

Q00-00-00 Policy Statement – QMS
Q00-00-01 QMS Flowchart

QUALITY MANAGEMENT SYSTEM (QMS)

Reference:
FDA Quality System Approach to cGMP Sept.2006;
FDA 21 CFR 210/211; ISO 9001-2000; ICH-Q10

E00 GOOD ENGINEERING PRACTICE (GEP)

- Q04-0102 Document Control
- Q04-0103 Good Documentation Practices
- Q04-0104 Change Control
- Q04-0105 Document Change Control

Q04 CORE CONCEPTS

Q05 Management Responsibilities & Requirements

ISO Section 5; FDA Section IV/A

Policy Statement

- Quality Policy, Quality Manual,
- Site Master Plan/File,
- Organization Chart,
- Quality Review Board,
- Validation Review Board,
- Validation Master Plan,
- Master Equipment List

Q06 RESOURCE REQUIREMENTS & MANAGEMENT

ISO Section 6; FDA Section IV/B

Policy Statement

Q06-01 Personnel/Human Resources Requirements
ISO Section 6.2, FDA IV/B/2

- Training Policy
- Training Management System
- Competency

Q06-30 Facility & Equipment Requirements
ISO Section 6.3, FDA IV/B/3

- Facility Requirements
- Facility Design Guidelines
- System Impact Assessment
- Component Criticality Analysis
- Equipment & Drawing Control
- Equipment Pre-Qualification Process & Documentation
- Q06-32 Equipment Qualification
- Q06-36 Maintenance Program
- Q06-37 Laboratory Facility

Q06-40 Control Outsourced Operation, Work Environment
ISO 6.4, FDA IV/B/4

- Suppliers – Technical Agreement
- Suppliers – External Audit, Monitoring
- Q06-46 Environmental Monitoring
- Q06-47 EH&S

Q07 Manufacturing Operations

ISO Section 7; FDA Section IV/C

Policy Statement

Q07-10 Plan Product Realization
ISO 7.1, FDA C/1

- Product Design Plan
- Quality Plan

Q07-20 Customer Related Process
ISO 7.2, FDA C/1

Identify & Review Customer's Requirements;
Customer Communications – product information, contracts, orders, complaints

Q07-30 Design, Develop & Document Product & Processes
ISO 7.3, FDA C/1

- Design & Development Plan;
- Define Inputs, Generate Outputs;
- Design Reviews;
- Design Verification/Validation;
- Design Change Control

Q07-40 Purchasing & Examine Inputs
ISO 7.4, FDA C/2

- Control Purchasing;
- Document Purchasing;
- Verify purchased products

Q07-50 Perform & Monitor Mfg Operations
ISO 7.5, FDA C/3

- Validation (CV, PV, CSV)
- Production & Process Control
- QC Criteria (In-process testing, Stability Program)
- QA & QC Checkpoints – batch release, sampling
- QC Lab Operations
- Storage & Warehousing

Q07-60 Control of monitoring & measuring devices
ISO 7.6, FDA C/3

- Calibration Program & Schedules of Devices;
- Equipment Control

Q07-70 Address Nonconformities
ISO 7.7, FDA C/4

- Document Deviations;
- Address & control CAPA

Q08 Evaluation Activities

ISO section 8; FDA IV/D

Policy Statement

Q08-01 Monitoring & measurement
ISO 8.2, FDA D/2

- Site Quality Council
- Customer Complaints
- Internal Audit
- Annual Product Review

Q08-02 Control of Non-conforming Product
ISO 8.3, FDA D4/5

- Deviation (CAPA)
- Product Recall

Q08-03 Analysis of Data
ISO 8.4, FDA D1

- Monitor trends
- Process Improvements

Q08-04 Make Quality Improvements
ISO 8.5, FDA D6

E02 PROJECT ENGINEERING

E03 COMMON PRACTICES & SYSTEMS

E04 OPERATIONS & MAINTENANCE

For details of GEP - see separate sheet

This flowchart is available in Microsoft Visio format at www.gmptemplates.com

The drawing is the property & copyright of www.GMPtemplates.com. Do not copy, distribute or reproduce without prior written permission from GMPtemplates.



www.GMPtemplates.com

Online Store for GMP Document Templates

Model for Quality Management System

info@GMPtemplates.com

SIZE

Filename

DWG NO

REV

A3

Q00-00-01 QMS Flowchart

2

SCALE

1:1

SHEET

1 OF 1