

Quality Management Maturity Pilots: CDER's Lessons Learned

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Operationalizing a QMM Program



CDER QMM Pilots

- ❖ CDER contracted two 3rd party assessors to conduct QMM pilots based on specific objective indicators
- ❖ Assessments should enable:
 - Establishing best practices
 - Cross-sectional comparison against industry peers
 - Quantitative overall rating
- ❖ QMM Finished Dosage Form Pilot Program
 - 7 domestic manufacturers
 - Contract awarded to Pacific Force Consulting Group, LLC
 - Completed SEP 2021
- ❖ QMM Active Pharmaceutical Ingredient Pilot Program
 - 8 foreign manufacturers
 - Contract awarded to Shabas Solutions, LLC
 - Completed MAR 2022
- ❖ Assessments were conducted virtually due to the ongoing COVID-19 PHE

FDA's Role

- ❖ Participated in the pilot assessments as spectators
 - To observe and learn
 - Provided feedback to 3rd party assessors throughout pilots
- ❖ Issued follow-up surveys to participating sites
 - Assessment tool
 - Assessment methods
 - Assessment reports
 - General QMM program questions

Assessment Process

Domestic vs. Foreign Assessment Process

Domestic Pilot

- ❖ Stage I: Self-Assessment Protocol
 - 24 questions
- ❖ Stage II: Follow-up Questions
- ❖ Six QMM Program Areas:
 - **Leadership and Governance**
 - **Operations**
 - **Continual Improvement**
 - **Stakeholder Engagement and Satisfaction**
 - **Knowledge Management**
 - **Workforce Engagement**

Foreign Pilot

- ❖ Facilitated Virtual Assessment
 - 15 practice areas
 - 66 questions
 - Ability to upload evidence
- ❖ Four QMM Pillars:
 - **Sustainability**
 - **Risk Management**
 - **Compliance**
 - **Quality Culture**

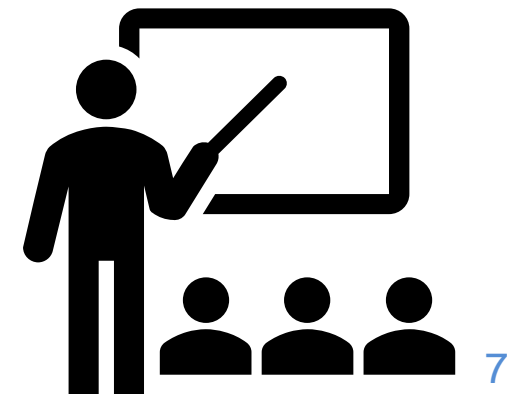
Key Learnings: Assessment Process

PREPARATION

- ❖ Need a one-pager or prep meeting on process and expected outcomes prior to kickoff
- ❖ Providing questions and guidance was beneficial (foreign pilot)
 - Should be sent sooner than two weeks in advance
- ❖ Need examples of evidence

TIMING

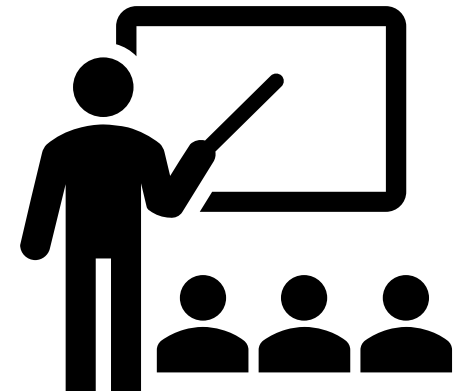
- ❖ Strict time limit per question was not effective
 - Should be more dynamic



Key Learnings: Assessment Process

ASSESSMENT QUESTIONS

- ❖ Standardize Assessment Approach for:
 - Documentation Level for Assessors
 - Verifiable Objective Evidence
 - Attributing scores for elements that cannot be scored (e.g., missing data)
- ❖ Optimize topic areas, number of questions, and complexity of levels
 - Group foundational corporate questions and site questions
 - Content duplication across different topic areas (e.g., QRM)
 - Consider sector-specific questions
- ❖ Minimize jargon



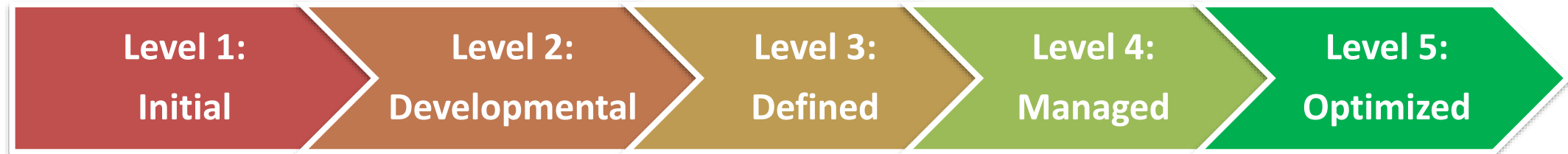
Key Learnings: Assessment Process

DISCUSSION

- ❖ Interactive assessments allowed for deeper dive (foreign pilot)
- ❖ Need guidelines for site presentations
- ❖ Speak with management and staff separately
- ❖ Assessments went smoother when coordinated to have the right site staff in the room for specific topic areas



Assessment Scoring Approach



Domestic Pilot Scoring

- ❖ Consider self-assessment scores, virtual assessment notes, evidence
- ❖ Apply level definitions and ADLI+R Dimensions: Approach, Deployment, Learning, Integration + Results
- ❖ Select % score with level range
- ❖ Consensus Process for disagreements >15%

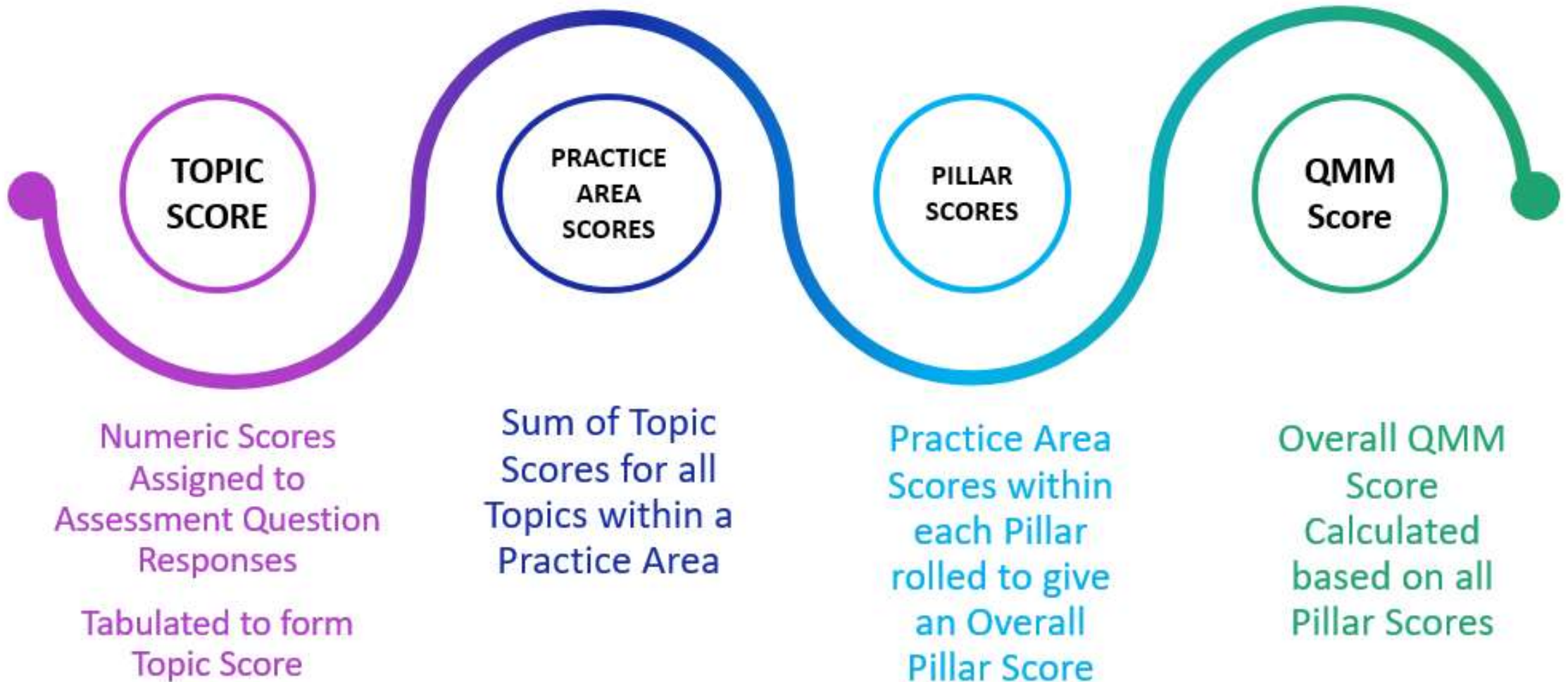
| | |
|---|---|
| <p>Level 2 30%, 35%, 40%, or 45%</p> | <ul style="list-style-type: none"> • Some beneficial or mixed performance levels are shown, some adverse trends are evident. (R) • An effective, systematic approach of some key processes is evident. (A) • The approach is deployed, although some areas or work units are in early stages of deployment. (D) • The beginning of a systematic approach to evaluation and improvement of key processes is evident. (L) • Approaches are in the early stages of alignment with basic organizational needs; most serve to support processes. (I) • Performance levels are provided, only some show beneficial trends. Beginning comparative data provided. (R) |
|---|---|

Example Domestic Site Report



| Item | Attribute | Site Self-Assessment Score | PFG Assessment Score |
|------|--|----------------------------|----------------------|
| 1.1 | Management Commitment | 4 | 4 |
| 1.2a | Management Reviews, Oversight, and Monitoring | 3 | 3 |
| 1.2b | Management Reviews, Oversight, and Monitoring | 3 | 3 |
| 1.3 | Internal Communications | 3 | 4 |
| 1.4 | Business Excellence and Societal Contribution | 3 | 3 |
| 2.1 | Customer/Patient Focus | 2 | 3 |
| 2.2a | Stakeholder Feedback and Engagement | 3 | 3 |
| 2.2b | Stakeholder Feedback and Engagement | 3 | 3 |
| 3.1a | Process Performance and Product Quality Monitoring | 3 | 4 |

Foreign Pilot Scoring



Example Foreign Site Report



1

Figure 1: Final Pillar Scores

Figure 2: Scores by Topic for Compliance

Figure 3: Scores by Practice Areas for Compliance



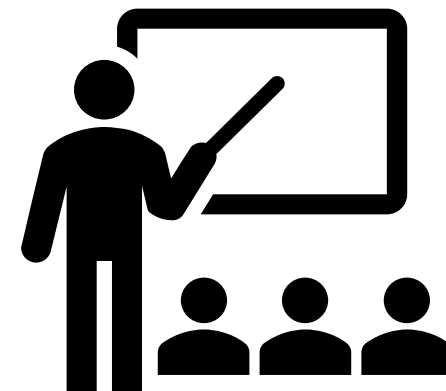
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3

Key Learnings: Scoring

- ❖ Objective criteria that can discern between levels is critical
 - Multiple assessors are needed per assessment
 - Need objective approach for managing conflicting scores to reduce bias
- ❖ Substantiate responses through supporting documentation
 - Need to define appropriate examples of evidence



Assessor Behaviors

Key Learnings: Assessor Behaviors

- ❖ Making sites feel comfortable is an art but best practices were identified
- ❖ Seize opportunity
 - Ask follow-up questions
 - Substantiate through evidence collection
- ❖ Avoid leading or Yes/No follow-up questions where open-ended would be better
- ❖ Don't ask questions that were previously answered during another question
- ❖ Minimize lecturing and opining
- ❖ Avoid tangents due to curiosity
- ❖ Understand the audience
 - Confusing when questions asked in quick succession or changed
 - Consider level of employee

Feedback From Pilot Participants

- ❖ Some questions were compound and complex, making it hard to understand.
- ❖ Helped sites identify strengths and weaknesses.
- ❖ Some topic areas have not been considered previously and were brought forward during assessment.
- ❖ Beneficial to continuous improvement program. Helps them to reflect on where they are and where they need to go.
- ❖ Appreciate the input and challenge to their systems. While they have many audits, the QMM pilot looked holistically at the big picture and pulled it all together.

Operationalizing a QMM Program

- ❖ Executed by FDA or 3rd Party
- ❖ Executed virtually or on site
- ❖ Incentives to promote voluntary participation
- ❖ Reassessment period
- ❖ Assigning a final rating
 - Considering assessment scores plus other factors

In Summary

- ❖ Pilots provided insight into the design and implementation of a future QMM assessment protocol
- ❖ Stakeholder engagement highlighted additional program considerations
- ❖ Overall sentiment on the program is positive!



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