

# Table of Contents

## **Introduction**

### **Section I – Quality Systems**

1. Inspection of Medical Device Manufacturers
2. Guide to Inspections of Quality Systems
3. Current Good Manufacturing Practice (CGMP); Final Rule
4. Design Control Guidance for Medical Device Manufacturers
5. Mammography Quality Standards Act (MQSA) Auditor's Guide

### **Section II – Third-Party Inspections Guidance**

1. Accredited Persons Inspection Program
2. Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria
3. Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program
4. Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program
5. Supporting Statement for Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program

### **Section III – Premarket Approval and 510(k) Guidance**

1. Likelihood of Inspection When Modifying Devices Subject to Premarket Approval
2. Quality System Regulation Information for Various Premarket Submissions
3. Updated 510(k) Sterility Review Guidance K90-1

### **Section IV – Bioresearch Monitoring (BIMO) Inspections**

1. Good Laboratory Practice (Nonclinical Laboratories)
2. Good Laboratory Practice Program (Nonclinical Laboratories) EPA Data Audit Inspections
3. Institutional Review Board

4. Sponsors, Contract Research Organizations and Monitors
5. Clinical Investigators

#### **Section V – Foreign Manufacturers**

1. Guide to Inspections of Foreign Medical Device Manufacturers