

## FDA Fact Sheets: Postmarket Inspections

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FDA inspects medical device manufacturers to evaluate their compliance with the Quality System (QS) regulation and other pertinent requirements. Inspections assess the firm's systems, processes and procedures to ensure that manufacturers can produce devices in a consistent manner that meets all specifications.

Routine QS inspections are typically preannounced, but the notice varies depending on the nature of the inspection and the facility location. FDA inspections follow a risk-based schedule that accounts for factors such as the establishment's compliance history, recalls linked to the establishment, and the risk of devices manufactured at the establishment. Manufacturers of low-risk devices are not routinely inspected unless there is a specific cause for the inspection or a possible health hazard.

Routine inspections follow a "top-down" approach – known as the Quality System Inspection Technique (QSIT) – that starts with a review of the company's quality systems rather than with specific problems. The investigator may notify the establishment about possible violations during and at the end of the inspection.

FDA conducts different types of medical device inspections depending on the reason for the inspection:

- **Level 1 (Abbreviated):** Used for routine surveillance and initial inspections of medium-risk device manufacturers if a Level 2 inspection cannot be conducted;
- **Level 2 (Comprehensive):** Used for initial inspections of high-risk device manufacturers, initial inspections of medium-risk device manufacturers when resources permit, foreign inspections, and in other specified circumstances;
- **Level 3 (Compliance Follow-Up):** Used if the previous inspection found serious violations and when directed by assignment; and
- **For Cause:** Carried out in response to specific questions, concerns or problems with an FDA-regulated firm or device. May be triggered by results of a sample analysis, prior inspections, recall or market withdrawal, consumer or employee complaint, and suspicion of fraud.