

Key Components to Assure Pharmaceutical Quality

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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

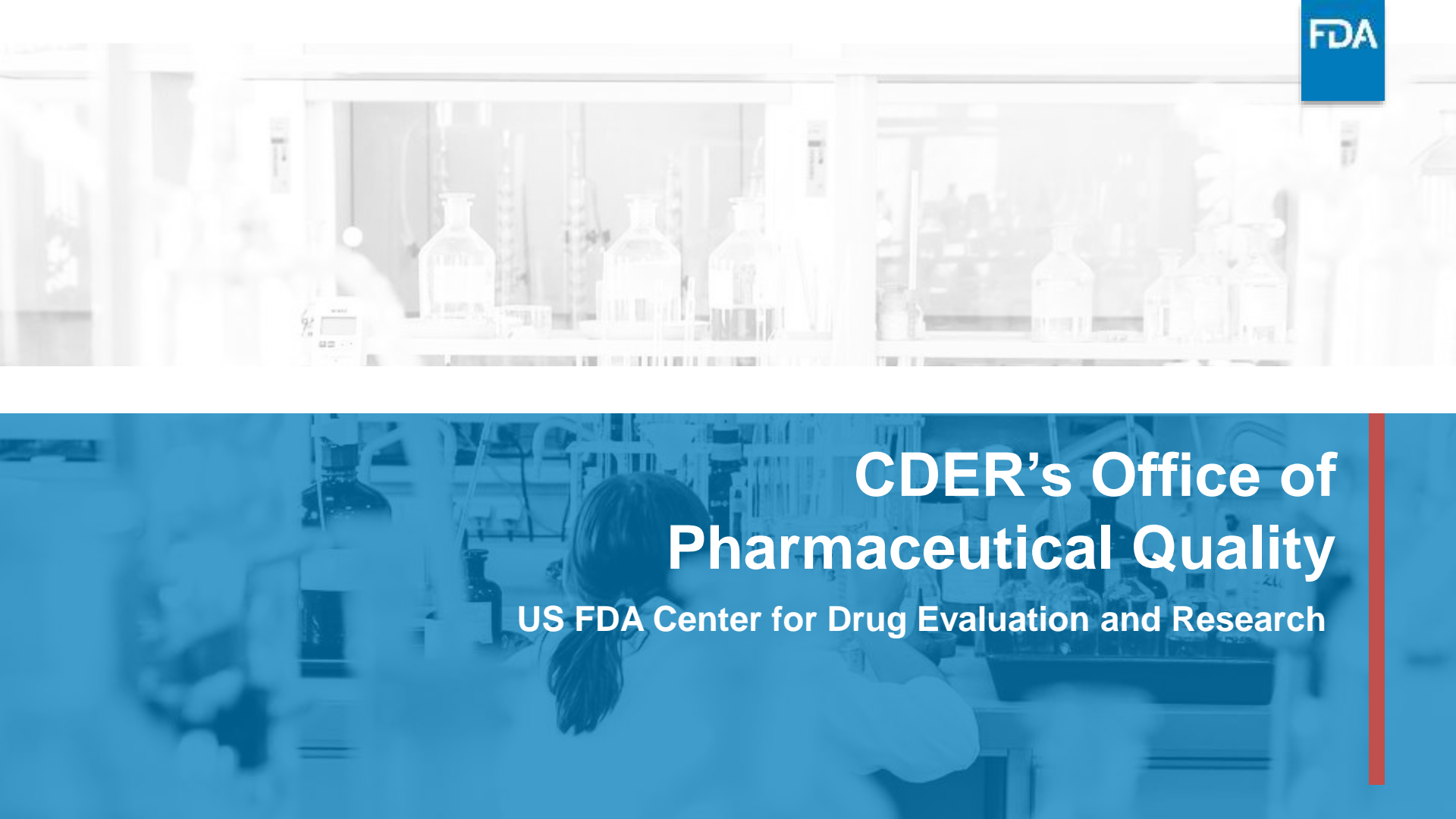
Every dose is safe and effective and free of contamination and defects

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

Assessment

Inspection

Surveillance

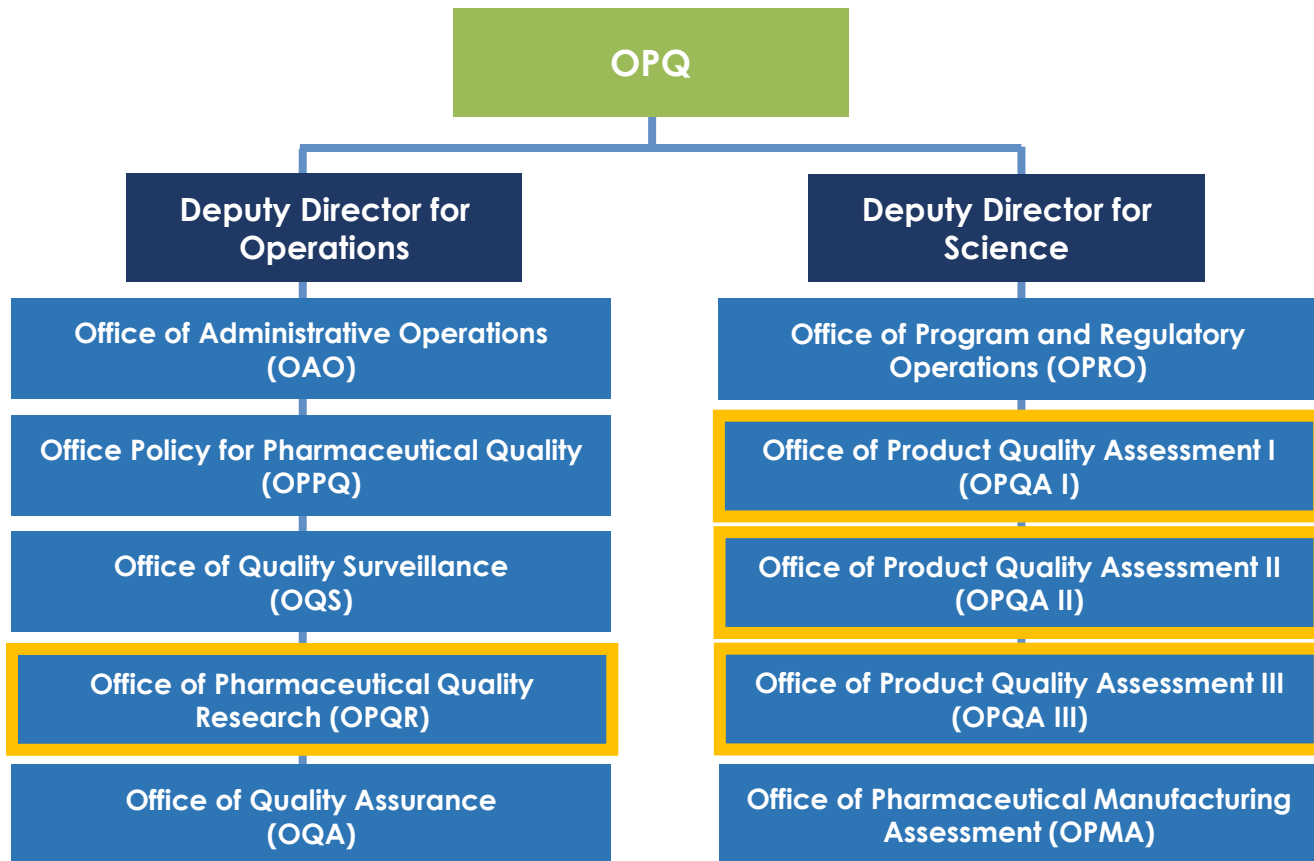
Policy

Research

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

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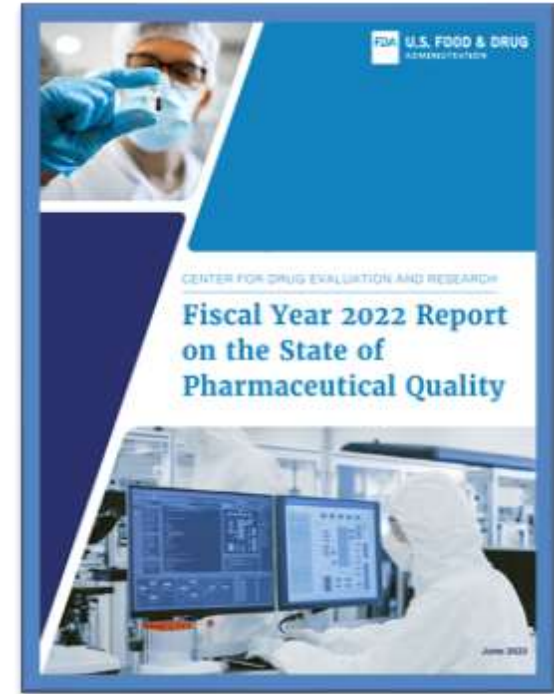
State of Pharmaceutical Quality

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.

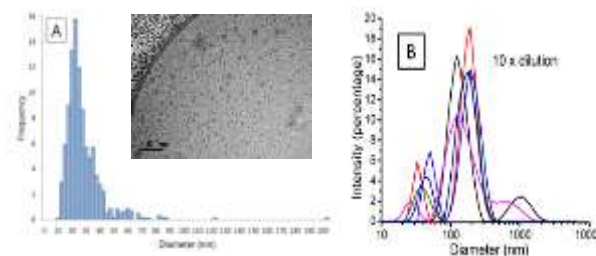
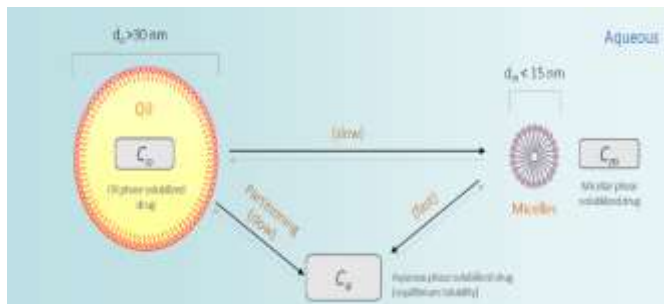
- High-quality communication
- Submission of high-quality applications
- Availability of high-quality drug products



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

MAFP 5821.5 Rev. 1

POLICY AND PROCEDURES

OFFICE OF PHARMACEUTICAL QUALITY

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

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Quality Management Maturity

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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

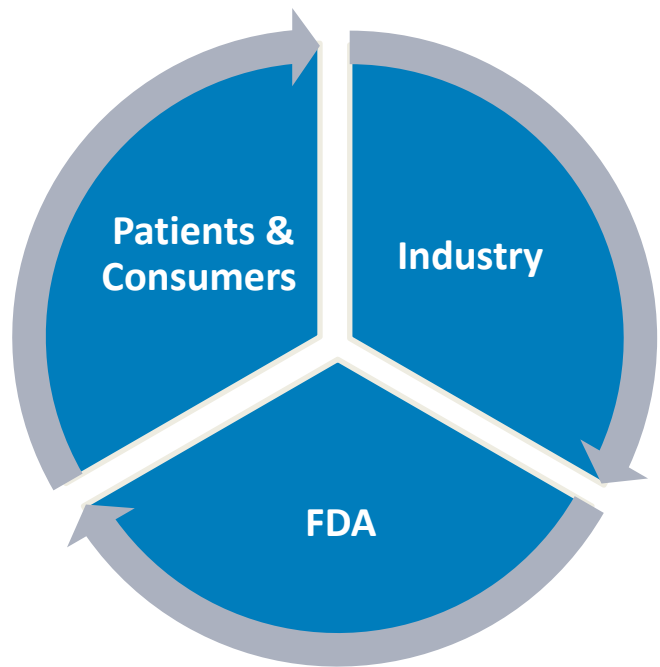
Continual Improvement

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**

A close-up photograph of a person's hands. The left hand holds an orange plastic pill bottle, tilted to pour several white, oval-shaped capsules into the palm of the right hand. The bottle has a white label with some text, including the word "buscopan" visible. The background is blurred, focusing attention on the action of dispensing the medication.

**Achieving pharmaceutical quality
requires the commitment of
regulators and manufactures.**

**Let's continue working together to
assure quality medicines are
available to patients.**

