

Table of Contents

1	Introduction	7
1.1	Rationale.....	7
1.2	New and Revised Material.....	8
1.3	Purpose.....	8
1.4	Scope.....	9
1.5	Business Benefits.....	10
1.6	Structure	10
2	Key Concepts	13
2.1	Key Concepts.....	13
2.2	Key Terms	15
3	Life Cycle Approach	19
3.1	Computerized System Life Cycle.....	19
3.2	Specification and Verification.....	20
3.3	Computerized System Validation Framework	21
4	Life Cycle Phases	23
4.1	Concept.....	23
4.2	Project.....	24
4.3	Operation	30
4.4	Retirement	38
5	Quality Risk Management	43
5.1	Science-Based Quality Risk Management.....	43
5.2	Quality Risk Management Process.....	44
5.3	Initial Risk Assessment	44
5.4	Implement and Verify Appropriate Controls	47
5.5	Review Risks and Monitor Controls	48
6	Regulated Organization Activities.....	49
6.1	Governance for Achieving Compliance.....	49
6.2	System Specific Activities	50
7	Supplier Relationships	53
7.1	Leveraging Supplier Knowledge and Documentation	54
7.2	Supplier Assessment	54
8	Appendix 1 – Categories of Software	57
9	Appendix 2 – System Description	61
10	Appendix 3 – Data Integrity	67
10.1	Introduction	67
10.2	Critical Success Factors	67

11 Appendix 4 – Simple Systems.....	71
11.1 Generic Activities for Simple Systems	71
11.2 Example 1 – Analytical Balance.....	75
11.3 Example 2 – Ph Meter	78
11.4 Example 3 – Electronic Pipette.....	81
12 Appendix 5 – Medium Systems	83
12.1 Scope of Activities When Connected to an External System.....	83
12.2 Generic Activities for Medium Systems.....	84
13 Appendix 6 – Complex Systems	91
13.1 System Architecture.....	91
13.2 Multidisciplinary Approach to Validation.....	92
13.3 Order of Validation Activities	92
13.4 Validation Activities	92
14 Appendix 7 – System Interfacing Considerations	107
14.1 LIMS Overview.....	107
14.2 ELN Overview.....	107
14.3 Aspects to Consider.....	108
14.4 ELN/LIMS Interface Verification Approach.....	113
15 Appendix 8 – Robotics Systems	119
15.1 Overview.....	119
15.2 Planning Considerations	119
15.3 Risk Management Considerations	121
15.4 Verification Activities for Robotics Systems	122
16 Appendix 9 – Defining Electronic Records and Raw Data.....	129
16.1 Regulatory Rationale for Defining Records and Raw Data.....	129
16.2 Illustrative Example: Defining Raw Data/Electronic Records for a Chromatography Data System (CDS).....	131
17 Appendix 10 – Security Management for Laboratory Computerized Systems	135
17.1 Introduction	135
18 Appendix 11 – Supplier Documentation and Services	139
18.1 System Development by the Supplier.....	139
18.2 Supplier Assessment	139
18.3 Supplier Good Practices	142
19 Appendix 12 – References	145
20 Appendix 13 – Glossary	147
20.1 Acronyms and Abbreviations	147
20.2 Definitions	149