

# **The Importance of Quality in Our Medicines**

## **Join Us in a Commitment to Quality**

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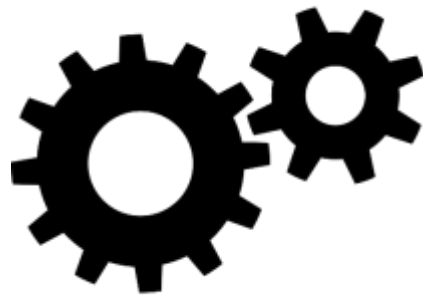
# Outline



- **Pharmaceutical Quality: What It Means**
- **U.S. FDA's Office of Pharmaceutical Quality (OPQ)**
- **OPQ's Strategic Priorities**
- **Conclusions**

# Learning Objectives

- Understand what is meant by ‘pharmaceutical quality’
- Learn and appreciate the priorities of the FDA’s Office of Pharmaceutical Quality



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# Pharmaceutical Quality

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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.

# A History of Quality Events



**Congress and FDA have acted because companies failed to adequately ensure quality**

**1938**

>100 deaths from elixir sulfanilamide

1938 Food, Drug, and Cosmetic (FD&C) Act

**Safety studies required for new drugs**

**1962**

Children born with severe birth defects from thalidomide

1962 Kefauver-Harris Amendments to the FD&C Act

**Need to prove that drugs are safe and effective**

**2015**

Serious injuries and deaths from global heparin crisis

FDA establishes Office of Pharmaceutical Quality

**Integrates functions and elevates FDA's commitment to quality**



Congressional Hearing April 29, 2008

**I watched my husband and my best friend slip away before my eyes.**

**As a nurse, I thought that I would be there to save my husband from any errors, but I guess I was naïve.**

**I never thought the life-saving medication we were relying on might be contaminated.**



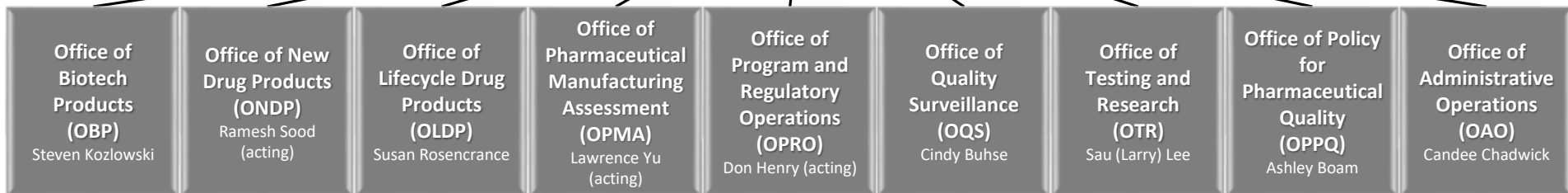
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# U.S. FDA's Office of Pharmaceutical Quality

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# Office of Pharmaceutical Quality





Performs the duties as prompt scientific staff work/evaluating & assessing data in preclinical  
 development, NDAs, ANDAs, BLAs, supplements



# One Quality Voice

FDA



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# OPQ Strategic Priorities: 2018-2022



**COLLABORATE:** Strengthen OPQ's collaborative organization

**INNOVATE:** Promote availability of better medicines

**COMMUNICATE:** Elevate awareness and commitment to the importance of pharmaceutical quality

**ENGAGE:** Strengthen partnerships and engage stakeholders



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## **COLLABORATE**

**Strengthen OPQ's collaborative organization**

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# Quality Assessment: By the Numbers



Around **1,400** staff in OPQ

## SESSION 4: Happenings in Biologics: Biosimilars and Transition Products

- Around **4,000** generics
- Around **7,000** supplements

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## **INNOVATE**

**Promote availability of better medicines**

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Small Molecules



Biological Molecules



## SESSION 3: Emerging Technologies and the FDA

continuous manufacturing

- Continuous aseptic spray drying
- 3D printing manufacturing
- Ultra long-acting oral formulation

- Continuous manufacturing for a downstream process
- End-to-end integrated bioprocess
- Pharmacy-on-demand

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## **COMMUNICATE**

**Elevate awareness and commitment to the  
importance of pharmaceutical quality**

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# WE WANT YOU



# COMMITMENT TO QUALITY

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## ENGAGE

**Strengthen Partnerships and Engage Stakeholders**

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# Do You Have...

## **SESSION 2: Quality Beyond Application Approval**






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## Conclusions

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A close-up photograph of a person's hands. One hand is holding an orange plastic pill bottle, tilted to pour white, oval-shaped capsules into the palm of the other hand. The background is blurred, focusing attention on the action of taking medication.

**We can't do this alone**  
**Join us in a commitment to**  
**pharmaceutical quality**

# Challenge Question

- Is this statement true or false?

***“Quality is a concept unique to manufacturing pharmaceuticals.”***

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



# Challenge Question

- Which of the following is NOT a strategic priority of OPQ?
  - COLLABORATE
  - INNOVATE
  - CONSTIPATE
  - COMMUNICATE
  - ENGAGE



# A Shared Responsibility



**With a focus on patients and consumers, *together* we can provide them confidence in their *next* dose.**



