CDER's Commitment to Pharmaceutical Quality

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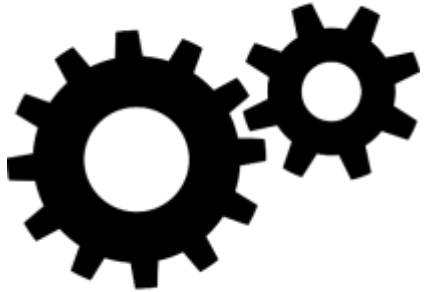
The Importance of Pharmaceutical Quality

- Pharmaceutical quality is what assures drugs ***on the market*** are safe and effective
- When quality goes wrong, everything can go wrong
- As we improve patient access to medicine, **we cannot sacrifice quality**

Learning Objectives

- Understand CDER's overall pharmaceutical quality program
- Learn the tools used to regulate pharmaceutical quality



CDER's Quality Program

CDER's Tools for Regulating Quality

Inspection

Assessment

Engagement

Surveillance

Outreach

Enforcement

Policy

Testing

Research

2019 Pharmaceutical Quality Symposium

1. Manufacturing and the Quality Assessment of Applications
2. Quality Beyond Application Approval
3. Emerging Technologies and the FDA
4. Happenings in Biologics: Biosimilars and Transition Products

Changes Are Needed

INTERNAL CHANGES

Modernizing Programs

- New Drugs Regulatory Program

Investing in IT Solutions and Tools

- Knowledge-aided Assessment and Structured Application (KASA)

Improving Inspections

- New Inspection Protocol Project (NIPP)

EXTERNAL CHANGES

Spurring Industry Innovation

- Emerging Technology Program

Encouraging Quality Culture and Quality Management Maturity

- Quality Metrics Feedback Program

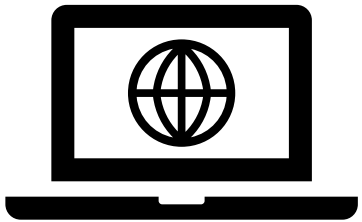
The Solutions

Modernization of the New Drugs Regulatory Program

- Therapeutically focused divisions
- Centralized project management organization
- Multidisciplinary, issue-based process for review of BLA/NDA
- Standardized first-in-humans and efficacy trial protocol review process and template

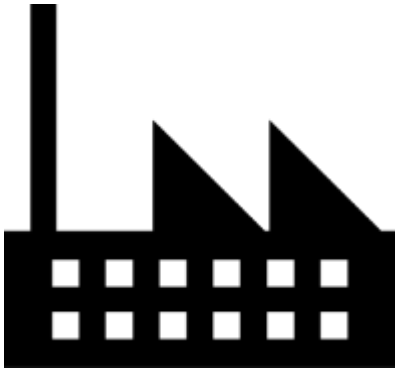
CDER's Technology Solutions

- IT portfolio organized around technology-enabled capabilities:
  - Application assessment (e.g., KASA)
  - Knowledge management
  - Safety signal management
  - Workflow management
- Development of new IT platforms and applications



FDA's New Inspection Protocol Project (NIPP)

- ORA and CDER paradigm to better assess and record the state of quality in manufacturing facilities
- NIPP uses **standardized electronic inspection protocols** and **templated semi-automated inspection reports**



CDER's Emerging Technology Program

- Supports industry's development and implementation of innovative approaches in **pharmaceutical design and manufacturing**
- Identifies and **resolves potential scientific and policy issues** related to new approaches

Manufacturers Must Take Ownership for Quality

- **Executive Management and Quality Culture**
  - Management sets the tone
  - Invest in people
  - Organizational objectives drive quality
  - Quality systems shape culture
  - Focus on innovation and continual improvement
  - Move to performance-based quality management


Everyone has a role to play.
Join us in a commitment to pharmaceutical quality.
Together we can give patients improved access to medicine without sacrificing quality.

Challenge Question

- Is this statement true or false?

  "CDER uses application assessments and inspections as tools to regulate quality."

- This is **TRUE**. However, these are not the **ONLY** tools.
- We have many other tools including surveillance, research, outreach, IT, and policy.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