Q00-0000 Policy Statement – QMS
Q00-0001 QMS Flowchart
(this flowchart)

QUALITY MANAGEMENT SYSTEM (QMS)

Reference:
FDA Quality System Approach to cGMP;
FDA 21 CFR 210/211; ISO-9001; ISO-13485;
PIC/S PI002-3; ICH-Q10;

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E00 GOOD ENGINEERING PRACTICE (GEP)

E01 Core Concepts
E02 Common Practices
E03 Project Quality System
E04 Operations & Maintenance
E10 Critical Utilities – WFI, Steam
E20 Engineering Tools
E60 Environment, Health & Safety

For details of GEP - see separate sheet

- *Q04-0102 Document Control*
- *Q04-0103 Good Documentation Practices*
- *Q04-0104 Change Control*
- *Q04-0105 Document Change Control*
- *Q04-0150 Risk Assessment*

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/Checklist*
- *System Impact Assessment*
- *Component Criticality Analysis*
- *Equipment & Drawing Control*
- *Equipment Pre-Qualification Process & Documentation*
- *Equipment Qualification*
- *Maintenance Program*
- *Laboratory Requirements*
- *Facility & Cleanrooms*

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

- *Suppliers – Technical Agreement*
- *Suppliers – External Audit, Monitoring*
- *Environmental Monitoring*
- *Environment, Health & Safety EHS*

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*

Q07-50/60
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*
- *Batch Records Documentation*
- *Product Release*
- *Storage & Warehousing*

Q07-70
Control of monitoring & measuring devices
ISO 7.6, FDA C/3

- *Calibration Program & Schedules of Devices;*
- *Equipment Control*

Q07-80
Address Nonconformities
ISO 7.7, FDA C/4

- *Deviations Reporting*
- *Deviation Investigation*
- *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*
- *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

- *Corrective Action*
- *Preventive Actions*

IMPORTANT NOTES:
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Model for
Quality Management System

SIZE	Filename	DWG NO	REV
A3		Q00-0001 QMS Flowchart	4
SCALE NTS		SHEET 1 OF 1	