## **Medical Device Complaint Management:**

## **A Guide for Compliance**

## **Table of Contents**

Introduction		
The Rules of	Complaint Management	6
Elements of a	an Effective Complaint Management System	10
Recognizing	and Researching Complaints	17
Medical Devi	ce Reporting Requirements	22
Electronic Su	ıbmission of MDRs	27
From Compla	aint to Correction	30
Conclusion		33
Appendices		
Appendix A:	Code of Federal Regulations, Title 21, Part 803 – Medical Device Reporting	
Appendix B:	Code of Federal Regulations, Title 21, Part 806 – Medical Devices; Reports of Corrections and Ren	novals
Appendix C:	Code of Federal Regulations, Title 21, Part 820 – Quality System Regulation, Section 820.198 – Complaint Files	
Appendix D:	Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and I Staff	
Appendix E:	FDA Safety Information and Adverse Event Report Program, Forms 3500 and 3500A	rting

**Appendix F: Proposed Rule — Medical Device Reporting: Electronic** 

**Submission Requirements** 

Appendix G: Draft Guidance for Industry, User Facilities and FDA

**Staff: eMDR - Electronic Medical Device Reporting** 

Appendix H: eSubmitter Quick Guide

**Appendix I: Sample Letters of Non-Repudiation**