

Table of Contents

1	Introduction	7
1.1	Background.....	7
1.2	Scope.....	7
1.3	Key Concepts.....	9
1.4	How to Use This Guide	11
2	Concepts and Regulatory Philosophy	13
2.1	Introduction	13
2.2	Critical Parameters	14
2.3	Level of Product Protection.....	14
2.4	Product Protection Factors	17
2.5	Design Conditions and Operating Range	19
2.6	Quality Systems	19
3	Science-Based Quality Risk Management	21
3.1	Introduction	21
3.2	Quality Risk Management for PACLAW Facilities.....	21
3.3	ICH Q9 Quality Risk Management Approach.....	22
3.4	Overview of the Quality Risk Management Process.....	23
3.5	Initiating Quality Risk Management	24
3.6	Risk Assessment.....	24
3.7	Risk Control	24
3.8	Risk Communication.....	25
3.9	Risk Review	25
3.10	Quality Risk Management Tools	26
4	Facilities Requirements	29
4.1	Introduction	29
4.2	Parameter Based User Requirements.....	31
4.3	Regulatory Requirements	40
4.4	Maintenance and Monitoring.....	41
5	Architecture/Layout.....	45
5.1	Introduction	45
5.2	Operational Layout Considerations.....	45
5.3	Facility Layout Considerations.....	46
5.4	Packaging	47
5.5	Labeling	50
5.6	Warehousing.....	51
5.7	Special Design Considerations.....	54
5.8	Material and Finishes.....	55
6	Heating, Ventilation, and Air Conditioning (HVAC).....	57
6.1	Introduction	57
6.2	Requirements Definition.....	57
6.3	Critical Parameters	58
6.4	System Design Criteria	62
6.5	Other Design Condition Considerations.....	62
6.6	Air Systems.....	65
6.7	Cleaning and Maintenance of HVAC Systems.....	68

7	Process Support and Utility Systems	69
7.1	Introduction	69
7.2	System Classifications	69
7.3	Electrical	72
8	Control and Monitoring	75
8.1	Introduction	75
8.2	Control Systems Components	76
8.3	Control and Monitoring System Documentation	78
8.4	Networks	80
9	Commissioning and Verification	81
9.1	Introduction	81
9.2	Maintaining a Validated Status.....	81
10	Temperature Mapping.....	83
10.1	Introduction	83
10.2	Humidity Sensors.....	84
10.3	Commissioning and Verification.....	84
10.4	Verification	85
10.5	Cost Considerations and Sustainability	86
11	Appendix 1 –European Aspects	89
11.1	Introduction (General).....	90
11.2	Environmental Impact Issues.....	91
11.3	Water Quality	92
11.4	Qualification and Validation.....	93
12	Appendix 2 – Japanese Aspects	95
12.1	Introduction	96
12.2	Quality Requirements in Japan.....	96
12.3	Regulatory Requirements in Japan.....	96
12.4	Automated Inspection for Pharmaceutical Products	97
13	Appendix 3 – References	99
14	Appendix 4 – Glossary	103
14.1	Acronyms and Abbreviations	104
14.2	Definitions	106