



A Regulatory Perspective on Innovations in Pharmaceutical Manufacturing

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**FDA/PQRI Workshop on the Regulatory
Framework for Utilization of Artificial Intelligence
in Pharmaceutical Manufacturing**

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What is Advanced Manufacturing?

- ››› Integrating **novel technological approaches**
- ››› Using established techniques **in a new or innovative way**
- ››› Applying production methods **in a new domain** where there are no defined best practices or experience



Advanced Manufacturing Benefits

-  **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.

Support for Advanced Manufacturing



FDA's Advanced Manufacturing Initiatives Helping to Provide Quality Human Drugs for Patients

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CDER's Advanced Manufacturing Initiatives:

- »»» Emerging Technology Program (ETP)
- »»» Advanced Manufacturing Science & Research
- »»» Framework for Regulatory Advanced Manufacturing Evaluation (FRAME)

CDER AI Initiatives

2019

**CDER
Priorities
and Focus**

2020

***Established AI Steering
Committee and AI Strategy***

Oversee CDER's AI Strategy for
CDER's use of AI

Align CDER AI Strategy with FDA-
wide and HHS initiatives

2021

***Established AI
Community of Practice***

Forum for practitioners to
establish best practices,
influence policies, and
exchange innovative ideas

2022

Updated AI Strategy

Increase and maintain AI
awareness and understanding

Promote **alignment and
consistency** in CDER's AI
strategies and communications

CDER AI Initiatives



2023

*Executing
AI Strategy*

CDER Priorities and Focus

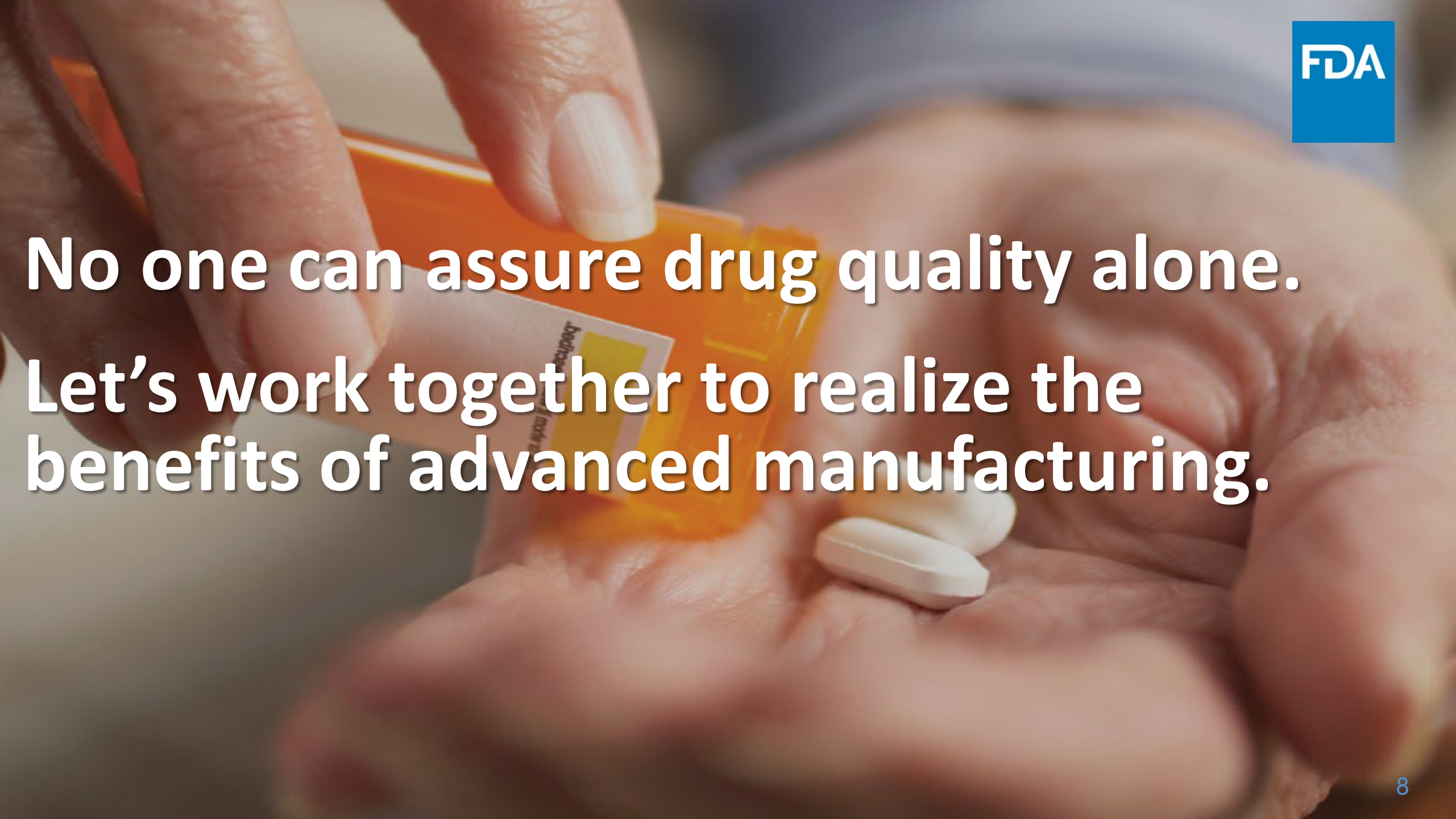
External Discussion Papers

- [Artificial Intelligence in Drug Manufacturing](#)
- [Using Artificial Intelligence & Machine Learning in the development of Drug & Biologics](#)



Potential Benefits of AI in Drug Manufacturing

- **Improved process design and scale up**
 - Less development time and process waste
- **Greater control over quality**
 - Less human involvement and error
- **Improved monitoring**
 - Less process downtime
- **Fewer deviations**
 - Better root cause identification

A close-up photograph of a hand pouring white, oval-shaped pills from an orange plastic pill bottle into the palm of another hand. The background is blurred, focusing on the action of dispensing the medication.

**No one can assure drug quality alone.
Let's work together to realize the
benefits of advanced manufacturing.**



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