ISO 15378:2015-10 (E)

Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2008, with referenc e to Good Manufacturing Practice (GMP)

Contents

Page

Foreword v

Introduction vi

1 Scope 1
1.1 General 1
1.2 Application 2

2 Normative references 2

3 Termsanddefinitions 2
3.1 Terms relating to quality 3
3.2 Terms relating to management 3
3.3 Terms relating to organization 3
3.4 Terms relating to processes and product 4
3.5 Terms relating to characteristics 7
3.6 Terms relating to conformity 8
3.7 Terms relating to documentation 9
3.8 Terms relating to examination 9
3.9 Terms relating to risk management 11

4 Quality management system 12
4.1 General requirements 12
4.1.1 Risk management 13
4.2 Documentation requirements 14
4.2.1 General 14
4.2.2 Quality manual 15
4.2.3 Control of documents 15
4.2.4 Control of records 16

5 Management responsibility 17
5.1 Management commitment 17
5.2 Customer focus 17
5.2.1 Customer audits 17
5.3 Quality policy 17
5.4 Planning 18
5.4.1 Quality objectives 18
5.4.2 Quality management system planning 18
5.5 Responsibility, authority and communication 18
5.5.1 Responsibility and authority 18
5.5.2 Management representative 19
5.5.3 Internal communication 19
5.6 Management review 19
5.6.1 General 19
5.6.2 Review input 20
5.6.3 Review output 20

6 Resource management 20
6.1 Provision of resources 20
6.2 Human resources 21
6.2.1 General 21

6.2.2 Competence, training and awareness 21
6.3 Infrastructure 22
6.4 Work environment 22
6.4.1 Work environment requirements 22
6.4.2 Classification of clean zones/cleanrooms 23
6.4.3 Risk control of contamination 23
6.4.4 Pest control 23
6.4.5 Materials and utilities (ancillary services) 23

6.5 Maintenance and cleaning activities 24

7 Product realization 25
7.1 Planning of product realization 25
7.2 Customer-related processes 25
7.2.1 Determination of requirements related to the product 25
7.2.2 Review of requirements related to the product 26
7.2.3 Customer communication 26
7.3 Design and development 27
7.3.1 Design and development planning 27
7.3.2 Design and development inputs 28
7.3.3 Design and development outputs 28
7.3.4 Design and development review 28
7.3.5 Design and development verification 29
7.3.6 Design and development validation 29
7.3.7 Control of design and development changes 29
7.4 Purchasing 30
7.4.1 Purchasing process 30
7.4.2 Purchasing information 31
7.4.3 Verification of purchased product 31
7.5 Production and service provision 32
7.5.1 Control of production and service provision 32
7.5.2 Validation of processes for production and service provision 34
7.5.3 Identification and traceability 35
7.5.4 Customer property 36
7.5.5 Preservation of product 36
7.6 Control of monitoring and measuring equipment 37

8 Measurement, analysis and improvement 37
8.1 General 37
8.2 Monitoring and measurement 38
8.2.1 Customer satisfaction 38
8.2.2 Internal audit 38
8.2.3 Monitoring and measurement of processes 39
8.2.4 Monitoring and measurement of product 39
8.3 Control of nonconforming product 40
8.4 Analysis of data 41
8.5 Improvement 41
8.5.1 Continual improvement 41
8.5.2 Corrective action 42
8.5.3 Preventive action 42

Annex A (normative) GMP requirements for printed primary packaging materials 43

Annex B (informative)Guidanceonverification,qualificationandvalidationrequirements for primary packaging materials 47

Annex C (informative) Relationship between clauses of this International Standard and the high level structure 59

Bibliography 62