

Emerging Technology Program (ETP) 2.0

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Pharmaceutical Quality



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



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.

Learning Objectives

- Learn about the Emerging Technology Program (ETP)
- Understand how ETP identified a need to mature its operating model and developed the steps to achieve its future state
- Learn how ETP 2.0 enhances program efficiency and encourages and supports industry adoption of advanced manufacturing technologies

What is the Emerging Technology Program?



- Program established in late 2014
- Promotes and facilitates the adoption of innovative approaches to pharmaceutical product design and manufacturing
- Cross-functional team with representation from all relevant FDA quality review and inspection programs (OPQ, OC, ORA)
- Program provides opportunity to discuss, identify, and resolve technical and regulatory issues during a novel technology's development and adoptions

Examples of ETP Technologies



- Continuous Manufacturing
- Aseptic Technologies
- Novel Dosage Forms
- Modular Manufacturing
- Novel Unit Operations
- Analytics
- Modeling
- Artificial Intelligence/Machine Learning
- Container Closures
- Industry 4.0/Smart Manufacturing

Why Was There a Need for Change?



- ETP's original processes and stakeholders were instrumental in ETP's early success
- Between 2014 and 2020, ETP had:
 - Increasing ETP proposal submission rate
 - Industry satisfaction rating of 8.9/10
 - Published of Continuous Manufacturing Guidance
 - Approved 12 regulatory applications

Why Was There a Need for Change?



- As ETP workload increased, program encountered challenges to effectively deliver against program's mission and purpose:
 - Increasing number of requests to work with ETP
 - Industry requested more support from ETP

What Was the Solution?



- Document and review existing operating model (current state)
- Establish ETP 2.0 operating model (future state)
 - Focus on program's growth and needs
 - Standardize and streamline scalable processes
- Create implementation roadmap

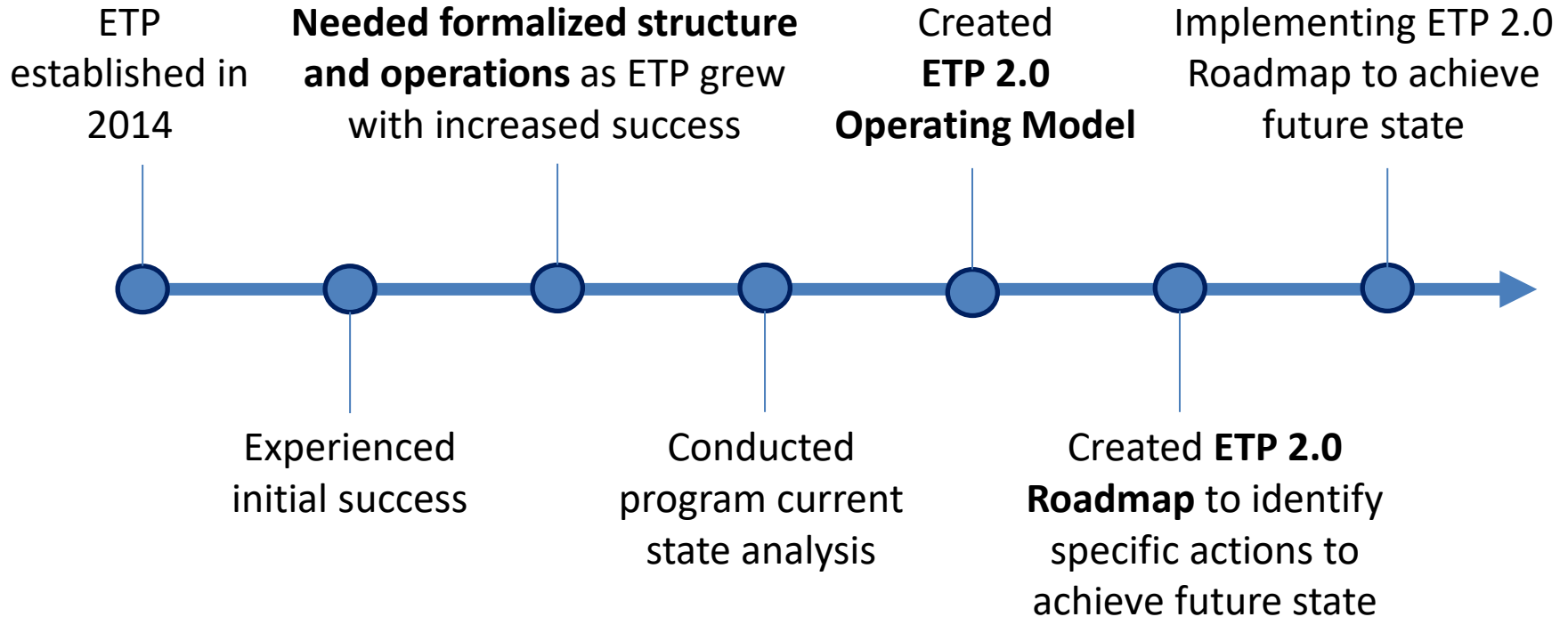
Defining ETP 2.0

- Aligns organizational and existing quality assessment components and processes
- Identifies opportunities to strengthen performance

ETP 2.0 Priorities

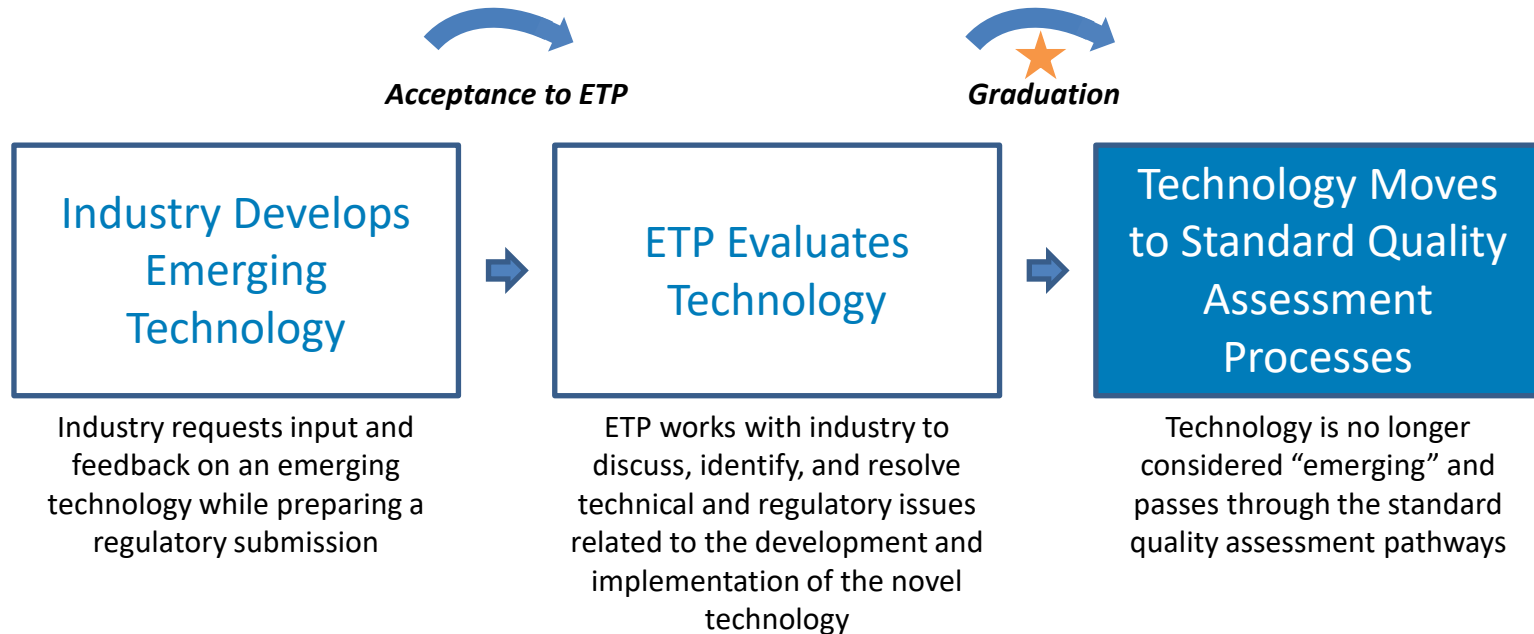
- Graduation
- Knowledge Management and Transfer
- Governance
- Intake
- Engagement
- Communications
- Technology and Tools
- Skills and Training
- Workload Management
- Strategy
- Awareness

Program Maturity



ETP 2.0 Example: Graduation

- Graduation is a new component of ETP 2.0





Benefits of Graduation

- FDA has sufficient experience with a technology and is confident industry will submit successful future applications
- FDA has capacity to accept future emerging technology to keep pace with industry innovation
- FDA can review more applications while continuing to meet user fee goal dates

Summary

- ETP 2.0 enhances program efficiency and encourages and supports the adoption of innovative technology to modernize pharmaceutical development and manufacturing through close collaboration with industry and other relevant stakeholders



Challenge Question #1

True or False: The Emerging Technology Program has members from OPQ, OC, and ORA

- A. True
- B. False



Challenge Question #2

Between 2014 and 2020, how many applications did ETP approve?

- A. 10
- B. 11
- C. 12
- D. 13

Thank You!

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