appraisal method by which medical device manufacturers could better understand, measure, and improve their capability to develop high-quality products for patients.

For more information, review the [FDA Final Guidance](#) document.

4. MDDAP Appraiser Qualification

Review the qualification pathway for your desired role:

- [Internal ATMs](#) (from within appraised organizations)
- [ISACA ATMs and ATLS](#) (working on behalf of ISACA)

4.1 ATM Candidate Observation

MDDAP ATM candidates (those who desire to become internal ATMs or ISACA ATMs) will be observed during the first appraisal that they participate in as part of their apprenticeship. An ATM Observer, who is a seasoned MDDAP ATM, will be assigned by ISACA to conduct the observation. Review the Observation Evaluation checklist (a copy will be provided once the observation has been scheduled).

4.2 Tips for a Successful Observation

Consider the following to increase the likelihood of a successful observation:

- Talk to your observer several weeks prior to the appraisal
 - Review the checklist and talk through expectations
- Meet frequently during the appraisal
 - Seek guidance and coaching
- Have a wrap-up session with the observer prior to the checklist submission
 - Checklist submission is due one week after the appraisal

After the observation, a coach will be assigned for each appraisal during the apprenticeship period. It is likely that each observer and coach will continue to be a resource for candidates outside of appraisals.

4.3 ATL Nuances

Each ATL brings a unique set of experiences and skills resulting from their shared advanced CMMI training. While all appraisals follow a formal method and specific requirements for MDDAP, there are many activities that allow for tailoring to the organization's or appraisal's specific objectives. While this variability is common, it may be confusing for a new ATM.

It is important for MDDAP ATM Candidates to ask questions, participate, learn, and adjust.

5. Appraisal Information

5.1 Appraisal Type

MDDAP is a tailored version of the CMMI Evaluation Appraisal. This means that appraisal results include the characterization of model practices (Satisfied or S, Partially Satisfied or P, or Deficient or D) and aggregate Practice Area (PA) percentages (the average of each practice percentage is equally weighted; S = 90%, P = 40%, and D = 0%). However, no capability or maturity level ratings are generated.

Since it is often impossible to review every single process, document, and system an organization uses to do work, appraisals use a sampling method, which is why the highest characterization is capped at 90%.

5.2 Appraisal Planning and Preparation

5.2.1 Team Composition

Each MDDAP appraisal team must include at least two people whose combined experience includes ATL CMMI knowledge and three years of medical device experience (or experience on three MDDAP appraisals). Having multiple appraisers enables the team to maintain accountability and objectivity in appraisal activities.

The number of internal ATMs on an MDDAP appraisal may not exceed 50% of the team; however, there is an exception for MDDAP ATM candidates completing their observation or apprenticeship—these individuals participate as “extra” team members for the core appraisal team (which is the minimally required team size for successfully completing appraisal activities).

Extra ATMs have fewer responsibilities than core team members, who will take on additional responsibilities if necessary. These mitigation steps reduce appraisal schedule and quality risk while ATM candidates are being vetted to become full ATMs.

Team size is impacted by several factors, including but not limited to the variety and volume of products, number of full-time employees/part-time employees, complexity of work, number of organizational functions in scope, number of PAs selected, and practice group levels.

ISACA assigns the ATL to an MDDAP organization’s appraisal and then, based on the core team size and other appraisal criteria (language, model domains, etc.), sends a recommended list of eligible and available ATMs to the ATL for selection. MDDAP ATMs and ATLs must provide their availability in the VIP Portal.

5.2.2 Intake Call

Newly assigned ATLs conduct an intake call with VIP participants for the first step in the appraisal planning process. There is an optional MDDAP template to help ATLs facilitate these calls to better understand the organization’s objectives, pain points, structure, products, etc. The ATL will typically share their notes with the selected ATMs so they can become familiar with the organization ahead of appraisal activities.

5.2.3 Scope Submission

The ATL must submit the MDDAP appraisal scope details to ISACA before ATM eligibility can be determined and the team can be selected. This information can be shared with internal ATMs upon request.

5.2.4 Appraisal Objectives

The development of MDDAP appraisal plans starts with the organization's business objectives. The most significant business objectives are selected and translated into appraisal objectives, which form a charter for the appraisal team to identify opportunities that specifically support the organization in achieving its business objectives. It is important that ATMs understand and incorporate the appraisal objectives into their responsibilities.

5.2.5 Selecting Practice Areas (PAs)

The ATL will work with the organization to map appraisal objectives to potential PAs.

1. **Year 1 Baseline:** There is a required set of PAs for all first-year (baseline) appraisals. Organizations can choose to go above and beyond this selection. There are rare exceptions where a PA might not be applicable to an organization. In these instances, the ATL should submit a request to exclude the PA to ISACA with a rationale for submitting an escalation and approval request to the FDA.
2. **Year 2+ Reappraisal:** Every appraisal after the baseline (a reappraisal) must include the three core MDDAP PAs of Practice Group Level 2+: Governance (GOV), Implementation Infrastructure (II), and Managing Performance and Measurement (MPM). Outside of this requirement, organizations can tailor their PA selection through discussions with their ATL, keeping the organization and appraisal objectives in focus. Reappraisals also require a rationale to be submitted to FDA for approval. The ATL will make the reappraisal rationale available to the appraisal team.

The ATL will also discuss which practice group levels are appropriate for each PA with the organization. MDDAP appraisals can only evaluate PAs up to Practice Group Level 3.

5.2.6 Appraisal Sites

An ISACA SharePoint site will be set up by ISACA, and access will be given to all ATMs. This site is your resource center during the appraisal. It will store the plan, heatmaps, presentations, interview scripts, interview notes, and deliverables.

All appraisal information will be entered into ISACA's CMMI Appraisal System (CAS). The ATL will create the appraisal record in CAS and invite ATMs to participate in the [appraisal record creation](#). ATMs are responsible for logging into CAS and signing the appraisal confidentiality agreement, appraisal plan, and final findings (appraisal results). ATMs are also required to provide feedback on the ATL and other ATMs.

CAS stores all appraisal records and generates an appraisal ID for each record, which the organization will use to demonstrate its participation in VIP and leverage regulatory opportunities made available by the FDA.

5.2.7 ATL Assigns Specific PAs

Once PAs have been selected or the FDA has approved the reappraisal rationale, the ATL will assign PAs to each ATM. ATMs are responsible for facilitating discussions around every PA assigned (this may be covered in a singular group session or across multiple group sessions), reviewing other team member's notes on the PA, and entering information for the PA tab in the appraisal heatmap, including a first attempt at characterizing each PA practice (using S, P, or D), and drafting results.

5.2.8 Appraisal Plan

The appraisal plan is automatically generated in CAS based on the data input by the ATL. The plan includes objectives, appraisal team information, PAs selected, scope (projects, products, etc.), risks, logistics, and results. MDDAP appraisals strive to consider the appraised organization as holistically as possible to provide insights, not just within individual projects but also where cross-functional teams or processes intersect. The plan appendix includes information on the organization's participants—see [MDDAP Participant Considerations](#) to better understand how participants may be selected.

5.2.9 Appraisal Team Training

The ATL typically leads an appraisal team training the week before an appraisal. For MDDAP appraisals, this is frequently part of the readiness review. A typical agenda for the appraisal training includes team introductions and a review of the appraisal week schedule, PA responsibilities, team norms, logistics, and travel plans.

5.2.10 Appraisal Schedule

The ATL will provide a schedule for all appraisal activities throughout the appraisal week. A typical MDDAP appraisal schedule is five days:

- Day 1: Kick-off and site tour
- Day 1-3: Discussions between the team and site
- Day 4: Follow-up and preliminary results sessions
- Day 5: Executive brief (optional), results presentation, and lessons learned

5.2.11 Objective Evidence Review (Prior to Onsite)

Baseline (First year): An organization's first and second MDDAP appraisals tend to focus on affirmations as the primary source of Objective Evidence (OE). One of MDDAP's primary objectives for an organization's first appraisal is to build trust in the process by demonstrating that MDDAP is different from a regulatory audit or inspection and that the appraisal team is there to help the organization improve.

Annual Reappraisal (Subsequent years): By the third MDDAP appraisal, many organizations conduct a deeper review of their documented processes and appraisal schedules that may even include dedicated time to review artifacts outside of the typical appraisal schedule. The purpose of this documentation review is to get a better understanding of the organization's implementation of specific process areas. Organizations often provide two to three pieces of documentation for each PA in scope, including presentations, meeting minutes, tool outputs, and more.

5.3 Conduct Appraisal

5.3.1 ATM Responsibilities (Onsite)

ATM candidates are only assigned one PA during their observation. The number of assigned PAs typically increases by one to two with each subsequent appraisal during their apprenticeship, up to five PAs. Fully qualified MDDAP ATMs are expected to take on up to half of all appraisal PAs. For more information, see [MDDAP Roles and Responsibilities](#).

5.3.2 Discussions

MDDAP typically tries to schedule discussions with individual contributors in addition to, rather than only with, management and leadership staff. Discussion sessions generally take one to two hours, with no more than –six to eight site participants.

ATMs will be responsible for facilitating discussions for their assigned PA(s). This includes providing context for the purpose and intent of the conversation, initiating the discussion, ensuring the PA practices are all covered, and making closing remarks. Each session closes with a discussion of Implementation Infrastructure (II) as it pertains to the primary PA(s) discussed. Discussion templates are provided to guide ATMs through the process. Try to ask questions that encourage open and transparent dialogue. Allow and invite other team members to ask additional questions.

Mini-teams are not leveraged during MDDAP appraisals, so all team members must be in discussions to establish a full-team consensus of appraisal results. Consensus is achieved using the thumbs up, sideways, or down method.

Demonstrations, tours, and presentations are all considered discussion sessions where questions can be asked. ATMs must take notes during all discussion sessions. Notes should be complete and timely. Internal ATMs may find it more challenging to take comprehensive notes if they already know the information.

ATMs are responsible for ensuring that enough OE has been collected (via discussion sessions and/or artifact review) for all practices within their assigned PA(s).

5.3.3 Heatmap

MDDAP uses a specific heatmap tool to capture which OE supports the characterizations and result statements. ATMs are responsible for completing the assigned PA tab(s) in the heatmap workbook:

- Notes should be consolidated and put in the “evidence/comment” field for each practice
- Initial practice characterizations must be determined by ATMs for each assigned PA:
 - Satisfied (meets practice intent)
 - Partially Satisfied (sometimes meets practice intent)
 - Deficient (does not meet practice intent).

All final practice characterizations will be determined by team consensus, meaning all team members agree to support the final decision. MDDAP is a type of Evaluation Appraisal, which means practice characterizations for the sampled projects or support functions are not required. MDDAP Evaluation Appraisals also do not assign a capability or maturity level rating or a practice group or PA rating to the appraised organization.

5.3.4 Results Statements

Result statements should be clear, actionable, and demonstrate the value of addressing. They should avoid using absolutes, specific examples, and suggested solutions. Possible result types include:

- Strengths: Rare exemplary areas
- Opportunities: Gaps (required for non-satisfied practices)
- Notes: Neither strength nor opportunity
 - Warning: No gap against the model but an observation that the current implementation may cause risk
 - Benefit: No strength, but there may be an improvement project underway that should be expanded to other areas to further benefit the organization

The appraised organization owns the appraisal results, and leadership is encouraged to prioritize only the responsive actions that are most valuable. For more information, see [MDDAP Scoring Guide](#)

5.3.5 Preliminary Results Validation

Reviewing preliminary results with the appraisal participants provides an opportunity for feedback on whether the results are accurate (the organization may provide additional evidence), can be understood a month from now (clear and actionable), and avoid any hot-button words. This activity is unique compared to a typical audit or inspection and begins the transition of result ownership to the organization. MDDAP leverages a specific template for consistent delivery. ATMs typically facilitate these validation sessions; however, ATMs should be prepared to speak to their result statements if questions arise. All final results must first be validated.

5.3.6 Appraisal Team Behavior

Medical device organizations are very adept at completing audits and inspections. ATMs must foster an open and welcoming environment so that appraisal participants feel comfortable sharing information not typically included in a compliance activity. Building trust can be a challenge at any point in a participant organization's journey as new individuals are brought into the activities, but especially in the first year. An ATM's demeanor must remain conversational instead of interrogational.

5.4 Post-Appraisal

5.4.1 Team Lessons Learned

The ATL will facilitate a lessons-learned session to review what went right, what went wrong, and ideas for improvements to the MDDAP appraisal process.

5.4.2 Destroy ALL Notes

The confidentiality and non-attribution agreement requires that ALL notes from discussions, preliminary results, and demos (including those sent via email) are destroyed.

5.4.3 CAS Close Out

The ATL is responsible for entering all required CAS record data and submitting the appraisal. ATMs are responsible for signing the confidentiality and non-attribution agreement, appraisal plan (the ATL will provide a copy), and final results. ATMs must also provide feedback for each ATM, including the ATL.

ISACA may take up to 30 days to review MDDAP appraisals for quality assurance, after which the FDA will receive a summary set of the results (a copy is presented to the organization during the final results session). At that point, the appraised organization will be eligible to leverage regulatory flexibilities for Premarket approval (PMA) submissions (using their CAS appraisal ID number).

5.4.4 Checkpoints

After the appraisal, the organization will be expected to participate in quarterly checkpoints where the ATL provides guidance and assistance on prioritizing the highest impact gaps identified, tracking the status of continuous improvement projects, reviewing any organizational changes, and collecting performance reports. Internal ATMs are often asked to support these projects and ongoing checkpoint activities. For more information, see the [MDDAP Checkpoint Guidelines](#).

5.4.5 Performance Report

The MDDAP Performance Report is a tailored version of the CMMI Performance Report and is leveraged differently to align with the FDA's requirements. The MDDAP Performance Report is introduced in the first checkpoint following the first appraisal. The initial submission is due during the second checkpoint (approximately six months from the appraisal). The report is submitted quarterly thereafter, including during the reappraisal. The Performance Report is typically included in Year 3+ artifact reviews.

5.4.6 Annual Reappraisal

MDDAP requires an annual reappraisal to continue providing a lens for organizations to identify opportunities for improvement and demonstrate a commitment to a quality culture above and beyond regulatory requirements.

Sites are not expected to demonstrate improvement against gaps, as the scope of the appraisal may change significantly based on the organization's new annual business objectives. For more information, see the [MDDAP Reappraisal Guidelines](#).

6. ISACA Appraiser Responsibilities

Any ATMs or ATLS working on behalf of ISACA will be required to regularly provide their availability to participate in MDDAP appraisals. For more information, see the [Pipeline & Availability Workbook](#).

ATM candidates and qualified MDDAP ATMs will have access to the [MDDAP Appraiser Collaboration SharePoint](#) site after completing their Professional Services Agreement (PSA). This website provides ATMs with a variety of materials, resources, and updates about the MDDAP program, such as:

- [MDDAP Appraiser Meeting Minutes](#)
- [ISACA Travel Policy](#)

In addition, questions can be posted on the [discussion board](#) in the MDDAP Collaboration SharePoint site, where ISACA and the MDDAP appraiser community regularly review and respond.