www.degrandson.co.uk

ISO 13485

IMPLEMENTATION HANDBOOK

FOR CERTIFICATION TO THE MEDICAL DEVICES MANAGEMENT SYSTEM STANDARD

deGRANDSON Global

Written by

Dr. John FitzGerald, Founder and CEO of deGRANDSON Global

Usage note

The intent of this document is to help you recognize the activities related to establishing a MDMS. This document should not be considered as professional consulting for establishing or implementing a MDMS.

Use of this handbook does not guarantee a successful implementation nor an implementation that is ready for certification. If you want to implement a MDMS, consider hiring a professional consultant who specializes in implementing ISO 13485 compliant MDMS.

Contents

USAGE NOTE 1

INTRODUCTORY NOTE 4

OVERVIEW OF A MEDICAL DEVICE MANAGEMENT SYSTEM 5

1 PURCHASE A COPY OF THE ISO STANDARDS 8

2 INITIATING THE MDMS PROJECT 9

2.1 OBTAIN MANAGEMENT SUPPORT (#1) 9

Example of a high-level Quality Policy Statement: 9

2.2 ASSEMBLE MDMS PROJECT TEAM (#2) 11

2.3 COMPLETE GAP ANALYSIS 11

2.4 PREPARE MDMS PROJECT PLAN (#3 CONT'D) 12

3 THE CONTEXT OF THE ORGANISATION 14

3.1 DETERMINE THE CONTEXT OF THE ORGANISATION (#4) 14

3.2 IDENTIFY THE APPLICABLE LEGAL AND REGULATORY REQUIREMENTS (#5) 15

Example of addition of applicable Legislation to Scope of MDMS Statement 15

Regulation of Medical Devices – the Global Scene 16

3.3 DETERMINE OTHER INTERESTED PARTIES' NEEDS (#6) 25

4 DEFINE AND ESTABLISH A MEDICAL DEVICE MANAGEMENT SYSTEM 26

4.1 DEFINE THE SYSTEM'S PROCESSES AND THEIR INTER-RELATIONSHIPS (#7) 26

4.2 DEFINE THE SCOPE OF THE MDMS (#8) 29

Example of Scope of MDMS Statement 30

4.3 PREPARE DETAILED QUALITY POLICIES (#9) 30

4.4 DEFINE KEY ROLES AND RESPONSIBILITIES (#10) 32

5 THE PLANNING 34

What is Risk-based Thinking? 34

Where does Risk-based thinking arise in the revised Standard? 34

5.1 DETERMINE ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES (#11) 35

Risk-based thinking, PDCA and the process approach 37

5.2 ESTABLISH MDMS OBJECTIVES AND PLAN TO ACHIEVE THEM (#12) 40

6 ESTABLISH DESIGN AND DEVELOPMENT PROCESSES (#13) 41

7 OPERATIONAL PLANNING AND CONTROLS 45

7.1 DETERMINE THE OPERATIONAL PLANNING AND CONTROL NEEDS (#14) 45

7.2 IDENTIFY MONITORING AND MEASUREMENT NEEDS [INCL. CALIBRATION] (#15) 46

7.3 ESTABLISH OPERATIONAL CONTROLS AND MONITORING (#16) 47

8 DEVELOP THE DOCUMENTATION REQUIRED 48

8.1 ESTABLISH CUSTOMER SATISFACTION METHODS (#17) 48

© deGRANDSON Global (2016)

8.2 Develop a process for managing MDMS Changes (#18) 48
8.3 Develop operational and other necessary documentation (#19) 50
The 29 specific requirements for documented information 51

9 DETERMINE AND SECURE THE REQUIRED RESOURCES (#20) 54

9.1 Determining the Resources Required 54
9.2 Identify and secure the Human Resources 54
9.3 Identify and secure the Infrastructure (hardware, software, support services & utilities) 55
9.4 Establish suitable working environments 55

10 ESTABLISH PROCUREMENT PROVISION (#21) 56

10.1 Establish Procurement Policy and Criteria 56
10.2 Supplier Evaluation 56
10.3 Product and Service Specification, Sourcing and Verification 56
10.4 ESTABLISH PROCESS FOR THE CONTROL OF OUTSOURCED PRODUCTS AND SERVICES 57

11 PRE-LAUNCH ACTIVITIES 58

11.1. Establish Internal and External Communications (#22) 58
11.2 Deliver Employee Awareness Training (#23) 58
11.3 Finalise & issue MDMS Documentation (#24) 60
11.4 COMPLETE JOB-SPECIFIC TRAINING #25) 62
Example of Employee Training Record incl. competency check: 63

12 GO LIVE! IMPLEMENT POLICIES, PROCEDURES AND QUALITY OBJECTIVES PLAN (#26) 64

12.1 Deploy Policies 64
12.2 IMPLEMENT PROCEDURES 64
12.3 Control of nonconforming outputs 65

13 ESTABLISH CUSTOMER-RELATED REQUIREMENTS (#27) 66

13.1 Establish Customer Communication 66
13.2 Determine Customer requirements 66
13.2 Review Customer Requirements, including changes 66

14 ESTABLISH PRODUCTION AND SERVICE PROVISION PROCESSES (#28) 68

14.1 Establish control of Production & Service Provision 68
14.2 Establish Identification, traceability and quality status requirements 68
14.3 Establish control of customer property, Preservation, Post-delivery Activities & Control of changes to production and service provision 68

15 RELEASE OF PRODUCTS AND SERVICES (#29) 70

16. MONITOR THE EFFECTIVENESS OF THE MDMS IMPLEMENTATION 71

16.1 CONDUCT PERIODIC INTERNAL AUDITS 71
16.2 Conduct periodic analysis and evaluation of the MDMS [incl. Customer Satisfaction] (#31) 73
16.3 Conduct periodic Management Reviews (#32) 74

17 IMPLEMENT CONTINUAL IMPROVEMENT (#33) 76

Example: of a MDMS Improvement Plan outline 76

18 PREPARE FOR A CERTIFICATION AUDIT 77

19 ASK FOR HELP 78

APPENDICES 79

Appendix A: The Path to ISO 13485:2016 Certification – the 33 Steps 80
Appendix B: The question of Retained Documentation in ISO 13485:2016 81
Appendix C: Typical MDMS Documentation 84
Policies & Procedures 84
Records 84
Appendix D: Sample Procedures & Records 86

MDMSP-001: Customer Contract Processing 86
MDMSP-002: Purchasing 86
MDMSP-003: Control of Maintained Documentation 86
MDMSP-004: Control of Retained Documentation 86
MDMSP-005: MDMS Internal Audits 86
MDMSP-006: MDMS Management Reviews 86
MDMSP-007: Control of Monitoring and Measuring Devices 86
MDMSP-008: Design and Development of Products & Services 86
MDMSP-009: Non-conformances, Corrective Action & Preventive Action 86
APPENDIX E: EXAMPLE OF MANAGEMENT REVIEW RECORD 114
APPENDIX F: SEVENTEEN ISO GUIDANCE DOCUMENTS FOR ISO 13485:2016 118
APPENDIX G: OVERVIEW OF THE INTERNATIONAL REGULATORY SCENE FOR MEDICAL DEVICES 119
The 2020s will be a period of continuous Regulatory change 119
It's complicated! 119
Regulation of Medical Devices – the global scene 119
Definitions 119
Classification 121
Standardization & regulatory concerns 125
The Medical Device Regulations of the European Union (EMA) 126
The Medical Device Regulations of the United Kingdom (MHRA) 129
The Medical Device Regulations of the United States (FDA) 130
The Medical Device Regulations of the MDSAP Countries 131
The Medical Device Regulations of the Rest of the World (WHO) 132