Table of Contents: EudraLex Vol. 4, Good Manufacturing Practice (GMP) guidelines, Part I, Basic Requirements for Medicinal Products

1. Pharmaceutical Quality System

Principle

Pharmaceutical Quality System 1.1 – 1.7

Good Manufacturing Practice For Medicinal Products 1.8

Quality Control 1.9

Product Quality Review 1.10 - 1.11

Quality Risk Management 1.12 - 1.13

2. Personnel

Principle

General 2.1 - 2.4

Key Personnel 2.5 – 2.9

Training 2.10 - 2.14

Personnel Hygiene 2.15 – 2.22

Consultants 2.23

3. Premises And Equipment

Principle

Premises

General 3.1 - 3.5

Production Area 3.6 – 3.17

Storage Areas 3.18 – 3.25

Quality Control Areas 3.26 - 3.29

Ancillary Areas 3.30 - 3.33

Equipment 3.34 - 3.44

4. Documentation

Principle

Required GMP Documentation

Generation and Control of Documentation 4.1 - 4.6

Good Documentation Practices 4.7 – 4.9

Retention of Documents 4.10 – 4.12

Specifications 4.13 – 4.16

Manufacturing Formula and Processing Instructions 4.17 – 4.21

Procedures And Records 4.22 – 4.32

5. Production

Principle

General 5.1 – 5.16

Prevention of Cross-Contamination in Production 5.17 – 5.22

Validation 5.23 - 5.26

Starting Materials 5.27 – 5.39

Processing Operations: Intermediate and Bulk Products 5.40 – 5.44

Packaging Materials 5.45 – 5.48

Packaging Operations 5.49 – 5.62

Finished Products 5.63 – 5.65

Rejected, Recovered and Returned Materials 5.66 – 5.70

Product Shortage Due to Manufacturing Constraints 5.71

Table of Contents: EudraLex Vol. 4, Good Manufacturing Practice (GMP) guidelines, Part I, Basic Requirements for Medicinal Products

6. Quality Control

Principle

General 6.1 - 6.4

Good Quality Control Laboratory Practice 6.5 – 6.6

Documentation 6.7 – 6.10

Sampling 6.11 - 6.14

Testing 6.15 – 6.25

On-Going Stability Programme 6.26 - 6.36

Technical Transfer of Testing Methods 6.37 - 6.41

7. Outsourced Activities

Principle

General 7.1 - 7.3

The Contract Giver 7.4 – 7.8

The Contract Acceptor 7.9 – 7.13

The Contract 7.14 – 7.17

8. Complaints And Recalls

Principle

Personnel and Organisation 8.1 – 8.4

Procedures - Investigating Complaints Including Possible Quality Defects 8.5-8.9 Investigation and Decision-Making 8.10-8.15

Root Cause Analysis and Corrective nnd Preventative Actions 8.16 – 8.19

Product Recalls and Other Potential Risk-Reducing Actions 8.20 – 8.31

9. Self Inspection

Principle 9.1 – 9.3