Pharmaceutical Quality
Ensuring Patients Remain Top Priority

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

Maintaining Excellence

🎯 Operational Excellence

- Maintained assessment performance across programs despite disruptions

Regulatory Review Performance

- **>90% on-time performance** across ANDA submissions and amendments*
- **>90% on-time completion** for GDUFA controlled correspondence**

👥 Organizational Strategies

- **Expand capacity:** career development & crossing training
- **Leverage innovation:** Knowledge-Aided Assessment and Structured Application (KASA) & AI tools

* https://www.fda.gov/industry/generic-drug-user-fee-amendments/generic-drugs-program-fiscal-year-2025-activities-report
** https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-generic-drug-user-fee-amendments-performance-generic-drug-applications-and-supplements

Introducing FDA PreCheck

A Two-Phase Approach

FDA's Strategy

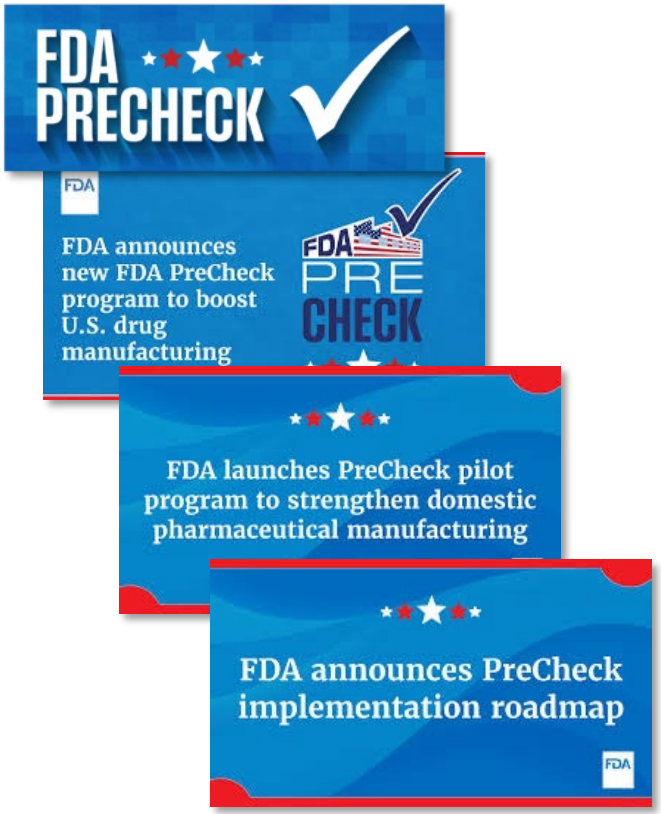
Comprehensive program to accelerate high-priority new manufacturing facilities in the U.S.

Core Feature

Proactive engagement before facilities become operational

Target

New domestic manufacturing facilities for critical medicines and supply chain strengthening



Key PreCheck Dates

9/30/25…	Public meeting
10/30/25…	Written comments due
2/1/26…	**Program launch**
3/1/26…	Submission deadline
4/1/26…	FDA selects finalists
7/1/26…	Engagements begin

Nitrosamines: Collaborative Approach to Patient Safety

Our Shared Commitment:

Addressing nitrosamine impurities while ensuring continued patient access to needed medicines

Requires:

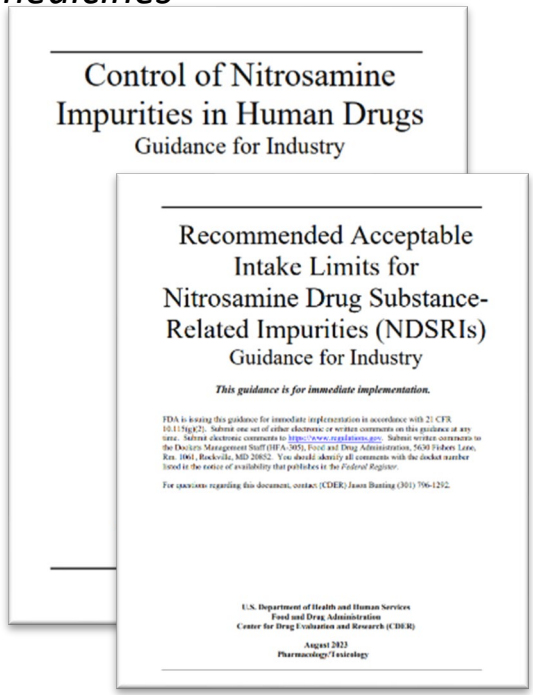
- Following FDA's nitrosamine guidance
- Assessing risks and conducting confirmatory testing
- Implementing mitigation strategies

Recent Updates

- August 2025 Progress Report
- FDA reviewing submissions

Engagement Opportunities

- Direct communication
- GDUFA Public Workshop (June 2026)



CDER's Quality Management Maturity (QMM) Program

Investment** in robust **quality management** has long been credited as a **key factor** for business **success.

IN THE 1950S, QUALITY MANAGEMENT EMERGED AS A CORE COMPONENT OF MODERN MANUFACTURING.

MODERN RESEARCH CONFIRMS THAT STRATEGIC INVESTMENTS IN QUALITY MANAGEMENT YIELD POSITIVE RETURNS.

OPQ WHITE PAPER (JULY 2025):

QUALITY MANAGEMENT INITIATIVES IN THE PHARMACEUTICAL INDUSTRY

QMM Program Updates

2024 Prototype Assessment Protocol Evaluation Program (Cohort 1)

- ✓ Completed 9 assessments
- ✓ Prototype assessment tool distinguished differences in maturity

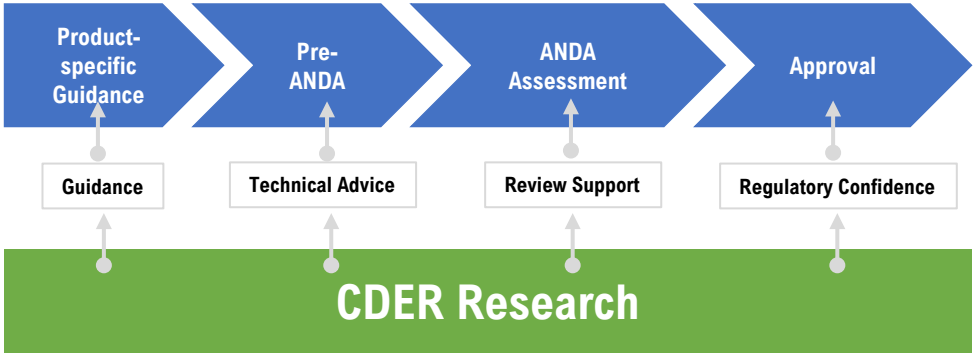
2025 Prototype Assessment Protocol Evaluation Program (Cohort 2)

- ✓ 9 assessments planned (7 completed)
- ✓ Refined the prototype protocol

2026 Prototype Assessment Protocol Evaluation Program (Cohort 3)

- ✓ February 2026: Federal Register Notice soliciting volunteers

Research Supporting Generic Drug Development



Tools to efficiently evaluate complex generic equivalence

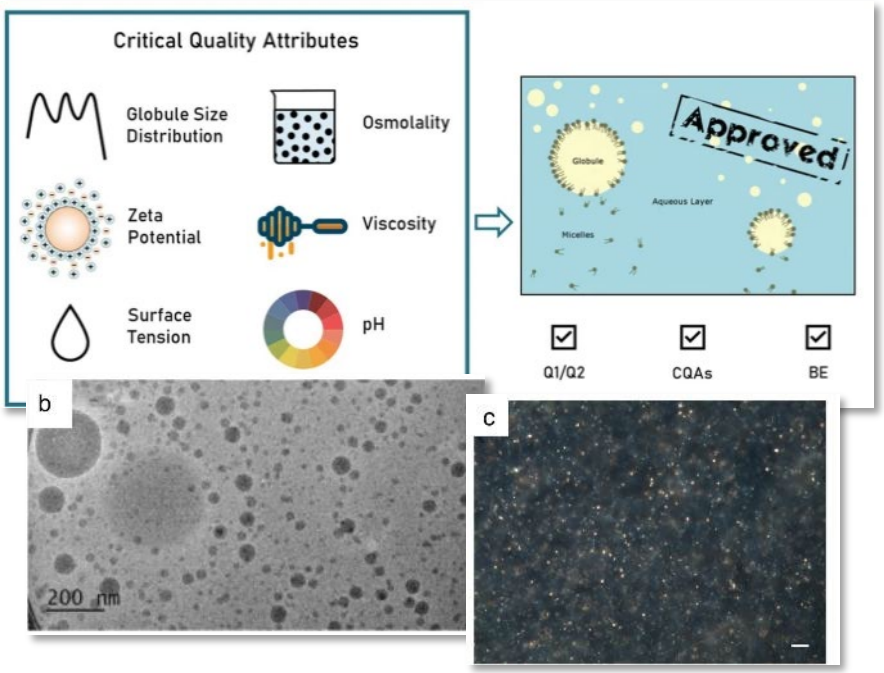
Research spans the product lifecycle

In-house labs conduct hands-on research

Results shared via publications, meetings, and guidance

Research in Action: Advancing Generic Drug Science

Example: Cyclosporine ophthalmic emulsion research



- **Peptides & oligonucleotides**
  - New equivalence assessment approaches
- **Inhalation products**
  - Performance testing methodologies
- **Topical and transdermal**
  - Bioequivalence strategies
- **Long-acting implants and injectables**
  - In vitro characterizations and in vivo prediction
- **Nitrosamine risk mitigation**
  - Analytical and formulation strategies

* Belenos A, et al. Product quality research for developing and assessing regulatory submissions for generic cyclosporine ophthalmic emulsions. *AAPS J* (2023)

Generic drugs are *essential* for accessible healthcare.

Let's maintain confidence in generic products, keep patients the top priority, and ensure every American has access to high-quality medicines.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