The Advanced Manufacturing Technologies Designation Program

Ranjani Prabhakara, Ph.D.
Policy Lead, Office of Policy for Pharmaceutical Quality
Office of Pharmaceutical Quality
CDER | US FDA

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Learning Objectives

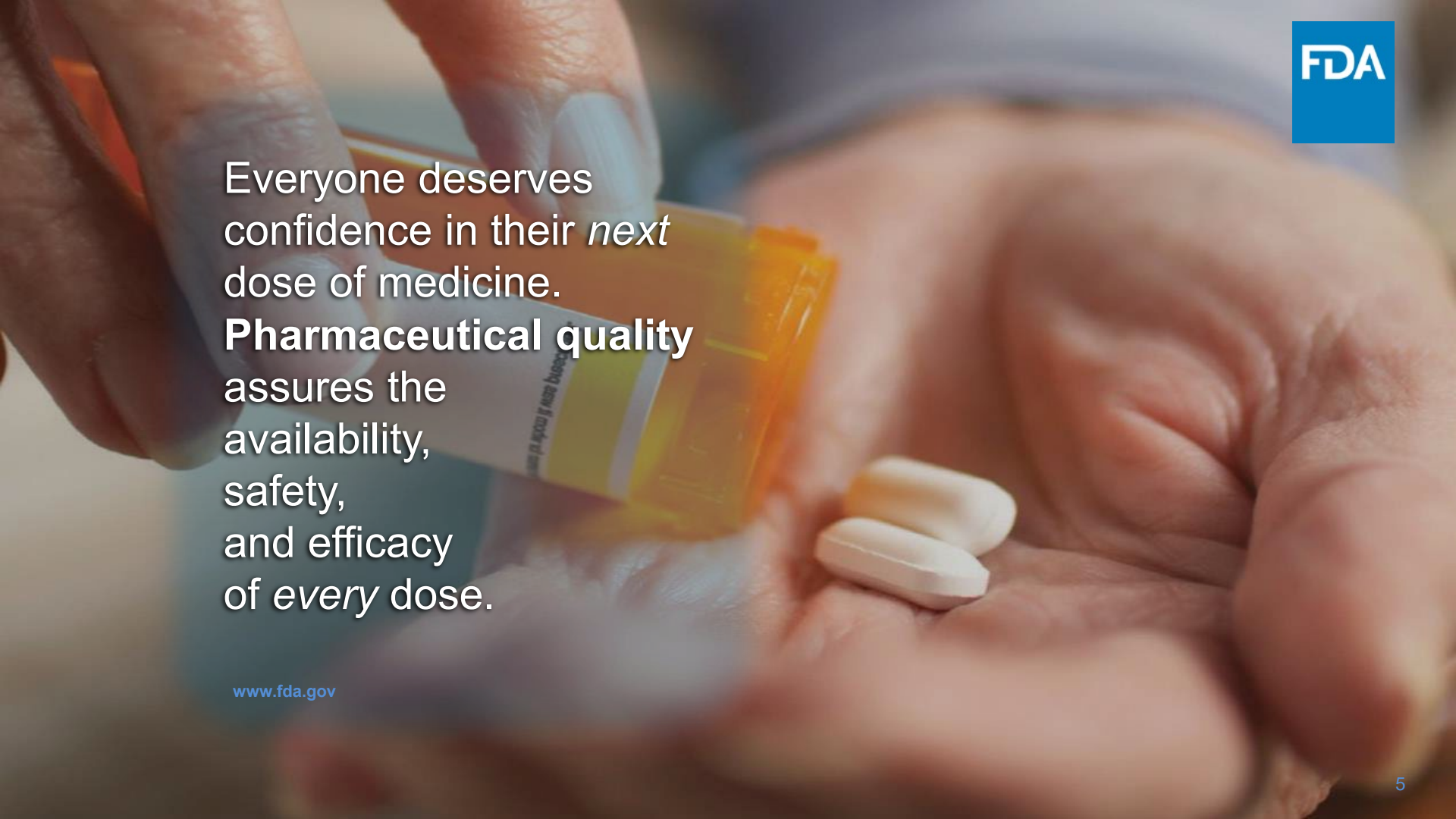
- Define pharmaceutical quality
- Introduce the Advanced Manufacturing Technologies Designation Program
- Summarize feedback from the Innovative Manufacturing Public Workshop
- Provide an overview of the Advanced Manufacturing Technologies Designation Program Guidance
  - Describe the background of this guidance
  - Explain the program's process and benefits
  - Compare and contrast with related FDA programs

What is Pharmaceutical Quality?

Pharmaceutical Quality

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

- Drugs are no different.


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

Introduction to Advanced Manufacturing

What is Advanced Manufacturing?

- New manufacturing technologies that:
  - Integrate **novel approaches**
  - Use established techniques in an **innovative way**
  - Are applied in a **new domain** without defined best practices or experience

- In every field, different production techniques considered advanced

https://www.fda.gov/emergency-preparedness-and-response/ocet-advanced-manufacturing/about-advanced-manufacturing-public-health-emergency-preparedness-and-response

Why Consider Advanced Manufacturing?

- Production of high(er) quality drugs
- Prevention of drug shortages due to quality-related manufacturing issues
- Faster drug development
- Stronger domestic drug manufacturing
- Greater agility and flexibility during a public health emergency

The Advanced Manufacturing Technologies Designation Program

The Consolidated Appropriations Act, 2023

- Omnibus spending bill signed into law December 29, 2022
- Included several quality-related provisions
  - "PREVENT Pandemics Act" (Title II)
    - Sec. 2503 Platform Technologies
    - Sec. 2511 Ensuring Registration of Foreign Drug and Device Manufacturers
    - Sec. 2512 Extending Expiration Dates for Certain Drugs
  - "Food and Drug Omnibus Reform Act of 2022" (FDORA, Title III)
    - Sec. 3203 Emerging Technology Program
    - Sec. 3213 Advanced Manufacturing Technologies Designation Program
    - Sec. 3613 Improving Food and Drug Administration Inspections

What Is an Advanced Manufacturing Technology (AMT)?

- "A **method of manufacturing***, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if such method or combination of methods incorporates a **novel technology**, or uses an established technique or technology in a **novel way**, that will **substantially improve** the manufacturing process for a drug while maintaining equivalent, or providing superior, drug quality, including by—
  - "(1) **reducing development time** for a drug using the designated manufacturing method; or
  - "(2) **increasing or maintaining the supply** of—"(A) a drug that is life-supporting, life sustaining, or of critical importance to providing health care; or "(B) a drug that is on the drug shortage list under section 506E.

*21 CFR 207.1: "…Manufacture includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process…"

The Advanced Manufacturing Technologies Designation Program

- "(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall **initiate a program** under which persons may **request designation**
- "(b) DESIGNATION PROCESS.—The Secretary shall establish a **process for the designation** under this section of methods of manufacturing **drugs**, including **biological products**, and **active pharmaceutical ingredients** of such drugs, as advanced manufacturing technologies...
- "(c) EVALUATION AND DESIGNATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—
  - "(1) SUBMISSION.—A person who requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing meets the criteria described in subsection (b) in a particular context of use...

Challenge Question #1

Which of the following does NOT describe an AMT?

A. Limited to one method of manufacturing per AMT

B. Can use an established technique or technology in a novel way

C. Substantially improves the manufacturing process for a drug

D. Can provide either equivalent or superior drug quality.

Next Step: 2023 Innovative Manufacturing Public Workshop

Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches

- Hosted by the Duke Margolis Center for Health Policy on June 8, 2023
- Fulfilled FDORA and Prescription Drug User Fee Act (PDUFA) VII commitments
- Included FDA officials, pharmaceutical industry representatives, and academics
- Discussion focused on:
  - Current state of innovative manufacturing technologies
  - Incentives for widespread adoption

AMT Panel Key Takeaways

- Support for the general approach
  - Encourages greater adoption of AMTs
  - Does not limit participation to applicants or sponsors
- Guidance feedback included the need for:
  - Balance between flexibility and certainty
  - Clarity on the benefits of AMT designation
  - Definition of key elements (e.g., *data and information*, *context of use*)

The Advanced Manufacturing Technologies Designation Program DRAFT Guidance

Why Develop a Guidance?

- “(2) PROGRAM GUIDANCE .—
  - “(A) IN GENERAL.—The Secretary shall—
    - “(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the program under this section; and
    - ‘(ii) not later than 2 years after the date of enactment of this section, issue final guidance regarding the implementation of such program.

What Does the Guidance Cover?

- "(B) CONTENT.—The guidance described in subparagraph (A) shall address—
  - "(i) the process by which a person may request a designation under subsection (b);
  - "(ii) the data and information that a person requesting such a designation is required to submit under subsection (c), and how the Secretary intends to evaluate such submissions;
  - "(iii) the process to expedite the development and review of applications under subsection (d); and
  - "(iv) the criteria described in subsection (b) for eligibility for such a designation.

Why Do We Need a Guidance?

- Communicate FDA's current thinking on AMTs*
- "Fill in the blanks" of the statute; for example:
  - What is the designation process?
  - What should be submitted in a designation request?
  - How does an AMT affect application assessment?
- Explain other important details of the program

*This guidance is currently in draft; once finalized, it will be implemented.

AMT Designation Process

Requestor develops a proposed AMT and submits a designation request

- AMT designation requests submitted independent of an application
- Requests can be submitted by anyone

Designation received

Designated Lead facilitates interactions with AMT holders and applicants

- Early interaction is with AMT requestors
- After AMT designation, interaction can be with applicants or requestors

AMT in Application

Designated Lead facilitates prioritized application assessment

- To increase application assessment efficiency

Designation Request Content

- Supporting data and information should:
  - Describe the proposed AMT
  - Demonstrate that statutory eligibility criteria are met
  - Be specific to a particular context of use (e.g., class of drugs)
  - Include AMT development data
  - Contain batch analysis data generated using either a product under development or a model drug

Designated AMT Benefits

- Early FDA interaction with requestors
- Assignment of a designated lead
  - Primary subject matter expert for a request
  - Coordinates FDA discussions
- Prioritized interaction with applicants
  - Higher priority for applications using a designated AMT
  - Designated lead facilitates quality assessment of applications to increase efficiency

Difference Between AMT Designation and Other FDA Programs

AMT	Emerging Technologies Program/CBER Advanced Technologies Team
Limited or no previous FDA assessment or inspectional experience with the technology for a proposed context of use	Limited or no previous FDA assessment or inspectional experience with the technology
Limited to methods of manufacturing that are novel or used in a novel way	Intended for novel elements, including but not limited to manufacturing processes
Data generated for a context of use (i.e., data from a model drug)	Data may not yet be generated
Applicants can communicate with FDA when using, referencing, or relying on a designated AMT	Applicants can communicate with FDA prior to submission of an application
Interactions focused on technology developers, applicants, and sponsors	Interactions with multiple public and private stakeholders; Includes training, education, and grants

Challenge Question #2

Which of the following is generally NOT included in an AMT designation request:

A. A description of the proposed AMT

B. Data and information demonstrating eligibility for a particular context of use

C. Process validation data for a specific product

D. Batch analysis data generated using either a product under development or a model drug

Resources

- Draft Guidance for Industry: Advanced Manufacturing Technologies Designation Program
- Draft Guidance Federal Register Notice
- About Advanced Manufacturing for Public Health Emergency Preparedness and Response
- FDA News, Events, and Funding Opportunities Related to Advanced Manufacturing
- FDA/CDER Office of Pharmaceutical Quality
- @ CDER-OPQ-Inquiries

Summary

- The draft guidance provides information about the AMT Designation Program, including:
  - Recommendations on how and when to submit an AMT designation request
  - The designation request evaluation process
  - The benefits of AMT designation
  - Differences between AMT designation and similar FDA programs


Innovation is the active ingredient in regulating pharmaceutical quality.

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Ranjani Prabhakara, Ph.D.
Policy Lead, Office of Policy for Pharmaceutical Quality
Office of Pharmaceutical Quality
CDER | US FDA
CDER-OPQ-Inquiries@fda.hhs.gov