

CONTENTS

Introduction..... 3

Definition of a Complaint..... 3

Complaint Handling Requirements..... 3

FDA Enforcement..... 4

Sources of Complaints..... 4

Service and Repair Complaints..... 5

Complaint Investigation..... 5

Complaint Investigation – Receiving Complaints..... 6

Complaint Investigation – When to Investigate..... 7

Complaints and the Corrective Action Process..... 9

Complaints and Risk Management..... 9

Maintaining Complaint Files..... 10

Closing Complaints..... 11

Quality Data Analysis..... 11

Medical Device Reporting – FDA..... 12

Medical Device Reporting – European Union..... 13

Medical Device Reporting – Canada..... 14

FDA’s Postmarket Surveillance Initiatives..... 14

MedSun – The Medical Product Safety Network..... 15

Unique Device Identifier..... 15

Sentinel Initiative..... 15

Effective Complaint Systems..... 15

Conclusion..... 16

Annex A – Excerpts from FDA Regulations..... 18

Annex B – Excerpts From ISO 13485:2003..... 20

Annex C – Excerpts from MEDDEV 2.12-1
Guidelines on a Medical Devices Vigilance System..... 21

Annex D – Excerpts from SOR/98-282
Medical Devices Regulations..... 24

Annex E – Checklist for Selected US Regulations..... 26