Advancing Pharmaceutical Quality

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Everyone deserves
confidence in their *next* dose
of medicine.
Pharmaceutical quality
assures the
availability,
safety,
and efficacy
of *every* dose.

OPQ's Quality Assessment

Integrated Quality Assessment (IQA)

- OPQ Director
  - Deputy Director for Science
    - Office of Program and Regulatory Operations (OPRO)
    - Office of Product Quality Assessment I (OPQA I)
    - Office of Product Quality Assessment II (OPQA II)
    - Office of Product Quality Assessment III (OPQA III)
    - Office of Pharmaceutical Manufacturing Assessment (OPMA)

Purpose for the OPQ Transformation

- Enable OPQ to carry out its 2023-2027 Strategic Plan and meet our vision and mission
- Increase our ability to respond to changes in an evolving workload, increasing complexity of pharmaceutical supply chains, and public health emergencies
- Create a more agile, connected, and influential organization

OPQ Assessment Future State Vision

OPQ's Lifecycle Approach: To efficiently and effectively manage and conduct quality assessment for small or large molecules through the entire process from IND to NDA or BLA, Biosimilars and ANDAs, and all post-approval changes.

- Provides holistic perspective to enhance decision-making ability
- Leverages knowledge across user fee programs and applications
- Promotes agility within assessment offices
- Broadens capabilities improving our ability to balance workload

OPQ Year in Review: The Numbers

AGILE

- **>1,000** drug product approvals
- **~15,000** supplement assessments
- **25** proposals accepted by Emerging Technology Program
- **15** expedited assessments due to hurricanes

CONNECTED

- **>70** inspections
  - **13** states, **24** countries
- **10** guidance documents
- **5** Manuals of Policies and Procedures (MAPPs)
- **~50** peer-reviewed scientific articles

INFLUENTIAL

- **3** ICH documents implemented
  - Q2(R2), Q14 & Q5A(R2)
- **2** international pilot programs
  - Post approval & hybrid inspections
- **9** establishments assessed in Quality Management Maturity Program

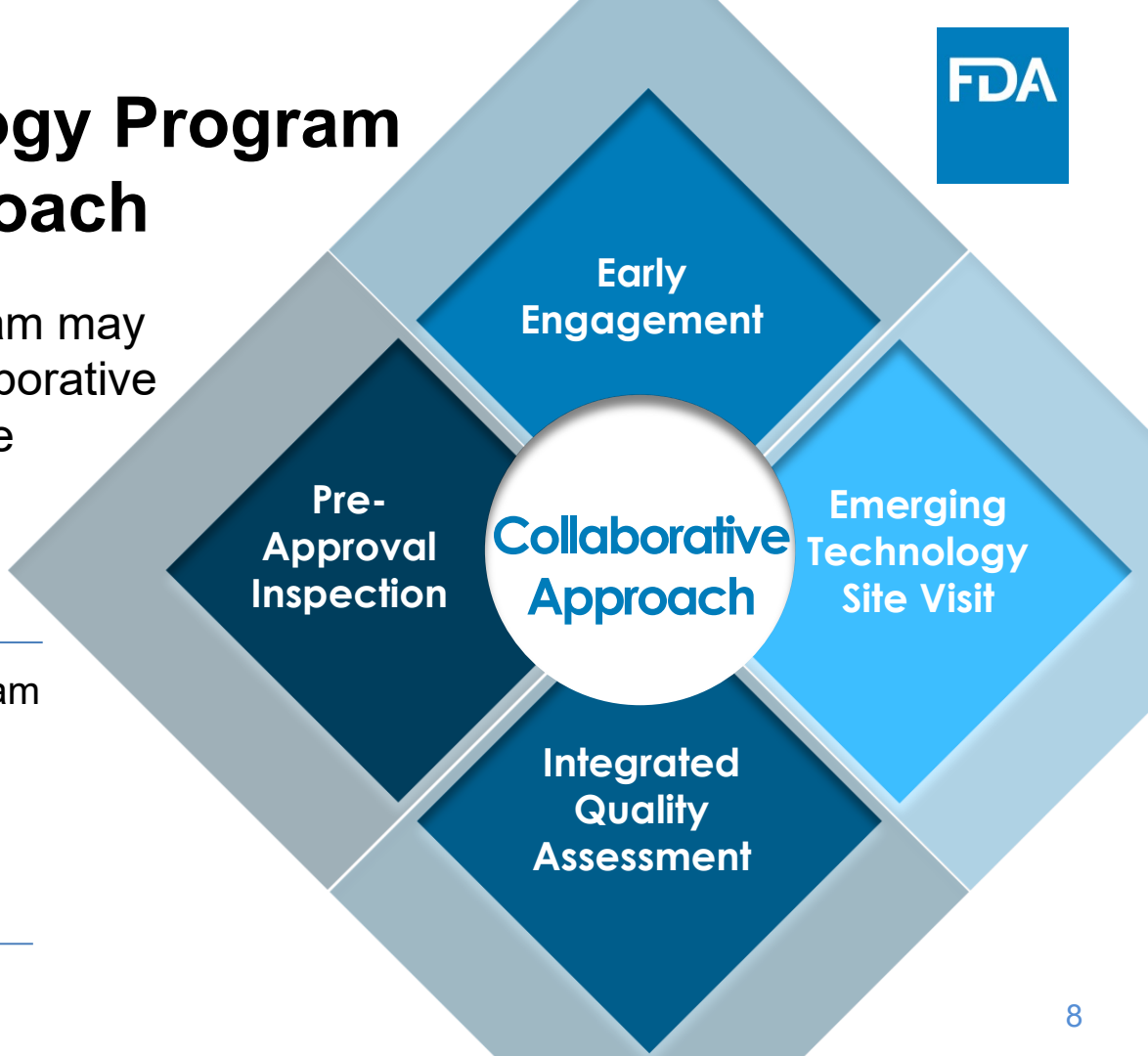
The Emerging Technology Program

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

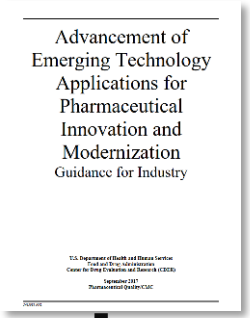
Emerging Technology Program Collaborative Approach

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.



Ten Years of the ETP


Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization
Guidance for Industry

CM Analysis Impact

2014

First ETT Approval

3D Printing Approval

2016

First approval Switch from Batch to CM

First CM Approval for Protein

2018

2020

10th Approval

First CM approval for an API

2022

First Approval for a CMO for CM

2024

24th Approval

ETT By the Numbers

Metric	Total Number
Accepted Meeting Requests	183
Site Visits	25
Approved Applications	24
Programs by Technology Type	68 Continuous Manufacturing 22 Analytics 20 Unique Operation 16 Aseptic Technology 15 Novel Dosage Form 9 Modeling/Simulation/AI 5 Distributed Manufacturing
Number of Graduated Technologies	3

** Numbers as of December 2024

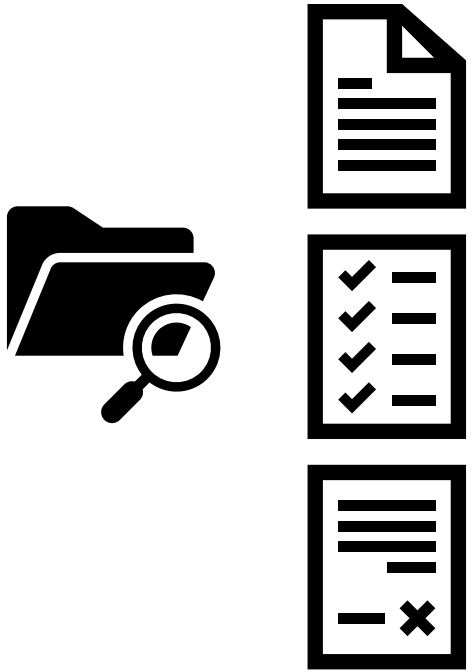
Continuing Pharmaceutical Quality

- Quality information in generic drug applications (e.g., Considerations of Drug Product Labeled for Alternate Dosing Administration)
- Best practices for ensuring product safety and compliance with evolving nitrosamine-related regulations

Continuing Pharmaceutical Quality

- Deficiencies in ANDAs, DMFs, and drug manufacturing processes

- Current GDUFA III data and best practices for industry




No one can assure drug quality alone.
We must work together.
Collaboration is critical.


FDA
U.S. FOOD & DRUG
ADMINISTRATION