

Table of Contents

1	Introduction	7
1.1	Background and Purpose	7
1.2	Rationale for this Third Edition.....	8
1.3	Scope.....	15
1.4	Key Terms	17
2	Technology Transfer – Planning Considerations and Success Criteria.....	21
2.1	Introduction	21
2.2	Technology Transfer Planning Considerations.....	21
2.3	Technology Transfer Success Criteria	27
3	Technology Transfer Project Phases	31
3.1	Form Transfer Team and Develop Charter	31
3.2	Consolidate Knowledge for Transfer and Develop Technology Transfer Proposal.....	35
3.3	Identify Risks, Conduct Risk Assessments, and Develop Technology Transfer Plan	37
3.4	Operational Readiness	44
3.5	Process (Procedure) Qualification	47
3.6	Finalize Transfer and Perform Review.....	48
4	Technology Transfer of Analytical Methods.....	53
4.1	Introduction	53
4.2	Technology Transfer Process.....	54
4.3	Points to Consider.....	64
4.4	Additional Sources of Information.....	65
5	Technology Transfer of Drug Substance.....	67
5.1	Introduction	67
5.2	Technology Transfer Process.....	67
5.3	Points to Consider.....	79
5.4	Example Gap Analyses for Small Molecule and Large Molecule Processes.....	79
6	Technology Transfer of Drug Product.....	83
6.1	Introduction	83
6.2	Technology Transfer Process.....	83
7	Quality Aspects of Technology Transfer.....	89
7.1	Introduction	89
7.2	Quality Representation on the Technology Transfer Team	89
7.3	Quality by Design and Control Strategy.....	89
7.4	Quality Risk Management.....	90
7.5	Analytical Comparability/Similarity and Stability Strategy	91
7.6	Process Validation/Process Performance Qualification Strategy.....	92
7.7	Change Management	93
7.8	Execution	94

8 Appendix 1 – Checklist of Information/Documents for Large and Small Molecule Technology Transfer.....	95
9 Appendix 2 – Case Studies: Biologics.....	97
9.1 Summary.....	97
9.2 Main Challenges	97
9.3 Overview of Technology Transfer Phases.....	98
9.4 Risk Management.....	100
9.5 Technology Transfer Case Studies	101
9.6 Conclusions/Lessons Learned.....	111
10 Appendix 3 – Case Studies: Small Molecule	113
10.1 Summary.....	113
10.2 Main Challenges	113
10.3 Technology Transfer Process.....	113
10.4 Technology Transfer Case Studies	115
11 Appendix 4 – Engineering Considerations for Technology Transfer.....	123
11.1 Introduction	123
11.2 Examples	126
11.3 Lessons Learned	128
12 Appendix 5 – Example of a Failure Mode and Effect Analysis (FMEA) for a Non-Sterile Drug Product	135
13 Appendix 6 – Example of Information that May be Included in Technology Transfer Report	137
14 Appendix 7 – References	141
15 Appendix 8 – Glossary.....	145
15.1 Acronyms and Abbreviations	145
15.2 Definitions	146