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ORA and CDER:
A New Concept of Operations (ConOps)

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- On June 6, 2017, FDA's Office of Regulatory Affairs (ORA) and Center for Drug Evaluation and Research (CDER) entered into a concept of operations (ConOps) agreement, designed to facilitate increased coordination and collaboration between investigators and review staff.
  - For preapproval inspections, CDER and ORA will form Integrated Quality Assessment Teams, consisting of CDER review staff and ORA investigators. CDER and ORA will take a similar approach to post-marketing inspections.
  - ConOps outlines workflows and responsibilities between ORA and CDER staff in decision trees for pre- and post-approval, surveillance, and for-cause inspections.
  - ConOps implements FDA's GDUFA II commitment to communicate final inspection classifications within 90 days, and extends that commitment to branded drugs.
  - FDA expects to produce Establishment Inspection Reports, facility classifications, and Warning Letters more quickly under this approach.
- ConOps follows reorganization of ORA from a geographically-aligned structure to a program-aligned structure, and is part of FDA's broader program alignment initiative.

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- ConOps is a step toward addressing difficulties faced by industry during the inspection and review process.
  - Lack of alignment between CDER staff and ORA inspectors and compliance officers has resulted in inconsistency and delays in FDA's evaluation of pre-approval inspections and post-market enforcement decisions.
  - Marketing applications have increasingly been stalled by manufacturing facility cGMP issues. In 2016, the number of complete response letters issued by CDER increased to 14, with cGMP issues often the primary deficiency.
- Review and inspection will occur simultaneously, rather than in a stepwise fashion.
- Industry will be able to engage with specialized ORA staff experienced in the subject-matter relevant to their products or product candidates.