U.S. FOOD & DRUG ADMINISTRATION

Key Components to Assure Pharmaceutical Quality

Susan Rosencrance, Ph.D.
Acting Deputy Director of Science
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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Everyone deserves
confidence in their *next* dose
of medicine.
Pharmaceutical quality
assures the
availability,
safety,
and efficacy
of *every* dose.

An Array of Quality

Pharmaceutical Quality

*Gives patients confidence in their **next** dose of medicine*

*Gives manufacturers confidence every batch will be **acceptable to release***	**QUALITY MANAGEMENT**	Performance and patient focus identifies areas of improvement and implements changes
*Gives manufacturers confidence in every batch they **release***	**PROCESS QUALITY**	Manufacturing risks are controlled to provide a quality drug product
*Gives patients confidence in every dose they **take***	**PRODUCT QUALITY**	Every dose is safe and effective and free of contamination and defects

Key Components of Pharmaceutical Quality

- CDER's Office of Pharmaceutical Quality
- Quality Communication
- Quality Innovation

CDER's Office of Pharmaceutical Quality

US FDA Center for Drug Evaluation and Research

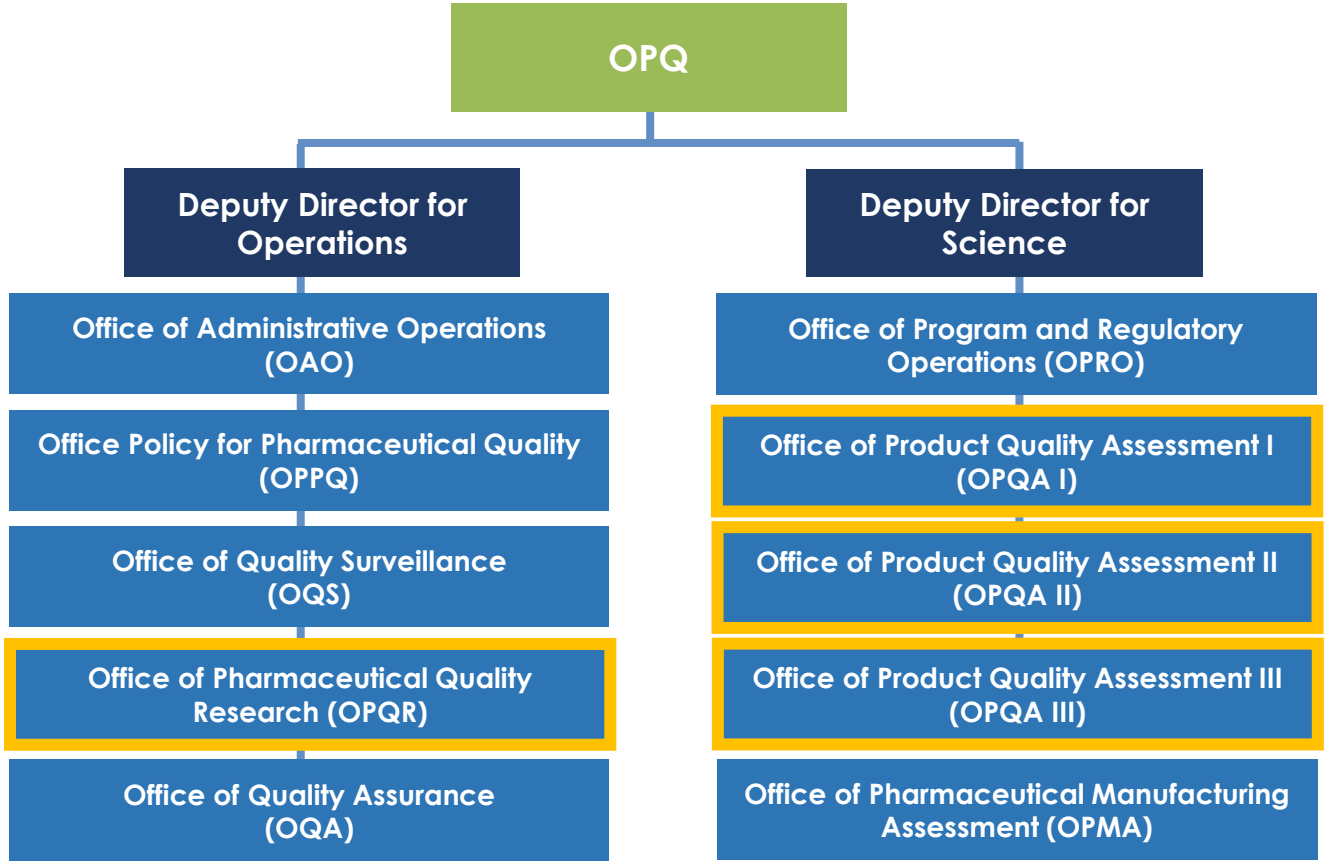
CDER's Office of Pharmaceutical Quality

Established in 2015

One Quality Voice

Uniform human drug quality program across all product types and manufacturing sites

OPQ's New Organizational Structure



Interacting with OPQ

OPQ's reorganization will have little to no impact on how we interact with industry.

User fees facilitate the **timely availability** of human medicines **without compromising** FDA's **commitment** to **scientific integrity**, **patient safety**, and **transparency**.

- **Generic Drug User Fees Amendments (GDUFA)**
- **Prescription Drug User Fee Amendments (PDUFA)**
- **Biosimilar User Fee Amendments (BsUFA)**

Quality Communication

US FDA Center for Drug Evaluation and Research

State of Pharmaceutical Quality

Sites:

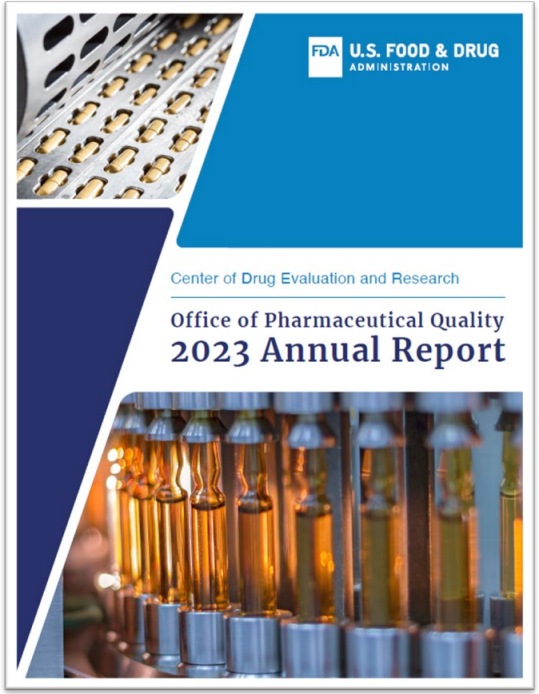
- Surveillance inspections of human drug sites tripled from FY2021 to FY2023
- More than **4,800** manufacturing sites (>40% in the U.S.)

Products:

- >**140,000** application and nonapplication products
- **12,835** ANDAs
- **3,538** NDAs
- **325** BLAs

2023 OPQ Annual Report

- OPQ performed quality assessment of more than **1,100** approved product applications, including:
  - **118** new drug applications,
  - **956** generic drug applications,
  - **29** biologics license applications (including biosimilars)
- Supported **55** novel drug approvals
- Performed **359** expedited quality assessments to address drug shortages and **28** priority assessments to address orphan diseases



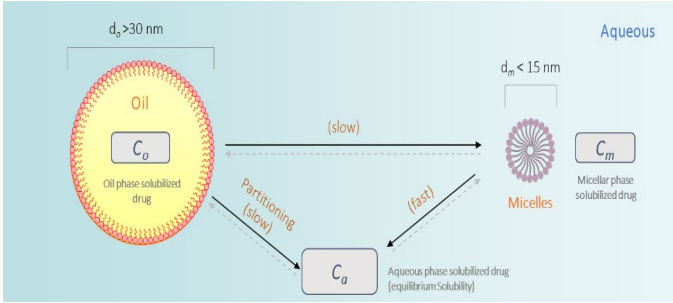
GDUFA III Program

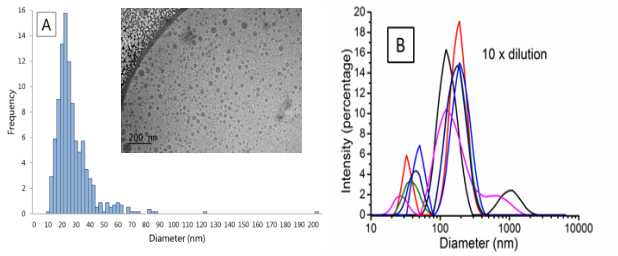
OPQ's GDUFA III efforts will help ensure that the American public has access to safe, effective, and high-quality generic drugs.

- High-quality **communication**
- Submission of high-quality **applications**
- Availability of high-quality **drug products**

Product-Specific Guidance

PSG outlines FDA's current product-specific thinking on the development and approval of a ***safe***, ***effective***, and ***high-quality*** generic drug product.

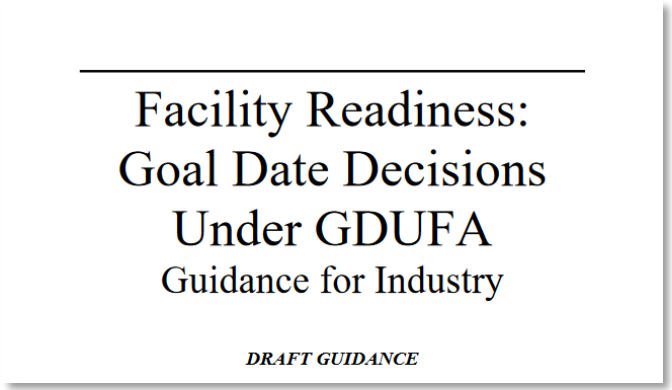




Example: cyclosporine ophthalmic emulsion

- 9 years research
- 20+ publications and presentations
- Supported draft and revision of the PSG
- First generic approval in Feb 2022

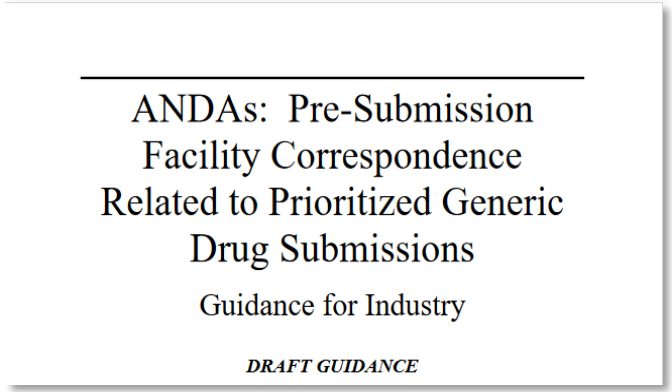
Quality-led Policy in GDUFA III



Facility Readiness: Goal Date Decisions Under GDUFA

Guidance for Industry

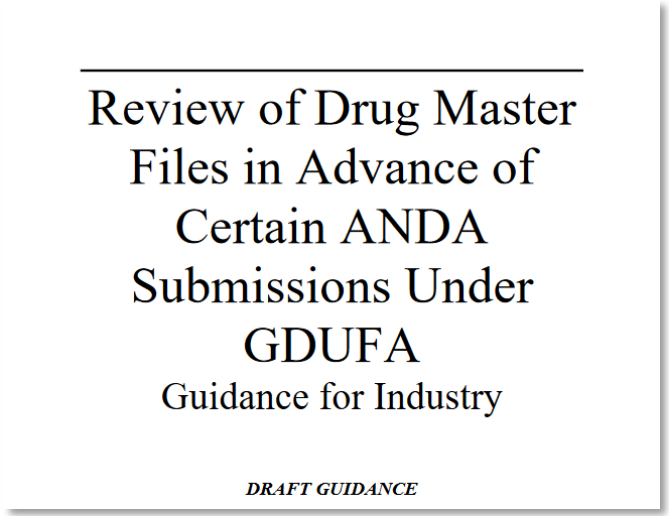
DRAFT GUIDANCE



ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions

Guidance for Industry

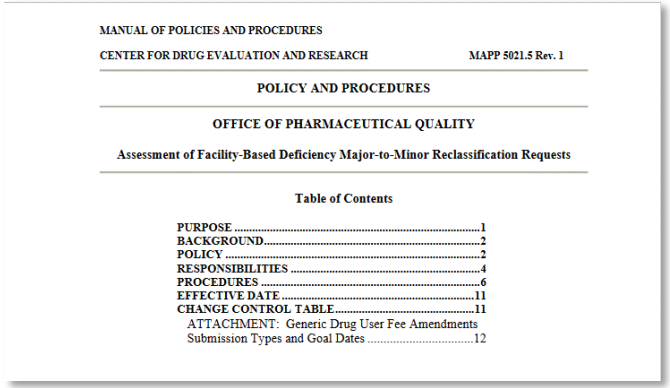
DRAFT GUIDANCE



Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA

Guidance for Industry

DRAFT GUIDANCE



MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH MAPP 5021.5 Rev. 1

POLICY AND PROCEDURES

OFFICE OF PHARMACEUTICAL QUALITY

Assessment of Facility-Based Deficiency Major-to-Minor Reclassification Requests

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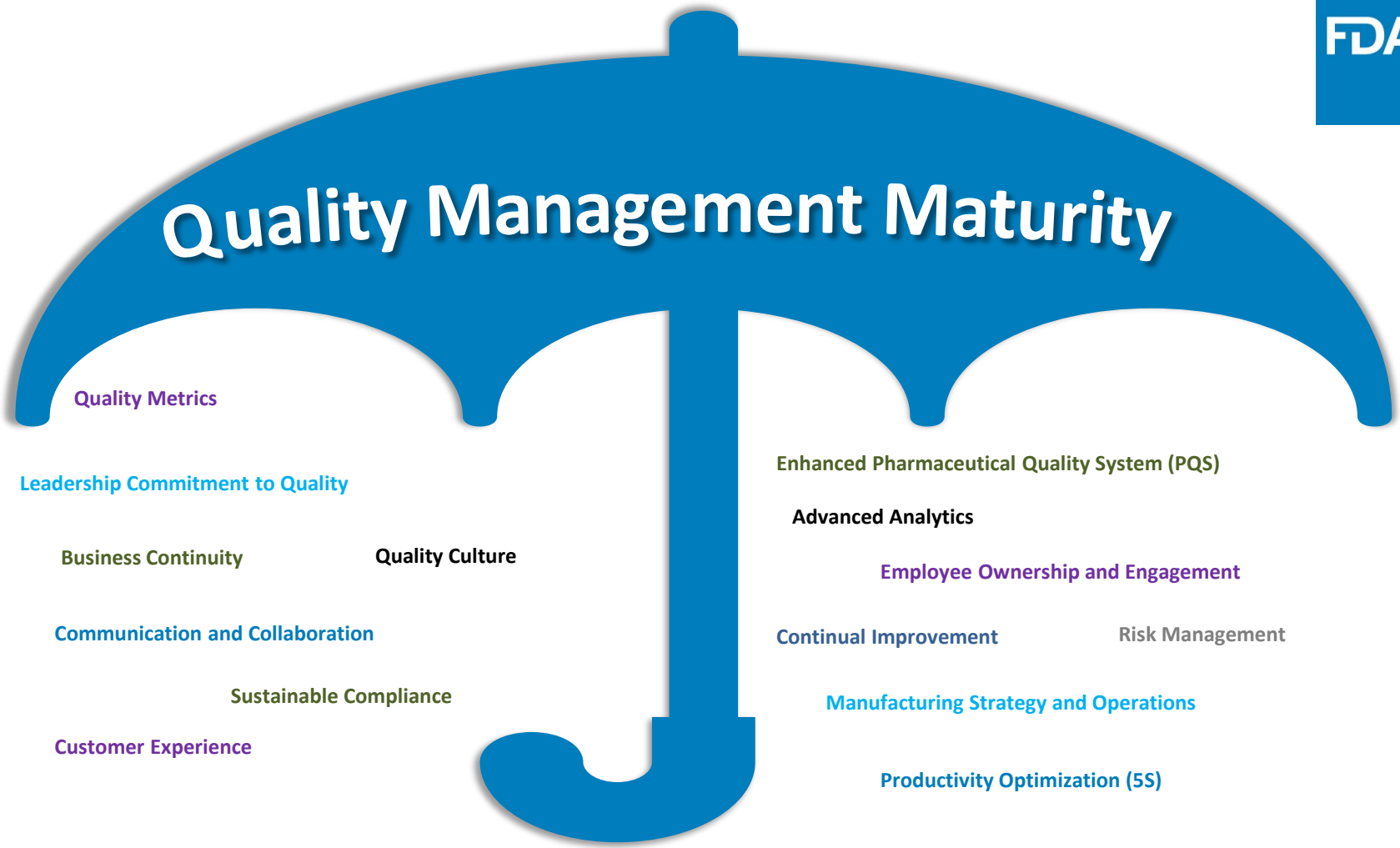
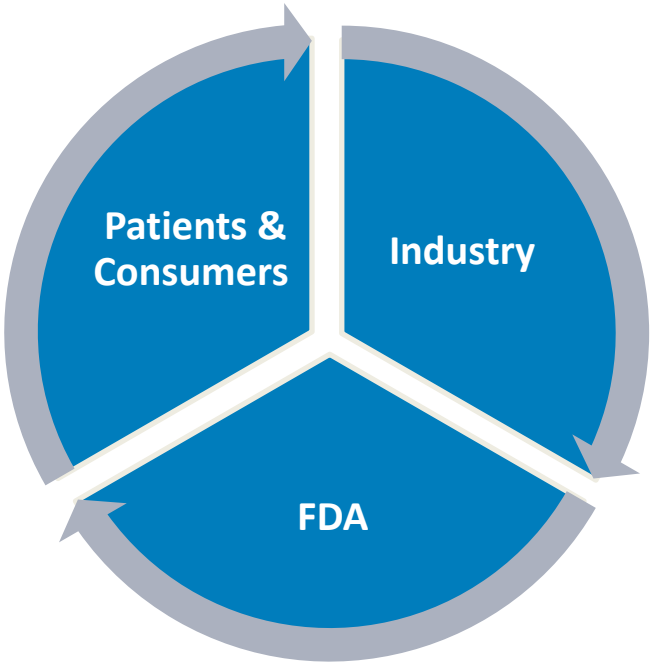
Quality Management Maturity

US FDA Center for Drug Evaluation and Research


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)

The Benefits of QMM



Patients and Consumers

- **Increases access** to reliable drug products

Industry

- **Improves** pharmaceutical quality systems
- **Rewards** "good actors"

FDA

- **Provides insight** to deploy surveillance tools and inspections

QMM Program Development

What's New

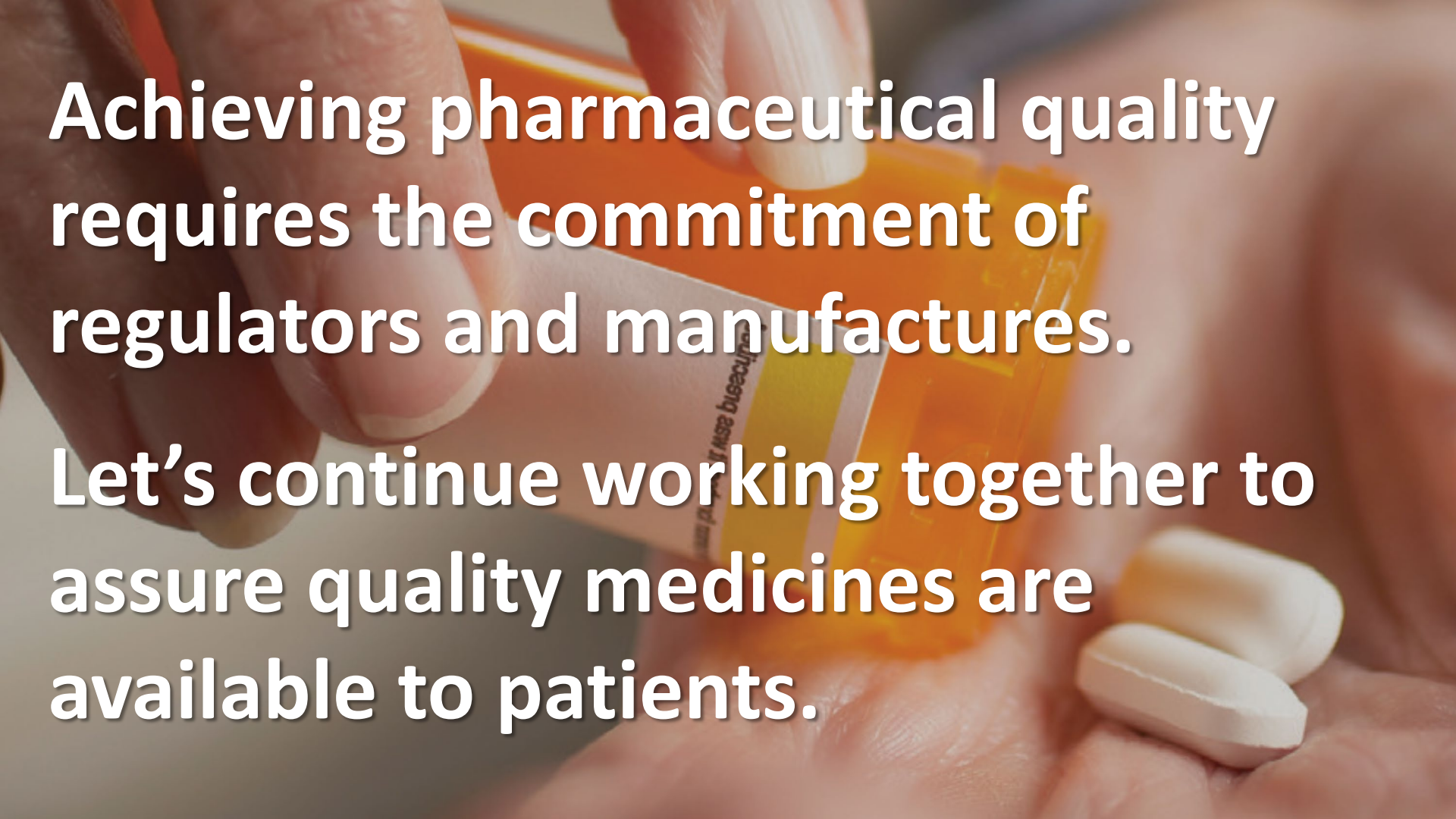
- **QMM Prototype Assessment Protocol Evaluation Program**: Following announcement in the Federal Register, the FDA accepted requests, during January 25 – March 25, 2024, to participate in a program involving the use of a prototype assessment protocol to evaluate Quality Management Maturity (QMM). A limited number of establishments will participate in this 2024 program.
  - Additional Information for Interested Establishments (PDF - 110 KB)
- **Public docket for comments:** During September 15 – December 14, 2023, the FDA solicited comments on CDER's QMM program via a public docket. The comments received will assist the Agency in developing a QMM program for establishments manufacturing human drugs, including biological products, regulated by CDER.

In Closing

US FDA Center for Drug Evaluation and Research

2024 Generic Drug Forum

- Controlled Correspondence
- ANDA Submission Best Practices
- Nitrosamines and Drug Master Files
- Post-approval changes
- Ophthalmic Products
- Extractables & Leachables
- Facility Assessments
- Advanced Manufacturing Technologies Designation Program
- Sterility Assurance
- Endotoxins


Achieving pharmaceutical quality requires the commitment of regulators and manufactures.
Let’s continue working together to assure quality medicines are available to patients.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