



HLL BIOTECH LIMITED				
INTEGRATED VACCINES COMPLEX, Chengalpattu				
nne pharmaplan®	User Requirement Specifications			
	Equipment/System	Plant Manager		
	Identification #	U-CPM 02	Document#	URS/U/CPW 02
	Effective Date	23.05.2014	Revision#	00
<div>  <div> HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise) </div> </div>				
<div> <div>User Requirement Specifications</div> <div>Chilled Plant Manager</div> <div>Equipment ID: U-CPM 02</div> </div>				
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Annexure List

S No.	Drawing / Document No.	Detail
NA	NA	NA

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1. APPROVAL SIGNATURES

This document is prepared by project team of NNE Pharmaplan for the Integrated Vaccines Complex (IVC)+(NPI project number: 120310) of HLL Biotech limited under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team/Engineering team of HLL Lifecare limited, and authorized by the appropriate Project Authority.


NNE Pharmaplan India Ltd.	Name and Designation	Signature	Date
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2. OVERVIEW 2.1 Project introduction <p>HLL Biotech Limited (HBL), a subsidiary of HLL Lifecare Limited, (a CPSU under Ministry of Health & Family Welfare, Government of India, is implementing "an Integrated Vaccines Complex (IVC) - a project of national importance' at Chengalpattu, near Chennai. The proposed complex is a state of the art facility with cGMP compliance for manufacturing vaccines required for the immunization programme of Government of India.</p> <p>For this purpose, NNE Pharmaplan has been appointed as consultants for setting up this facility, incorporating the latest standards of GMP and best practices</p> 2.2 Objective <p>This document is mainly prepared to define the user requirements for the plant manager for utility equipments like chiller, cooling tower, distribution pumps and control valves.</p> <p>The VENDOR being the organization which will respond to this tender by a quotation and subsequently is contracted accordingly.</p> <p>It is the responsibility of the VENDOR to get familiar with the local situation prior to the start of the design work either by studying building and layout drawings or by an inspection on site.</p> <p>The client expects from the vendor a careful review of the supplied documents with special regard to:</p> <ul style="list-style-type: none"> ➤ Consideration of recent knowledge in science and technology ➤ Consideration of local regulatory requirements ➤ General engineering rules as well as other regulations and guidelines to be considered ➤ Qualification/suitability/adequacy for the planned use/scope of work ➤ Warranty to provide a defect free, operative performance/service ➤ In case the text of an item in the specification allows different interpretation the vendor/bidder is obligated to indicate this in the proposal. Unclear passages have to be mutually clarified with the client prior to signing the contract. If the vendor fails to do this, the interpretation of the client applies. 					
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2.3 Scope of Work

The Contractor's scope of work shall include Supply, Installation, Testing and Commissioning & Validation of entire complete plant manager as package to control and operate the utility equipment as per desired parameter.

Plant Manager should be flexible enough to accommodate various combinations of plant equipment and their operating sequences at the same time, smart enough to stage/operate them to optimize for power and performance.

Plant manager shall be BMS compatible and configured for functionality of below major equipments and Valves.

- Water Cooled Brine Chiller. (3 Nos.)
- Motorized valves for inlet of condenser and evaporator side.
- Motorized valves for cooling water return for individual cooling tower.(1 No)
- Temperature transmitters in supply and return header
- Pressure transmitters.
- Primary distribution pumps for chilled water.
- Cooling water distribution pumps.

Communication and control cables shall be included in the scope of supply and installation

Depending on target temperature and actual outlet evaporator temperature, individual controller loads / unloads the chiller using PID control. Chiller Manager shall continuously monitors the operating percentage of each chiller and water temperature in common headers for evaporator.

During steady state condition Chiller Manager evaluates different combinations of operating percentage of chillers and comes up with best possible combination to cater external load and accordingly decides whether to ON/OFF Next chiller. Each ON/OFF of chillers, shall be accompanied by staging of pumps if required and ON/OFF of Motorized valves as per requirement.

Apart from operating above equipment for safe and reliable plant operation, Plant Manager also shall provide features, like optimization for power of overall plant, run-hours management of all the equipment, facility to set stand-by equipment, auto shift to stand by equipment in case of break down, weekly scheduling, etc.

The vendor shall clearly indicate the battery limits, the termination points, utilities required, etc., in the detailed offer.


The vendor shall come back with any suggestions if, found to be more effective and efficient / better than that specified in this specification.

The Client shall be entitled to inspect and audit the supplier's Quality Management System (QMS) and the facilities, if desired, prior to any business agreement.

The vendor should take full responsibility for the function of the chilled water generation system.

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This requirement and respective document attached shall define the minimum requirement to be met by the vendor.

Below is the list of minimum I/O list required for plant manager system.

Utilities (Metals)					
Description	Analog		Digital		Function
	I	O	I	O	
CENTRAL BRINE CHILLER SYSTEM					
CHILLER - 3 NO	--	--	--	--	Software integration of plant manager for complete control & monitoring through data exchange of Chiller. Microprocessor panel
Chiller start/stop command	--	--	--	3	On / Off Command
Chilled Brine Isolation Valve Open/Close command	--	--	--	3	On / Off Command
Chilled Brine Isolation Valve Open/Close command status monitor	--	--	3	--	Display / Monitor
Cooling water Isolation Valve Open/Close command	--	--	--	3	On / Off Command
Cooling water Isolation Valve Open/Close command status monitor	--	--	3	--	Display / Monitor
PRIMARY CHILLED BRINE PUMPS					
Primary chilled Brine pump start/stop command	--	--	--	4	On / Off Command
Primary chilled Brine pump run status monitoring	--	--	4	--	Display & monitor
Primary chilled Brine pump Auto/Manual operation status	--	--	4	--	Display & monitor

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COMMON INDICATIONS						
Chilled Brine supply header temperature monitoring		1	--	--	--	Display / Monitor
Chilled Brine return header temperature monitoring		1	--	--	--	Display / Monitor
Chilled Brine supply header Pressure monitoring		1	--	--	--	Display / Monitor
Chilled Brine return header Pressure monitoring		1	--	--	--	Display / Monitor
Ambient Temperature sensor		--	1	--	--	Display / Monitor
COOLING TOWER						
Cooling water pump start/stop command		--	--	--	3	On / Off Command
Cooling water pump run status monitoring		--	--	3	--	Display & monitor
Cooling water Isolation Valve Open/Close command		--	--	--	3	On / Off Command
Cooling water Isolation Valve Open/Close command status monitor		--	--	3	--	Display / Monitor
Fan Trip		--	--	3	--	Display / Monitor
Cooling water main header temperature supply/Return		--	--	2	--	Display / Monitor
Total		4	1	25	19	

Software Integration (6 Nos. each) for below mentioned points shall be consider in the scope

Leaving chilled liquid . Set-point

Motor current limit -Set point

Leaving chilled liquid - Temperature

Entering chilled liquid - Temperature


Leaving condenser liquid - Temperature

Entering condenser liquid - Temperature

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Evaporator pressure
 Condenser pressure
 Oil . low differential pressure
 Motor Fla current
 Discharge pressure
 Operating hours
 Unit safety fault code
 Unit cycling fault code
 Operation code
 Evaporator . low pressure
 Evaporator . low-pressure . smart freeze
 Evaporator . transducer or leaving liquid probe
 Condenser . high pressure
 Condenser . pressure transducer out of range
 Discharge . low temperature
 Oil . high temperature
 Oil . low differential pressure
 Oil . clogged filter
 Motor controller . loss of current
 Oil . high pressure
 Oil . separator . low level
 Leaving chilled liquid - low temperature

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Motor controller . loss of current

System oil temperature

System oil pressure

System oil filter pressure

Slide valve position

System discharge temp

System evaporator saturation temperature

System evaporator sub temperature

System condenser saturation temperature

Evaporator refrigerant temperature

Evaporator small temperature difference

Condenser small temperature difference

System start times

2.4 Control Philosophy

2.4.1 Staging of pumps:


For constant flow / variable flow distribution system pumps shall be staged as per chiller staging. Just before Next chiller ON both evaporator and condenser flows shall be established.

Pumps with VFDs implemented for secondary variable flow through secondary pump shall be staged based on feedback from pressure transmitter at farthest AHU. That means speed of all the ON pumps will be varied proportional to the decrease in water pressure at AHU/ distribution piping till they reach to maximum speed and afterwards Next Pump shall be ON.

In case of increase in water pressure at AHU/distribution header there shall be proportional reduction in speed of all pumps ON till they reach minimum speed and afterwards Next Pump will be OFF.

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2.4.2 Staging of Chillers:

Depending on target temperature and actual outlet evaporator temperature, individual controller loads / unloads the chiller using PID control.

Plant Manager shall continuously monitor the operating percentage of each chiller and water temperature in common headers for evaporator. This helps in understanding the exact external load demand.

During steady state condition Plant Manager shall evaluates different combinations of operating percentage of chillers and comes up with best possible combination to cater external load and accordingly decides whether to ON/ OFF Next chiller.

Each ON/OFF of chiller will be accompanied by staging of pumps, ON/ OFF of Motorized valves as per requirement, ON/OFF of cooling water distribution pumps etc.

During transient period Plant Manager shall achieve target temperature as quickly as possible.

3. GENERAL REQUIREMENTS

3.1 Safety Requirements:

Vendor shall consider all safety requirements in accordance with good engineering practices and local regulation.

All technical equipment shall have a CE sign confirming that the product meets the demands of all relevant guidelines and regulations of the European Union (EU). The VENDOR is fully responsible for the accordance with all appropriate regulations.

A CE certificate referring to the relevant CE directives shall be supplied.

The noise level of the system shall be as low as possible, and must not exceed 70 dB (A) measured at operator working place.

In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the article remain in a safe condition.

3.2 Name Plates:


Each item shall carry a nameplate in accordance with client's standard which shall be fitted in a conspicuous position on brackets projecting 25 mm from the vessel or insulation as applicable. Equipment tag number shall also be included.

3.3 Painting:

Outside carbon steel surfaces (other than machined) shall be thoroughly cleaned, scale free and shall be painted according to vendor's specification duly approved by client. Chiller shall be provided with anti-corrosive paint.

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3.4 Available Utilities

The following media interfaces are provided:

- Electrical power 415V/ 3 Phase/4 Wire/ 50 Hz
230V/ 1 Phase/ 50 Hz
- Compressed air

4. TESTING, COMMISSIONING & INSPECTION:

Inspection and tests shall be made by Vendor in accordance with requirement requisition document and/or any correlative standards and codes.

Testing and commissioning will be carried out by the VENDOR. The Client's representatives have the right to participate in testing and commissioning.

During testing and commissioning future operators/technicians shall be trained in all equipment / system functions (e.g. preparation, start-up, operation, shut down, maintenance, etc. - as far as applicable).

All testing and commissioning documents, recordings and reports shall be in English language.

The VENDOR shall notify the customer/purchaser one month in advance of the start of FAT.

4.1 QAP

Vendor to submit a detailed quality assurance policy along with offer for hold, review, witness points at factory and at site.

4.2 Testing:

If in case Vendor proposes a testing procedure the same shall be approved by Client.

4.3 Inspection:

Client reserves the right to carry out inspection & further performance at any time during fabrication before shipment. Inspection shall be done by the Client or their representative and / or their nominated inspection authority.

4.4 Installation


The Manufacturer shall be responsible for unloading & installation.

The Manufacturer shall also be responsible for the re-assembly of sections or components of the packaged equipment, if any, including piping, wiring, instrumentation and any other equipment and components shipped separately or in sections.

Client shall provide the following:

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- Foundations if any required (Successful Bidder shall submit detailed fit for construction foundation drawings within two weeks from the date of placement of order by Client)
- Connecting utilities
- Electrical, utility services and drain hook-ups

The manufacturer shall also be responsible for the reassembly of sections or components of packaged equipment if any including piping, wiring, instrumentation, other equipments & components shipped separately or in section

The system must be transported to the erection place and placed in position under the supervision of the Vendor representative.

4.5 Commissioning

The commissioning plan shall be submitted to the Client 4 weeks prior to the commissioning dates and the approved document shall be used during the commissioning.

All the commissioning spares / consumables shall be supplied by the Manufacturer. Any component / instrument failure or damage noted during commissioning shall be replaced by the Manufacturer at no additional cost.

Commissioning may include, but is not limited to the following tests:

- Equipment, components and instruments installation check (with verifications of drawings, BOM etc.)
- Instrument calibration check
- Document check (especially components literature)

4.6 Training


The Vendor shall provide operator training at site for not less than 2 days at no extra cost. The training imparted shall include, but not be limited to, the following:

- Start-up and shut-down procedures
- Typical operations
- Emergency shutdown
- Safety training
- Troubleshooting procedures
- Control system & instrumentation operation and diagnostics
- Control system hardware maintenance
- Servicing and preventative maintenance schedules and procedures

The Vendor shall ensure that the operation and maintenance manual is available at site for reference. The Vendor shall issue certificates to the persons trained by them after successful completion of training at no extra cost.

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5. PRIORITY OF DOCUMENTS:

In case of conflicts between the engineering specification, data sheets and other reference code and standards, priority shall be given in the following order:

- Local authorities codes
- Client's Data Sheets
- Client's Purchase Contract
- Refer to codes and standards
- Vendor's Documents (agreed by Client).

6. DOCUMENTATION:

General: This package is not a qualified package. However, vendor shall follow Good Engineering Practices.

All documentation for the chiller shall be distinctly marked with Unique Name, Identity No. and Version No.

All documentation must be in English.

Specified list of all delivered documents, such as test protocols, drawings and specifications.

The documentation shall be delivered as four paper copies and one electronic version (CD-ROM). The documentation shall have final as built status.

The documentation provided by the vendor must allow

- Training of operators
- Operation, maintenance and calibration (Complete technical documentation)
- Testing or Qualification of equipment incl. generation of related documents (Testing plan, IQ & OQ).
- Dimensions for space needed for installation.
- Unit size dimensions.
- Utility consumptions
- Weights


Vendor should provide a document list of his standard documentation together with examples for review and final approval by client. The review & approval of design documents will be as per good engineering practices. Client will check installation of compressor against design documents issued for construction according to good engineering practices.

Vendor shall submit before order placement the detailed supplier document index (to be approved by client), listing all drawings and documents that will be supplied and their delivery dates.

It is included in the vendor scope of work the preparation and supply of all documents (i.e. drawings, calculations, etc.) and all obligations requested by local Authorities, in order to fulfill the applicable laws & regulations. Vendor shall provide the following list of documents for the complete package:

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6.1 List of Documentation:


VENDOR shall provide the following documents for the complete package unit:

Document Name	Remark
General	
Functional design specification	
List of the used material: List of spares & consumables for trouble free operation for two and five years separately from the date of commissioning.	
Process description, functional description	
Guarantee/ Warrantee: 18 Months from the date of supply or 12 months from the date of commissioning whichever is earlier.	
Schemes for approval	
Quality Assurance Policy	
P&ID drawings	
Layouts, overview plan	
GA Drawings	
Electrical & Control circuit diagram and panel layout with dimensions.	
Instrumentation	
Input/output signal list	
Parameter list of intelligent instruments, valves	
Specification of hardware components and specification of battery limits	
List of components	
List of instruments	
Operation / Service / Electronic Data Service	
Operation and maintenance manuals (including parts from sub- vendors)	
Lists of spare parts with ordering information	
Detailed manuals for single equipment	

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Training																																																							
	Documented trainings for operators																																																						
<p>7. DELIVERY AND INSTALLATION:</p> <p>Vendor shall be responsible for the delivery of the complete Package Unit to HLL Biotech Limited, (IVC), Chengalpattu, Near Chennai.</p> <p>Vendor shall be responsible for the positioning and installation of the complete Package Unit.</p> <p>The responsibility for packing, transport and insurance is with the Vendor of the system. The costs must be included in the offer as separate price.</p> <p>Before packing and dispatch, the system must be well cleaned inside as well as outside and dried. For the transport, the system shall be completely empty and dry. The packing shall be rigid to protect the PU against damage.</p> <p>All nozzle flange faces should be protected from rust and shall be further protected with a wood or metal cover to prevent damage during shipment. Threaded connections are to be protected with thread protectors. Machined surfaces are to be covered with temporary metal protective. Both partly fabricated and completed items liable to suffer distortion during transit and erection shall be braced. Open ends shall be covered to keep out dirt and other foreign matter. Spare gaskets, bolts, nuts, etc., and any other loose items shall be boxed separately from the main equipment. Such boxes shall be suitable for site storage and clearly and permanently marked to show:</p>																																																							
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- Order number
- Item number (for which the parts are intended)

The item number shall be prominently painted on the side of the equipment.

All loose items have to be carefully fixed or packed in a separate box.

The Package Unit shall be equipped with appropriate lifting lugs and provisions for transport allowing easy loading, offloading and transportation inside the building.

7.1 Installation

The erection and installation of the system is part of the scope of supply.

The manufacturer shall also be responsible for the reassembly of sections or components of packaged equipment if any including piping, wiring, instrumentation, other equipments & components shipped separately or in section

The system must be transported to the erection place and placed in position under the supervision of the Vendor representative.

7.2 Spare part

The spare parts for commissioning and start-up are included in Vendor scope of supply. List of commissioning and start-up spare parts has to be included in the bid based on the selected Manufacturer's models.

Spare parts required for two years of trouble free operation shall be listed and quoted separately item by item.

8. GUARANTEE:

➤ Mechanical Guarantees:

Vendor shall guarantee all equipment and components against defective materials; faulty design and poor workmanship and any failure resulting from normal usage for the guarantee period specified in the Purchase Order (at least 1 year after hand over and or agreed start operation).

Vendor shall guarantee that units will operate in safe, efficient and reliable manner under the stipulated conditions of service and environmental.


If any defects, failure or operational problems occur during the guarantee period, Vendor shall make all necessary improvements, repairs and replacements at no cost to the Client, in accordance with the Purchase Order.

➤ Performance Guarantees:

All equipment shall be guaranteed for satisfactory performance at all operating condition specified at the pertinent paragraphs of this specification with no negative tolerance.

HLL BIOTECH LIMITED

INTEGRATED VACCINES COMPLEX, Chengalpattu

nne pharmaplan®	User Requirement Specifications				 <div>HILL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</div>
	Equipment/System	Plant Manager			
	Identification #	U-CPM 02	Document#	URS/U/CPW 02	
	Effective Date	23.05.2014	Revision#	00	

If any performance deficiency or defects occur during the guarantee and warranty period, Vendor shall provide any modification / improvement, repair and replacements free of charge.

Vendor shall also guarantee the power and utilities consumptions.

9. QUALITY ASSURANCE:

The VENDOR must have a well-implemented QM-system, e.g. ISO 9000 certification. Capability and experience in working for the GMP-related industry must be proven. Auditing of QM-system with focus on software development methods / strategy has to be possible.

A quality assurance plan has to be delivered latest with placement of order.

10. ATTACHMENT:

N/A

11. ABBREVIATIONS

QMS	Quality Management System
PU	Package Unit
EU	European Union
CE	the abbreviation of French phrase "Conformité Européene" which literally means "European Conformity"
GMP	Good Manufacturing Practice
OEM	Original Equipment Manufacturer
ASTM	American Society of Testing Materials
ASME	American Society of Mechanical Engineers
ARI	Air-Conditioning and Refrigeration Institute
ASHRAE	American society of Heating Refrigeration and Air-Conditioning Engineers
TEMA	Tubular Exchanger Manufacturers Association
PLC	Programmable Logic Controller
ERW	Electric Resistance Welding
PID	Process and Instrumentation Diagram
VFD	Variable Frequency Drive
HMI	Human and Machine Interface
FAT	Factory Acceptance Test

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User Requirement Specifications

Equipment/System

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SAT	Site Acceptance Test
DQ	Design Qualification
IQ	Inspection Qualification
OQ	Operation Qualification
PQ	Performance Qualification

12. REVISION INDEX

Revision	Date	Reason for revision
00	2014.03.22	First Draft