

Center Updates: CDER

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September 12, 2017

Central Messages

- Three innovative and ongoing activities chosen
- Focus on illustrating CDER support for product quality and innovation through
 - Process improvement
 - Targeted new resources

Concept of Operations for Facility Evaluations

- Goals:
 - Improved consistency, efficiency, and transparency in facility evaluations, inspections, and regulatory decision-making for marketing applications
 - Improved FDA's operational capacity by eliminating overlap of effort amongst various CDER and ORA offices
- Progress (with ORA and OC):
 - Designed the processes for pre-approval and surveillance inspections
 - Defined/Clarified the roles and responsibilities of CDER and ORA
- Next Steps: Continue to work on implementation plan

New Inspection Protocol Project

- Goal:
 - Enhanced inspectional assessments
 - Enhanced production, utility, and consistency of the establishment inspection reports
- Progress:
 - In 2016, in collaboration with ORA and OC, OPQ
 - Completed pilot for sterile drug process facilities
- Next Steps: 2nd Pilot, Work on Inspection Protocols

Emerging Technology Team (ETT)

- Goals:
 - Supporting industry’s development and implementation of innovative approaches in pharmaceutical design and manufacturing
 - Shared learning about challenging areas: packaging, continuous manufacturing, delivery systems.....
 - Identifying/Resolving potential scientific and policy issues related to the new approach
- Progress:
 - In 2016, OPQ
 - Enabled the approval of the first switch from batch to continuous manufacturing process for an approved drug
 - Accepted 15 projects into the ETT on a variety of innovative technologies
- Next Steps: Continued meetings. Docket open for comment to help us on our approach*. Working on Draft ETT Guidance.

*<https://www.gpo.gov/fdsys/pkg/FR-2017-06-23/html/2017-13195.htm>

Conclusions

- Supporting innovative manufacturing and controls systems is a priority for FDA

Thank You

