Quality Management Maturity (QMM)

U.S. FOOD & DRUG ADMINISTRATION

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SBIA
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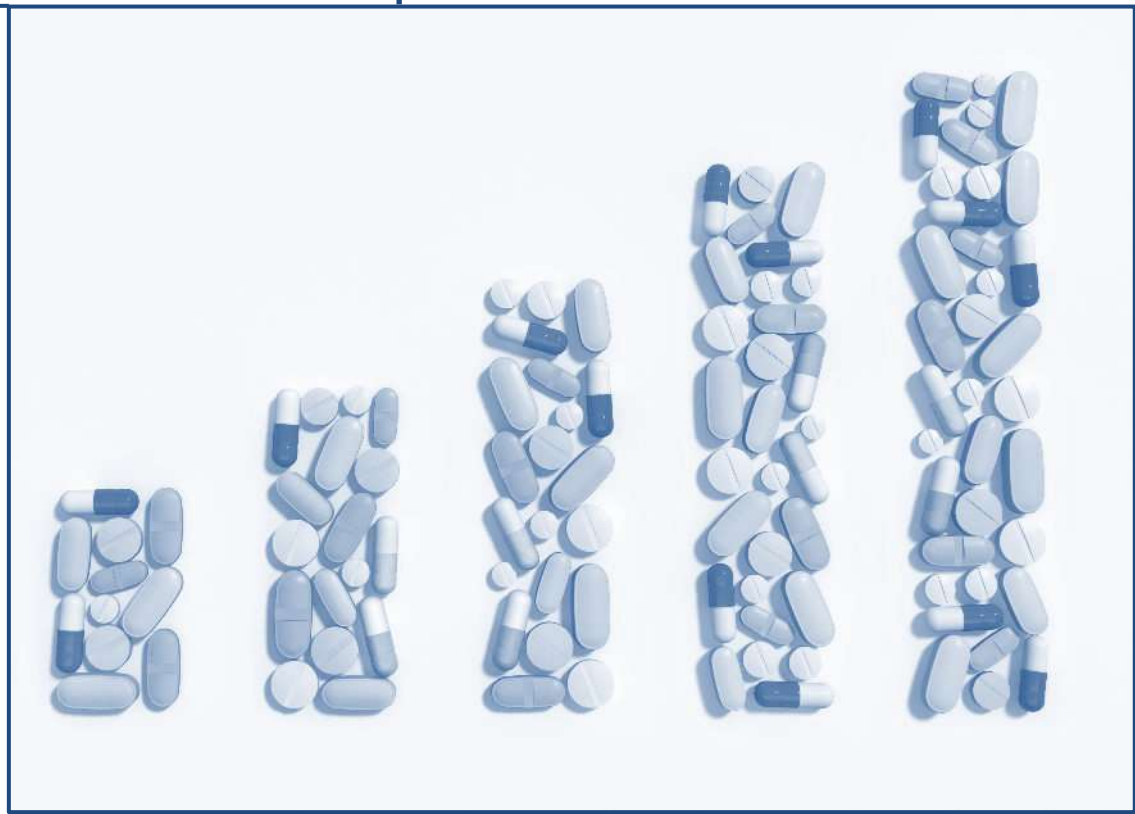


Agenda

- Quality Management Maturity (QMM)
- QMM Program Development

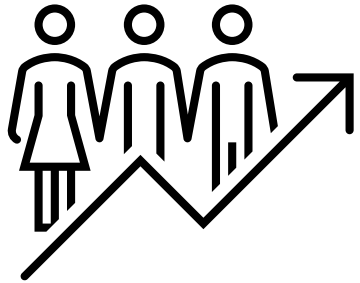
Quality Management Maturity (QMM)

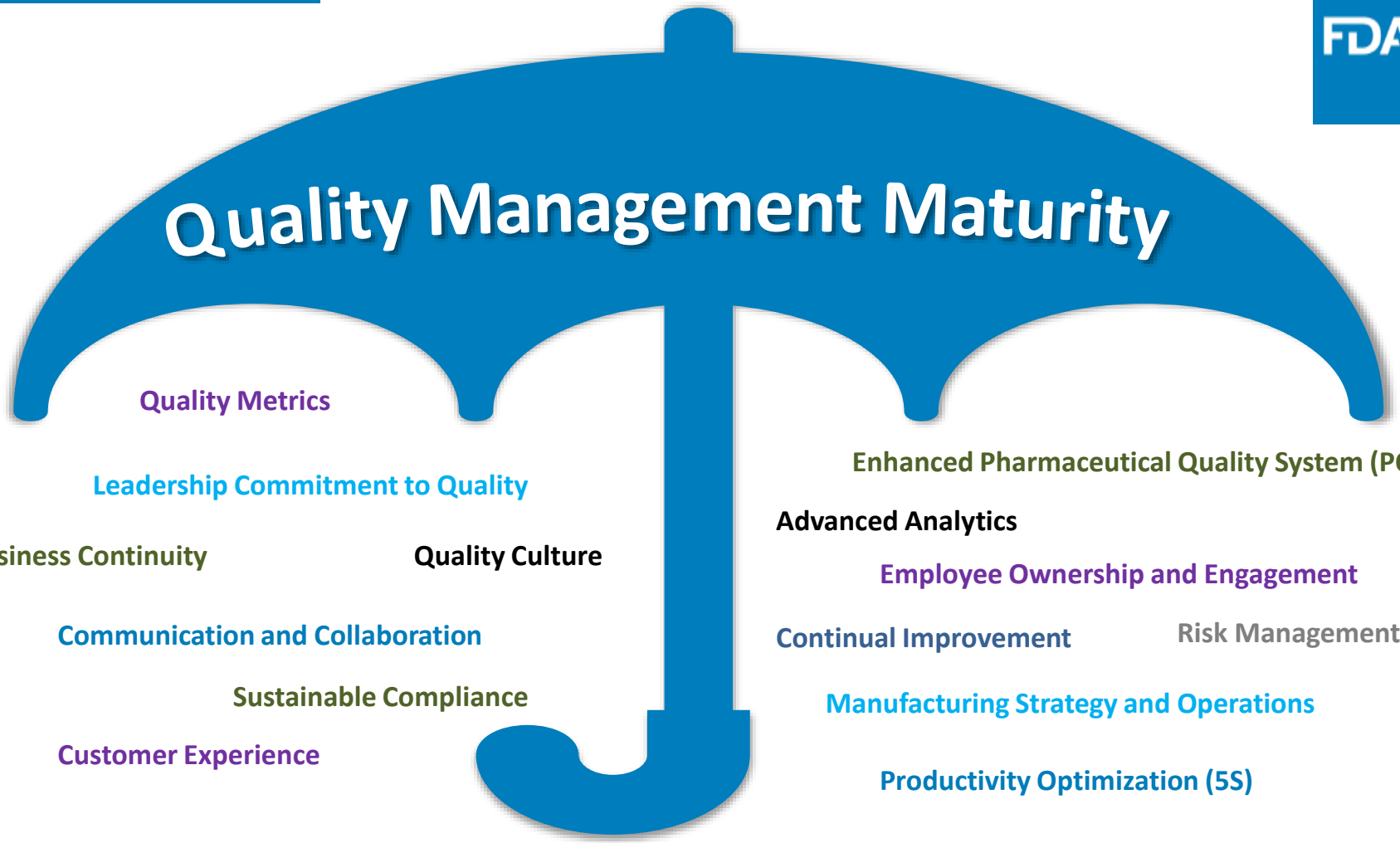
Drug Shortages - A Potential Solution

- Root Cause: ***The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues***
- Enduring Solution: ***Developing a rating system to incentivize drug manufacturers to invest in QMM***

Understanding QMM

Drug manufacturers achieve higher levels of QMM when they successfully integrate business and manufacturing operations with quality practices and technological advancements to optimize product quality, enhance supply chain resiliency, and drive continual improvement




Quality Management Maturity
Quality Metrics
Leadership Commitment to Quality
Business Continuity
Quality Culture
Communication and Collaboration
Sustainable Compliance
Customer Experience
Enhanced Pharmaceutical Quality System (PQS)
Advanced Analytics
Employee Ownership and Engagement
Continual Improvement
Risk Management
Manufacturing Strategy and Operations
Productivity Optimization (5S)

QMM is Nothing New

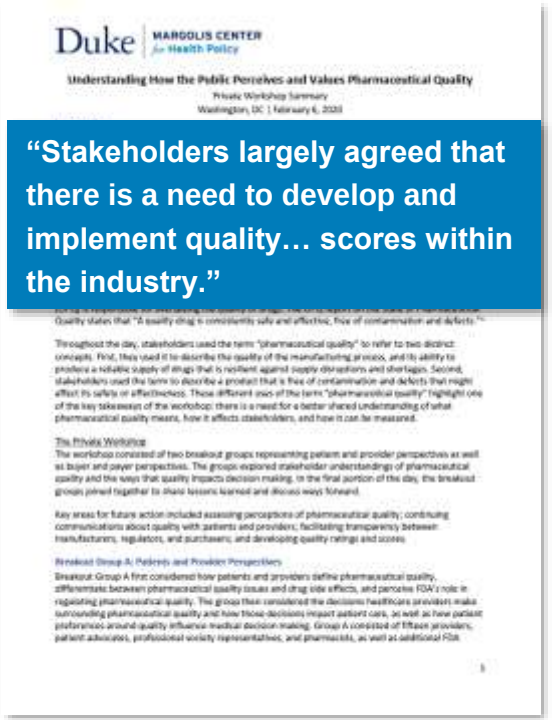
- "Quality always costs less" – W Edwards Deming
  - Achieving quality outcomes requires investment
  - Good quality does not imply higher costs
  - Organizations whose quality practices are the most sophisticated are not necessarily the ones that spend the most
- Cost of poor quality – Loss of production, rework, scrap, loss of business, recalls
- Cost of quality – Inspection and prevention costs
  - Labor costs for audits, preventive/predictive maintenance, training, design improvement, implementation of advanced control mechanisms (e.g., SPC)
- High levels of QMM will lead to:
  - Greater customer satisfaction
  - Operational efficiencies – increase in productivity
  - Higher revenues

Complementary Efforts

- Learn from efforts to date
  - PDA Quality Culture Initiative
  - ISPE Advancing Pharmaceutical Quality Program
  - University of St. Gallen Operational Excellence Research
  - FDA/CDRH Case for Quality Pilot Program
  - Dun & Bradstreet Quality Benchmarking Study

Road to FDA's QMM Program

2020


Duke | MARGOLIS CENTER for Health Policy

Understanding How the Public Perceives and Values Pharmaceutical Quality

Private Workshop Summary

Washington, DC | February 6, 2020

"Stakeholders largely agreed that there is a need to develop and implement quality… scores within the industry."

2021

"FDA should lead the development of a framework to measure… a facility's quality management maturity with engagement from industry, academia, and other stakeholders."

2022

"Establishing a quality rating system… is a long-term initiative that will have to be developed in collaboration with business partners and with stakeholders."

QMM Program Development

Recent Milestones and Publications

- Two QMM Pilots: completed in 2022
- SBIA Workshop: May 24-25, 2022
- Advisory Committee: November 2, 2022

October 2022

The AAPS Journal (2022) 24:111
https://doi.org/10.1208/s12248-022-00761-7

RESEARCH ARTICLE

Benchmarking the Quality Practices of Global Pharmaceutical Manufacturing to Advance Supply Chain Resilience

Matt Fellows[1] · Thomas Friedli[2] · Ye Li[3] · Jennifer Maguire[3] · Nandini Rakala[3] · Marten Ritz[2] · Matteo Bernasconi[2] · Mark Seiss[1,4] · Neil Stiber[3] · Mat Swatek[1] · Alex Viehmann[3]

January 2023

The AAPS Journal (2023) 25:14
https://doi.org/10.1208/s12248-022-00777-z

COMMENTARY

Lessons from CDER's Quality Management Maturity Pilot Programs

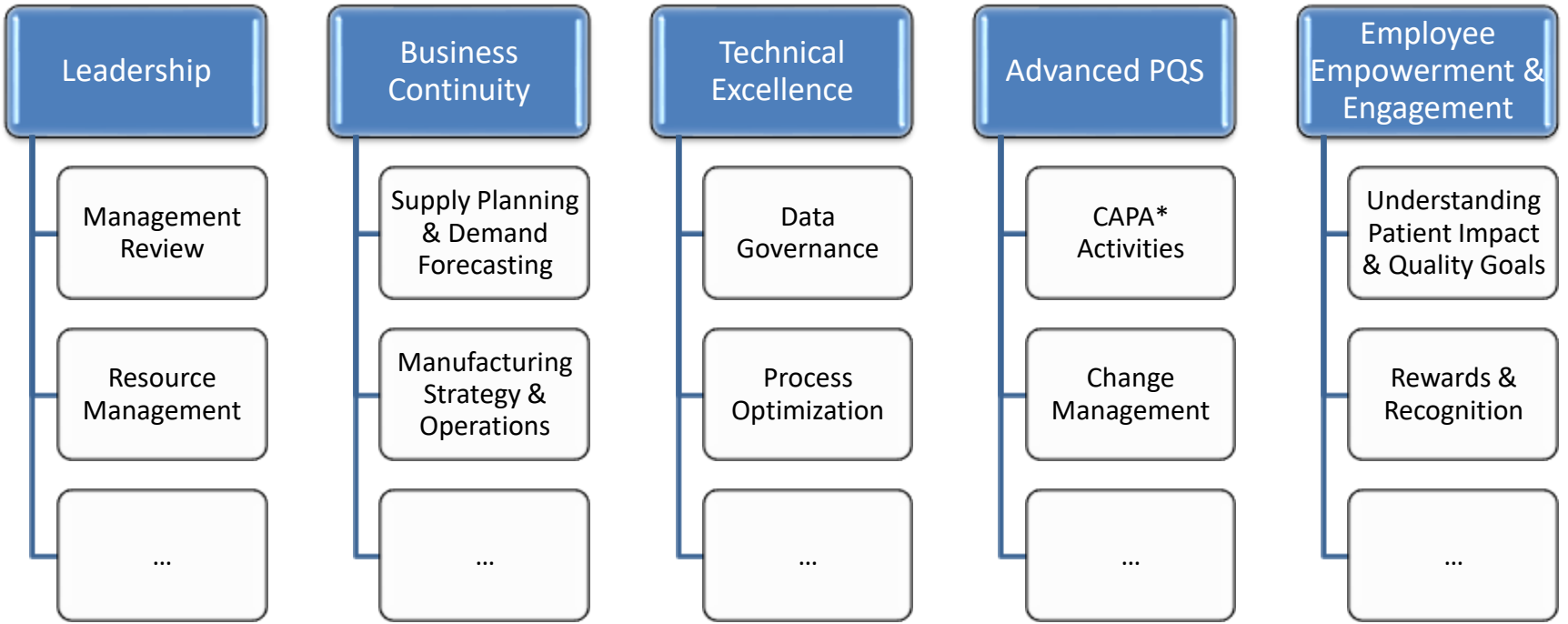
Jennifer Maguire[1] · Adam Fisher[1] · Djamila Harouaka[1] · Nandini Rakala[1] · Carla Lundi[1] · Marcus Yambot[1] · Alex Viehmann[1] · Neil Stiber[1] · Kevin Gonzalez[1] · Lyle Canida[1] · Lucinda Buhse[1] · Michael Kopcha[1]

Program Under Development - 2023

Designed as a VOLUNTARY program!

Assessment & Rubric

Practice Areas will be assessed according to a defined rubric.



**CAPA – Corrective Action and Preventive Action*

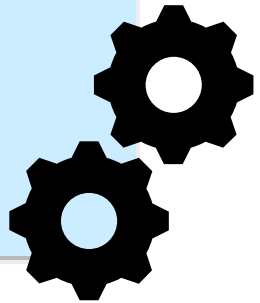
Scoring System

Scores need to be meaningful to participants indicating areas of strength and areas for improvement

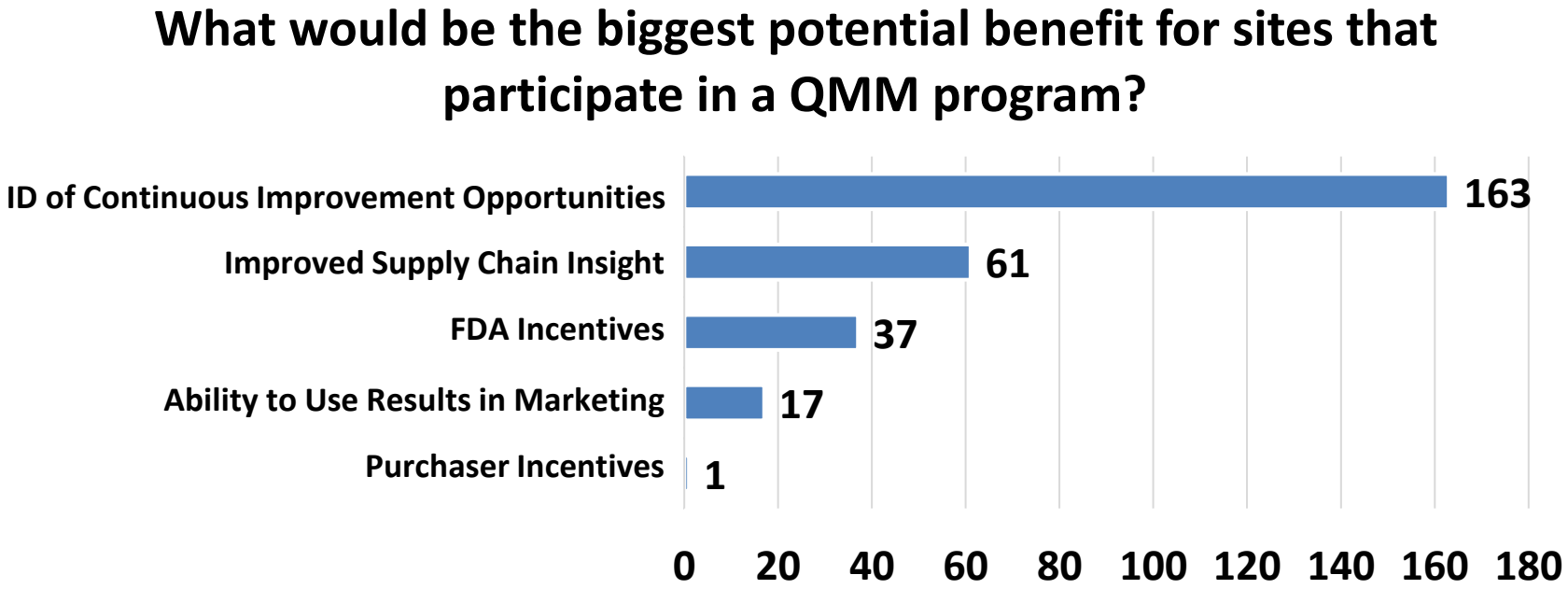
- Develop scores for each practice area and an overall score for the site.
- Develop objective algorithm to score each Practice Area of the assessment
- Determine weighting for each Practice Area
- Provide scores and a benchmark against peers

Operational Decisions

- Eligibility criteria (e.g., manufacture at least one CDER-regulated product)
- Executed by FDA and/or contractor
- Executed virtually and/or on-site
- Level of transparency
- Reassessment period
  - Shelf-life of assessment
  - Modified protocol
- Assigning a final rating
- Incentives for participation



Stakeholder Feedback on Incentives



Should QMM Ratings be Public?

There are key considerations for making a rating public:

- Publicizing ratings for a voluntary program might disincentivize participation
- Supply chain benefits the most if the least mature sites are incentivized to participate in the program
- Public information may be misinterpreted, e.g., establishment performance may be conflated with product quality
- Manufacturers could share ratings directly with purchasers

Communications

- Maximize benefits of the program
- Prevent unintended consequences
- Engage stakeholders to understand drivers and challenges
- Transparent development process
- Combat misconceptions

A QMM assessment is:

NOT intended to be used in lieu of, or as a surrogate for, establishment inspections. Does not evaluate CGMP* compliance.

A QMM rating is:

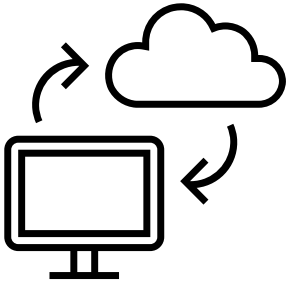
NOT a measure of product quality. It is an evaluation of an establishment's behaviors and quality practices.

**CGMP – Current Good Manufacturing Practice*

Guidance Development

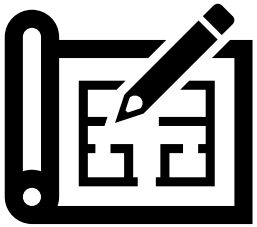
- Drafting guidance to address topics such as
  - Eligibility criteria for voluntary participation
  - Components of the program
  - Incentives
- Opportunity for public comment

IT Development



- Developed an IT Roadmap to facilitate design and development in FY2024 and FY2025
- An IT system will:
  - Manage eligibility screening and scheduling of voluntary participants
  - Receive, exchange, and store data
  - Automate assessment scoring
  - Share final reports and visualizations

Implementation and Planning



- Funding
- Hiring
- Training
- Business process development

QMM is Valuable to All

- **Patients and Consumers** – Strengthens availability of drugs with fewer recalls and shortages
- **Manufacturers** – Enables continual improvement, promotes a robust supply chain, and informs selection of contract sites
- **Purchasers and Payers** – Enhances supply chain transparency and market knowledge with less need to respond to shortages
- **Healthcare Professionals** – Increases confidence in the supply of drugs prescribed and/or dispensed with less risk of drug shortages
- **Pharmacies** – Reduced risk of failing to meet demand because supply chain is more robust and transparent
- **FDA** – Enhanced risk-based allocation of surveillance tools





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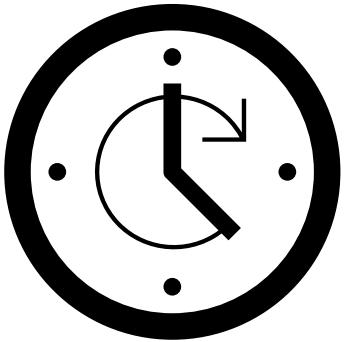
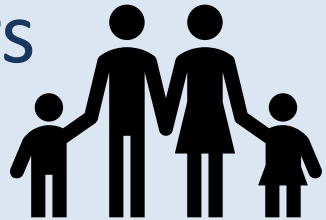
The Future: Proactive Regulation

- QMM is one piece of achieving supply chain resiliency
- Other programs also move toward proactive regulation:
  - CDER's Emerging Technology Program
  - CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) Initiative
  - Holistic Supply Chain Understanding
  - International Regulatory Harmonization



No one can do this alone…

Let us work together to assure global pharmaceutical quality to improve the lives of patients and consumers

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