ISO 13408-6:2005-06 (E)

Aseptic processing of health care products - Part 6: Isolator systems

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 Quality system elements 3
4.1 General 3
4.2 Management responsibility 3
4.3 Design control 3
4.4 Measuring instruments and measuring systems 3

5 Design of isolator systems 4
5.1 General 4
5.2 Types of isolators 4
5.3 Materials of construction 4
5.4 Air-handling system 4
5.5 Operator interface 5
5.6 Ancillary equipment 6

6 Facility requirements 6
6.1 Surrounding room classification 6
6.2 Process utilities 7

7 User requirements 7
7.1 Product/process application 7
7.2 Ergonomics 7
7.3 Cleaning 7
7.4 Bio-decontamination 8

8 Validation 10
8.1 General 10
8.2 Design qualification 11
8.3 Installation qualification 11
8.4 Operational qualification 12
8.5 Performance qualification 13
8.6 Review and approval of validation 14
8.7 Requalification 14

9 Routine monitoring and control 14
9.1 Procedures 14
9.2 System integrity 14
9.3 Bio-decontamination process monitoring 15
9.4 Environmental monitoring 15
9.5 Change control 15
9.6 Maintenance and calibration 15

10 Personnel training 15

Bibliography 17