

Table of Contents

Part 1: The Advancing Pharmaceutical Quality (APQ) Program

1	Introduction to the APQ Program and Guide Series	7
1.1	Objectives	7
1.2	Scope.....	8
1.3	Benefits.....	8
1.4	About the ISPE APQ Guide Series	9
1.5	How to Use This Guide	11
2	Understanding the APQ Program.....	13
2.1	Link to the ICH Q10 PQS Model.....	13
2.2	Link to Cultural Excellence and Operational Excellence.....	15
3	APQ Assess, Aspire, Act, and Advance Framework.....	17
3.1	APQ Framework Process	18
3.2	APQ Self-Assessment Tool.....	19
3.3	Cross-Functional Team Approach.....	23
4	APQ Benchmarking.....	25
4.1	Benchmarking Questionnaire.....	25
4.2	APQ Pre-Assessment Benchmarking	27
4.3	APQ Post-Action Benchmarking	27

Part 2: Practical Application of the APQ Framework to the CAPA System (APQ-CAPA)

5	Introduction to APQ-CAPA.....	29
5.1	Key Concepts of the CAPA System	30
5.2	Seven Sub-Elements of the APQ-CAPA System	32
6	APQ Assess Phase.....	33
6.1	Assessing Sub-element 1 – CAPA Documentation.....	34
6.2	Assessing Sub-element 2 – Problem Identification.....	36
6.3	Assessing Sub-element 3 – Root Cause Analysis.....	38
6.4	Assessing Sub-element 4 – Corrective and/or Preventive Actions	40
6.5	Assessing Sub-element 5 – CAPA Effectiveness	42
6.6	Assessing Sub-element 6 – CAPA Metrics	44
6.7	Assessing Sub-element 7 – Governance, Management Oversight, and CAPA Prioritization	47
7	APQ Aspire Phase	51
7.1	Evaluation of the Assigned Maturity Ratings.....	53
7.2	Prioritization of Targeted Improvements	53
8	APQ Act Phase.....	55
9	APQ Advance Phase	57

Appendices

10 Appendix 1 – APQ Program Drivers and Goals	59
10.1 What Does Advancing Pharmaceutical Quality Mean?.....	59
10.2 APQ Program Overarching Goals.....	60
11 Appendix 2 – APQ Program History: From Quality Metrics to Advancing Pharmaceutical Quality	65
12 Appendix 3 – APQ Maturity Assessment Tool for the CAPA System	67
13 Appendix 4 – APQ Catalog of Improvement Tools and KPIs for the CAPA System.....	75
14 Appendix 5 – Example APQ-CAPA Assess and Aspire Report.....	77
15 Appendix 6 – Example Template for APQ-CAPA Improvement Action Plan	99
16 Appendix 7 – APQ Benchmarking Tool.....	103
17 Appendix 8 – Example APQ Benchmarking Report.....	117
18 Appendix 9 – References	127
19 Appendix 10 – Glossary.....	129
19.1 Acronyms and Abbreviations	129
19.2 Definitions	130