

Table of Contents

1	Introduction	7
1.1	Purpose.....	8
2	Scope	9
2.1	Similarities and Differences between GMP and GCP Systems	9
3	Regulatory Overview	13
3.1	History.....	13
3.2	Regulations and Documents.....	16
4	Process Overview.....	17
4.1	The Project Nature of Clinical Studies	17
4.2	Stakeholders in Clinical Studies.....	18
4.3	Conducting a Clinical Study.....	18
4.4	Support through Computerized Systems.....	19
4.5	Validation Layer Model.....	19
5	Process Model.....	23
5.1	Process: Study Protocol and Submission for Approval.....	23
5.2	Process: Project and Clinical Study Management.....	24
5.3	Process: Electronic Data Capture System Life Cycle and Validation	29
5.4	Process: Electronic Patient Reported Outcome System Life Cycle and Validation	36
5.5	Process: Site/Partner Qualification	37
5.6	Process: Investigational Medicinal Product Management	43
5.7	Process: Subject Recruitment, Inclusion, and Randomization	53
5.8	Process: Data Aggregation and Review	57
5.9	Process: Severe Adverse Event Reporting.....	68
5.10	Process: Mid-Study Changes and Change Management.....	73
5.11	Process: Statistical Analysis and Programming.....	74
5.12	Process: Study Report, Study Closure, and Submission.....	76
5.13	Process: Quality Assurance and Quality Control	83
5.14	Process: Laboratory Analysis and Sample Logistics	86
6	Data Integrity.....	89
6.1	Definition	89
6.2	Risks	90
6.3	Data Ownership and Governance.....	91
6.4	Data Life Cycle.....	91
6.5	Data Integrity in Computerized Systems Used in Clinical Trials: electronic Source Data (eSource Data).....	92
6.6	Data Integrity in Computerized Systems Used in Clinical Trials: Audit Trails and Audit Trail Reviews	94
6.7	Data Integrity in Integrated eClinical Platforms: Dataflow and End-To-End Validation	96
6.8	Data Integrity for Electronic Documents Used in Clinical Trials: Electronic Signatures and Digital Signatures.....	97
6.9	Data Integrity for Electronic Documents Used in Clinical Trials: Certified Copy of Original Documents (Source Documents).....	98
6.10	Risk Identification for Data Integrity and Data Quality	100

7 Interfaces and Dataflows through Different Systems (eClinical Platforms/Architectures)	103
7.1 Generic eClinical Platforms versus Trial-Specific eClinical Platforms.....	105
7.2 Interfaces	106
7.3 Dataflow and End-To-End Validation	109
7.4 Validation in Different Organizations.....	111
8 Appendix 1 – References	113
9 Appendix 2 – Glossary.....	119
9.1 Acronyms and Abbreviations	119
9.2 Definitions	121