

# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>9</b>
1.1	Background.....	9
1.2	Case for Quality Program .....	9
1.3	Purpose.....	10
1.4	Scope.....	10
1.5	Structure of the Guide.....	11
1.6	Key Terms .....	11
1.7	Key Roles and Responsibilities.....	14
<b>2</b>	<b>Foundations to Data Integrity by Design .....</b>	<b>15</b>
2.1	Governance to Achieve Data Integrity by Design .....	15
2.2	Data Ownership .....	19
<b>3</b>	<b>Retention Strategy .....</b>	<b>23</b>
3.1	Retention Periods .....	24
3.2	Readability .....	25
3.3	Availability .....	28
3.4	Access .....	30
3.5	Protecting Records and Data.....	31
3.6	Managing System Retirement.....	36
3.7	Records Management and Retention through Mergers, Acquisitions, and Divestments .....	41
<b>4</b>	<b>Implementing Data Integrity by Design .....</b>	<b>43</b>
4.1	A Process to Achieve Data Integrity by Design.....	43
4.2	Business Process .....	47
4.3	Data Flow Diagrams .....	48
4.4	Data Classification and the Intended Use of the Data .....	49
4.5	Business Process Risk Assessment .....	50
4.6	Data Lifecycle .....	51
4.7	Data Nomenclature .....	55
<b>5</b>	<b>System Planning .....</b>	<b>59</b>
5.1	Planning Computerized Systems to Efficiently Support the Optimized Business Process .....	59
5.2	Addressing Individual Systems .....	61
5.3	System Risk Assessment.....	63
<b>6</b>	<b>Active Records.....</b>	<b>67</b>
6.1	Creation .....	67
6.2	Processing .....	69
6.3	Review, Reporting, and Use .....	75
<b>7</b>	<b>Semi-active and Inactive Records .....</b>	<b>81</b>
7.1	Semi-active Records.....	81
7.2	Retention of Inactive Records.....	81
7.3	Return to Active State (Retrieval).....	86
7.4	Destruction.....	87

**Management Appendices**

**8 Appendix M1 – Knowledge Management..... 89**

8.1 Introduction ..... 89

8.2 Key Concepts..... 89

8.3 Managing Knowledge ..... 92

8.4 Mindsets and Behaviors..... 94

8.5 Conclusion ..... 95

**9 Appendix M2 – Understanding Data Integrity Compared to Data Quality ..... 97**

**10 Appendix M3 – Third-Party Data ..... 99**

10.1 Introduction ..... 99

10.2 Assessments and Responsibilities..... 99

10.3 Data Governance for CxO ..... 99

10.4 Data Storage Off-Premise..... 100

10.5 Conclusion ..... 101

**Development Appendices**

**11 Appendix D1 – Example Business Process Mapping: Laboratory System.....103**

**12 Appendix D2 – Instrument Devices with Electronic Record Storage.....105**

12.1 Introduction ..... 105

12.2 Background..... 105

12.3 Instrument Use..... 106

12.4 Accounting for Original Data ..... 106

12.5 Challenges ..... 107

12.6 Remediation Strategies..... 107

12.7 Risk Register..... 109

12.8 Example Data Integrity Risks, Interim Controls, and Actions to Consider ..... 109

12.9 Conclusion ..... 110

**Operation Appendices**

**13 Appendix O1 – Data Analytics and Technical Solutions Supporting Data Integrity..... 111**

13.1 Introduction ..... 111

13.2 Detecting Data Integrity Issues with Business Rules..... 112

13.3 Technical Solution Using Computer Lockdown via Software Shells ..... 116

**14 Appendix O2 – Good Practices for General Archiving ..... 119**

14.1 What is Archiving? ..... 119

14.2 What to Archive..... 119

14.3 How to Archive..... 119

14.4 Managing an Archive ..... 120

<b>15 Appendix O3 – GLP Archiving Considerations .....</b>	<b>123</b>
<b>16 Appendix O4 – Example Retention Periods and Requirements .....</b>	<b>125</b>
<b>17 Appendix O5 – Maintaining Legacy Software .....</b>	<b>139</b>
17.1 Introduction .....	139
17.2 Non-Disposal of Retired Systems .....	139
17.3 Compatibility to Modern Operating Systems .....	139
17.4 Virtual Machine Solution .....	139
17.5 The Hardware Museum .....	140
17.6 Conclusion .....	140

### Special Interest Topics Appendices

<b>18 Appendix S1 – Artificial Intelligence: Machine Learning .....</b>	<b>141</b>
18.1 Introduction .....	141
18.2 Background .....	141
18.3 Scope .....	141
18.4 Data Lifecycle (Iterative, Autonomous, and Adaptive) .....	142
18.5 Concept Phase (Understanding the Business Case) .....	142
18.6 Project Phase (Data Modeling and Evaluation) .....	144
18.7 Operation Phase (Deployment and Monitoring) .....	145
18.8 Further Reading .....	146
<b>19 Appendix S2 – Computer Software Assurance .....</b>	<b>147</b>
19.1 Introduction .....	147
19.2 Establishing a Lifecycle-based Approach and Basic Assurance .....	152
19.3 Risk-based Assurance .....	153
19.4 Example: Applying Risk-based Approach from <i>ISPE GAMP® 5</i> and CSA .....	157
19.5 Example: Applying <i>ISPE GAMP® 5</i> and CSA Using Direct Leveraging of Testing Throughout the System Lifecycle .....	160
19.6 Conclusion .....	162

### General Appendices

<b>20 Appendix G1 – References .....</b>	<b>163</b>
<b>21 Appendix G2 – Glossary .....</b>	<b>169</b>
21.1 Acronyms and Abbreviations .....	169
21.2 Definitions .....	171