U.S. FOOD & DRUG ADMINISTRATION

CDER Initiatives to support US based Generic Drug manufacturing

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GRx + Biosims
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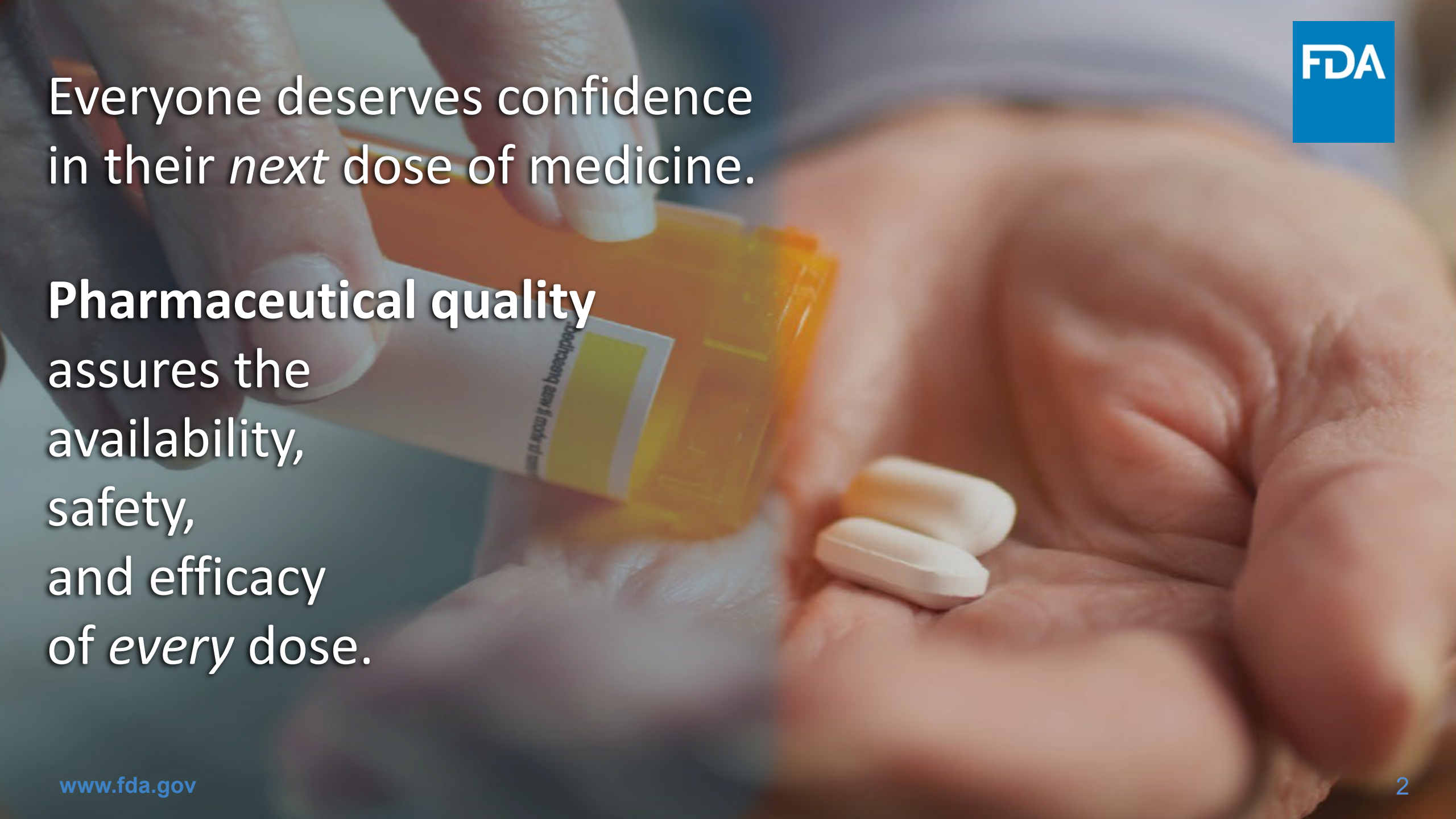


Everyone deserves confidence in their *next* dose of medicine.

Pharmaceutical quality assures the availability, safety, and efficacy of *every* dose.

Supporting Scaling of Domestic Drug Manufacturing

Executive Order 14293 : “Regulatory Relief to Promote Domestic Production of Critical Medicines”, May 5, 2025

CDER Initiatives:

Advanced Manufacturing

- Advanced manufacturing is a collective term for new or innovatively applied medical product manufacturing technologies that can improve drug quality, address shortages of medicines, and speed time-to-market

Pre check pilot

- A strategic initiative to strengthen domestic drug manufacturing, improve resilience of U.S drug supply chain
- Launched on Feb 1, 2026
- 7 companies selected to participate in the pilot, includes generic companies https://www.fda.gov/news-events/press-announcements/fda-selects-seven-participants-precheck-pilot-program-advance-us-drug-manufacturing
- FDA to engage with program participants during early stages of facility design to gain alignment
- Applicable only for new domestic manufacturing facilities

Equip-A-Pharma Program

- A joint initiative between U.S Department of Health & Human Services (HHS), Administration for Strategic Preparedness and Response (ASPR) and Defense Advanced Research Projects Agency (DARPA)
- To support agile domestic manufacturing of generic drugs at point of care
- Selected participants in this program will use advanced pharmaceutical manufacturing technologies such as 3D printing, continuous flow manufacturing, AI

https://www.aspr.gov/news-updates/newsroom/2025-05/trump-administ-ration-launching-projects-aimed

CDER's Advanced Manufacturing (AM) Programs

Assessment and Inspection

- Emerging Technology Program (ETP)
- Advanced Manufacturing Technology Designation Program (AMTDP)
  - Created under Food & Drug Omnibus Reform Act 2022 (FDORA)
  - AMT is a statutory designation granted by the agency

Science

- In house AM science and research
- Broad Agency Announcement (BAA) to fund extramural research on AM

Policy

- Framework for Regulatory Advanced Manufacturing Evaluation (FRAME)
  - Address risks
  - Clarify regulatory expectations for AM technologies for which FDA has limited background such as Super Intelligence, Distributed Manufacturing
  - Harmonize globally

Continuous Manufacturing (CM) – An Advanced Manufacturing (AM) Process

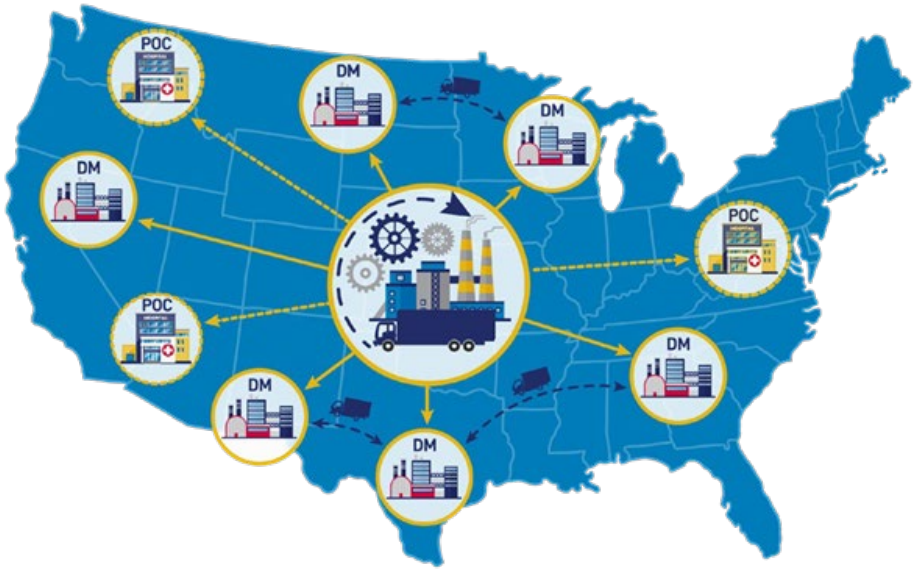
- Allows quality to be built directly into process design
- Amenable to PAT/real-time measurements and release
- Reduced environmental footprint
- Supports consistent drug manufacture
- Flexible operation, feasible to manufacture small batch sizes
- Capability to adjust production to meet demand
- Faster response to drug shortages and emergencies
- More than 17 applications with CM approved to date
- No substantial regulatory barriers identified CM applications related to manufacturing process changes or preapproval inspections (‘*An audit of pharmaceutical continuous manufacturing regulatory submissions and outcomes in the US*’ International Journal of Pharmaceutics, June 2022)

Quality & Speed



Distributed Manufacturing (DM): An Advanced Manufacturing Process

- A decentralized manufacturing strategy, following a "hub-and-spoke" model
  - Hub provides a centralized quality oversight for the spokes
  - Spokes (DM Units) are equivalent manufacturing units at one or more locations
- Provides an **agile approach** to manufacturing to meet patient's needs
- Manufacture based on demand by adding, removing or re-locating spokes
- Spokes can be in a range of geography areas thus improve supply chain resiliency
- Rule proposed in July 2026, to amend CFR 21 CFR 207, to streamline registration pathway for DM



A "hub-and-spoke" DM Establishment (DME)

Thank you!

General questions, comments, concerns:

CDER-OPQ-Inquiries@fda.hhs.gov