ISO 13485:2016-03 (E)

Medical devices - Quality management systems - Requirements for regulatory purposes

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Quality management system 6
4.1 General requirements 6
4.2 Documentation requirements 7
4.2.1 General 7
4.2.2 Quality manual 7
4.2.3 Medical device file 7
4.2.4 Control of documents 8
4.2.5 Control of records 8

5 Management responsibility 9
5.1 Management commitment 9
5.2 Customer focus 9
5.3 Quality policy 9
5.4 Planning 9
5.4.1 Quality objectives 9
5.4.2 Quality management system planning 9
5.5 Responsibility, authority and communication 10
5.5.1 Responsibility and authority 10
5.5.2 Management representative 10
5.5.3 Internal communication 10
5.6 Management review 10
5.6.1 General 10
5.6.2 Review input 10
5.6.3 Review output 11

6 Resource management 11
6.1 Provision of resources 11
6.2 Human resources 11
6.3 Infrastructure 12
6.4 Work environment and contamination control 12
6.4.1 Work environment 12
6.4.2 Contamination control 12

7 Product realization 12
7.1 Planning of product realization 12
7.2 Customer-related processes 13
7.2.1 Determination of requirements related to product 13
7.2.2 Review of requirements related to product 13
7.2.3 Communication 14
7.3 Design and development 14
7.3.1 General 14

7.3.2 Design and development planning 14
7.3.3 Design and development inputs 14
7.3.4 Design and development outputs 15
7.3.5 Design and development review 15
7.3.6 Design and development verification 15
7.3.7 Design and development validation 15
7.3.8 Design and development transfer 16
7.3.9 Control of design and development changes 16
7.3.10 Design and development files 16

7.4 Purchasing 17
7.4.1 Purchasing process 17
7.4.2 Purchasing information 17
7.4.3 Verification of purchased product 17
7.5 Production and service provision 18
7.5.1 Control of production and service provision 18
7.5.2 Cleanliness of product 18
7.5.3 Installation activities 18
7.5.4 Servicing activities 19
7.5.5 Particular requirements for sterile medical devices 19
7.5.6 Validation of processes for production and service provision 19
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems 19
7.5.8 Identification 20
7.5.9 Traceability 20
7.5.10 Customer property 20
7.5.11 Preservation of product 20
7.6 Control of monitoring and measuring equipment 21

8 Measurement, analysis and improvement 22
8.1 General 22
8.2 Monitoring and measurement 22
8.2.1 Feedback 22
8.2.2 Complaint handling 22
8.2.3 Reporting to regulatory authorities 23
8.2.4 Internal audit 23
8.2.5 Monitoring and measurement of processes 23
8.2.6 Monitoring and measurement of product 23
8.3 Control of nonconforming product 24
8.3.1 General 24
8.3.2 Actions in response to nonconforming product detected before delivery 24
8.3.3 Actions in response to nonconforming product detected after delivery 24
8.3.4 Rework 24
8.4 Analysis of data 24
8.5 Improvement 25
8.5.1 General 25
8.5.2 Corrective action 25
8.5.3 Preventive action 25

Bibliography 36