

Table of Contents

1	Introduction	9
1.1	Background	9
1.2	Purpose	9
1.3	Scope	10
1.4	Structure of this Guide	10
1.5	Key Concepts	11
1.6	Key Terms	15
2	Regulatory Focus	17
2.1	Introduction	17
2.2	Data Integrity Requirements	17
3	Data Governance Framework	21
3.1	Introduction	21
3.2	Overview	21
3.3	Elements of the Data Governance Framework	23
3.4	Human Factors in Data Integrity	30
3.5	Data Integrity Maturity Model	31
4	Data Life Cycle.....	33
4.1	Introduction	33
4.2	Data Creation	34
4.3	Data Processing	35
4.4	Data Review Reporting and Use	36
4.5	Data Retention and Retrieval	39
4.6	Data Destruction	42
5	Quality Risk Management	43
5.1	Introduction	43
5.2	Process Risk Assessment	43
5.3	Quality Risk Management Approach	43
5.4	Product and Process Context	45
 <u>Management Appendices</u>		
6	Appendix M1 – Corporate Data Integrity Program.....	47
6.1	Introduction	47
6.2	Is a Corporate Data Integrity Program Required?.....	47
6.3	Indicators of Program Scope and Effort	48
6.4	Implementation Considerations.....	50
6.5	Keys to Success.....	52
7	Appendix M2 – Data Integrity Maturity Model	55
7.1	Maturity Model.....	55
7.2	Data Integrity Maturity Level Characterization	59

8	Appendix M3 – Human Factors	67
8.1	Introduction	67
8.2	Corporate and Local Cultures	67
8.3	Classification of Incidents.....	68
8.4	Human Error.....	69
8.5	Data Falsification and Fraud	70
8.6	Impartiality.....	71
8.7	Behavioral Controls.....	71
9	Appendix M4 – Data Audit Trail and Audit Trail Review	75
9.1	Introduction	75
9.2	Regulatory Background.....	76
9.3	Application and Use of Audit Trails.....	77
9.4	Audit Trail Review	79
9.5	Technical Aspects and System Design	79
10	Appendix M5 – Data Auditing and Periodic Review	81
10.1	Introduction	81
10.2	Auditing for Data Integrity.....	81
10.3	Periodic Review	82
10.4	Other Reviews.....	83
10.5	Documenting Review Processes	83
11	Appendix M6 – Inspection Readiness	85
11.1	General Procedures.....	85
11.2	Key Information for Regulatory Inspections	86
12	Appendix M7 – Integrating Data Integrity into Existing Records Management Processes	91
12.1	Introduction	91
12.2	Record Creation.....	92
12.3	Active Records.....	92
12.4	Semi-active Records.....	92
12.5	Inactive Records	92
Development Appendices		
13	Appendix D1 – User Requirements	93
13.1	Introduction	93
13.2	Business Process.....	93
13.3	General Data Integrity Requirements.....	94
14	Appendix D2 – Process Mapping and Interfaces.....	99
14.1	Introduction	99
14.2	Process Flowcharts.....	99
14.3	Data Flow Diagrams.....	102
14.4	How Much Is Needed?.....	103

15 Appendix D3 – Risk Control Measures for Records, Data, and Electronic Signatures.....	105
15.1 Introduction	105
15.2 Record and Data Controls.....	105
15.3 Electronic Signature Controls.....	105
15.4 Implementation of Record and Data Controls	107
15.5 Rigor of Controls	110
16 Appendix D4 – Data Integrity Concerns Related to System Architecture	111
16.1 Data Resides on a Local Hard Disk	111
16.2 Internally Managed Central Database.....	112
16.3 Internally Managed Distributed Data.....	112
16.4 Outsourced Managed Services.....	113
17 Appendix D5 – Data Integrity for End-User Applications.....	117
17.1 Introduction	117
17.2 Data Integrity for Spreadsheets	117
17.3 Data Integrity for PC Databases	119
17.4 Data Integrity for Statistical Tools.....	120

Operation Appendices

18 Appendix O1 – Retention, Archiving, and Migration.....	121
18.1 Introduction	121
18.2 Retention Options	121
18.3 Protection of Records.....	121
18.4 Record Aging and Risk.....	122
18.5 Archival	122
18.6 Hybrid Situations and Archives	123
18.7 Audit Trail Considerations	124
18.8 Alternative Systems	125
18.9 Converting Electronic to Alternative Format or Alternative Media Hybrids.....	126
19 Appendix O2 – Paper Records and Hybrid Situations.....	131
19.1 Paper Records	131
19.2 Hybrid Situations.....	133
19.3 Use of Forms to Enforce Procedures.....	135

General Appendices

20 Appendix G1 – References	137
21 Appendix G2 – Glossary	141
21.1 Acronyms and Abbreviations.....	141
21.2 Definitions	143