Emerging Technology Program

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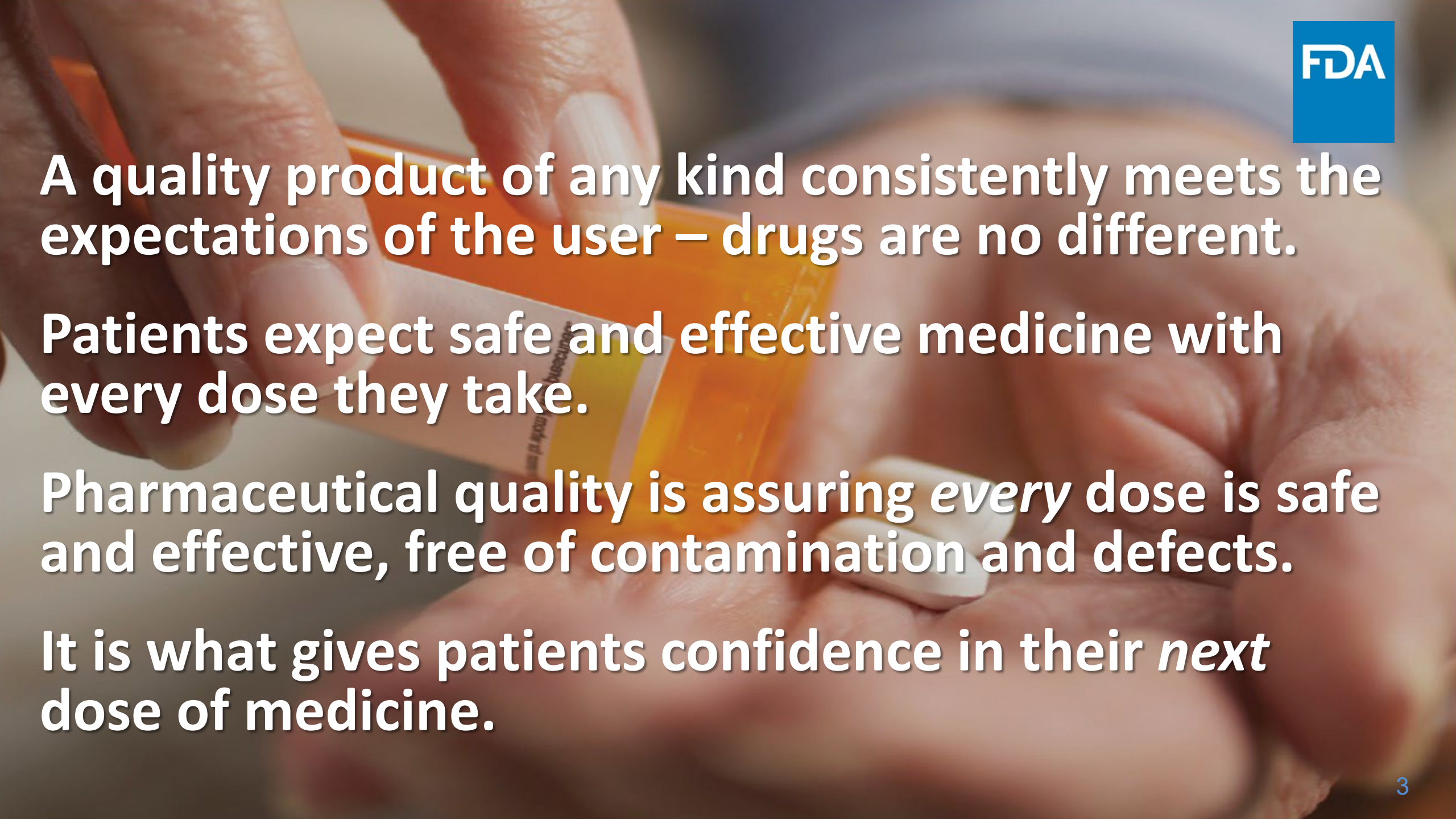
Office of Pharmaceutical Quality

US FDA Center for Drug Evaluation and Research

Introduction to 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.

About the Emerging Technology Program

Mission

Encourage and support the adoption of innovative technology to modernize pharmaceutical development and manufacturing through close collaboration with industry and other relevant stakeholders

Team

A small cross-functional Emerging Technology Team (ETT) of 20-30 members, with representation from all relevant FDA quality review and inspection programs

Team members come from:

Office of Pharmaceutical Quality (OPQ)
Office of Compliance (OC)
Office of Regulatory Affairs (ORA)

Chair	Joel Welch
Vice Chair	Tom O'Connor
Project Manager	Elisa Nickum
Senior Scientific Advisor	Sau (Larry) Lee

Program Objectives

To serve as a centralized location for external inquiries on novel technologies

To provide a forum for firms to engage in early dialogue with FDA to support innovation

To ensure consistency, continuity, and predictability in review and inspection

To engage international regulatory agencies to share learnings and approaches

To identify and evaluate potential roadblocks relating to existing guidance, policy, or practice

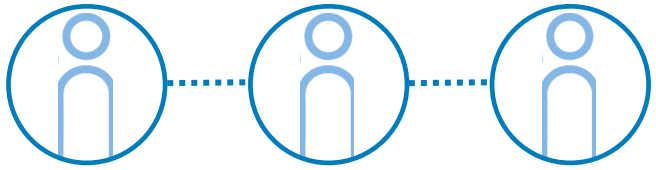
To facilitate knowledge transfer to relevant CDER and ORA review and inspection programs

To help establish scientific standards and policy, as needed

ETP Lifecycle at a Glance

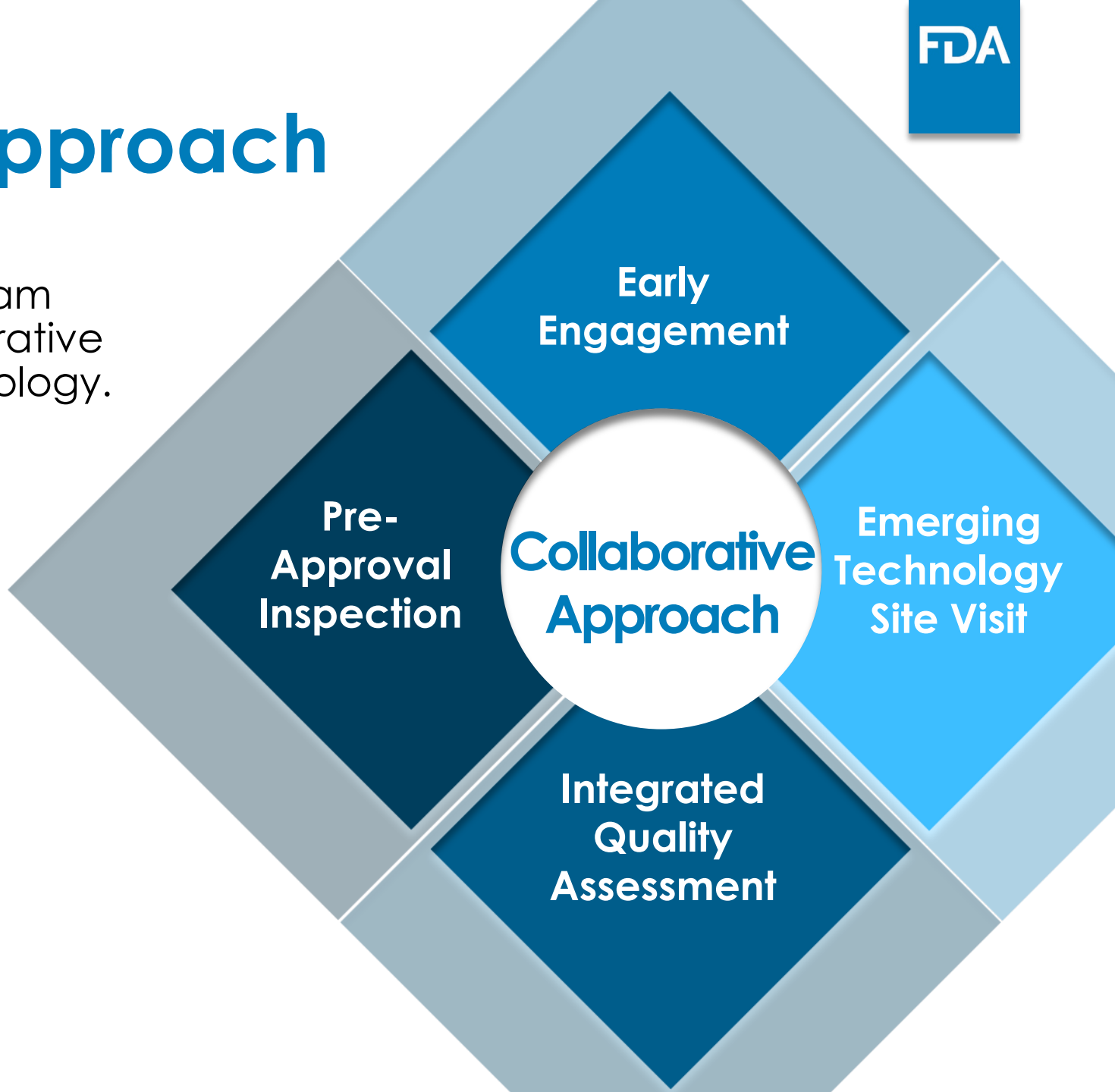
ETP Collaborative Approach

Over the course of the ETP Technology Lifecycle, the Emerging Technology Team may employ a combination of collaborative approaches to engage with the technology.



The same Emerging Technology Team representative(s) will be involved in the entire process.

The composition of a review team will likely remain the same throughout the entire process.



ETP Collaborative Approach

Early Engagement (Pre-submission)

- Meeting(s) with the Emerging Technology Team (ETT) provide upfront scientific input under the Emerging Technology Program

Emerging Technology Site Visit

- Participation by OPQ (including the ETT member(s)) and/or ORA members

Integrated Quality Assessment (IQA)

- Interdisciplinary team with experts in Drug Substance, Drug Product, Process/Facility, Biopharm, and/or Inspection
- ETT member as an Application Technical Lead (ATL) or co-ATL to lead the IQA team when the ET impacts most parts of a CMC section

Pre-Approval Inspection (PAI/PLI)

- Conducted by team members from OPQ (including the ETT Member(s)) and ORA

Lifecycle of an ETP Technology

Industry requests input and feedback on an emerging technology while preparing a regulatory submission

ETP works with industry to discuss, identify, and resolve technical and regulatory issues related to the development and implementation of the novel technology

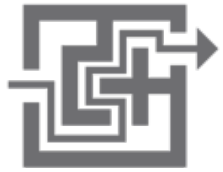
Technology is no longer considered "emerging" and passes through the standard quality assessment pathways

**A technology is eligible to graduate from ETP when at least three applications have been received from three unique companies. Meeting this threshold does not automatically initiate graduation.*

Graduation Definition

An emerging technology qualifies for graduation and is no longer considered emerging within ETP when:

FDA has gained sufficient experience with the technology

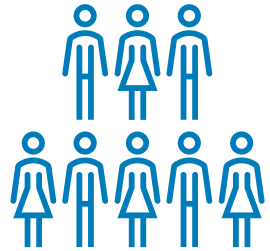


The technology can proceed fully through the standard assessment process with no or minimal support from ETT members

Graduation Benefits

Graduation indicates that FDA has gained sufficient experience with the graduating technology and is **confident in the ability of industry to submit successful future applications**

By transferring responsibility for the graduated technology to other FDA offices, ETP has the capacity to **accept future emerging technologies to keep pace with industry innovation**



With more assessors trained to review the graduated technology, **FDA can review more applications while continuing to meet the user fee goal dates.**

ETP core members remain available to FDA assessors as needed on regulatory submissions of graduated technologies.

ETP Transfers Review Responsibility

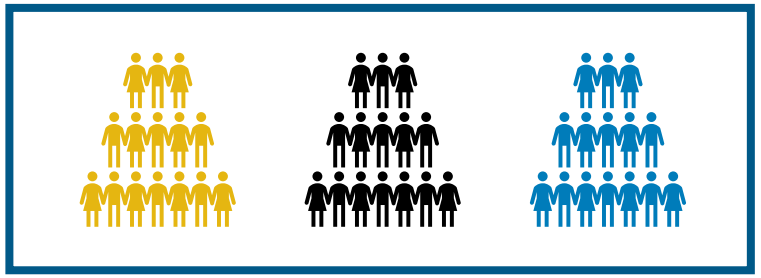
ETP determines technology's readiness to move forward with graduation

ETP manages knowledge transfer related to the technology and trains FDA assessors to be prepared to review future application submissions

Technology qualifies for graduation*

ETP core members remain available to FDA assessors as needed on new applications

Emerging Technology Program



FDA assessors review future applications from a graduated technology

*A technology is eligible to graduate from ETP when at least three applications have been received from three unique companies. Meeting this threshold does not automatically initiate graduation.

Engaging with the Emerging Technology Program

How to Apply to ETP

01

Start early in development (even potentially without a drug candidate identified)

02

Follow procedures described in the ETT guidance found on our website to request participation in the ETP

03

Develop proposal

- Describe the technology and explain why it is novel or unique
- Describe how it improves products
- Summarize development plan and implementation roadblocks
- Describe submission timeline

The sponsor must justify how the proposed emerging technology meet two criteria:

(1) Pharmaceutical Novelty
(2) Product Quality Advancement

* More detail can be found at:
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program

Engaging with ETP: FAQs

Who can participate in the Emerging Technology Program?

ETP is open to companies that intend to include a novel technology as part of a regulatory submission reviewed by the Center for Drug Evaluation and Research (CDER).

Does the submitter of a proposal need to wait until a molecule is identified before joining ETP?

The group can join ETP before a molecule is identified as long as the technology used meets the criteria for acceptance.

Does the submitter of a proposal need to wait until a regulatory submission (e.g., an IND) is intended to join ETP?

The group can join ETP before a submission is intended.

Engaging with ETP: FAQs

What if the submitter of a proposal is still developing a particular technology and still determining what questions to ask. Should they wait to submit a proposal?

Waiting is not needed as the ETP engagement is not designed to be a single interaction. Rather, it's ideally a series of engagements throughout technology development.

How will the ETP be notified of an emerging technology within a regulatory submission?

If the technology in the application is part of a previous engagement, the ETT will be included in future interactions. It is helpful to reference the acceptance into the ETP in the cover letter of the submission and to notify the ETP mailbox upon submission.

Engaging with ETP: FAQs

Are new proposals appropriate for legacy products or only for new molecules in development?

Proposals are appropriate for new molecules in development as well as products that have been on the market for a long time. Proposals are appropriate for any type of molecule.

What is the criteria to be accepted into the ETP?

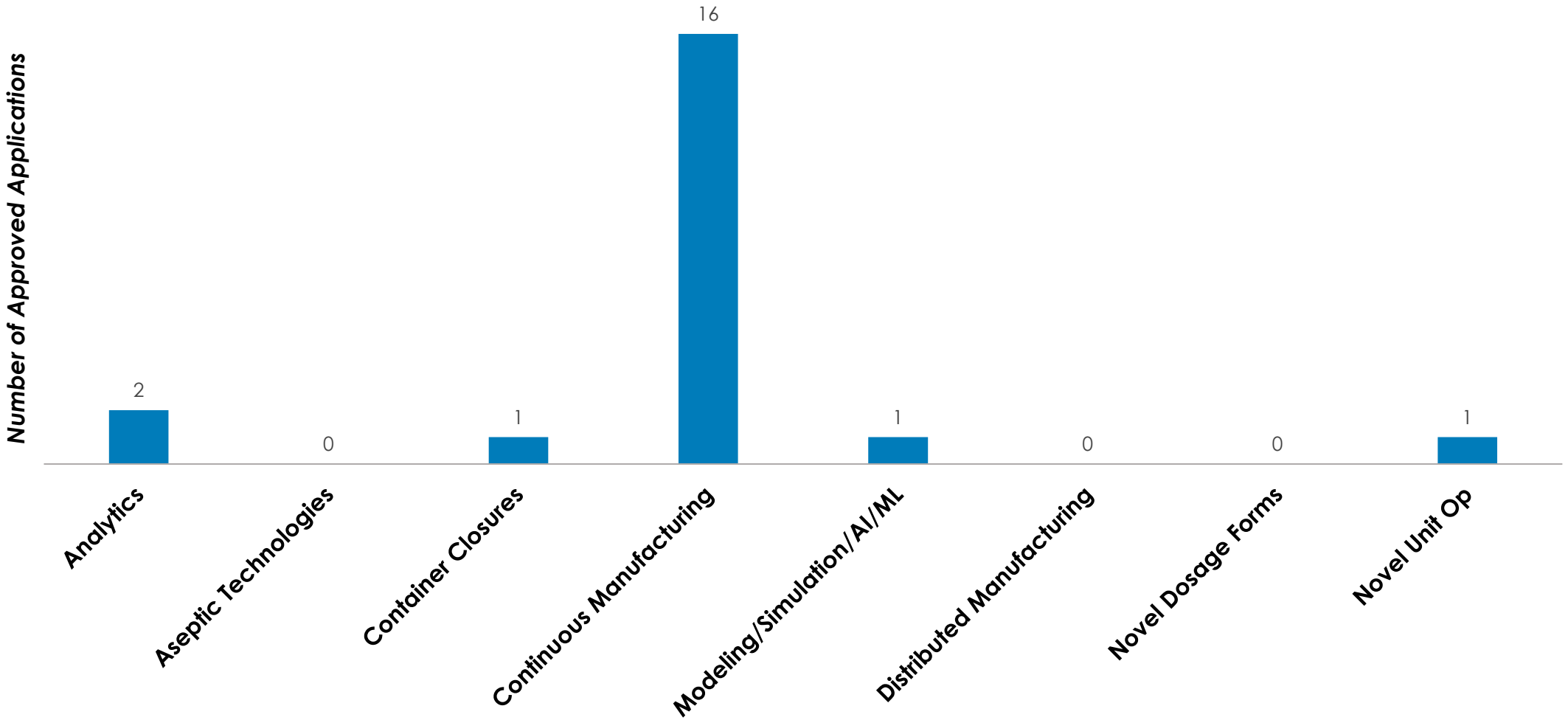
Acceptance is not guaranteed.

The ETT limits acceptance into the program to technologies that are likely to advance product design or modernize pharmaceutical manufacturing, and with which the Agency has limited prior experience and knowledge.

The proposed technology in the planned submission must have the potential to improve product safety, identity, strength, quality, or purity.

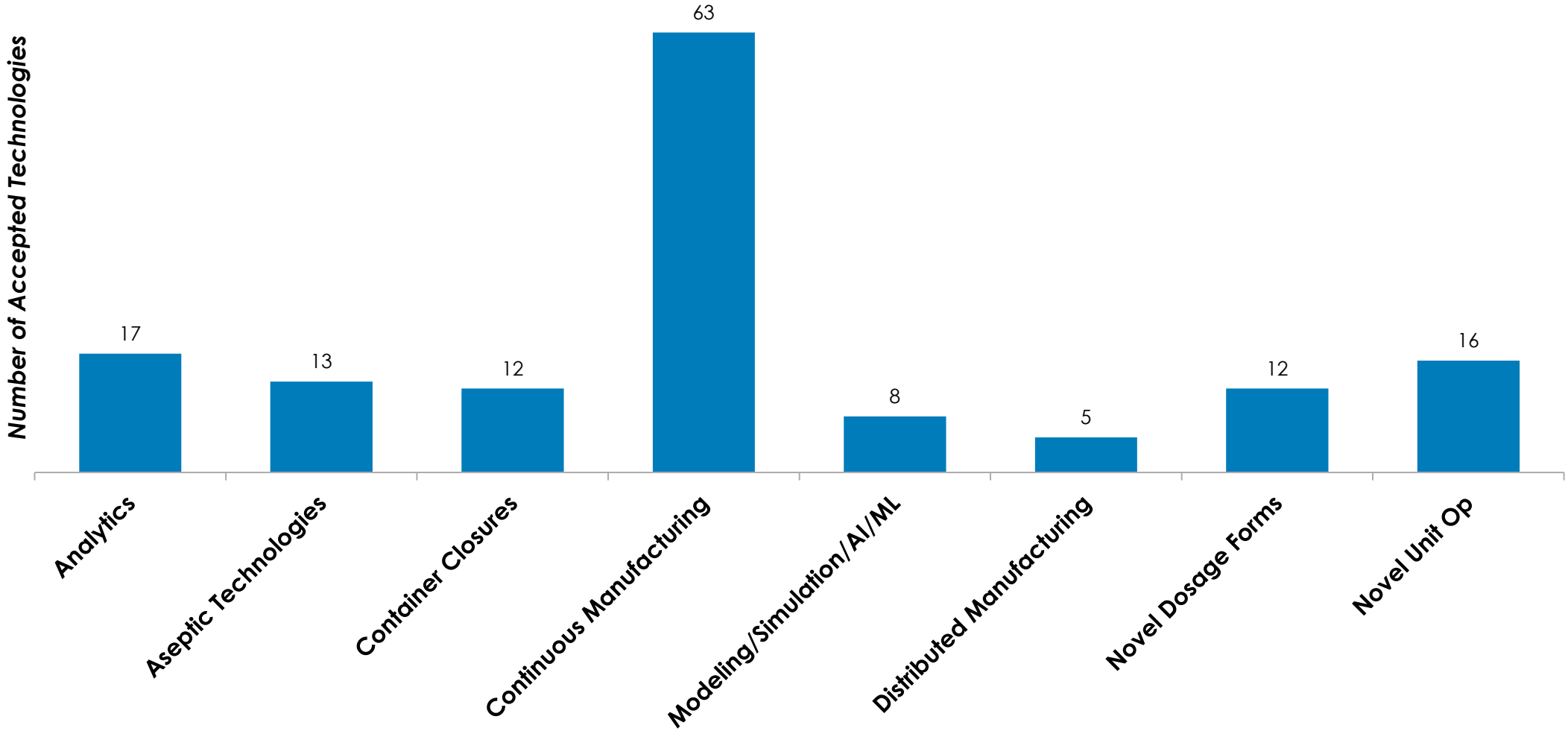
Approved Application Technologies

There have been 21 approved applications since July 2015.



*As of February 2024

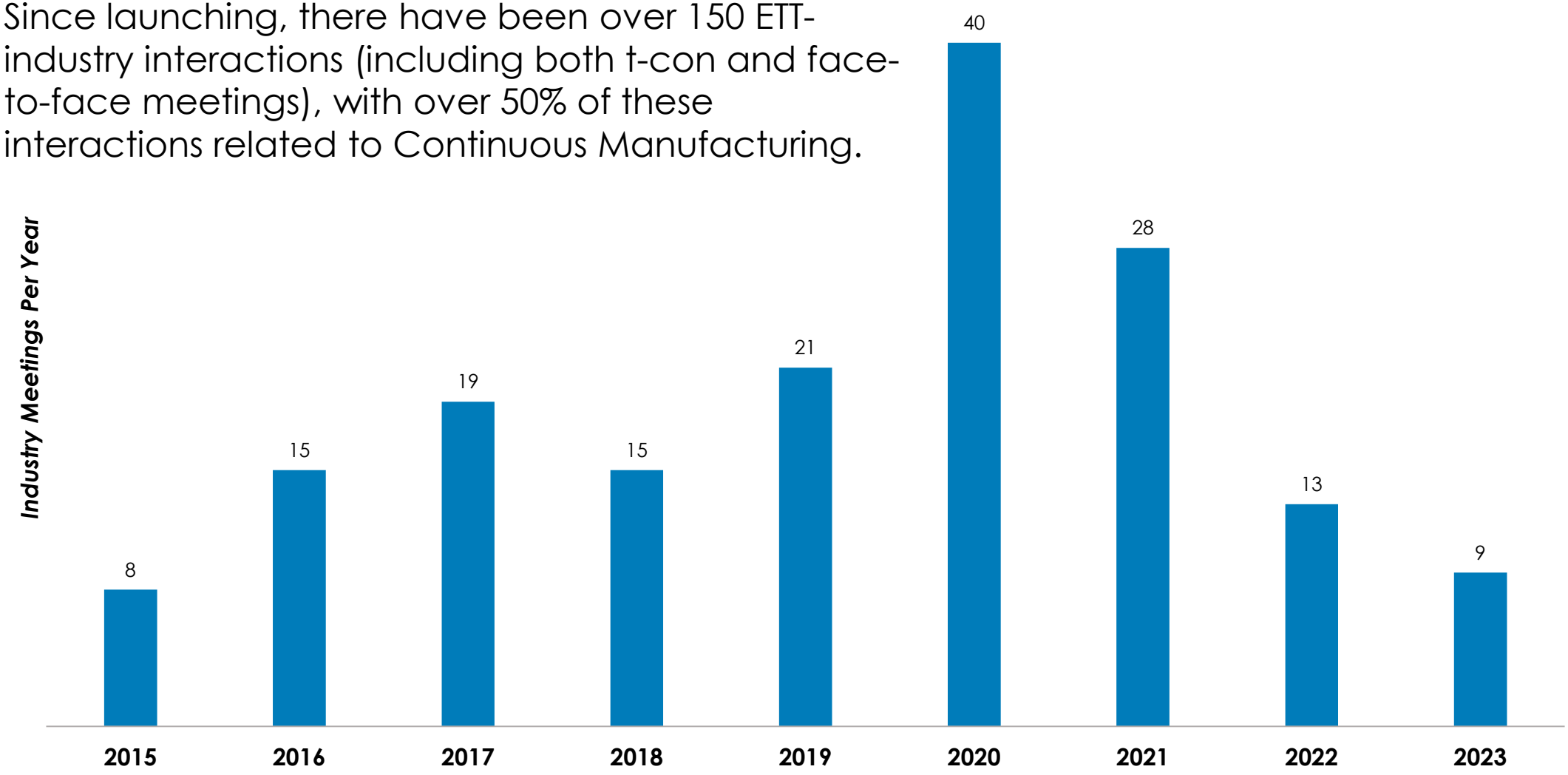
ETP Accepted Submissions by Technology



*As of February 2024

Accepted Meeting Requests

Since launching, there have been over 150 ETT-industry interactions (including both t-con and face-to-face meetings), with over 50% of these interactions related to Continuous Manufacturing.



*As of February 2024

Conclusion

- The Emerging Technology Program serves as a centralized location for external inquiries on novel technologies, providing a forum for industry to engage in early dialogue with CDER/FDA.

- Through this early engagement, the ETP can identify and evaluate potential roadblocks relating to existing guidance, policy, or practice.

- Once FDA has enough confidence in industry's ability to successfully submit applications using the technology, it then "graduates" from the ETP.

- To request participation in the ETP, develop a proposal and be sure to:
  - Describe the technology, explain why it is novel, and how it improves products
  - Summarize development plan and implementation roadblocks
  - Describe submission timeline

Additional procedures are described in the ETT guidance found on our website:
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/how-participate-etp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Thank You!