

TABLE OF CONTENTS

Introduction **iii**

What to do and expect before, during and after an FDA investigator’s visit.

Inspection of Medical Device Manufacturers **Section 1**

This guidance document represents the agency’s current thinking on the enforcement of the Quality System (QS), Medical Device Reporting (MDR), Medical Device Tracking, Corrections and Removals, and the Registration and Listing regulations.

Guide to Inspections of Quality Systems **Section 2**

This document provides guidance to the FDA field staff on an inspectional process that may be used to assess a medical device manufacturer’s compliance with the Quality System Regulation and related regulations. The inspectional process is known as the “Quality System Inspection Technique” or “QSIT.”

Good Manufacturing Practice Regulations **Section 3**

Final rule implementing the Quality System Regulation, FDA’s core document on what it expects to see concerning management responsibilities, quality audits, personnel and training standards, design controls, purchasing controls, production and process controls, equipment and inventory controls, postmarket tracking, corrective and preventative actions and other areas.

Third-Party Inspections Guidance **Section 4**

Latest guidance on the qualification criteria and procedures for participating in the accredited persons inspections program.

Design Control Guidance for Medical Device Manufacturers **Section 5**

This guidance is intended to assist manufacturers in understanding quality system requirements concerning design controls. Assistance is provided by interpreting the language of the quality systems requirements and explaining the underlying concepts in practical terms.

**Likelihood of Inspection When Modifying
Devices Subject to Premarket ApprovalSection 6**

This guidance document represents the agency’s current thinking on various types of PMA submissions (including PDP and HDE submissions) and the corresponding factors that influence the likelihood that an inspection will occur.

**Quality System Regulation Information for Various
Premarket SubmissionsSection 7**

This guidance has been prepared by the Center for Devices and Radiological Health (CDRH), in coordination with the Center for Biologics Evaluation and Research (CBER), to assist medical device manufacturers in preparing and maintaining the QS information required in premarket submissions.

510(k) Sterility ReviewSection 8

Guidance on what is needed to show that a device subject to premarket notification meets FDA standards for sterility, including information on sterility assurance levels, validation methods, description of packaging and label samples.

Bioresearch Monitoring (BIMO) InspectionsSection 9

Seven guidances reflecting CDRH’s increased scrutiny of clinical trial facilities and practices. Guidances cover FDA’s expectations for in vivo bioequivalence; inspections of in vitro diagnostic devices; good laboratory practice in nonclinical laboratories; EPA data audit inspections of nonclinical laboratories; institutional review boards; sponsors, contract research organizations and monitors, and clinical investigators.

Mammography Quality Standards Act (MQSA) Auditor’s GuideSection 10

Guidance issued to MQSA auditors to help them implement the general audit requirements specified in Field Management Directive (FMD)-76, Evaluation of Inspectional Performance, Appendix D: Evaluation of MQSA Inspections. This document represents the agency’s current thinking on MQSA audits.

Guide to Inspections of Foreign Medical Device ManufacturersSection 11

This guide was prepared to address concerns about consistency and uniformity of inspection between the domestic and foreign inspection programs. Consistency and uniformity of inspection and enforcement represent high priority goals for the Office of Regulatory Affairs (ORA). This guide provides instructions regarding the approach to the foreign inspection.