DQ: COMPUTER SYSTEMS

Document Type: Protocol

NAME AND ADDRESS OF THE MANUFACTURER
DESIGN QUALIFICATION
PROTOCOL No. :..........................   **Effective date ……………………**
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1.0   Approval

Pre approval of this protocol will be the joint responsibility of the following functional areas.

Functional Area	Name	Signature	Date
Quality Assurance			
Production			
Engineering			
Product Development			

Post approval of this protocol will be the joint responsibility of the following functional areas.

Functional Area	Name	Signature	Date
Quality Assurance			
Production			
Engineering			
Product Development			

2.0   Statement of Purpose

The purpose of this protocol is to provide an outline for the design of the NEW Computer System be procured. The system shall be designed to fulfil the intended purpose without errors and shall meets the current Good Manufacturing Practices (cGMP) requirements and all other regulatory obligations

3.0   Design Input

3.1   Purpose of System
i)   Clear statement of what the system is to do.
ii)   Expected benefits.
iii)   Relation to other system.

3.2   Controlled Function

Operating Modes
a)   Automatic mode.
b)   Manual mode.
c)   Maintenance mode.

d)   Operational interlocks.

Description of Operations.

a)   Sequence of operation.
b)   Modifiable parameters.
c)   Limiting conditions.

Controlled elements.

a)   Valves, heaters, motors……
b)   I\P, relays, solenoids, motor starters ….

3.3   Computer System

Hardware.
a)   CPU
b)   Memory devices.
c)   Recording devices.
d)   Communication interfaces.
e)   Operator terminals

Software
a)   Operating System
b)   Communication drivers.
c)   Network Controllers.
d)   Configurable Programs.
e)   Application Programs

3.4   Information Input

Measured Inputs
a)   Number, Type, and location of each sensor.
b)   Type, Model Number, and software version of all transducers and signal converters.
c)   Model number and software version of all analog input modules.
d)   Tag name, location, data type, and valid range of all analog inputs.

Discrete Inputs
a)   Type, model number, and software version of all discrete input modules.
b)   Tag name and location of all discrete inputs.

Operator Inputs

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a)   Entry and verification means.
b)   Entry modes.
c)   Error detection.
d)   Error correction
e)   Tag name, description, and range of parameters.
f)   Electronic Signatures.

Recipe Inputs
a)   Definition.
b)   Loading.
c)   Verification.
d)   Security.
g)   Tag name, description, and range of parameters.
e)   Electronic Signatures.

Input from other Systems.
a)   Source.
b)   Communication mode.
c)   Error detection.
d)   Error correction
e)   Tag name, description, and range of parameters.

Material Input
Loading
a)   Manual Loading.
b)   Automatic loading.
c)   Input from other system.

Checks on Material Inputs
3.5   **Data Processing**

Input Data
a)   Data conversions.
b)   Scaling.
c)   Calibration means.
d)   Error detection and correction.

Calculations.
a)   tag names and input parameters.
b)   Algorithms.
c)   Control strategies.
d)   Tag names and ranges of output parameters.

e)   Error detection and correction.

3.6   Information Output

Control

a)   Tag name, location, range, and default value of analog outputs.
b)   Model number, software version, and location of each analog output Module.
c)   Type, model number, software version, and location of each output driver.

Alarms

a)   Tag name, type, and location of alarm outputs.
b)   Type and location of alarm indicator.
c)   Acknowledgement means.

Displays

a)   Tag name of the data values.
b)   Tag name of status indicators.
c)   Event indicators
d)   Alarm indicator.

Printed Reports.

a)   Tag name of the data values.
e)   Tag name of status indicators.
f)   Event recording.
g)   Alarm recording
h)   Report generation

3.7 Transmission to other systems.

a)   Tag name of the data values.
b)   Tag name of status indicators.
c)   Event Transmission.
d)   Alarm transmission
e)   Report transmission.
f)   External request of data.

Archived Data

a)   Tag name of the data values.
b)   Tag name of status indicators.
c)   Event recording.
d)   Alarm recording
e)   Report generation

f)   Audit trail.

3.8 Operational Features.

Alarm Management.
a)   Action.
b)   Priority.
c)   Reporting.
d)   Acknowledgment.
e)   Power failure.

Security

a)   Levels
b)   Means of access.
c)   Parameter modification.
d)   Program access.

Safety
a)   Physical Interlocks.
b)   Software interlocks.
c)   Emergency shutdown and recovery.

System Failure.

a)   Failure Modes
b)   Default state
c)   Recovery modes.

Analog data update Time
a)   control inputs
b)   alarms
c)   Displays.
d)   Reports.
e)   Archived data.
f)   Transmission to other system.

Discrete data update time

a)   Control outputs.
b)   Alarms.
c)   Displays.
d)   Reports.
e)   Archived data

f)   Transmission to other systems.

Response to operator inputs.
a)   Analog.
b)   Discrete
c)   Alarm.

3.9   **Physical Requirements**

System Structure.
a)   Layout of components.
b)   Relation to facilities and other systems.

Size Restrictions.

Materials.
a)   Type.
b)   Finishes.

Utilities.
a)   Electrical.
b)   Water.
c)   System
d)   Air.

Environmental.
a)   Temperature.
b)   Vibration.
c)   Electrical interference.
d)   Humidity.

4.0   **System Description**
(Component Details)

Describe All component details

a) Hardware

Vendor

Model

Sr No

b) Software

Vendor

Version

c) Peripherals

Cables

Power Supply Devices

UPS

Voltage Stabilizers

d) Ancillary Equipmets/Adapters/Interfaces

Modem

Printer

CDROM Drive

Scanner

Interface for Speaker

5.0   Line Diagram of complete system

(Attach the copy of drawing given by the supplier)

6.0   Vendors Communication
(Attach the copy of communication received from the Vendor)

Specify the Reference Documents required e.g.

°   Complete Details and Specifications on hardware, software
°   and Peripherals used in the system

°   Installation Manual-

°   Software User manual

°   Line Diagram of the System

°   Calibration and maintenance manual

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- Utilities Requirements

- Working Environment details

- IQ, OQ and PQ details for the system

- Validation Checks Performed before Supply

- Test Report on the system and on individual components
- Operators Qualification and Experience Details

- FAQ on Handling the System

- Contact details

- Security System employed and its operational details

7.0 Vendor Qualifications

7.1 Company Information

7.2 Human and Financial resources.

7.3 Knowledge of GMP requirements

7.4 Organization
- a)   Structure
- b)   Responsibilities.

7.5 Customer Support
- a)   Installation and service.
- b)   Technical support
- c)   User training.

7.2   Quality System –General.

a) Management's stated policy and commitments.

b) Quality group's responsibility and authority.

c) Written Company quality plan.

d) Management Review of quality system.

7.3   Quality System –Software Development.

Development Plan
- a)   Functional Requirements.
- b)   Software design specifications.
- c)   Programming standards and procedures.
- d)   Programming tools.
- e)   Review procedures.

Test Plan
- a)   Types of Tests.
- b)   Test tools and methods.
- c)   Error correction and re-test.
- d)   Test review.
- e)   Acceptance criteria.
- f)   Test reports.

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Configuration Management.

a) Organization and responsibilities.
b) Identification and traceability.
c) Configuration tools.
d) Change control procedures.
e) Version identification control policy.
f) Release approval procedures.
g) Configuration history and status report.

Program Documentation

a) Source code.
b) Logic diagrams.
c) List of all inputs and outputs.
d) List of all modifiable parameters.
e) List of all operator inputs.
f) Description of interfaces to other systems.
g) Description of alarms and interlocks.
h) Description of error detection and recovery.
i) Description of all data displays.
j) Description of all reports.

Document Control

a) Documents to be controlled.
b) Approval of issue procedures.
c) Change control procedures.
d) Retention and security procedures.

Personnel Qualification

a) Formal education.
b) Internal training.
c) Experience in software development.
d) Experience with specific programs used.
e) Experience with application.

7.4 **Product Information**

7.5 **Validation Features.**
a) Security.

b)   Self documentation.
c)   Automatic program change audit trail.
d)   Simulation capability.
e)   Program compare.
f)   Revision documentation detail.

7.6   History of Use

a)   Customers of all version.
b)   Customers of present version.
c)   Configuration history and status report.

7.7   Expected Life

a)   Present version
b)   Revised products.

7.8   Revision Policy

a)   Notification of problems.
b)   Change required to fix problems.
c)   Change to add or modify features.
d)   Notification of revisions.
e)   Support old versions.