

# ETP and AMTDP: Which program is right for me?

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# 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

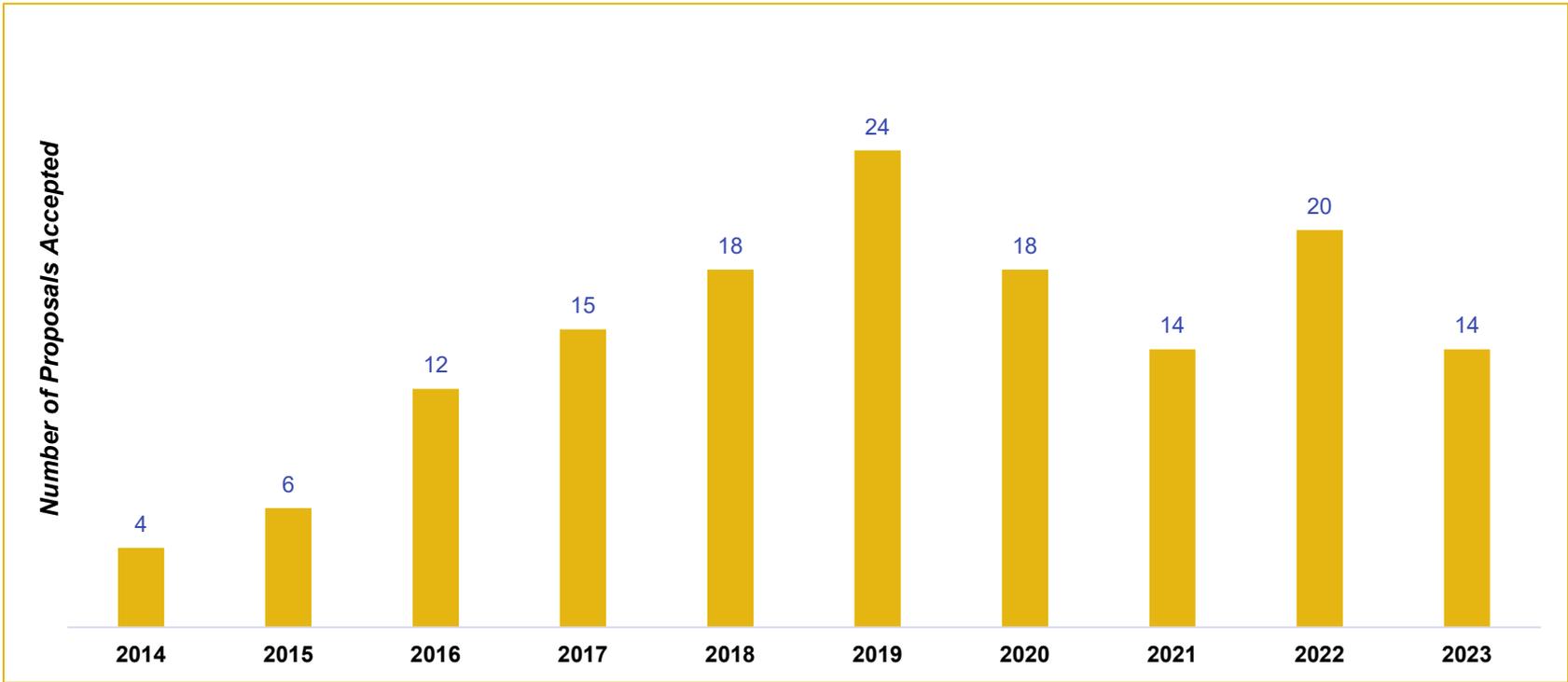
# ETP Criteria

- 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

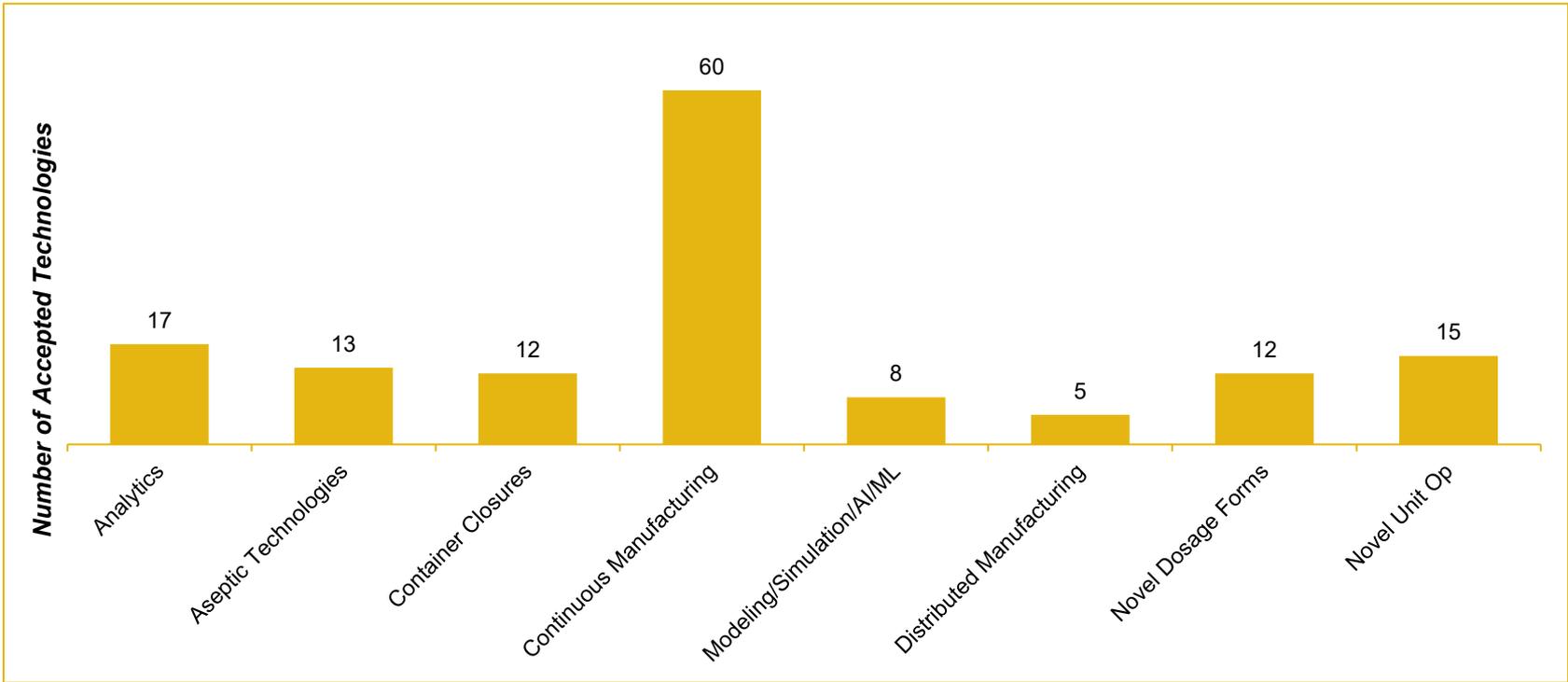
# How to Apply to ETP

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

# 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

# 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?

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# Closing Thought



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

If you have questions, please reach out!

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