

Table of Contents

1	Introduction	7
1.1	Background.....	7
1.2	Overview	8
1.3	Scope and Purpose	9
1.4	Benefits.....	9
1.5	Objectives	10
1.6	Key Terms	11
2	GMP and GCP Considerations	13
2.1	EU GMP Annex 13 and Other Regulations.....	13
3	Recommendations/Good Practice	15
3.1	Introduction	15
3.2	Structure and Format of Booklet Labels	15
3.3	Labeling Details	20
3.4	Recommended Training.....	26
4	Good Practice Solutions	27
4.1	Standard	27
5	Appendix 1 – Subject Training Confirmation	29
6	Appendix 2 – References	31
7	Appendix 3 – Glossary	33
7.1	Acronyms and Abbreviations	34
7.2	Definitions	34