

# **Pharmaceutical Quality:** *Innovations in a Changing World*

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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.**

A close-up photograph showing a hand holding an orange pill bottle, tilted to pour three white, oval-shaped pills into the palm of another hand. The background is blurred, focusing attention on the action of taking medication.

**Patients expect safe and effective  
medicine with every dose they take**

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

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

# Quality, Manufacturing & Supply Chain



# Learning from the COVID-19 Public Health Emergency

Session 1: 9:20-12:05

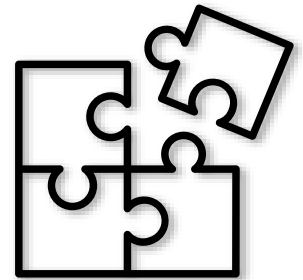
# Learning from COVID-19

- **Communication was critical**
  - Over 30 [guidance documents](#) since the start of the pandemic
    - Hand sanitizers, manufacturing & supply chain, monoclonal antibodies
- **Collaboration was essential**
  - CDER and ORA worked closely together
    - Determining mission criticality
    - Conducting inspections with travel restrictions
    - Using remote regulatory assessments



# Evaluating Facilities in a Pandemic

- **Innovation was needed**
  - FDA relied heavily on “alternative tools” to inspections
    - Requesting information in lieu of an inspection
    - Remote Interactive Evaluations (RIEs)
- **Engagement with international regulatory partners was vital**
  - Mutual Recognition Agreements (MRA)
    - Reports from other trusted regulatory partners





# Innovations at FDA

Session 2: 12:35-16:00

# Innovations at FDA



## Knowledge-Aided Assessment & Structured Application (KASA)

Management of quality risks across drug products and facilities

## Quality Surveillance Dashboard (QSD)

Framework for the surveillance of CDER-regulated facilities

## CARES Act

Portal to collect the amount of drugs by registrant

## Quality-Related Compliance

Innovations fuel facility compliance and enforcement actions

## International Harmonization

The importance of regulatory harmonization and convergence

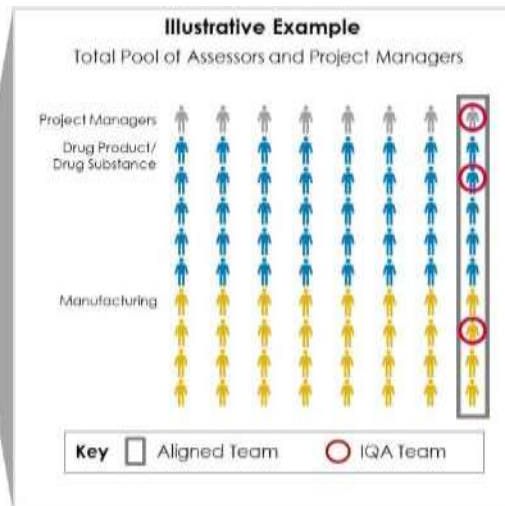
## Quality Management Maturity (QMM)

Ratings to inform purchasers about facilities making drugs

## Integrated Quality Assessment (IQA): Aligned Teams

Smaller, more stable pools of interdisciplinary assessment staff for applications

# The Aligned Teams Solution



Application Type	Aligned Teams Launch Date	Related UFA Programs
BLA	6/22/20	PDUFA BsUFA
ANDA	8/10/20	GDUFA
NDA	9/13/21	PDUFA



# A Foundation of Science

Session 3: 8:55-12:00

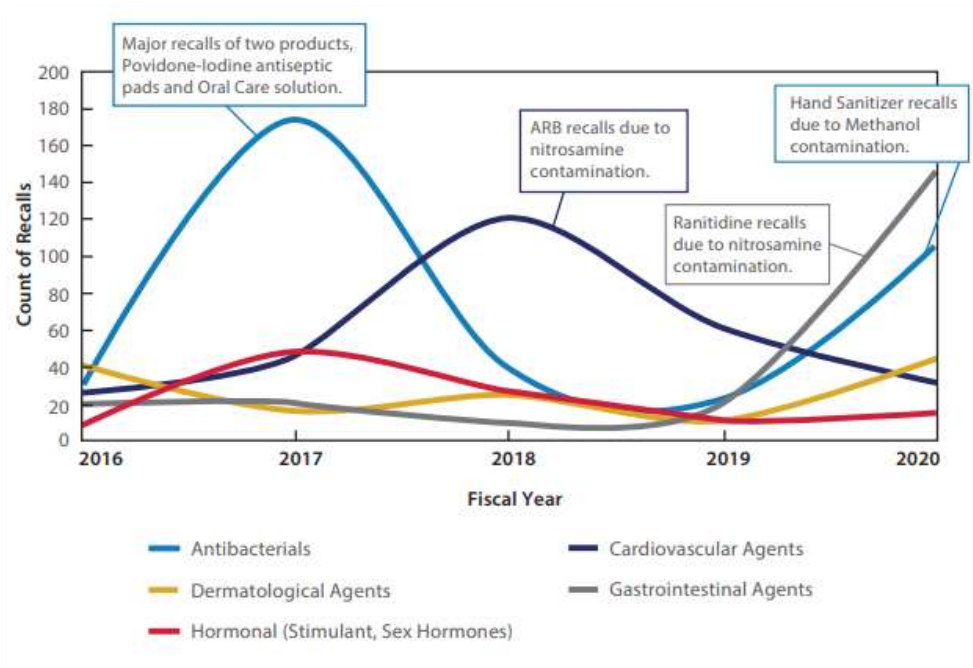
# Research Fuels Approvals



- Laboratory facilities in **Silver Spring, MD** and **St. Louis, MO**
- Research **enables the approval** of complex medicines



# The State of Pharmaceutical Quality





# Advancing Advanced Manufacturing

Session 4: 12:30-15:15

# Advanced Manufacturing Benefits



**Advanced manufacturing** can improve manufacturing and ensure quality medicine is available.

-  **Produce better quality medicine.** Facilitates six-sigma operation, no more than 3.4 defects per 1M opportunities.
-  **Re-shore drug manufacturing facilities.** Helps domestic drug manufacturers compete in a global market.
-  **Develop drugs rapidly.** Speeds the development of novel or patient-focused therapeutics.
-  **Prevent drug shortages.** Reduces today's quality-related manufacturing issues causing 62% of drug shortages.
-  **Improve emergency preparedness.** Provides more agility and flexibility to help pivot in a public health emergency.

# Advancing Advanced Manufacturing

**Advanced manufacturing** is providing quality drugs to patients with cystic fibrosis, HIV, breast cancer, leukemia, and asthma.





**In Closing**



We were all forced to solved the  
problems of a changing world.

Now let's continue to *innovate*  
today to improve the quality of  
medicine tomorrow.

