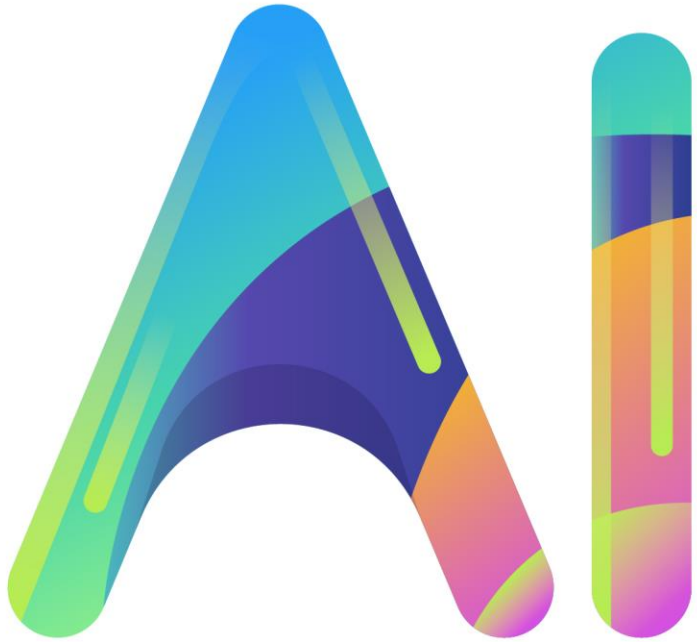
PIA INNOVATION THAT CARES
Pharmaceutical Industry Association Of Puerto Rico

Welcome to the

22nd PIA REGULATORY CONFERENCE



THE FUTURE IS NOW

AI IN QUALITY

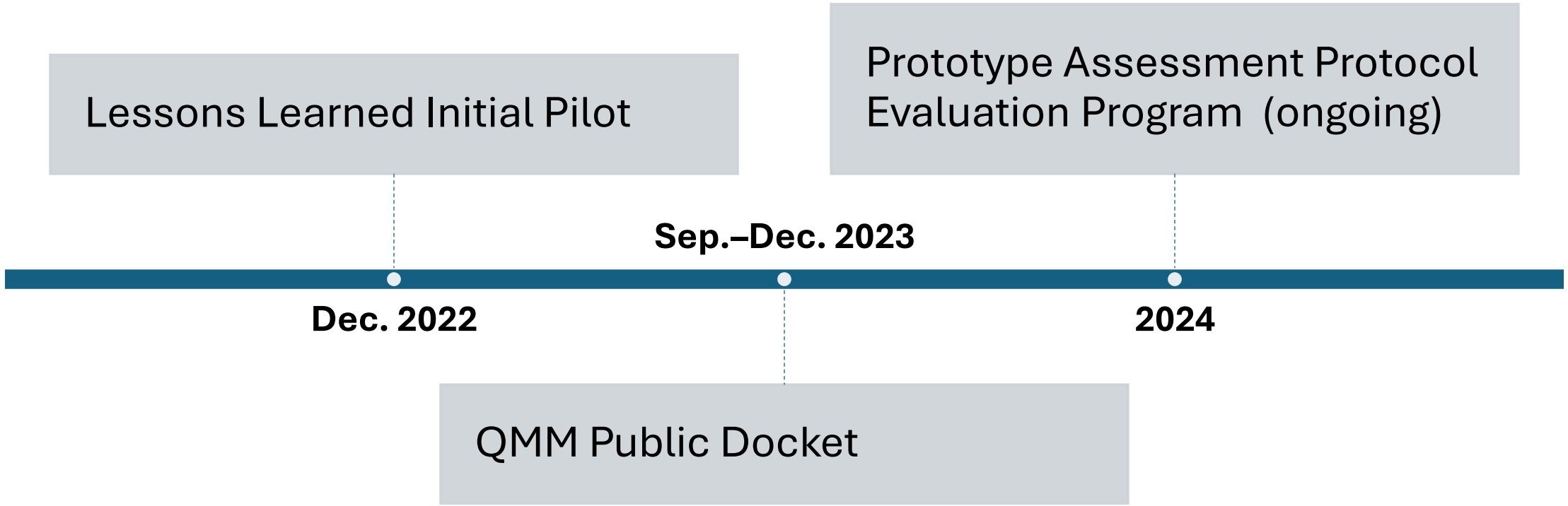
What is next for the FDA QMM Program?

Denyse Baker, P.E., RAC
Associate Vice President Global Quality Compliance
External Engagement and Advocacy
Eli Lilly and Company

Outline for Today - What is new since 2022?

- FDA Developments
- Industry Responses
- Lilly Experience

FDA QMM Program – steady progress



FDA's QMM "Thesis Statement"

"The **overall supply chain should also benefit** as manufacturers with higher QMM, focus on **continual improvement** and are therefore more likely to **embrace advanced manufacturing technologies** that enhance the capability, robustness, and commitment to quality by the pharmaceutical industry."

Lessons from CDER's QMM Pilot Programs, AAPS Journal Dec 2022

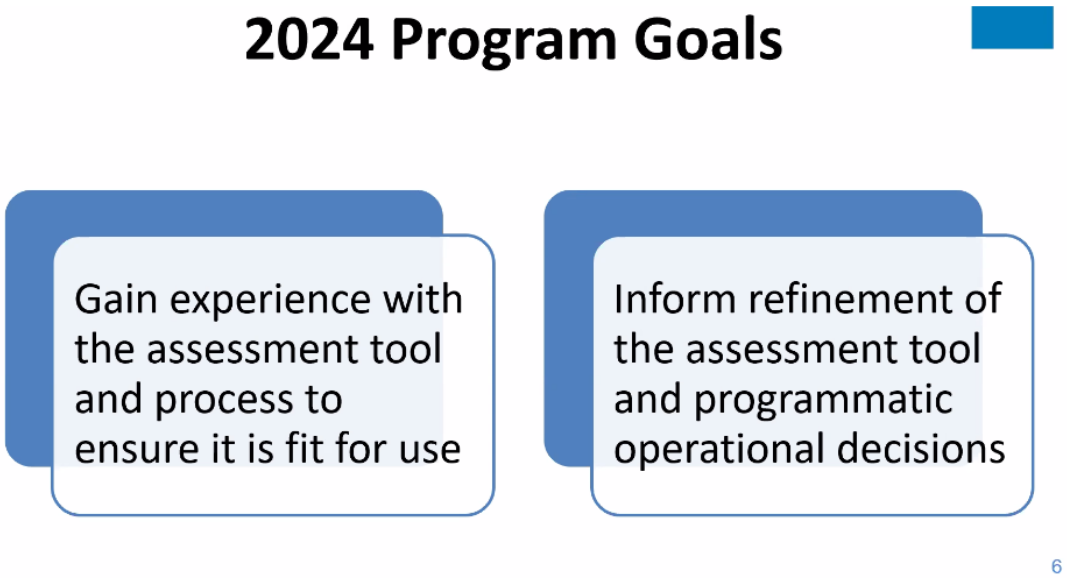
Industry 4.0 for Pharmaceutical Manufacturing June 2021

Janet Woodcock's Vision

"A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight."

Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach

FDA's 2024 Pilot



- CDER Assessment Teams
  - All assessors are from Office of Q Surveillance.
  - Same team throughout assessment to ensure consistency
- Program features coming directly from lessons learned in earlier pilot
  - Brief orientation meeting
  - Self Assessment
  - Balance of records requested in advance and on-site assessment

Five Assessment Areas

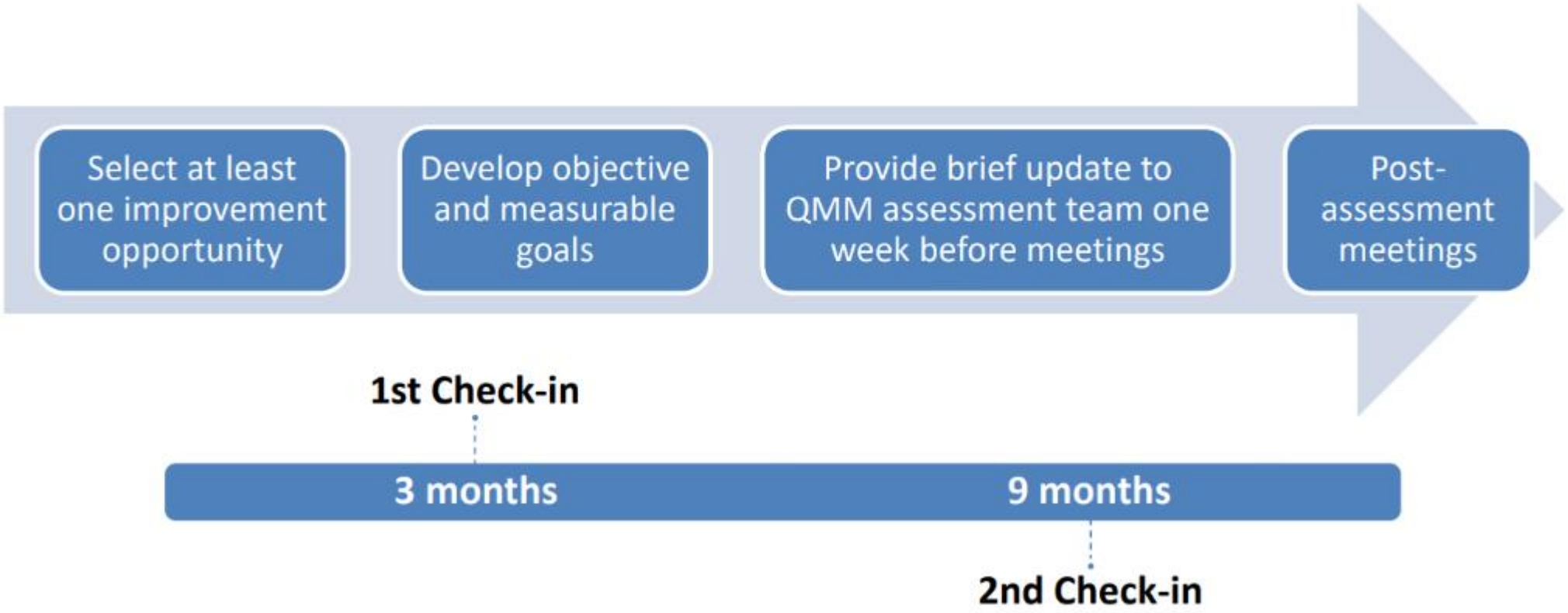
Pre-assessment

- All participants receive same questions
- Asking for 2-3 examples to support responses
- Requests Supporting Documentation
- No scoring

Assessment

- 1 week: On-Site or Hybrid
- Team of 3 including a Lead; May also have observers
- Assessors score individually
- Strengths and improvement opportunities
- Scoring report sent w/in 15-20 business days
- Close out meeting 5 days post report

Post-Assessment Engagement



Comments to FDA Docket December 2023

(MS CoPilot Summary)

- **Support for Enhanced Quality Systems**:
  - Many commenters expressed support for a QMM program that encourages drug manufacturers to go beyond current good manufacturing practice (CGMP) requirements.
  - They emphasized the importance of fostering a strong quality culture mindset.
- **Suggestions for Implementation**:
  - Commenters recommended practical approaches for assessing quality management maturity.
  - They highlighted the need for clear criteria, scoring mechanisms, and assessor training.
- **Balancing Rigor and Flexibility**:
  - Some comments discussed striking the right balance between rigorous assessment and flexibility to accommodate different types of establishments.
- **Supply Chain Resilience and Drug Availability**:
  - Several commenters emphasized that a robust QMM program could enhance supply chain resiliency and minimize risks to drug availability.

Comments to FDA Docket December 2023

(Human analysis)

- Assessments will vary dramatically
- Conduct additional research to establish a correlation
- Risk of misinterpretation or poor conclusions made by the public

- Do not create incentives to avoid products that may not “score well”

- Do not anticipate any advantages specific to the CMO/CDMO sector to participating
- Sharing QMM information …not a replacement for cGMP requirements

This is a “metric” mindset not a “maturity” mindset!

Comments to FDA Docket December 2023 (cont.)

- could shift purchasers to wanting to work with specific suppliers with a higher rating and avoid other suppliers
- which could lead to the higher-performing suppliers not being able to meet market demand.

A reminder to be careful of unintended consequences…

Recent Industry Responses- *going beyond CGMP compliance to create a community of practioners*

BENEFIT: evaluating the maturity of the quality management system allows continual improvement in quality performance.

OPPORTUNITIES:

- Applications to supplier maturity and good supply practices
- Linking QMM to QRM
- Understanding QMS agility and PQS Effectiveness(Q12)
- Many tools now available for industry self assessment

BARRIER: demonstrating value to executive business and quality leaders of the focus on quality cultural excellence.

CHALLENGES:

- Industry self assessment vs. FDA assessment or oversight
- Blurring the lines between assessment & audit
- Disclosure of results
- Unintended consequences by creating the wrong incentives

Lilly's quality culture assessments

Scope and approach

- Conducted at all 14 mfg. sites
- To identify baseline and look for strengths and opportunities
- Team of 2-3 with same project lead in most

Process and frequency

- Completed in 3-4 days
- Included site tours, interview panels, and observation of meetings.
- Plan to repeat periodically to monitor the progress and changes.
- Aligned with safety and OpEX site assessments

Tools and data sources

- PDA Model Output
- ISPE APQ Guide Results
- Narrative Summary of Observations
- Existing employee engagement survey data

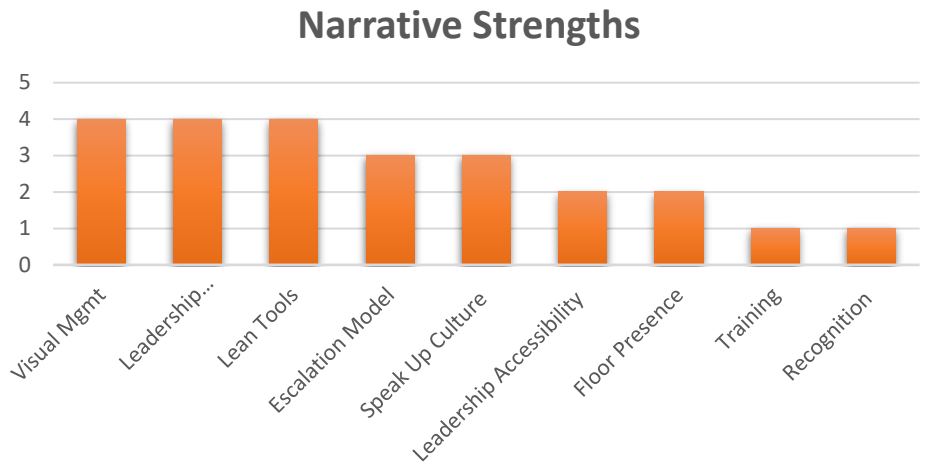
Outcomes and Benefits

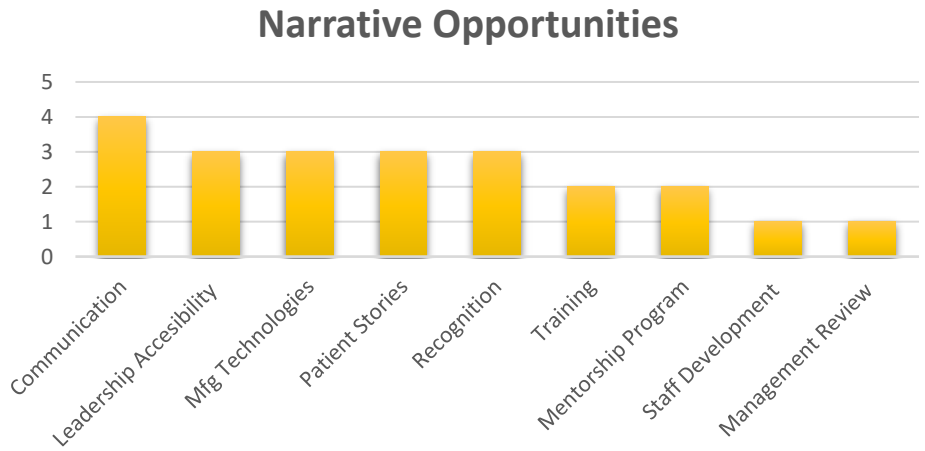
- Identified improvement opportunities
- Assessed maturity of QRM and Human Error programs
- Helped the leaders identify practices to reinforce quality culture

Each site received a report, and we holistically analyzed the data.

Heat Map of Maturity Model Scores

Metric	Site 1	Site 2	Site 3	Site 4	Site 5
Impact on Product Quality					
Patient Impact					
Process Ownership and Engagement					
QMS Processes					
Root cause					
Human Error					
Continuous Improvement					
Manufacturing Technologies					
Training					
Business Conduct					
Quality Risk Management					
Accountabilty and Quality Planning					
Safety Program					
Rewards & Recognition					
Feedback & Staff Development					
Quality Communication					
Management Reviews					
Metrics					
Internal Stakeholder Feedback					





This slide contains fictious data for illustrative

Courtesy of Christine Teipen Smith

Effective leadership practices to elevate culture.

MENTORSHIP	BALANCED MESSAGING	COMMUNICATION	MINDSET SHIFT
Formal mentorship programs ensure technical growth and foundational learning.	Balanced messaging for quality, safety, and supply enhances understanding of producing reliable supply with safety first and quality always.	Complete communication creates conditions for knowledge sharing and problem solving.	Deliberate modeling of behaviors that are expected within the organization.
A team's tenure gives insight on how much support they need Organizations with high job rotation can accelerate learning with mentorship	Visual displays of quality messaging Messaging in townhall meetings, newsletters, etc. Transparent rationale of decision-making	Increases the opportunity for shared learning Improves understanding a compliance position Reduces possibility for individuals to underestimate the severity of risk	Leader models expected behavior Employees notice the leader's change in behavior The culture changes as employees model the leader's behavior

Courtesy of Christine Teipen Smith