

Table of Contents

1	Introduction	7
1.1	Background.....	7
1.2	Purpose.....	7
1.3	Scope.....	8
1.4	How to Use This Guide	8
1.5	Terminology.....	10
2	Data and Records.....	17
2.1	What Is Special about Manufacturing Systems?.....	17
2.2	What Is Regulated Data?.....	19
3	Data Flows and Data Lifecycle.....	23
3.1	Mapping Data Flows	23
3.2	Typical GMP Data Flows.....	23
3.3	Data Lifecycle	27
4	Risk Management Approaches.....	41
4.1	Initial Data Integrity Risk Assessment and Identifying the Impact of Poor Data Integrity Controls	41
4.2	Identifying Data Flows with Impact on Patient Safety, Product Quality, and Data Integrity	41
4.3	Performing Functional Risk Assessments and Identifying Controls.....	41
4.4	Implement and Verify Appropriate Controls	42
4.5	Reviewing Residual Risks and Monitoring Controls	42
5	Detecting Data Integrity Issues	43
5.1	Data Review Requirements	43
5.2	Critical Thinking	52
6	Preventing Data Integrity Issues.....	57
6.1	Data Integrity Culture	57
6.2	Supplier Management Considerations.....	57
6.3	Essential Technical Features	61
6.4	Policies and Procedures	64
6.5	Access Considerations	66
6.6	Critical Validation Activities	70
7	Quick Wins	71
7.1	Quick Wins for Existing Systems	71
7.2	Quick Wins for New Projects	75
7.3	Quick Wins for Governance	76
8	Appendix 1 – Process Control System Risk Assessment Example	79

9 Appendix 2 – Risks to Data Integrity Associated with Specific Data Types.....	81
9.1 Automatically Captured Process Data	82
9.2 Simple Calculated Values	83
9.3 Manually Entered Process Data	85
9.4 Process Data Originating in Another System.....	86
9.5 Alarms and Events.....	88
9.6 Exception Reports.....	89
9.7 Images and Image Recognition	90
9.8 Complex/Statistical Transformations.....	92
9.9 Outputs Used Manually by the Operator.....	93
9.10 Production Definition Management – Master Recipes.....	94
9.11 Production Resource Management – Material Control.....	95
9.12 Production Resource Management – Equipment Control.....	96
9.13 Production Resource Management – Personnel Control.....	97
9.14 Production Dispatching	98
9.15 Production Execution – Control Recipes and Workflows.....	99
9.16 Production Data Collection and Production Tracking.....	100
9.17 Production Performance Analysis	100
9.18 Manufacturing Production Record Review, Release, and Disposition.....	101
10 Appendix 3 – Data Integrity Maturity Factors	103
11 Appendix 4 – Essential Technical Features.....	113
12 Appendix 5 – Policies and Procedures	121
13 Appendix 6 – Example Segregation of Duties.....	125
14 Appendix 7 – Validation Activities	129
15 Appendix 8 – Data Integrity Citations by Regulators.....	137
16 Appendix 9 – References	145
17 Appendix 10 – Glossary.....	149
17.1 Abbreviations and Acronyms	149
17.2 Definitions	151