



FDA Inspection Program for MDSAP-participating Firms

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Scope

MDSAP participating firms are not subject to FDA's routine surveillance inspections, however all other situations listed under the FDA's Compliance Program Guidance Manual (CPGM) 7382.845, Inspection of Medical Device Manufacturers, still apply.

Objectives

Discuss these situations that can lead to an FDA inspection:

- For Cause (with various scenarios)
- Risk Based Work Plan
- Pre/post-approval inspections
- Bioresearch Monitoring (BIMO)
- Compliance Follow Up inspections
- Electronic Product Radiation Control (EPRC)
- Inspections from other Centers

For Cause

For Cause inspections are carried out in response to specific information that raises questions, concerns, or problems associated with a FDA regulated firm or commodity. This information could come to the attention of FDA from any source and including, but not limited to, the following:

- Results of a sample analysis
- Observations made during prior inspections
- Recall or market withdrawal
- Consumer or employee allegation
- Adverse reaction report
- Suspicion of fraud

Risk Based Work Plan

The risk based work plan inspection program was developed to focus limited resources on key public health needs. It reflects the broader goals of the Center and Agency to utilize science-based risk management in the selection and prioritization of sites for inspection. This provides the most health promotion and protection to the public at the least cost by focusing on medical devices and firms which pose the greatest risk.

Data collected throughout the total product life cycle (e.g. premarket submissions, recalls, adverse event reports) is analyzed to detect risks posed by medical devices. The beneficial public health impact of the devices and the potential risks of device failure are also considered. In general, the project's objectives include the following:

- a more consistent, rigorous, science-based approach to selection of sites for inspection
- increased transparency and rigor in decision making
- employment of limited resources towards sites that pose the potentially greatest risk to public health

Pre/Post Approval Inspections

- In making the determination of the firm's ability to design, manufacture or process the device, CDRH may issue an inspection assignment to the appropriate FDA Division within the Office of Regulatory Affairs. The inspection assignment will be issued when CDRH has determined that the manufacturer has demonstrated in the PMA submission that the design and manufacturing process meets the QS regulation requirements and the facility is ready for inspection.
- Postapproval inspections are conducted within eight to twelve months of approval of the PMA submission. The inspection will primarily focus on any changes that may have been made in the device design, manufacturing process, or quality systems.

Bioresearch Monitoring (BIMO)

BIMO inspections involve evaluation of the clinical investigator's or sponsor-investigator's practices and procedures to determine compliance with applicable regulations.

- PMA or PMA Supplement
- PDP Notice of Completion
- IDE
- 510(k)

Compliance Follow Up

Compliance follow up inspections are necessary after a firm is found to have Situation I conditions during a previous QS inspection which was classified Official Action Indicated (OAI).

Electronic Product Radiation Control (EPRC)

- The intent of these requirements is to protect the public from unnecessary exposure to electronic products radiation.
- Manufacturers are responsible for producing products that do not emit hazardous or unnecessary radiation and that comply with all applicable radiation safety performance standards.
- All electronic product manufacturers must comply with applicable requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005.

Inspections from other Centers

- Center for Biologics Evaluation and Research (CBER)
 - Devices Regulated by CBER
 - The medical devices regulated by CBER are associated with blood collection and processing procedures as well as the cellular therapies regulated by CBER. CBER has developed specific expertise in blood, blood products and cellular therapies and the integral association of certain medical devices with those biological products supports the regulation of those devices by CBER.
 - Part 4, Combination products
- Center for Drug Evaluation and Research (CDER)
 - Part 4, Combination products

Questions?

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Press 1 to speak to the Consumer Team

Press 2 to speak to the Industry Team