FDA Center Updates: CDER

Douglas C. Throckmorton MD
Deputy for Regulatory Programs, CDER FDA

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Central Messages

- FDA is committed to the thoughtful regulation of innovative medical products
- Innovative and ongoing activities chosen to illustrate ongoing CDER support for innovation in processes and policies related to quality manufacturing:
  - Process improvement
  - Policy development and coordination
  - Engagement

Pharmaceutical Quality for the 21st Century

- *A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight*

--Janet Woodcock MD, Director, CDER FDA

Understanding Manufacturing through Quality Metrics

- Goals:
  - Get additional quantitative and objective insight into the state of quality for product and facility
  - A new approach for regulatory oversight of pharmaceutical products
    - Enhance risk-based surveillance inspection scheduling model
    - Improve effectiveness of inspections
  - Help to identify factors leading to supply disruption/shortage
- Part of larger quality systems work including Pharmaceutical Quality Systems, supporting the goals of ICH Q10, and recognizing the importance of quality culture

Understanding Manufacturing through Quality Metrics (cont)

- Progress--2 new QM efforts underway:
  - Feedback Program
    - FDA seeking information from drug manufacturers that have implemented and are currently using quality metrics programs
    - Any data shared is for demonstration/informational purposes only
    - The pilot program will close July 29, 2019
  - Site Visit Program
    - Provides on-site learning for FDA staff on industry use of QMs
    - Provides stakeholders with the opportunity to explain the advantages and challenges they've experienced with their quality metrics programs
    - Window for proposals extended to December 17, 2018
- Ongoing academic collaboration with St. Gallen University

Understanding New Science: Emerging Technology Team (ETT)

- Goals:
  - Supporting industry's development and implementation of innovative approaches in pharmaceutical design and manufacturing
    - Examples: continuous manufacturing, 3-D printing, closed aseptic filling systems, ultra-long-acting formulations
  - To identify and resolve potential scientific and policy issues related to new approaches in manufacturing
    - Help FDA reviewers familiarize themselves with the new technologies and determine how they may be evaluated within the existing regulatory framework to speed innovation

Emerging Technology Team (cont)

- Progress:
  - A website and Guidance for Industry are posted
  - Three grants awarded to improve FDA readiness in this area, using our authority under the 21st Century Cures Act, to:
    - Rutgers University
    - Massachusetts Institute of Technology
    - Georgia Institute of Technology
  - Continued work with industry partners through stakeholder meetings and interactions
    - 12 meetings so far in 2018
    - Plans to work with other regulatory agencies and industry to develop common guiding principles for continuous manufacturing through ICH (ICH Q13)

Regulatory Harmonization: ICH Q12

- Goals:
  - To enable quicker post-approval changes to manufacturing internationally
  - To further incentivize manufacturers to make improvements, increase process robustness, and facilitate change implementation

- The objectives of ICH Q12 are to:
  - Harmonize change management in a more transparent and efficient manner
  - Facilitate risk-based regulatory oversight
  - Emphasize control strategy as a key component of the dossier
  - Support continual improvement and facilitate introduction of innovation
  - Enhance use of regulatory tools for prospective change management enabling strategic management of post-approval changes

ICH Q12 (cont)

- Progress:
  - Guidance released for comment May 2018
    - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609205.pdf

Improving FDA Review Process: KASA

- Knowledge-Aided Assessment and Structured Application (KASA) initiative
- Goal
  - Enhanced submission format for quality submissions to improve the efficiency and consistency of regulatory quality assessment

KASA (cont)

- The KASA system uses IT structures to move away from paper-based review:
  - Capture and manage knowledge - such as established conditions - during the lifecycle of a drug product
  - Establish algorithms for risk identification, mitigation, and communication
  - Perform computer-aided analyses of applications to compare regulatory standards and quality risks across approved applications and facilities; and
  - Provide a structured assessment tool that radically eliminates text-based narratives and summarization of provided information
- Progress:
  - Advisory Committee September 20, 2018

Conclusions

- CDER is working to support innovation throughout the product lifecycle and across Safety, Efficacy, and Quality domains
- For Quality, supporting innovative manufacturing and controls systems is a priority for FDA
  - Progress in policy and process
  - Continued stakeholder engagement

Thank You