Enabling Innovation and Emerging Technology Program 2.0

Center for Drug Evaluation and Research | Office of Pharmaceutical Quality

What is The Emerging Technology Program?

WHAT	An OPQ program established in late 2014 that promotes and facilitates the **adoption of innovative approaches to pharmaceutical product design and manufacturing**
WHO	A **cross-functional team** (approximately 30 members with additional ad-hoc SME members) with representation from all relevant FDA quality review and inspection programs **Offices include: OPQ, OC, ORA (*One Quality Voice*)**
HOW	The program provides an **opportunity for industry to engage and collaborate early with the FDA** to discuss, identify, and resolve technical and regulatory issues during a novel technology's development and adoptions

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 Accomplishments To Date

Initial Successes

ETP's original processes and stakeholders were instrumental in ETP's early success in proactively interacting with the pharmaceutical industry on emerging technologies

	2015	2016	2017	2018	2019	2020	2021
Proposals Received	9	21	25	19	39	22	13
Proposals Accepted in ETP	9	18	18	16	32	16	10
Proposals Denied to ETP	0	3	7	3	7	6	3
Sponsor Meetings	8	15	19	15	21	40	35
ETP Site Visits	0	1	2	1	5	4	6

Early Success

- Increasing ETP proposal submission rate
- Industry satisfaction rating: 8.9 out of 10
- Publication of Continuous Manufacturing guidance
- Approval of 12 regulatory applications under ETP

Why Was There a Need For Change?

Challenges

As ETP's workload increased, the program began to encounter several challenges to effectively deliver against the program's mission and purpose

Increasing number of requests to work with ETP

Increase in proposals received and accepted into the program limits ETP's ability to provide effective support to all novel technologies and industry members

Industry requested more support from ETP

Example include:

- *Expand scope and capacity of ETP*
- *Advance innovative mechanisms for evaluating technologies outside of product approvals*
- *Increase external engagement to facilitate innovation and increase awareness of readiness of CDER to evaluate innovative technologies*

Loss of staff members; Reduce Silos

Opportunities to improve continuity of program in cases of attrition

Potential to further improve communication across work units

What Was the Solution?

Strategic

Tactical

1	**Current State Analysis**	Document ETP 1.0 Operating Model (Current State) to identify and understand program gaps, inefficient processes and challenges
2	**Future State Design**	Create ETP 2.0 Operating Model (Future State) to support the program's future growth and needs by standardizing and streamlining scalable processes; establish future state baseline model to demonstrate usefulness of the program
3	**Roadmap Implementation***	Create roadmap to document all the tasks and actions required to move from Current State Operating Model to Future State Operating Model

*ETP is currently implementing the changes required to fully adopt its future state operating model.

ETP 2.0 Roadmap Overview

Priority	Status	Level of Effort	Impact/ Complexity[1]	Nature of Tasks
Graduation	In Progress	To be completed by September 2021	High Impact/High Complexity	Process Development, Communications, Monitoring
Knowledge Management and Transfer	In Progress	To be completed by September 2021	High Impact/High Complexity	Repository, Trainings, Internal Expertise, Documentation
Governance	In Progress	To be completed by September 2021	High Impact/Medium Complexity	Charter, GAP Analysis, Documentation
Intake	Pending	4 months with 0.25 FTE		
Engagement	Pending	6 months with 0.75 FTE		
Communications	Pending	3 months with 0.5 FTE		
Technology and Tools	Pending	4 months with 0.25 FTE		
Skills and Training	Pending	6 months with 0.5 FTE		
Workload Management	Pending	6 months with 0.5 FTE		
Strategy	Pending	4.5 months with 0.5 FTE		
Awareness	Pending	3 months with 0.5 FTE		

1. Graduation

Graduation refers to the transfer of application assessment responsibility from ETP to OPQ sub-offices. A technology achieves graduation when FDA gains enough experience with a technology and it proceeds through the standard assessment process with minimum or no involvement of ETT members. By graduating a novel technology, ETP can realize its mission of promoting the adoption of innovative approaches to pharmaceutical product design and manufacturing.

Expected Level of Effort	To be completed by September 2020
Expertise Required	Project Management, Process Improvement, Change Management, Communication Strategy, Subject Matter Expertise
Potential Contributors	ETT Project Manager, Quality Assessors, OPQ Learning and Professional Development, ETT Chair, Technology Leads
Impact Complexity	High Impact, High Complexity

Tasks to Achieve ETP 2.0

Tasks	Actions
Define graduation with ETP approval	• Draft a definition to formally describe what it means for a technology to graduate from ETP. • Gather and incorporate feedback from ETT members on graduation definition. • Confirm the approved graduation definition supporting ETP 2.0 operating model.
Define the criteria for a technology to graduate and the associated processes for implementation	• Identify requirements for current ETP technologies to qualify for graduation. • Create a decision tree to track a technology's path through graduation. • Create a Working Instruction that details the processes and frameworks for graduating a technology. • Create formal approval process to officially transfer assessment responsibility to the receiving OPQ sub-office(s).
Create the communication plan associated with a graduating technology	• Document ETT's roles and responsibilities regarding communications when graduating a technology. • Identify goals for planned communications. • Identify audience(s) who will be impacted by graduating a technology. • Develop messaging for target audiences.

- **Step-by-step guide to achieve ETP 2.0**
- Describes priorities, tasks, actions, expected level of effort, expertise required, potential contributors, impact/complexity, risks, and mitigation tactics

Priority Areas

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

Program Maturity for ETP

ETP established in 2014

Experienced initial success

Needed formalized structure and operations as ETP grew with increased success

Conducted program current state analysis

Created **ETP 2.0 Operating Model**

Created **ETP 2.0 Roadmap** to identify specific actions to achieve future state

Implementing ETP 2.0 Roadmap to achieve future state

NASEM Recommendations

1. Strengthen expertise in innovative technology throughout CDER
2. Expand the scope and capacity of the Emerging Technology Program
3. Advance innovative mechanisms for evaluating technology outside product approvals
4. Increase external engagement to facilitate innovation and increase awareness of readiness of CDER to evaluate innovative technology
5. Expand the leadership role in global regulatory harmonization efforts

Strengthen Expertise in Innovative Technology throughout CDER

NASEM Recommended Opportunities

- Cultivate innovation throughout CDER (not just ETP) to ensure consistency in review and inspection
- Examine internal practices to increase technical fluency among scientists
- Ensure staff-development plans support continuous education on innovative technologies

CDER Response

- Currently developing a systems approach (KASA*) for quality assessments which will include emerging technologies
- Began developing targeted trainings (including lab based) to quality assessors and ORA
- Already working with ORA to modernize the inspection program and train investigators to ensure consistency of FDA inspection

*Knowledge-aided Assessment & Structured Application

Advance Innovative Mechanisms for Evaluating Technology Outside Product Approvals

NASEM Recommended Opportunities

- Create new mechanisms and evaluate, expand, and consolidate existing pilot programs that allow consideration of innovative technology outside individual product submissions

CDER Response

- FDA approves drug products, not technologies. FDA will continue to approve applications based on drug products
- ETP already offers a non-product specific track that allows feedback on a proposed emerging technology
- Through ETP, OPQ has adopted risk-based approaches to help streamline implementation of technologies over multiple products using the existing regulatory framework
- OPQ will streamline, when possible, the regulatory approaches for implementing a new technology as post approval changes

Expand the scope and capacity of the Emerging Technology Program

NASEM Recommended Opportunities

- Dedicate independent funding to ETP
- Increase number of dedicated full-time employees in ETP
- Broaden criteria for entry to ETP
- Increase transparency of ETP capacity

CDER Response

- FDA has received funding to support advanced manufacturing, including ETP
- ETP utilizes all employees in OPQ to expand expertise and knowledge of new technologies and to improve connections with quality assessment offices
- Dedicated staff and separate funding could limit agility of ETP
- Criteria for entry into ETP are broad; ETP will increase external communication to educate industry regarding criteria for acceptance into program

Increase external engagement to facilitate innovation and increase awareness of readiness of CDER to evaluate innovative technology

NASEM Recommended Opportunities

- Increase engagement of regulatory scientists with public-private partnerships, nonprofits, and academic institutions
- Increase visible leadership in organizing, planning, and conducting open technical meetings and less structured "listen-and-learn" sessions
- Leverage agency investments, funding mechanisms, and partnerships with non-profit consortia and academia to define research priorities, create workforce-development training courses, and facilitate short-term sabbaticals for reviewers and inspectors

CDER Response

- Consortia can apply to ETP to discuss and get recommendations from ETP
- ETP 2.0 focuses on enhanced communications
- OPQ already supports extramural research and training in advanced manufacturing areas

<u>Additional opportunities under consideration:</u>

- Further improve knowledge transfer from intramural and extramural research to aid quality assessment of new technologies
- Offer more training opportunities to assessor and investigators

Expand the leadership role in global regulatory harmonization efforts

NASEM Recommended Opportunities

- Increase dedicated resources and incentives to support greater emphasis on consistency in implementation of existing ICH guidelines and to enable leadership in ICH working groups
- Pursue more direct interaction with key regulatory agencies through information exchange, training, and mechanisms to support mutual recognition programs for inspections
- Emphasize advancement of innovative manufacturing technology as an explicitly purpose and benefit of harmonization activities

CDER Response

- OPQ already works with ICH to develop guidelines on:
  - *Continuous Manufacturing of Drug Substances and Drug Products (ICH 13)*
  - *Analytical Procedure Validation and Development (ICH Q2(R2) and Q14)*
  - *Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (ICH Q5A(R1))*
- OPQ already shares its learning and expertise in advanced manufacturing with international regulators
- Work continues with other regulatory agencies to move toward global regulatory convergence through a variety of additional venues (e.g., PIC/S, ICMRA)