
Table of Contents

Preface	v
Introduction	ix
QSE 1 – Organization	1
Key Concepts	1
Key Terms	1
Examples of Objective Evidence	2
1. Organization	3
1.0 Organization	3
1.1 Executive Management	3
1.2 Quality System	4
1.3 Policies, Processes, and Procedures	4
1.4 Risk Assessment	5
1.5 Operational Continuity	5
1.6 Emergency Preparedness	5
1.7 Communication of Concerns	5
1.8 Customer Focus	6
Excerpt of Reference Standard 6.2.9A Relevant to Organization	6
QSE 2 – Resources	7
Key Concepts	7
Key Terms	7
Examples of Objective Evidence	7
2. Resources	8
2.0 Resources	8
2.1 Human Resources	8
Excerpt of Reference Standard 6.2.9A Relevant to Resources	10

Contents

QSE 3 – Equipment	11
Key Concepts	11
Key Terms	11
Examples of Objective Evidence	12
3. Equipment	13
3.0 Equipment	13
3.1 Equipment Specifications	13
3.2 Qualification of Equipment	13
3.3 Use of Equipment	13
3.4 Unique Identification of Equipment	14
3.5 Equipment Monitoring and Maintenance	14
3.6 Equipment Traceability	16
3.7 Information Systems	16
3.8 Storage Devices and Storage Containers for Components	18
3.9 Warming Devices	19
Excerpt of Reference Standard 6.2.9A Relevant to Equipment	19
QSE 4 – Suppliers and Customers	20
Key Concepts	20
Key Terms	20
Examples of Objective Evidence	21
4. Suppliers and Customers	22
4.0 Suppliers and Customers	22
4.1 Supplier Qualification	22
4.2 Agreements	23
4.3 Incoming Receipt, Inspection, and Testing	23
Excerpt of Reference Standard 6.2.9A Relevant to Suppliers and Customers	24
QSE 5 – Process Control	25
Key Concepts	25

Key Terms 25

Examples of Objective Evidence 26

5. Process Control 27

5.0 Process Control 27

5.1 General Elements 27

5.2 Consents, Approvals, and Notifications 33

5.3 Perioperative Collection 34

5.4 Component Administration 37

5.1.9A Handling, Storage, and Expiration of Perioperative
Autologous Red Cell Blood Components. 41

5.1.9B Handling, Storage, and Expiration of Perioperative
Autologous Non-Red-Cell Blood Components
for Reinfusion 44

5.1.9C Handling, Storage, and Expiration of Perioperative
Autologous Non-Red-Cell Blood Components for
Topical Application or Injectable Application. . . . 45

Excerpt of Reference Standard 6.2.9A Relevant
to Process Control 46

QSE 6 – Documents and Records. 47

Key Concepts 47

Key Terms 47

Examples of Objective Evidence 48

6. Documents and Records 49

6.0 Documents and Records 49

6.1 Document Control 49

6.2 Record Control 51

6.3 Electronic Records 53

Excerpt of Reference Standard 6.2.9A Relevant to
Documents and Records 55

6.2.9A Retention of Records 56

Contents

QSE 7 – Deviations, Nonconformances, and Adverse Events . . .	61
Key Concepts	61
Key Terms	61
Examples of Objective Evidence	61
7. Deviations, Nonconformances, and Adverse Events	63
7.0 Deviations, Nonconformances, and Adverse Events	63
7.1 Deviations	63
7.2 Nonconformances	63
7.3 Adverse Events	64
Excerpt of Reference Standard 6.2.9A Relevant to Deviations, Nonconformances, and Adverse Events	67
QSE 8 – Internal and External Assessments	68
Key Concepts	68
Key Terms	68
Examples of Objective Evidence	69
8. Internal and External Assessments	70
8.0 Internal and External Assessments	70
8.1 Internal Assessments	70
8.2 External Assessments	70
8.3 Management of Assessment Results	70
8.4 Quality Monitoring	70
Excerpt of Reference Standard 6.2.9A Relevant to Internal and External Assessments	72
QSE 9 – Process Improvement	73
Key Concepts	73
Key Terms	73
Examples of Objective Evidence	74

9. Process Improvement 75

 9.0 Process Improvement 75

 9.1 Corrective Action 75

 9.2 Preventive Action 75

 9.3 Performance Improvement 76

 Excerpt of Reference Standard 6.2.9A Relevant
 to Process Improvement 76

QSE 10 – Facilities and Safety 77

 Key Concepts 77

 Key Terms 77

 Examples of Objective Evidence 77

10. Facilities and Safety 78

 10.0 Facilities and Safety 78

 10.1 Safe Environment 78

 10.2 Biological, Chemical, and Radiation Safety 78

 10.3 Handling and Discarding of Biological Materials 78

 Excerpt of Reference Standard 6.2.9A
 Relevant to Facilities and Safety 78

LIST OF COMPONENTS AND PROCESSING METHODS 79

GLOSSARY 85

CROSSWALK 95

INDEX 101