U.S. FOOD & DRUG ADMINISTRATION

The Present and Future of Pharmaceutical Quality

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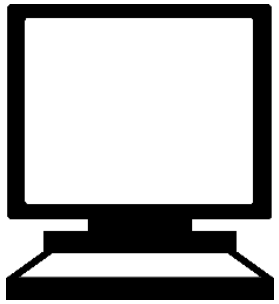
Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.



Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.

Drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is

assuring *every* dose is safe and effective, free of contamination and defects.

It is what gives patients confidence in their *next* dose of medicine.

The Present and Future of Pharmaceutical Quality

- **Facility Assessment**
- **Quality Management Maturity**
- **Advanced Manufacturing**

Facility Assessment

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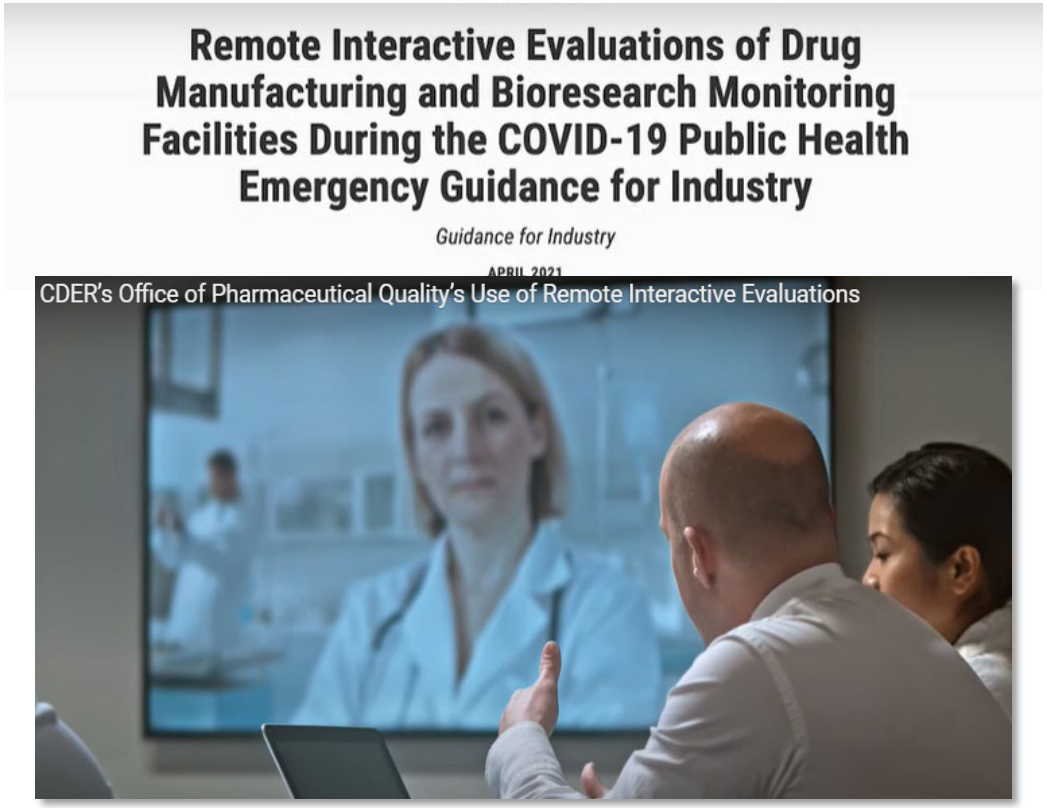
CDER Facility Assessments

- Maintaining **same quality standards** using risk-based assessment
- Using **alternative tools to inspections**
- **Conducting necessary inspections** consistent with FDA's Resiliency Roadmap

Innovation Was Necessary

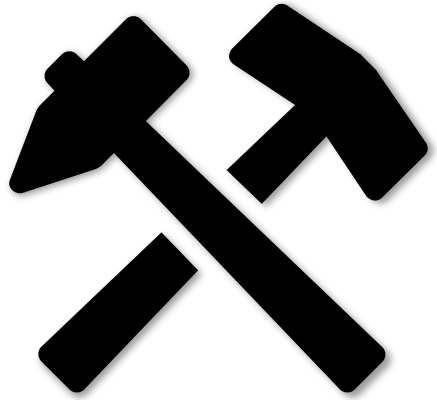
- **Alternative tools to inspections**
  - Information in lieu of inspection - FD&C 704(a)(4)
  - Mutual Recognition Agreement (EU and UK)
  - Info from regulators via confidentiality agreements
  - Remote Interactive Evaluations (RIEs)



Impact of Alternative Tools

Using Alternative Tools

- Supported the approval of **over 750** ANDAs & **over 8,000** application supplements
- Reduced pre-approval inspections by **over 50%** & enabled **over 250** quality assessments



Conducted **over 40** pre-approval inspections & **over 20** mission-critical inspections

State of Inspections

- On Feb. 7, FDA resumed **US domestic surveillance inspections** given the decline in COVID-19 cases
- FDA continues **foreign and domestic mission-critical inspections**
  - Still leveraging alternative tools
- Planning for additional **foreign surveillance inspections** is ongoing

"FDA remains committed to the health and safety of its investigators and will continue providing the protection needed to safely inspect facilities"

Quality Management Maturity

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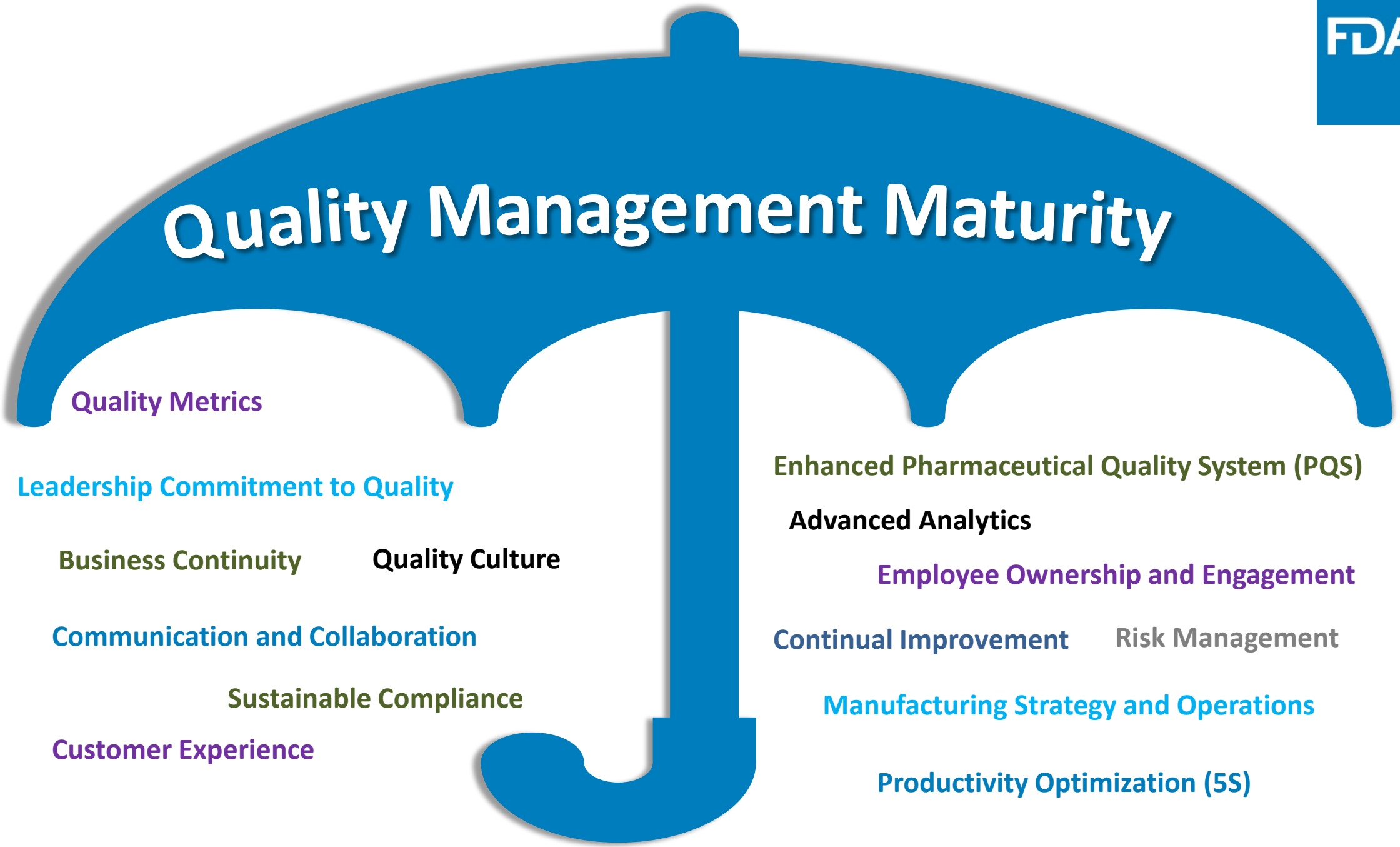
Quality Management Maturity



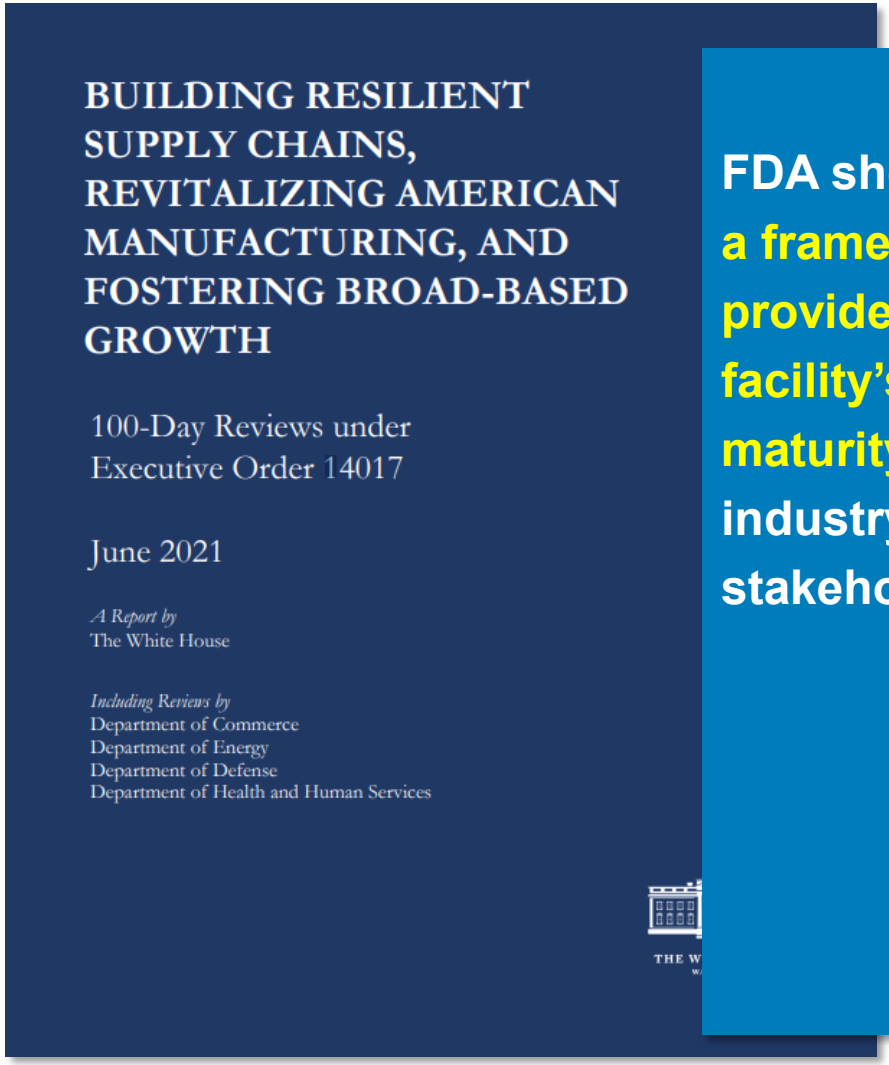
An Array of Quality

Pharmaceutical Quality

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

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

The Promise of QMM



FDA should lead the development of a framework to measure and provide transparency regarding a facility's quality management maturity with engagement from industry, academia, and other stakeholders.

– 100-Day Report by

The White House

THE WHITE HOUSE
WASHINGTON

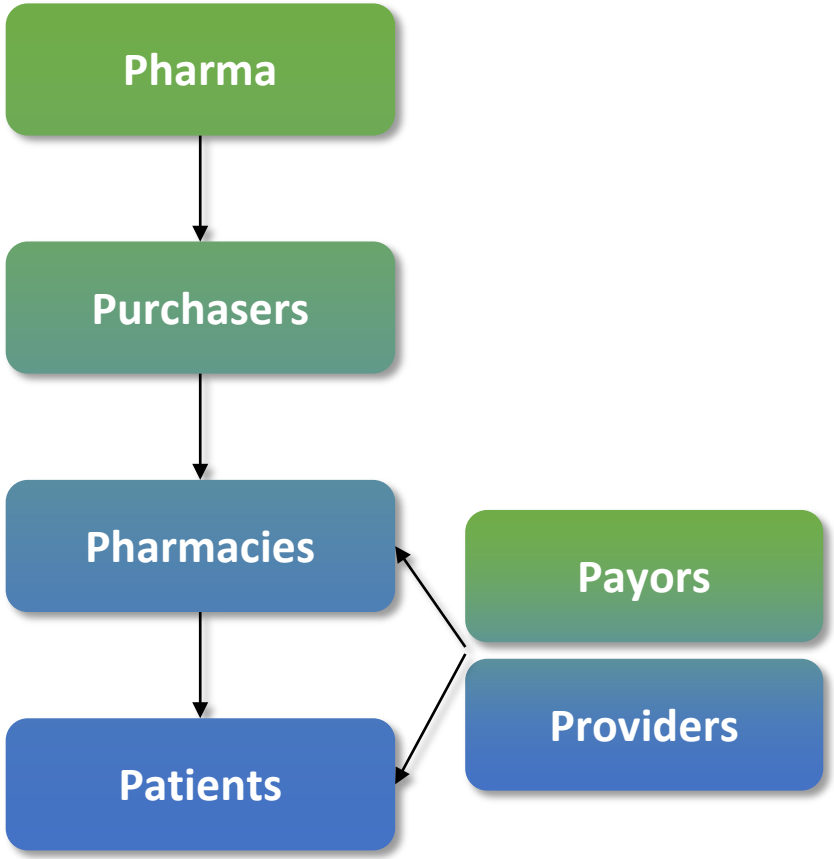
QMM ≠ QM

QMM =f(QM, x, y, z…)

Road to Achieving QMM

- **QMM white paper** released April 5
  - Importance of QMM
  - Key challenges and elements for successful QMM implementation
- **QMM stakeholder workshops** to be held May 24-25
- **QMM Advisory Committee** meeting to follow at a later date

“6 Ps” Impacted by QMM Ratings



Stakeholder	Benefits
Pharmaceutical Manufacturers	✓ Positive and proactive performance acknowledged ✓ “Good actors” rewarded
Purchasers[3]	✓ Improved supply chain transparency for decision-making ✓ Quality ratings backed by FDA insight and non-public data
Pharmacies	✓ Improved supply chain transparency ✓ Less risk of failing to meet demand and medication error
Payors	✓ Improved supply chain transparency for decision-making ✓ Less need to respond to drug shortage
Providers	✓ Less risk of drug shortage impacting their patients ✓ More confidence in the supply of drugs they prescribe
Patients	✓ Less risk of drug shortage impacting their care ✓ More confidence in drug availability

Advanced Manufacturing

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What is Advanced Manufacturing?

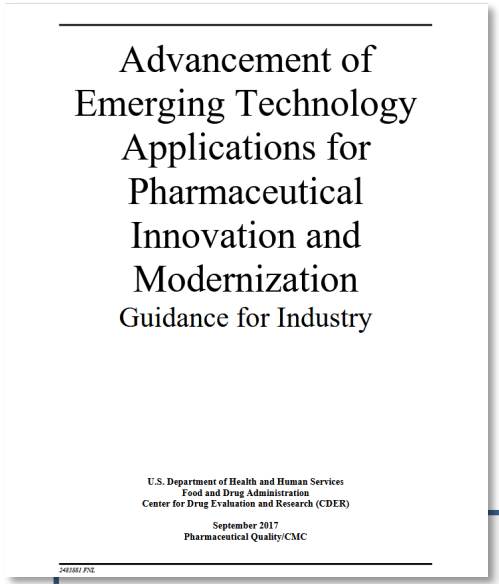
- Novel **manufacturing methods** to improve process robustness and efficiency
- Novel **dosage forms** or delivery systems to improve drug delivery and targeting
- Novel **analytical tools** to improve product characterization, quality testing, process monitoring and/or control

Advanced Manufacturing Benefits

Advanced manufacturing can improve manufacturing and ensure quality medicine is available.

- **Produce better quality medicine**. Facilitates six-sigma operation, no more than 3.4 defects per 1M opportunities.
- **Re-shore drug manufacturing facilities.** Helps domestic drug manufacturers compete in a global market.
- **Develop drugs rapidly.** Speeds the development of novel or patient-focused therapeutics.
- **Prevent drug shortages.** Reduces today's quality-related manufacturing issues causing 62% of drug shortages.
- **Improve emergency preparedness.** Provides more agility and flexibility to help pivot in a public health emergency.

Emerging Technology Program


Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

September 2017
Pharmaceutical Quality/CMC

Industry Develops Emerging Technology

ETP Evaluates Technology

Technology Moves to Standard Quality Assessment Processes

Acceptance to ETP

Graduation

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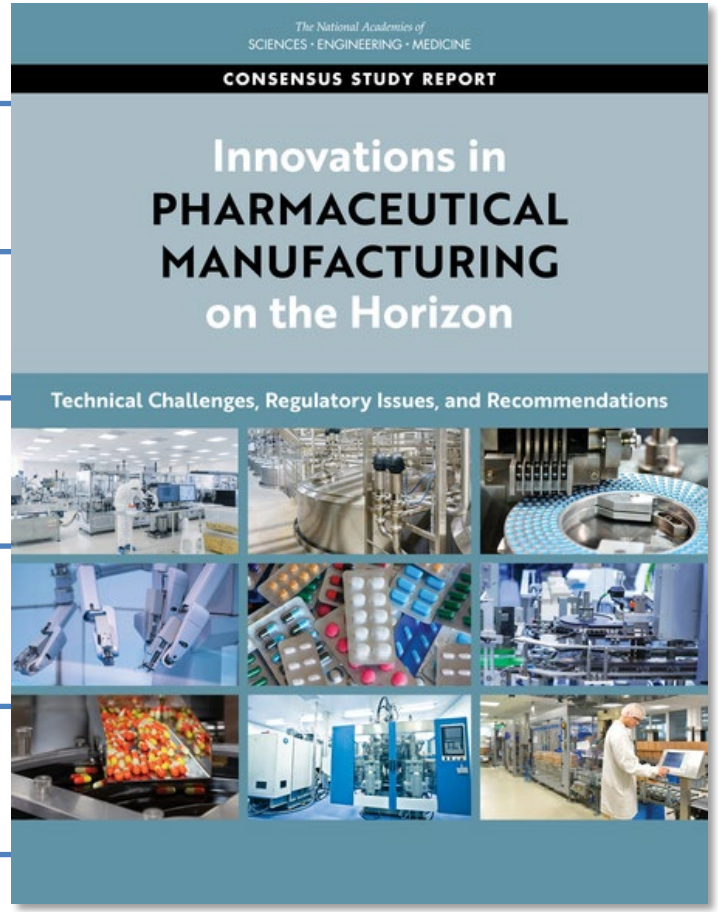
Framework for Regulatory Advanced Manufacturing Evaluation (**FRAME**)

FRAME: Framework for **R**egulatory **A**dvanced **M**anufacturing **E**valuation

- Establish a **regulatory framework that provides clarity and reduces uncertainty** for products manufactured with advanced technologies
- The framework will need to address both **current and future manufacturing innovation**.
- Scope: CDER's **submission pipeline in the next 5-10 years***.



*In NASEM's *Innovations in Pharmaceutical Manufacturing on the Horizon: Technical Challenges, Regulatory Issues, and Recommendations*

In Closing

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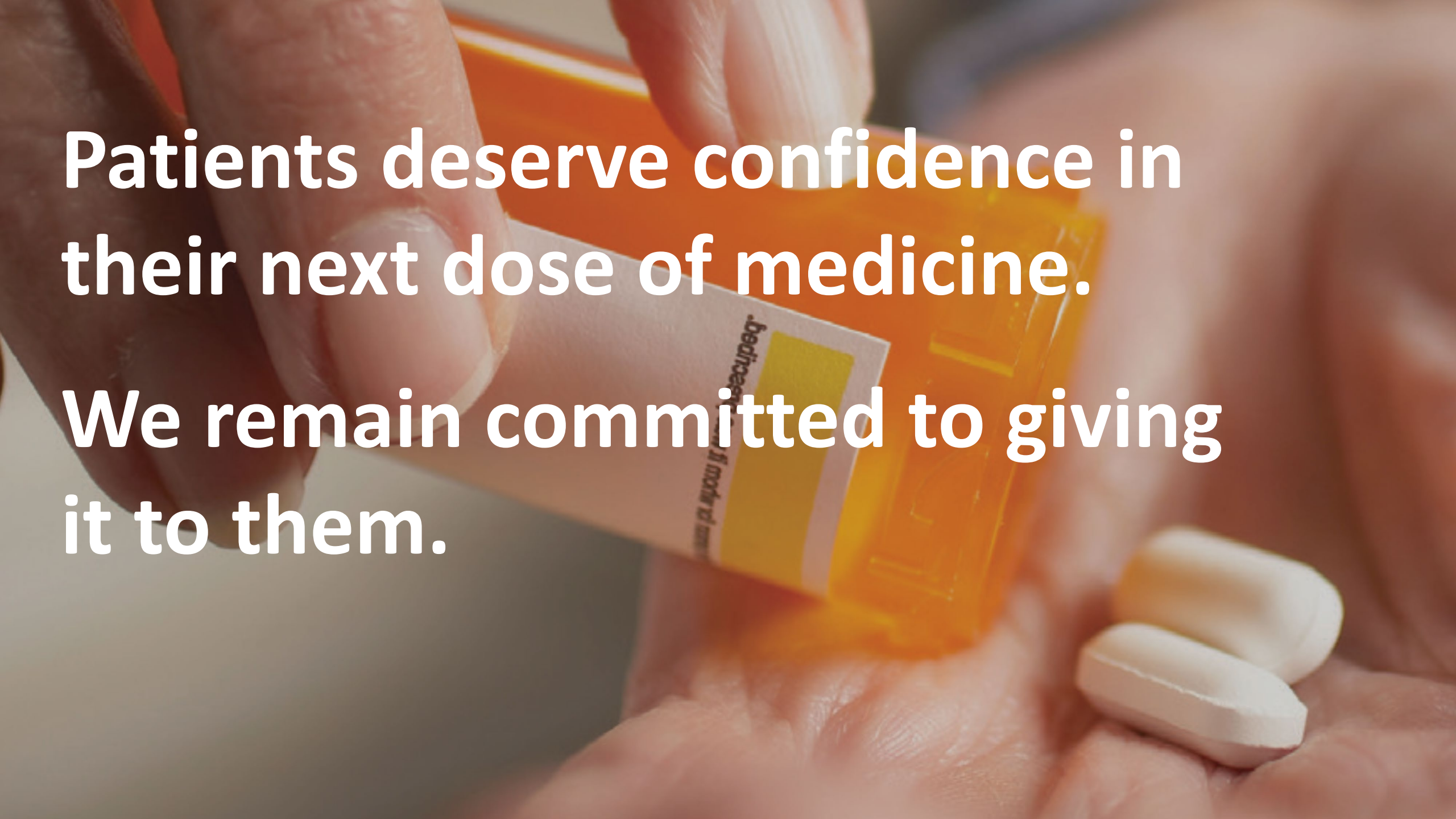
Patients deserve confidence in their next dose of medicine.
We remain committed to giving it to them.


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