
Table of Contents

GENERAL POLICIES	ix
QSE 1 – Organization	1
Key Concepts	1
Key Terms.....	1
Examples of Objective Evidence.....	1
1. Organization	2
1.0 Organization	2
1.1 Executive Management	2
1.2 Quality System	3
1.3 Policies, Processes, and Procedures	4
1.4 Risk Assessment	5
1.5 Operational Continuity	6
1.6 Emergency Preparedness	6
1.7 Communication of Concerns	7
1.8 Customer Focus	8
QSE 2 – Resources	9
Key Concepts	9
Key Terms.....	9
Examples of Objective Evidence.....	9
2. Resources	10
2.0 Resources	10
2.1 Human Resources	10
QSE 3 – Equipment	13
Key Concepts	13
Key Terms.....	13
Examples of Objective Evidence.....	13
3. Equipment	14
3.0 Equipment	14
3.1 Equipment Specifications	14
3.2 Qualification of Equipment	14
3.3 Use of Equipment	14
3.4 Unique Identification of Equipment	15
3.5 Equipment Monitoring and Maintenance	15
3.6 Equipment Traceability	17
3.7 Information Systems	17
3.8 Alarm Systems	19

QSE 4 – Suppliers and Customers	20
Key Concepts	20
Key Terms.....	20
Examples of Objective Evidence.....	20
4. Supplier and Customers	21
4.0 Suppliers and Customers	21
4.1 Supplier Qualification	21
4.2 Agreements	21
4.3 Notification	24
QSE 5 – Process Control	25
Key Concepts	25
Key Terms.....	25
Examples of Objective Evidence.....	25
5. Process Control	26
5.0 Process Control	26
5.1 General Elements	26
5.2 CGT Product Management	29
5.3 Methods and Operational Controls	29
5.4 CGT Product Identification and Traceability	30
5.5 Labels, Labeling, and Labeling Controls	30
5.6 Packaging, Transport, and Shipping	31
5.7 Storage, Preservation, and Dispensing	32
5.8 Verification	33
5.9 Dispensing	33
5.10 Disposal	34
QSE 6 – Documents and Records	35
Key Concepts	35
Key Terms.....	35
Examples of Objective Evidence	35
6. Documents and Records	36
6.0 Documents and Records	36
6.1 Document Control	36
6.2 Record Control	38
6.3 Electronic Records	42
QSE 7 – Deviations, Nonconformances, and CGT-Product-Related Unanticipated Events	44
Key Concepts	44
Key Terms.....	44
Examples of Objective Evidence	44

7. Deviations, Nonconformances, and CGT-Product-Related Unanticipated Events	45
7.0 Deviations, Nonconformances, and CGT-Product-Related Unanticipated Events	45
7.1 Deviations	45
7.2 Nonconformances	46
7.3 CGT Product-Related-Unanticipated Events	48
QSE 8 – Internal and External Assessments	49
Key Concepts	49
Key Terms.....	49
Examples of Objective Evidence.....	49
8. Internal and External Assessments	50
8.0 Internal and External Assessments	50
8.1 Internal Assessments	50
8.2 External Assessments	51
8.3 Management of Assessment Results	51
8.4 Quality Monitoring	51
QSE 9 – Process Improvement	52
Key Concepts	52
Key Terms.....	52
Examples of Objective Evidence.....	52
9. Process Improvement	53
9.0 Process Improvement	53
9.1 Corrective Action	53
9.2 Preventive Action	54
9.3 Performance Improvement	54
QSE 10 – Facilities and Safety	55
Key Concepts	55
Key Terms.....	55
Examples of Objective Evidence.....	55
10. Facilities and Safety	56
10.0 Facilities and Safety	56
10.1 Safe Environment	56
10.2 Biological, Chemical, and Radiation Safety	57
10.3 Handling and Disposing of Biological Materials	57
10.4 General Operational Controls	57
Glossary	59