

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION BUILDING MANAGEMENT SYSTEM

DESIGN QUALIFICATION OF BUILDING MANAGEMENT SYSTEM (BMS)

PREPAI M/s		

CLIENT NAME:





TABLE OF CONTENTS

1.0	APPF	ROVAL3
2.0	OVE	RVIEW 4
	2.1	Objective:
	2.2	Scope:
3.0	RESP	PONSIBILITIES4
4.0	SYST	TEM DESCRIPTION
5.0	TECH	HNICAL SPECIFICATIONS OF COMPONENTS AND SUB-COMPONENTS USED /
	BOU	GHT BY MANUFACTURER:7
6.0	DETA	AILS OF UTILITIES9
7.0	REVI	EW / EVALUATION OF VENDOR DESIGN AGAINST USER REQUIREMENTS 10
8.0	FINA	L REPORT
9.0	REFI	ERENCE DOCUMENTS
10.0	ABBI	REVIATIONS14
11.0	ATTA	ACHMENT(S) / ANNEXURE(S)



QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION BUILDING MANAGEMENT SYSTEM

1.0 APPROVAL

Prepared By:

Department	Name	Designation	Signature	Date

Checked By:

Department	Name	Designation	Signature	Date

Approved By:

Department	Name	Designation	Signature	Date
Engineering Head				
Quality Assurance Head				



2.0 OVERVIEW:

2.1 Objective:

Design Qualification is a comprehensive document providing all the details required ensuring that the proposed design of the system is suitable for its intended purpose.

It thus provides documented evidence that quality is built into the design of the equipment.

The objective of this specification is, therefore, to provide the construction and operation requirement of the system on the basis of which it is designed.

2.2 Scope:

This specification will define the responsibilities, acceptance criteria, basis of design, technical specifications, utility requirements, safety and GMP features and documentation requirements.

3.0 RESPONSIBILITIES:

CLIENT:

To provide the URS for the system

MANUFACTURER:

To design, engineer and provide the key technical details of the system pertaining to its design qualification viz.

- System Overview
- Specifications of the components and their make, model & quantity,
- Pre-installation requirements,
 - o To confirm the safe delivery of the system to the user site
 - O To ensure that unauthorized and/or unrecorded design modifications shall NOT take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.
 - To ensure the proper installation and commissioning of the system.



PHARMA DEVILS GUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION BUILDING MANAGEMENT SYSTEM

4.0 SYSTEM DESCRIPTION:

Brief Description:

The design of the System has integration of the smallest sensor to the operator workstations with all function of HVAC services available at the control stations. Integration shall mean all the parts of system are connected together through software and shall share all the information. The integration of all input/output points shall be achieved through software programs, electronic components, hardware packaging and communication through network for BMS.

The Building Management System shall carry out the monitoring & control following for

❖ Air Handling Unit:

During normal operation, control stations shall carry out their respective functions. This shall be governed by user level password access to prevent interference during normal operation.

The system will allow for operation scheduling, sequencing of various systems, apart from allowing the operational history of various systems to be recorded in the database, which information will be useful for reliability analysis and troubleshooting.

Siemens Building Management System comprise of following:

The BMS is capable of integrating multiple functions including equipment supervision & control, alarm management, historical data collection and archiving.

The BMS consists of the following:

a) Network able DDC (Direct Digital Control) Controllers.

System operation work station.

- a) Field Sensors (analog/Digital)
- b) Field Output devices/actuators

The system is modular in nature and permits expansion of both capacity and functionality through the addition of sensors, actuators, DDC Controller and operator devices within specified I/O range.

System architectural design eliminates dependence on the network for controlling and storing events. Each DDC Controller operates independently by performing its own specified input and output control and historical data collection. The failure of network connection will not interrupt the execution of control strategies at other operation devices.



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION BUILDING MANAGEMENT SYSTEM

DCC Controllers are able to access any data or send control commands and alarm reports directly to any other DDC Controllers or combination of controllers on the network without dependence upon a central processing device.

Control Logic:

Sequence for AHU Starting:

Normal Mode: In normal mode BMS system have two types of operations i.e. Scheduling and Manual Operation

Scheduling: If we schedule the system , AHUs will run as per desired schedule.

Manual Operation: Operator can command the system as per requirement by over-riding the schedule.

Power Fail & Resume: After resumption of power, normal operation will start. When the power is fail there will be no alarm highlighted except Fire Alarm.

VFD Control: - VFD Speed control is based on the DP sensor connected to the VFD for modulation.

Temperature / Humidity Control:

Chilled Water Control: The Chilled water valve Actuator operation is based on the present value (PV) and set point (SP) of Return air temperature and Humidity. If AHU is OFF, Actuator will not work. Control Parameter Settings

- ➤ Integral action time: 120 Seconds.(Adjustable)
- > Temperature Set point: As per Air Flow Deg. C.
- Proportional Band: 2 Deg. C.
- > Operation before startup: Chilled water valve actuator remains off until AHU is ON.

RAT & RARH PV <= Return Air Temperature & Humidity Set point Deg. C = Chilled Water Valve Actuator will remain 100% closed

RAT or RARH PV > Return Air Temperature or Humidity Set point Deg. C = Chilled Water Valve Actuator will remain 100% open.

Hot Water Control: The Hot water valve Actuator operation is based on the present value (PV) and set point (SP) of Return air temperature. If AHU is OFF, Actuator will not work. Control Parameter Settings.

Control Parameter Settings

- ➤ Integral action time: 120 Seconds.(Adjustable)
- > Temperature Set point : As per Air Flow Deg. C



PHARMA DEVILS GUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION BUILDING MANAGEMENT SYSTEM

Proportional Band : 2 Deg. C(Adjustable)

RAT PV <Return Air Temperature Set point Deg. C = Hot Water Valve Actuator will remain 100% closed

RAT PV >= Return Air Temperature Set point Deg. C = Hot Water Valve Actuator will remain 100% open.

AHU Safety Interlock:

> Door limit switch will be interlocked with electrical panel. System will not run if the door is open.

AHU Alarm Parameters:-

- ➤ Temp high/ Low alarm
- ➤ Humidity high/Low Alarm

Trends Configuration:

- 1. RA Temperature
- 2. RA Humidity
- 3. System On/Off Status.
- 4. DP Status

Interlocking of the systems:

- ➤ All valve actuators will remain OFF till the respective system is OFF.
- ➤ Dehumidifier will remain OFF if the AHU is OFF.

IO Point Summary:

As per attached "ANNEXURE-I"

5.0 TECHNICAL SPECIFICATIONS OF COMPONENTS:

Components	Specifications			
Duct Temperature Sensor				
Make	Dwyer			
Model	BTT D062			
Range	-40 to 60 °C			
Output Signal	DC 010 V			
Location	At Return Air Duct of AHU			
Differential Pressure Transmitter				



PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

Components	Specifications
Make	Dwyer
Model	MS311
Range	03 kpa
Output Signal	DC 010 V
Location	Across Fan
Duct Temperature & Humidity Trans	smitter with Sensor
Make	Dwyer
Model	RHP-3D22
Range	Temperature: -40 to 60 °C, Humidity:0100 % RH
Output Signal	DC 010 V
Location	At Return Air Duct of AHU
CHW Actuator	1
Make	Danfoss
Model	AME110NL
Closing Force	130 N
Stroke	5 mm
Location	At Chilled Water Outlet Duct
CHW Actuator	
Make	Danfoss
Model	AME435QM
Closing Force	200 N
Stroke	20 mm
Location	At Chilled Water Outlet Duct
Room Display Unit	<u>l</u>
Make	Hawkeye RTC
Port	RS485, Isolated



PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION BUILDING MANAGEMENT SYSTEM

Components	Specifications
Baud Rate	9600 bps
Protocol	Modbus RTU
Desigo Software	
Make	Siemens
Software	Desigo CC
Firmware Version	3.0
Function	Monitoring of system
DDC Controller	
Make	Siemens
Model	PXC50.E.D with expansion modules& PXC001.ED for MODBUS communication
Location	Second Floor
Power	24V AC (+/- 20%)

6.0 DETAILS OF UTILITIES:

S.No.	Utility	Requirement
1.	UPS Power	230V AC , 50 Hz



7.0 REVIEW/EVALUATION OF VENDOR DESIGN AGAINST USER REQUIREMENTS

Review the vendor design proposal, against each item, and comment whether, vendor design, meets requirements.

Description		Feat	tures		Remarks / Actions to
S. No.	of Requirement	SHPL Requirements	Vendor Specifications	(Yes/No)	be taken (if specificati on does not match)
	Equipment /	Building Management	Building Management System	Yes	NA
1.	System	System for AHU of the	for AHU of the Injection		
		Injection Facility	Facility.		
	Requirement	The purpose of this	BMS (Building Management	Yes	NA
		requirement definition	System) shall be used to:		
		document is to describe the	o To Control temperature of		
		User Requirement	Each AHU System		
		Specification for BMS	o To Control RH of Each		
		(Building Management	AHU System (As		
		System) which shall be used	applicable)		
2.		to:			
		o To Control temperature of			
		Each AHU System			
		o To Control RH of Each			
		AHU System (As			
		applicable)			



QUALITY ASSURANCE DEPARTMENT

	Describer	Feat	tures		Remarks / Actions to
S. No.	Description of Requirement / SHPL URS reference	of quirement HPL URS SHPL Requirements Vendor Specifications eference	Specification Matches (Yes/No)	be taken (if specificati on does not match)	
	Equipment	• The System to be installed at	• The System to be installed at		
	Installation	AHU of the Injection	AHU of the Injection		
		Facility.	Facility BMS Server PC		
		BMS Server PC shall be	shall be installed at BMS		
		installed at BMS Room which is also at 2 nd Floor.	Room which is also at 2 nd Floor.		
		 Return air Temperature + 	Return air Temperature +		
		RH sensor shall be installed	RH sensor shall be installed		
		in return air duct of	in return air duct of		
3.		respective AHU to control	respective AHU to control	Yes	NA
		temperature and RH of	temperature and RH of		
		respective AHU.	respective AHU.		
		• Differential Pressure	• Differential Pressure		
		transmitter shall be installed	transmitter shall be installed		
		in supply air duct of	in supply air duct of respective AHU.		
		respective AHU. • DDC controller shall be	DDC controller shall be		
		installed in the Electrical	installed in the Electrical		
		Room.	Room.		
		The BMS shall control the	The BMS shall control the		
		Temperature and Relative	Temperature and Relative		
		Humidity for the areas	Humidity for the areas		
		served by respective	served by respective	Yes	NA
		HVAC systems.	HVAC systems.		
		• The BMS shall store	• The BMS shall store		



QUALITY ASSURANCE DEPARTMENT

Degovintion		Feat	ture	es		Remarks / Actions to
S. No.	Description of Requirement / SHPL URS reference	SHPL Requirements		Vendor Specifications	Specification Matches (Yes/No)	be taken (if specificati on does not match)
	System	logged data, alarms and		logged data, alarms and		
	Specifications	history trends as specified		history trends as specified		
		in the document.		in the document.		
		• Access to the BMS	•	Access to the BMS		
		interface shall be through		interface shall be through		
		username and password		username and password		
		protection. A hierarchy of		protection. A hierarchy of		
		configurable user access		configurable user access		
		levels shall be available		levels shall be available		
		ranging from		ranging from		
		"Administrator" rights		"Administrator" rights		
		with full access and		with full access and		
		control to "user" rights		control to "user" rights		
		with read only access.		with read only access.		
		• DDC Panel shall run	•	DDC Panel shall run		
		through UPS power.		through UPS power.		
		• The system shall be				
		centralized and PC with				
		simple operating				
		techniques and shall be	•	The system shall be		
		used to control, manage,		centralized and PC with		
		alarm / report with		simple operating		
		reference to AHU		techniques and shall be		
		systems.		used to control, manage,		



QUALITY ASSURANCE DEPARTMENT

S. No. SHPL Requirements Suppose the control of the computent of the communicate of the		Requirement / SHPL URS	Fea	Remarks Actions to	
devices shall be communicated to DDC which shall communicate information to a central computer. • Editing and controlling of various set points shall be done from the central computer through password protection. • Editing and controlling of various set points shall be done from the central computer. • Editing and controlling of various set points shall be done from the central computer through			SHPL Requirements		Matches (Yes/No) (if specificat on does not
			devices shall be communicated to DDC which shall communicate information to a central computer. • Editing and controlling of various set points shall be done from the central computer through	reference to AHU systems. Signals from field level devices shall be communicated to DDC which shall communicate information to a central computer. Editing and controlling of various set points shall be done from the central computer through	



QUALITY ASSURANCE DEPARTMENT

Summari	zed By (Sign/D	late)•		
Summan	zeu by (Sigii/D	aic).		
Reviewed	By (Sign/Date):		

9.0 REFERENCE DOCUMENTS:

S.No.	Title	
1.	User Requirement Specifications (URS)	

10.0 ABBREVIATIONS

S.No.	Abbreviation	Description	
1.	%	Percent	
2.	°C	Degree Centigrade	
3.	AHU	Air Handling Unit	
4.	BMS	Building Management System	
5.	CFR	Code of Federal Regulations	
6.	DDC	Direct Digital Control	



S.No.	Abbreviation	Description	
7.	DP	Differential Pressure	
8.	HVAC	Heating Ventilation and Air Conditioning	
9.	LAN	Local Area Network	
10.	LED	Light Emitting Diode	
11.	Ltd.	Limited	
12.	MKT	Mean Kinetic Temperature	
13.	PC	Personal Computer	
14.	RH	Relative Humidity	
15.	HPL	Healthcare Pharmaceuticals Limited	
16.	Sr. No.	Serial Number	
17.	UPS	Uninterrupted Power Supply	
18.	URS	User Requirement Specifications	
19.	US FDA	United States Food and Drug Administration	
20.	w.r.t.	With respect to	

11.0 ATTACHMENT(S) / ANNEXURE(S)

S.No.	Description	Attachment No. / Annexure No.
1.	IO Point Summary	Annexure-I
2.	System Architecture Drawing	Attachment - I
3.	DDC GA Drawings	Attachment - II