

Contents

<i>Preface</i>	(v)
----------------------	-----

Chapter – 1

Quality Assurance and Quality Management Concepts

1.1 Introduction	1
1.1.1 Quality Control.....	2
1.1.2 Quality Assurance	2
1.1.3 GMP (Good Manufacturing Practices) and Requirements of Premises, Plant and Equipment	3
1.1.4 PART I: Factory Premises and Materials (Salient Features).....	3
1.1.5 PART II: Plant and Equipment (Salient Features)	5
1.2 TQM.....	9
1.2.1 Definition of TQM	9
1.2.2 The Key Principles of Total Quality Management	9
1.2.3 Benefits of Total Quality Management	10
1.2.4 Beliefs about Total Quality Management	10
1.2.5 The 8 Primary Elements of TQM.....	10
1.2.6 Influences on The Total Quality Management Philosophy	12
1.3 ICH Guidelines	14
1.3.1 Objectives of ICH.....	14
1.3.2 Purpose of ICH.....	15
1.3.3 Participants of ICH.....	15
1.3.4 ICH Structure	15
1.3.5 Steps in the ICH Process	16
1.3.6 Overview of QSEM.....	17
1.3.7 Quality Guidelines.....	17
1.3.8 Adverse Effects of Instability of Drugs.....	18
1.3.9 Types of Stability	18
1.3.10 Stability Testing	18
1.3.11 Q1A (R2): Stability Testing of New Drug Substances and Products	18

1.3.12	Q2-Analytical validation.....	23
1.3.13	Q3A- Q3D---Impurities	23
1.3.14	Q4: Pharmacopoeias.....	24
1.3.15	Q5A-Q5E---Quality of Biotechnological Products.....	25
1.3.16	Q6: Specifications for New Drug Substances and Products.....	26
1.3.17	Q7: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.....	27
1.3.18	Q8(R2): Pharmaceutical Development	27
1.3.19	Q9: Quality Risk Management.....	27
1.3.20	Q10: Pharmaceutical Quality System.....	28
1.4	QbD.....	28
1.4.1	Pharmaceutical Quality by Design.....	28
1.4.2	Identify Critical Quality Attributes, Process Parameters ...	30
1.4.3	Essential Five-Step for Qbd for the Purpose of Product Development.....	31
1.4.4	Software Usage during QbD	34
1.5	ISO	34
1.5.1	Benefits of ISO.....	34
1.5.2	ISO 9000	35
1.5.3	ISO 14000	37
1.6	NABL Accreditation	38
1.6.1	Introduction	38
1.6.2	Objectives.....	38
1.6.3	WHY Accreditation.....	38
1.6.4	Benefits of Accreditation	39
1.6.5	Scope of Accreditation	39
1.6.6	Getting Ready for Accreditation	40
1.6.7	Process of Accreditation.....	42

Chapter – 2

Industrial Organization, Personnel, Equipment and Raw Materials

2.1	Organisation and Personnel.....	45
2.1.1	Definition	45
2.1.2	Personnel.....	47

2.1.3	General	47
2.1.4	Personnel Shared Responsibilities.....	48
2.1.5	Personnel Qualification	50
2.1.6	Personnel Responsibilities.....	50
2.1.7	Types of Training	52
2.1.8	Personnel Hygiene.....	52
2.1.9	Personnel Records	53
2.1.10	Site Master File	54
2.2	Premises	54
2.2.1	Location.....	55
2.2.2	Design & Construction.....	56
2.2.3	Plan and Layout.....	56
2.2.4	Process Layout or Functional Layout.....	57
2.2.5	Maintenance	60
2.2.6	Sanitation.....	60
2.2.7	Environment Control.....	60
2.3	Equipment	61
2.3.1	Life Stages of Equipment.....	62
2.3.2	Equipment Identification.....	64
2.3.3	Cleaning and Maintenance	65
2.4	Raw Materials	66
2.4.1	Purchase Specification	66
2.4.2	Maintenance of Stores	67

Chapter – 3

Quality Control

3.1	Testing of Containers and Closures	69
3.1.1	Glass Containers for Injectable Preparation.....	69
3.1.2	Metal Containers for Eye Ointment	71
3.1.3	Plastic Containers.....	72
3.1.4	Test for Rubbers (Closures)	72
3.1.5	Test for Containers.....	73
3.2	Good Laboratory Practices (GLP)	74
3.2.1	Objectives of GLP.....	74
3.2.2	Organization and Personnel	74

3.2.3	Facilities	76
3.2.4	Equipment	77
3.2.5	Testing Facilities of Operations	78
3.2.6	Reagents and Solution	80
3.2.7	Test and Control Article	80
3.2.8	Records and Reports	82

Chapter – 4

Complaint

4.1	Types of Complaint	84
4.1.1	Steps Involved in Handling of Complaints	85
4.1.2	Product Complaint Data Sheet	86
4.1.3	Complaint Record	87
4.2	Handling of Return Goods (Drug Product / Material)	90
4.2.1	Purpose	90
4.2.2	Scope	90
4.2.3	Responsibilities – Handling of Returned Goods	90
4.2.4	Abbreviations – Handling of Returned Goods	91
4.2.5	Procedure – Handling of Returned Goods	91
4.3	Recalling	96
4.3.1	Recall Handling	96
4.3.2	SOP on Recall	96
4.3.3	Procedure	97
4.3.4	Recall Classification	97
4.3.5	Recall Policy	98
4.3.6	Health Hazard Evaluation	98
4.3.7	Recall Team	98
4.3.8	Recall Strategy	98
4.3.9	Termination of Recall	99
4.3.10	Product Recall Chart	99
4.4	Waste Disposal	99
4.4.1	Definitions	99
4.4.2	Types of Wastes	100

4.5 Document Maintenance in Pharmaceutical Industry	102
4.5.1 Introduction	102
4.5.2 Principle	102
4.5.3 Objectives of Documents	102
4.5.4 Scope	102
4.5.5 Characteristic of Document.....	103
4.5.6 Types of Documentation	104
4.5.7 Batch Formula Record	105
4.5.8 Master Formula Record.....	107
4.5.9 SOP	108
4.5.10 Quality Audit.....	111
4.5.11 Quality Documentation	112
4.5.12 Distribution Records	115

Chapter – 5

Calibration and Validation

5.1 Validation.....	119
5.1.1 Definitions.....	119
5.1.2 Principle	119
5.1.3 Scope of Validation	120
5.1.4 Importance of Validation	120
5.1.5 Phases in Process Validation.....	121
5.1.6 Planning for Validation	121
5.1.7 Documentation	122
5.1.8 Types of Validation.....	122
5.1.9 Change Control	125
5.1.10 Revalidation	125
5.1.11 Validation Master Plan (VMP)	126
5.2 Analytical Method Validation.....	128
5.2.1 Different Principle of Analytical Method Validation.....	129
5.3 Calibration.....	137
5.3.1 Calibration of pH Meter	138
5.3.2 How a pH Meter Works	138
5.3.3 Procedure.....	139

5.4	Qualification.....	140
5.4.1	Design Qualification	140
5.4.2	Installation Qualification.....	141
5.4.3	Operational Qualification	142
5.4.4	Performance Qualification	143
5.4.5	Performance Tests for UV-Vis Spectrophotometers.....	147
5.5	Good Warehousing Practice.....	150
5.5.1	Various Areas of Warehousing	150
5.5.2	Good Warehousing Practice.....	151
5.5.3	Storage of Raw & Packaging Materials	152
5.5.4	Handling & Issue – Raw Materials	153
5.5.5	Handling & Issue: Packaging Materials.....	153
5.5.6	Stock Management.....	153
5.5.7	Material Management	154
5.5.8	Handling of these Materials	156