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ConOps 2.0: FDA Updates Its Drug Facility Evaluation and Inspection Playbook

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The Food and Drug Administration (FDA) has **published** an updated version of "Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations" (ConOps). The ConOps is the agreement between the Center for Drug Evaluation and Research (CDER) and the Office of Inspections and Investigations (OII) that sets out how the two agency components coordinate marketing application assessments, inspections and related compliance activities. It applies to preapproval, postapproval, surveillance and for-cause inspections of human drugs. "ConOps 2.0" took effect on October 21, 2026, and replaces the original June 2017 version. While its title sounds technical, for products regulated by CDER, it provides valuable background into how inspection and compliance related activities are managed within the agency.

The ConOps governs who at FDA decides whether a site gets inspected, what investigators look at and how quickly a manufacturer learns where it stands. FDA identifies three key updates: alignment with the agency's October 2024 reorganization, the addition of remote regulatory assessments (RRAs) and Mutual Recognition Agreement (MRA) inspection reports as evaluation tools, and clearer roles and responsibilities for every inspection type.

FDA lists the goals of ConOps to manage the growing complexity of the pharmaceutical landscape by:

- Standardizing risk-based FDA oversight.
- Clarifying CDER and OII responsibilities.
- Improving coordination and reducing duplication.
- Expanding access to regulatory information.

- Meeting user fee commitments and accelerating regulatory actions.

The ConOps keeps the basic structure of the 2017 model. CDER, mainly through the Office of Pharmaceutical Quality (OPQ) and the Office of Compliance (OC), decides what needs to be evaluated and makes final regulatory determinations. Below are the various inspections and their purposes:

- **Preapproval.** CDER conducts preapproval evaluations to decide whether a preapproval inspection (PAI) or an RRA is needed.
- **Postapproval.** Postapproval inspections focus largely on the process validation lifecycle and on manufacturing changes made after approval. A change in perceived risk can also trigger one, even where FDA did not find a PAI necessary.
- **Surveillance.** Surveillance inspections are system-based Current Good Manufacturing Practice (CGMP) inspections rather than reviews of a specific drug. Before a surveillance inspection, the Office of Quality Surveillance (OQS) may prepare a Site Dossier on request. The dossier can cover inspection history, recalls, shortages, complaints, foreign regulatory inspection outcomes, Field Alert Reports and Biological Product Defect Reports, and a list of all drug products made at the site.
- **For-Cause.** For-cause inspections respond to specific events or information that raise questions about compliance or quality.

At the close of an inspection, investigators issue a Form FDA 483 if they identify significant objectionable conditions. Inspections ultimately receive one of three classifications: No Action Indicated (NAI), Voluntary Action Indicated (VAI) or Official Action Indicated (OAI). The ConOps notes that a final OAI classification can lead to regulatory action and FDA may hold the release of the Establishment Inspection Report (EIR) until such action is determined.

ConOps 2.0 applies to both domestic and international facilities; it does not create a separate track for foreign sites. The document notes that FDA may use recent inspection reports from MRA partners (such as the European Union (EU), Switzerland and the U.K.) to assess CGMP compliance and support application recommendations. Unlike RRAs, MRA inspection reports can fulfill the inspection requirements under section 510(h) of the Federal Food, Drug and Cosmetic Act.

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