

Pharmaceutical Quality

Ensuring Patients Remain Top Priority

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Generic Drug Forum
April 22, 2026

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...	<u>Program launch</u>
3/1/26...	Submission deadline
4/1/26...	FDA selects finalists
7/1/26...	Engagements begin

The screenshot displays the Regulations.gov website. At the top, it says "Regulations.gov" and "Your voice in Federal Decision Making". Below this, there's a "NOTICE" section titled "Onshoring Manufacturing of Drugs and Biological Products; Public Meeting; Request for Comments". It states "Posted by the Food and Drug Administration on Aug 8, 2025". There's a "Comment" button and a note that the "Comment Period Ends: Oct 30, 2025 at 11:59 PM EDT".

Below the notice, there's a "Document Details" section for Docket (FDA-2025-N-2489). It lists the Document ID (FDA-2025-N-2489-01), the number of comments received (11), and the comment due date (Oct 30, 2025). It also shows the Federal Register Number (2025-18083) and the document subtype (Request for Comments).

The main content area features an "FDA NEWS RELEASE" titled "FDA Launches PreCheck Pilot Program to Strengthen Domestic Pharmaceutical Manufacturing". The release is dated February 01, 2025. The text of the release states: "The U.S. Food and Drug Administration today began accepting requests to participate in the FDA PreCheck pilot program. FDA PreCheck is designed to strengthen the domestic pharmaceutical supply chain by increasing regulatory predictability, facilitating the construction of manufacturing sites in the U.S., and streamlining aspects of pharmaceutical manufacturing facility assessments in advance of a specific product application." It also includes quotes from FDA Commissioner Marty Makary, M.D., M.P.H., and mentions that the agency will select an initial cohort of new pharmaceutical manufacturing facilities to begin conducting PreCheck activities in 2026.

Nitrosamines: Collaborative Approach to Patient Safety

Our Shared Commitment:

Addressing nitrosamine impurities while ensuring continued patient access to needed medicines

Requires:

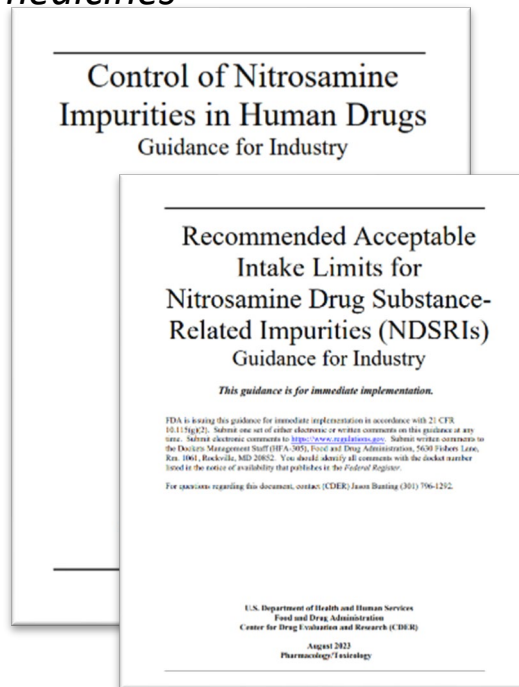
- Following FDA's nitrosamine guidance
- Assessing risks and conducting confirmatory testing
- Implementing mitigation strategies

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

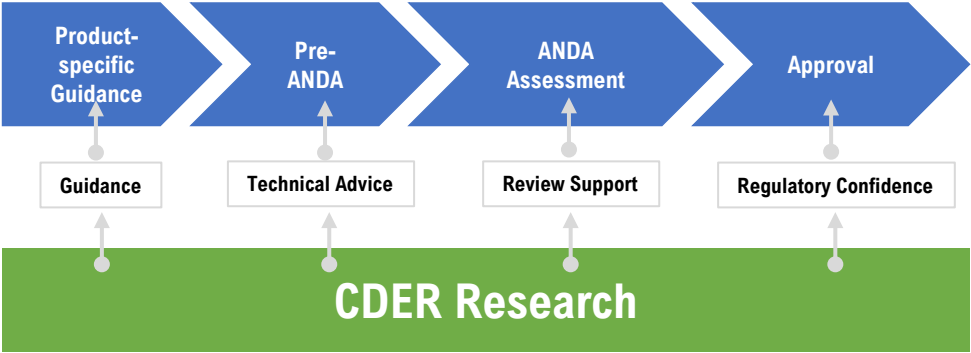
2025 Prototype Assessment Protocol Evaluation Program (Cohort 2)

- ✓ 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

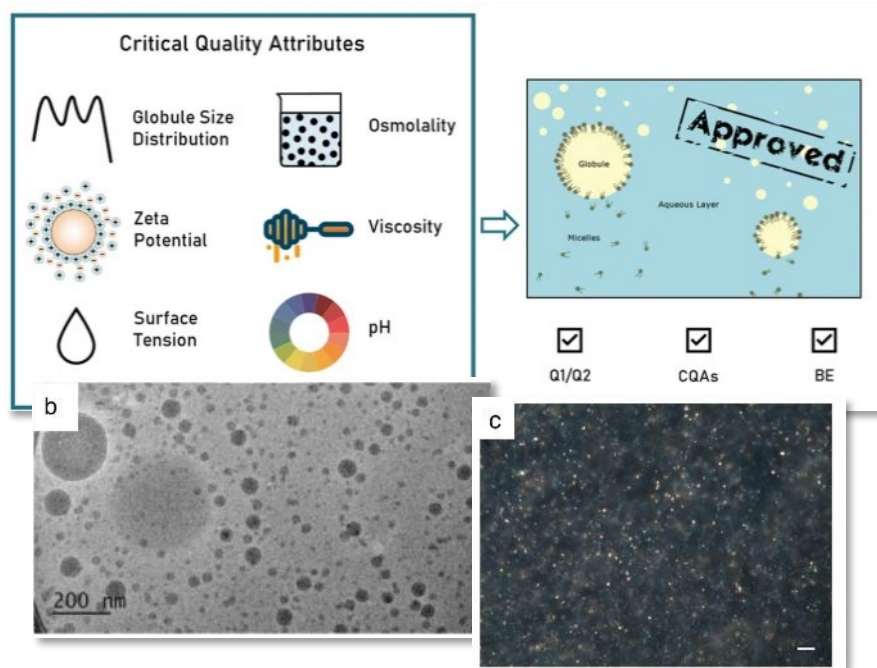
In-house labs conduct hands-on research



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

A close-up photograph of a person's hands. The left hand holds an orange plastic pill bottle, tilted to pour two white, oval-shaped pills into the palm of the right hand. The background is blurred, showing a person's arm and torso in a light blue shirt.

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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