

Table of Contents

1	Introduction	7
1.1	Background.....	7
1.2	Purpose and Objectives.....	7
1.3	Scope.....	8
1.4	Rationale for the Third Edition	9
1.5	Structure of the Guide.....	9
2	Key Concepts	11
2.1	Product and Process Understanding	11
2.2	Life Cycle Approach Within a Quality Management System (QMS)	13
2.3	Scalable Testing Activities.....	14
2.4	Science-Based Quality Risk Management.....	16
2.5	Leveraging Supplier Involvement.....	16
3	Designing an Effective Test Strategy	21
3.1	Influences on Test Activities	22
3.2	Testing Types	25
3.3	Hardware Verification.....	28
3.4	Test Management Tools and Automated Testing	29
3.5	Shift Left.....	29
3.6	Leveraging Supplier Testing.....	29
3.7	Component Supply Chain	29
3.8	Test Metrics.....	30
4	Key Roles and Skills	31
4.1	Core Test Team Roles.....	31
4.2	Essential Business Stakeholders.....	33
4.3	Required Knowledge and Skills	35
4.4	Review and Approval	36
4.5	Regulated Companies, Suppliers, and Service Providers	38
5	Leveraging Testing.....	41
6	Computerized Test Tools	45
6.1	Introduction	45
6.2	Electronic Test Management Tools	46
6.3	Automated Testing Tools.....	47
6.4	Assessing Tools According to <i>ISPE GAMP 5 (Second Edition)</i>	59
6.5	Management of Computerized Test Tools.....	62
6.6	Event Logs.....	63
7	Test Planning.....	65
7.1	Test Planning Considerations	65
7.2	Testing Practices.....	67

8	Test Execution.....	85
8.1	Appropriate Records for Test Execution	85
8.2	Test Incidents	90
8.3	Reviewing Completed Testing.....	96
9	Reporting.....	97
9.1	Traceability to Requirements and Test Objectives	97
9.2	Dashboards.....	98
9.3	Appropriate Records	98
10	Testing in Operations.....	101
10.1	Operational Changes and Testing.....	101
10.2	Change Testing Considerations	104
11	Test Metrics	105
11.1	Understanding Metrics	105
11.2	Selection of Metrics.....	106
11.3	Collection of Data.....	107
11.4	Calculation of Metrics.....	108
11.5	Common Test Metrics and Their Application in GxP Projects.....	108
11.6	Common Metric Fallacies	110
11.7	Value of Automation in Metrics.....	112

Special Interest Topics Appendices

12	Appendix S1 – Testing in Incremental, Iterative, and Exploratory Approaches ...	113
12.1	Introduction	113
12.2	Testing.....	115
13	Appendix S2 – Ensuring Appropriate Testing for SaaS Applications	119
13.1	Introduction	119
13.2	Responsibility for Compliance.....	120
13.3	Prerequisites to Testing.....	120
13.4	Test Planning	120
13.5	Additional Considerations for SaaS	121
13.6	Test Coverage.....	122
13.7	Managing Change.....	124
13.8	Paradigm Shift for Testing SaaS	127
14	Appendix S3 – Testing AI/ML.....	129
14.1	AI-Enabled Computerized Systems.....	129
14.2	Leveraging AI/ML for Enhanced Testing of Computerized Systems	132

General Appendices

15	Appendix G1 – References	135
16	Appendix G2 – Glossary	137
16.1	Acronyms and Abbreviations	137