ETP and AMTDP: Which program is right for me?

Elisa A. Nickum, PhD, PMP
Sr. Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
CDER | US FDA

Generic Drugs Forum 2024 – April 11, 2024

Learning Objectives

- Describe the programs
  - ETP: Emerging Technology Program
  - AMTDP: Advanced Manufacturing Technologies Designation Program
- List criteria of each program
- Understand how to apply to each program

Poll Question #1

What is your awareness level of the ETP and AMTDP?

A. I am familiar with the ETP and AMTDP.

B. I am interested in applying to ETP or AMTDP.

C. I have applied to ETP or AMTDP.

ETP Background

- Established in 2014
- Collaborative program where industry can meet with ETP
  - Development and implementation of a novel technology prior to filing
- Discuss, identify and resolve potential technical and regulatory issues

Who is the ETP?

- The Emerging Technology Team (ETT)
- A small cross-functional team of 20-30 members, with representation from:
  - Office of Pharmaceutical Quality
  - Office of Compliance
  - Office of Regulatory Affairs

ETP Criteria

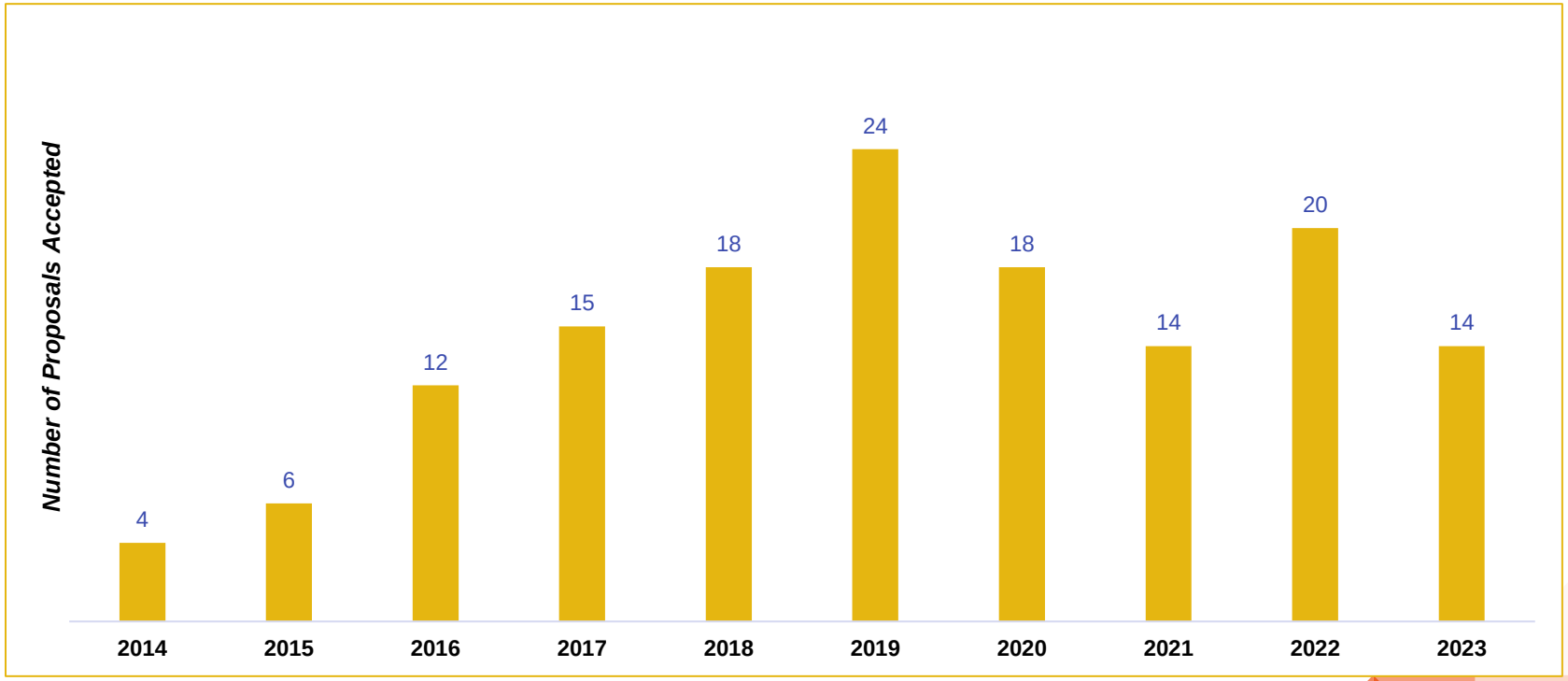
- Have the potential to improve product safety, identity, strength, quality, and purity
- Include one or more innovative or novel elements:
  - Product technology
  - Manufacturing process
  - Control strategy

How to Apply to ETP

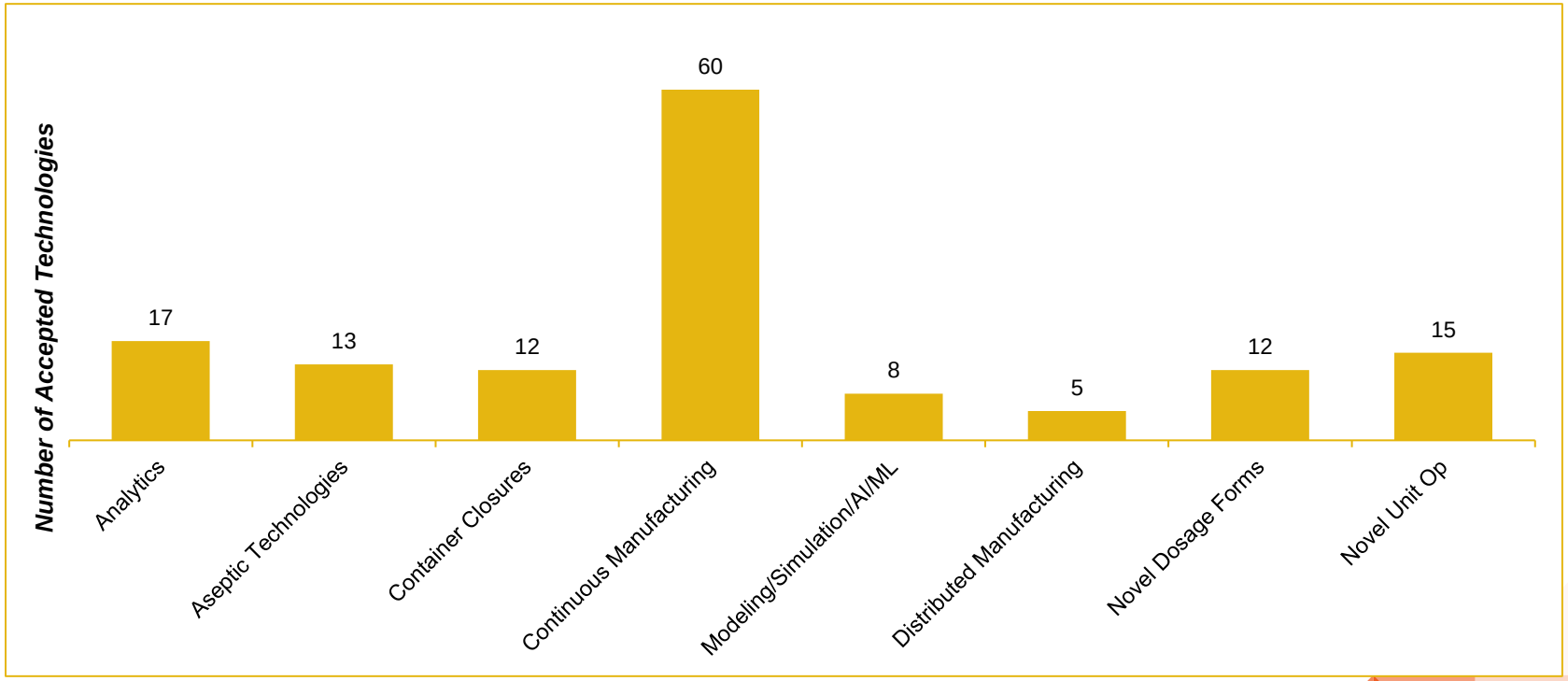
- Follow procedures described in ETP guidance on FDA website*
- Develop a proposal to describe technology and justify criteria
  - Pharmaceutical Novelty
  - Product Quality Advancement

* See Resources slide for link

ETP Accepted Proposals



ETP Accepted Proposals



AMTDP Background

- $1.7 trillion spending bill: “The Consolidated Appropriations Act, 2023”
  - 2023 fiscal year funding
  - Addressed a range of domestic policy priorities
- “Food and Drug Omnibus Reform Act of 2022” (FDORA, Title III)

AMTDP Background

- Section 3213: Advanced Manufacturing Technologies Designation Program
  - New Program
  - Public Meeting
  - Guidance
  - Report to Congress

Who is the AMTDP?

- A small cross-functional team consisting of members from:
  - ETT: CDER Emerging Technology Team
  - CATT: CBER Advanced Technologies Team

AMTDP Criteria

- Per the criteria described in section 506L(b) of the FD&C Act
  - Reducing development time; or
  - Increasing or maintaining the supply of critical medicines
- Intended for more mature methods and technologies
- Who can apply?

How to Apply to AMTDP

- Follow procedures described in AMTDP guidance on FDA website*
- Develop a proposal to describe technology and justify criteria
  - Novelty
  - Process Improvement
  - Model Data

* See Resources slide for link

Benefits of ETP and AMTDP

- Collaborative Approach
  - Pre-engagement with ETT and CATT
  - Same team for AMTDP process
- Early interaction with FDA
- Timely advice and communication
- Meetings

Resources

- FDA.gov: Emerging Technology Program
- FDA.gov: Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization Guidance for Industry, Final, September 2017
- FDA.gov: Advanced Manufacturing Technologies Designation Program, Draft, February 2024
- United States Code: 21 USC 356l: Advanced manufacturing technologies designation program
- June 8, 2023, meeting: Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches

Summary

- ETP and AMTDP encourage and support the adoption of novel technologies
- Both provide opportunities to gain Agency feedback
- Each program has criteria for acceptance
- Guidance Documents are available to assist in the application process

Challenge Question #1

What FDA Center or Centers are part of the Advanced Manufacturing Technologies Designation Program Team

A. CDER

B. CVM

C. CDRH

D. CDER and CBER

Challenge Question #2

When was the ETP established?

A. 2010

B. 2014

C. 2019

D. 2024

Questions?

Elisa A. Nickum, PhD, PMP
Sr. Regulatory Business Process Manager
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
CDER | US FDA

Closing Thought

The ETP and AMTDP are here to encourage and support the adoption of novel technologies.

If you have questions, please reach out!

CDER-ETT@fda.hhs.gov

AMT_designation_requests@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION