MDDAP: Lessons Learned

MDIC Case for Quality Forum
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Agenda

• Major Lessons Learned
• Customer-Facing Changes
• Feedback
• Working Groups
Technical Solution & Product Integration to Practice Group Level 3

Major Lessons Learned

Reasons for Change

1. Average and cumulative appraisal results for participants were generally strong against the practice areas: Technical Solution (TS) and Product Integration (PI).

2. Based on these datasets, we hypothesized that because of the CFR, medical device manufacturers were more likely to demonstrate capability in these areas.

3. To provide more value to participants and better insight back to the FDA, we changed the way we appraised against these areas.

Change

In a participant’s first appraisal, also known as a baseline appraisal, we typically appraise 11 foundational practice areas to practice group level 2 (considered to be a “managed” state).

We decided to start appraising participants to practice group level 3 for TS and PI; which seems to be more appropriate based on the appraisal results thereafter.

However, we are considering whether or not to include TS and PI in baseline appraisals for 2019.
Embedded Appraisal Team Members

Major Lessons Learned

Considerations
1. Participants were seeking additional informational or training opportunities to become familiarized with this new approach using the CMMI framework and appraisal methodology.

2. Participants were interested in investigating cost reduction options.

3. We had anticipated medical device industry consulting companies join our appraisal delivery team; however, that didn’t happen and we wanted more team members with medical device experience for scalability.

Outcome
We developed a new certification pathway for individuals from participating manufactures to become appraisal team members, with the potential to eventually replace our appraisers (except the Lead Appraiser) by meeting outlined criteria, ultimately reducing the appraisal cost.

- Resume submission demonstrating medical device experience
- Training Course, 4-days onsite
- Exam, successfully pass
- Observation, participate as an appraisal team member, responsible for leading ONE discussion and collaborating with appraisal team to finalize results.
Multi-Site Appraisals

Major Lessons Learned

Reason for Change

1. Although some enrolled facilities had design and development activities onsite, for most, the total product lifecycle existed across multiple sites and participants wanted to capture this view in their appraisal.

2. Some participants chose to enroll more than one facility, noting that their facilities shared a similar product or organizational structure, and wanted an appraisal of them as a whole.

3. Some participants enrolled facilities that were in such close geographic proximity that shared one of the above connections and were interested in any potential cost savings.

Change

Original assumption: one appraisal per facility, focused on manufacturing processes.

We’ve made the following adjustments to accommodate the inclusion of a multi-site appraisal in the pilot.

- Expanded the definition of “business unit” from a single facility to include multiple when certain criteria is met (ex: structural or TPLC).
- Review multi-site appraisal scope & schedule considerations with FDA before executing, ensuring appropriate coverage and inclusion of individuals from all sites.
- Discuss with participant any deviation from standard travel expenses when sites not geographically close.
Reappraisals

Major Lessons Learned

Considerations

1. We had to ensure that reappraisals balanced (A) value to participants, (B) FDA’s information needs, and (C) consistency.

2. We wanted to include the upcoming release of CMMI V2.0 Services practice areas since many participants did more than develop.

3. We heard the concerns around reappraisal cost / time being more than the baseline.

Outcome

Reappraisals will have the following attributes:

- 3 practice areas will be core (required): Governance, Implementation Infrastructure, Managing Performance and Measurement; with the remaining Development and Services practice areas elective inclusions, determined by the participant and lead appraiser

- We will try to keep the scope reasonably similar to the baseline: 65-75 practices

- Performance measures

- Reappraisal Rationale
Performance Data*

Major Lessons Learned

Reason for Change

1. Many discussions around the format for metrics being collected. How do we reduce burden of submission while balancing the need for consistency?

2. Questions regarding who should collect these measures; previously appraisers weren’t trained on expectations (that were still being defined) and participants were hesitant to submit certain data to FDA.

3. Alignment with other CfQ efforts, such as the “Quality Domains” from the Product Quality Outcomes Analytics Team.

4. Considerations for how to help participants ‘mature’ their metrics collection & analysis.

Change

*This activity is still in development. Changes:

- **Metrics Collection Form** submitted to Institute
- Metrics submitted direct to FDA in **any format**
- 4 of 7 **Quality Domains** incorporated (Safety, Effectiveness, Reliability, Availability)
- **Performance Report** to Appraisers during check points and reappraisals

Additional Considerations:

- **Transparency** could shift reapraisal activities
- More consistent data will help determine any **connection** between appraisal activities and improved performance and product quality
Customer-Facing Changes

- Two participants dropped from the pilot before receiving an appraisal; so to encourage engagement:
  - Moved routine inspection waiver benefit to after signing appraisal SOW
  - Moved submission benefits to start upon FDA’s receipt of appraisal results
- Many information requests and version issues with emailed documents
  - Uploaded many resources online, in the process of uploading all critical documents for participants that they could access by logging into the CMMI Institute website (free) and viewing their dashboard
  - Started recording participant meetings as group grows and scheduling conflicts are commonplace
  - Mentor program wherein a new participant can be paired with an experienced participant (who has undergone an appraisal) to learn first-hand what to expect next
  - Standard for MDICx Quarterly Webinars to now include a speaker sharing the participant experience
- FDA has improved their internal processes for providing modifications
  - Inspection waiver, timing on change review, participant collaboration on developing and testing docs
Feedback: Participant Surveys

158 responses - Positives

**Appraisers** are perceived as knowledgeable, unbiased, honest, skilled, well-prepared, friendly, and helpful.

**Planning** and **Appraisal Schedule** is well organized and efficient while also meaningful and engaging.

**Discussions** are well facilitated with a good depth of questions, the atmosphere is comfortable, safe, secure, non-threatening, and non-intrusive, with participants feeling at ease and able to speak freely.

**Validation sessions** ensure the results are properly understood and captured by incorporating feedback.

**Results** are accurate, legitimate, reasonable, and actionable; provides a holistic view that easily translates to business objectives beyond compliance in the QMS, fostered cross-functional collaboration, and provided leadership with areas of focus.

**Approach** made sense, complemented compliance activities, and really focused on (continuous) improvements.

**Benefits** are real and tangible, well worth the time and investment, game changing, and improve the relationship between industry and agency by building trust through proactive (rather than reactive) activities.
Feedback: Participant Surveys

158 responses - Improvement Opportunities

Expectations are not always clear to all participants before appraisal activities begin, but confusion was resolved before the end of the week. Perhaps additional informational resources could be provided to the site.

**Action:** Hold an onboarding call with participants to level-set expectations and answer questions.

Discussions didn’t always include the right people, topics, number of people, or amount of time.

**Action:** Cap the max individuals allowed per session and discuss the concept of ‘right’ people early.

Vocabulary was not always clear, or sometimes had different meaning depending on the context. This was resolved after clarifying, however, it may be useful to have a running list to avoid confusion in the future.

**Action:** Inform both appraisers and participants of this possibility early, avoid known issue-words.

Connection of activities to product quality not always obvious or evident when looking beyond the QMS.

**Action:** Guidance document created for appraisers to help explain or translate connections.

Results were occasionally minimal or high level. Unclear if opportunities will be pursued without enforcement.

**Action:** TS/PI to PGL3 in the baseline appraisal. Check points to identify engagement or lack thereof.
Feedback: Success Metrics

**Pros**
- Adequately growing delivery ability to meet demand.
- Organizations enrolling more than one site reduces onboarding time and increases understanding and awareness with each additional site.
- Multi-Site appraisals decrease the cost per facility and delivery resources needed per facility.
- Embedded ATMs help organizations to understand their results, drive improvements, reduce costs, and increase delivery capacity.
- Renewal to reappraisal timeline is shorter than enrollment to baseline timeline.

**Cons**
- Time to appraisal is still behind goal (110 vs 90 days), possibly driven by scheduling conflicts, scoping considerations, and/or legal negotiations.
- Late signing of Appraisal SOW after selecting a date (esp. international travel) can increase travel costs.
- Onboarding new appraisers can reduce consistency of timing and costs.
- Observing embedded ATMs can occasionally increase planning/scoping timelines.
Working Groups – Next Steps

Additional Regulatory Benefits
Objective: To identify, develop, test, and finalize any additional regulatory benefits in consideration for participants of the Program.

Program Features
Objective: To identify, develop, test, and finalize new desired features of the Program, as well as identify, analyze, and resolve any undesirable features of the Program.

Multi-Site Appraisals
Objective: To define and develop the standards and exceptions for conducting multi-site appraisals.

Reappraisals
Objective: To define and develop the standards and exceptions for conducting reappraisals.

Performance Measures
Objective: To identify the information needs, improvement opportunities to the methodology, and potential synergies for continuous monitoring and transparency to reduce reappraisal scope and/or increase the length of time in between reappraisals.

Medical Device Context
Objective: To define, build, and formally develop the additional CMMI model context to support the intended tailoring for the medical device industry.