

# Advancing Pharmaceutical Quality

**Geoffrey Wu, Ph.D.**  
Director  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

**Generic Drug Forum 2025**  
**April 9, 2025**

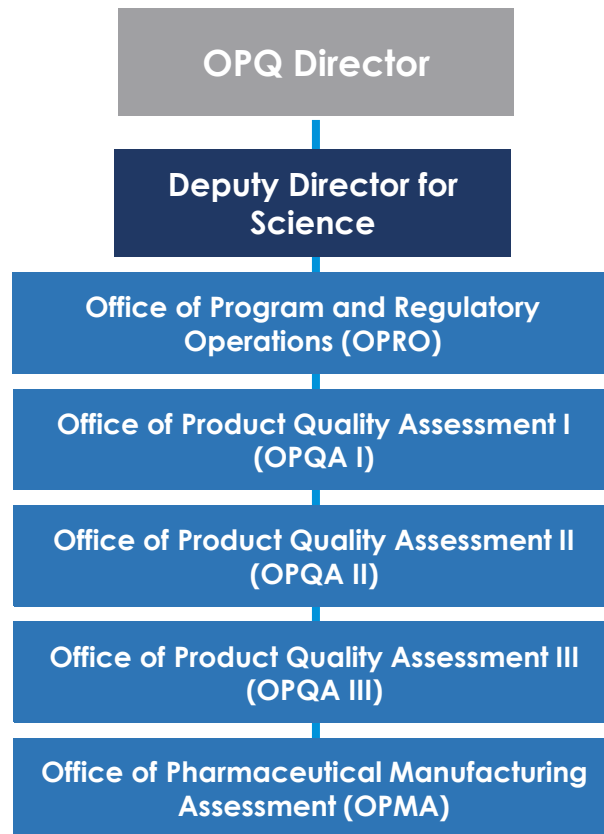


Everyone deserves  
confidence in their *next* dose  
of medicine.

**Pharmaceutical quality**  
assures the  
availability,  
safety,  
and efficacy  
of *every* dose.

# OPQ's Quality Assessment

Integrated Quality Assessment (IQA)



# 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



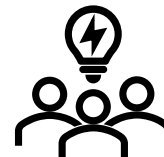
## CONNECTED

- **>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



## Mission

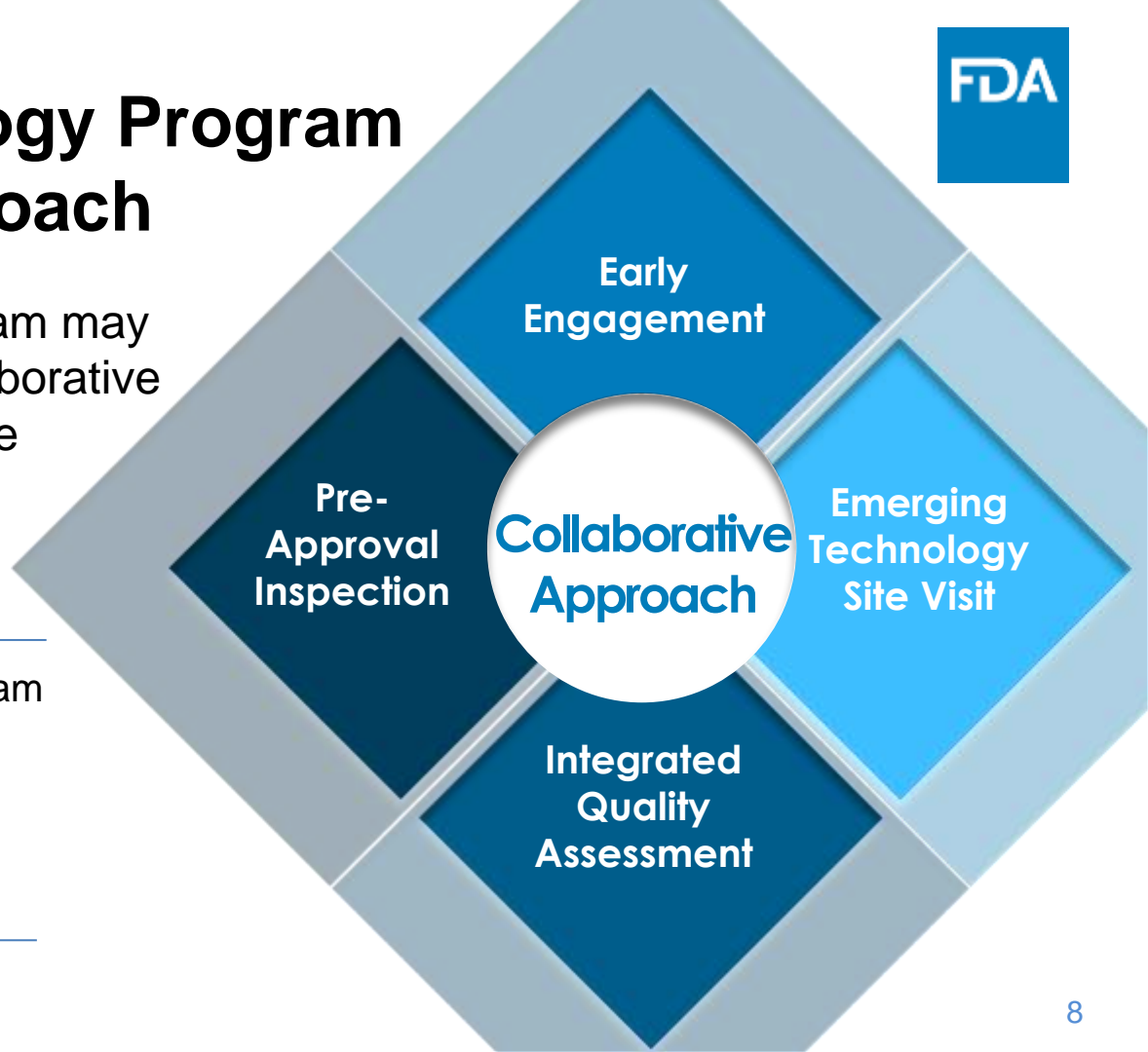
Encourage and support the adoption of innovative technology to modernize pharmaceutical development and manufacturing through close collaboration with industry and other relevant stakeholders

# Emerging Technology Program Collaborative Approach

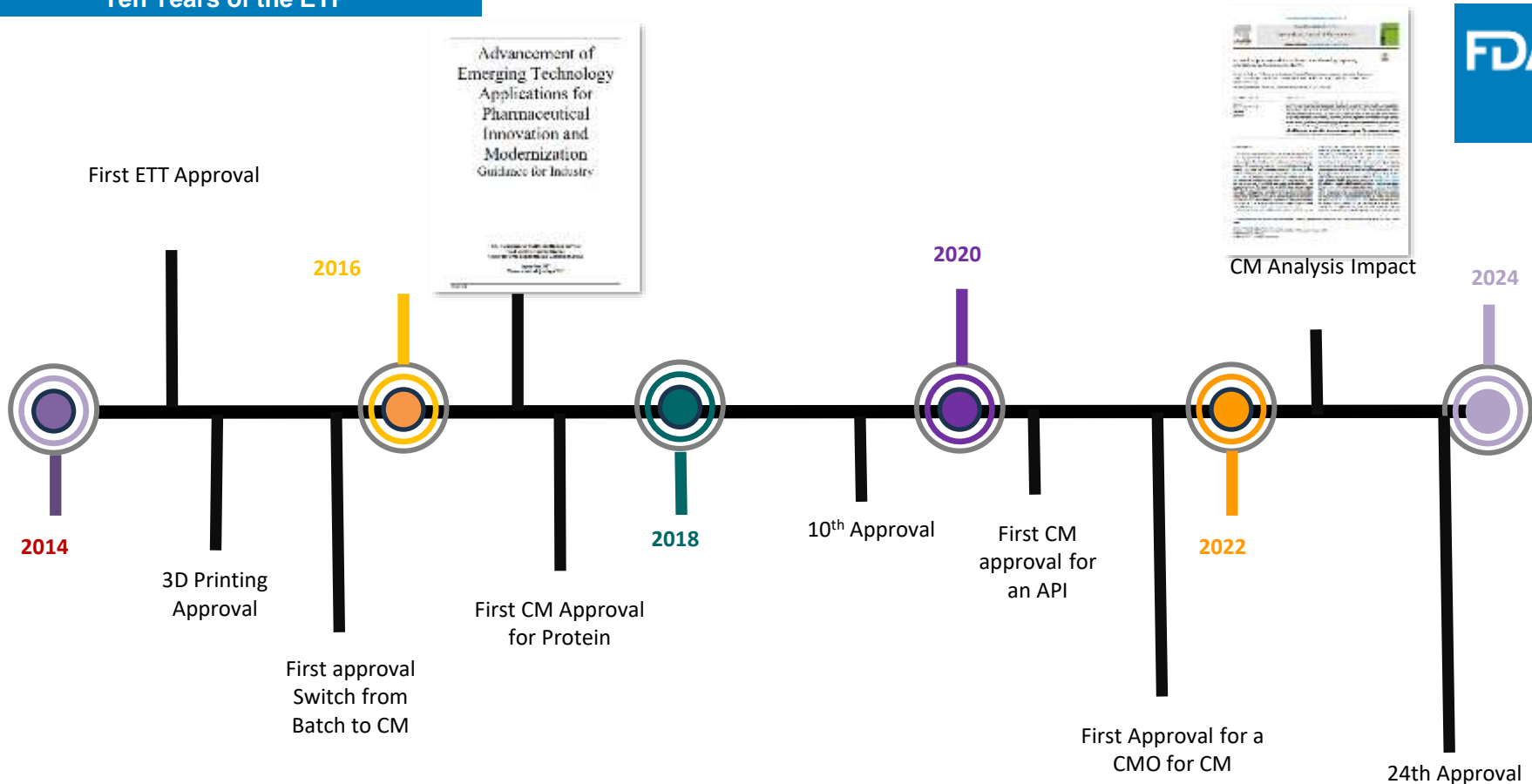
The Emerging Technology Team may employ a combination of collaborative approaches to engage with the technology.



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









# 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

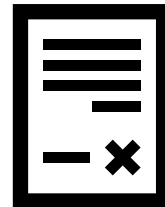
# Continuing Pharmaceutical Quality

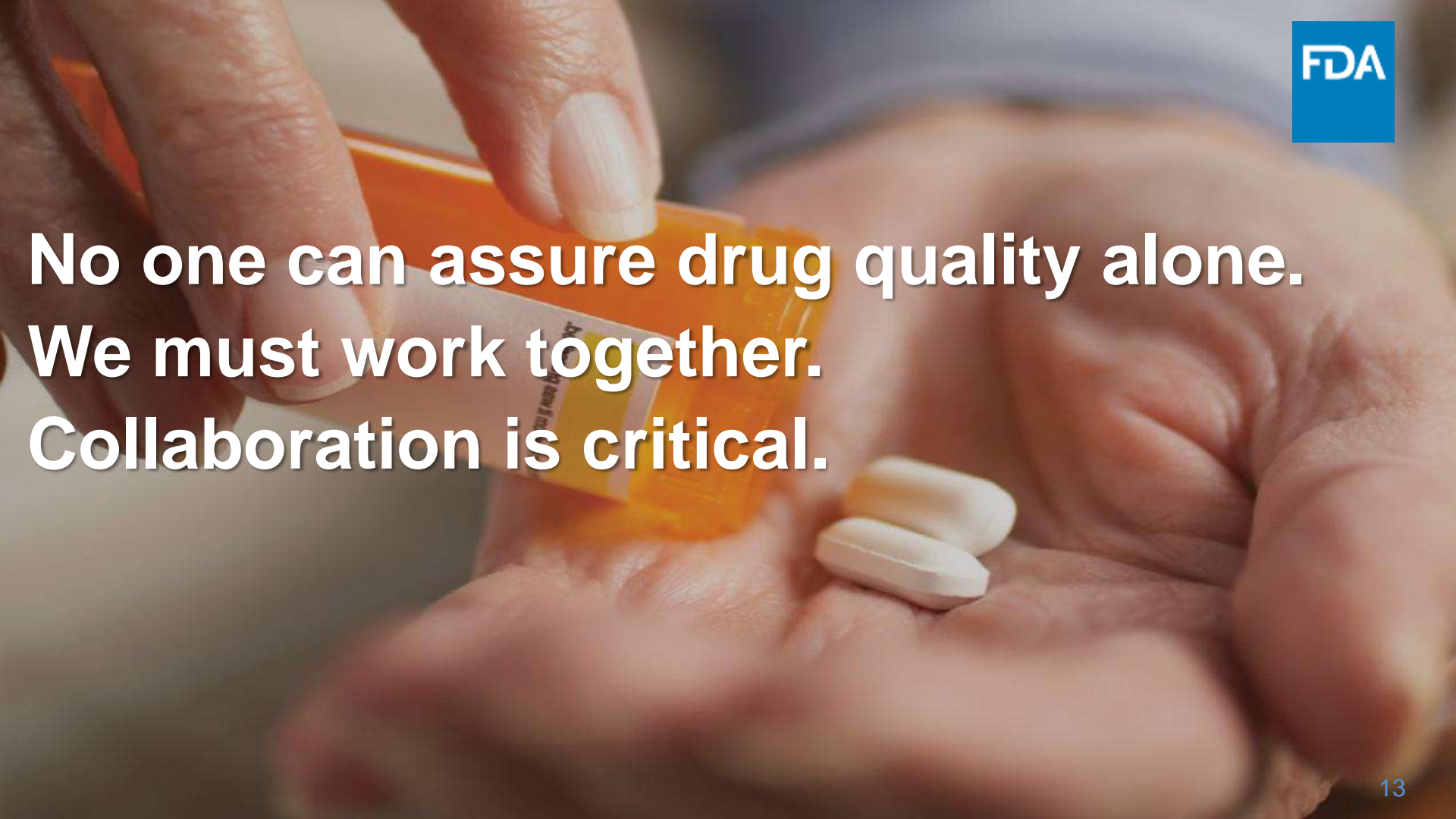
- Quality information in generic drug applications (e.g., Considerations of Drug Product Labeled for Alternate Dosing Administration)
- Best practices for ensuring product safety and compliance with evolving nitrosamine-related regulations



# 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.**

