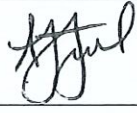


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**USER REQUIREMENT SPECIFICATION
HVAC SYSTEM FOR QUALITY CONTROL LABORATORY**

The following signatories indicate that this User Requirement Specification (URS) has been reviewed and approved.

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pharmaniaga LifeScience Sdn Bhd

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1. OBJECTIVE

The objective of this User Requirement Specification (URS) is to provide the specification for the renovation of existing Heating, Ventilation and Air Conditioning (HVAC) system for the use of Quality Control Laboratory at Pharmaniaga LifeScience Shd Bhd (PLS) in Puchong, Selangor, Malaysia. This document is issued to the Vendor for response and quotation.

2. SCOPE

2.1 This URS covers the requirements that apply to the HVAC system which must conform to Pharmaceutical industries validation procedures and current industry standard practices to cGMP and EU requirements, regulations and guidelines.

2.2 The Vendor also shall responsible for:

2.2.1 Providing a formal quotation for the design, manufacture, dismantling, installation (civil, mechanical and electrical), testing & commissioning, and documentation of the HVAC system. The cost for 1 year of planned maintenance shall be included in the package offered.

2.2.2 Abiding the information and conditions set forth by this document as well as the standard purchasing terms and conditions of PLS.

2.2.3 Indicate any non-conformance with the URS. Any issue not raised will mean that the bidder is in compliance and PLS will hold the bidder to these terms.

2.2.4 Establishing a schedule for the project, setting out all the key stages from design to final acceptance. This document is to be able to be updated monthly and is expected to include:

- Document issue and approval dates.
- Design qualification sign off date.
- Factory acceptance trial dates.
- The delivery date of machine ex works.
- The delivery period for a complete set of format parts/tooling ex-works.
- Commissioning and qualification period.

2.2.5 Unloading at Malaysia port including insurance, delivery to site and unloading to secure storage area at the site.

2.2.6 Meeting and abiding by the site regulations of the PLS appointed project management contractor at all times.

2.3 The system and all its ancillary items of equipment, but excluding consumable parts must be guaranteed for 12 months from the time of on-site acceptance. Any labour, travel or

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accommodation costs involved in the replacement of non-consumable parts during the guarantee period to be free of charge

- 2.4 The Vendor shall guarantee the availability of all spare parts for the equipment for at least 10 years from the date of supply.

3. OVERVIEW

- 3.1 The design and construction of the HVAC system shall comply with the requirements of the pharmaceutical industry and particular cGMP and the directives of the European Union (EU), Pharmaceutical Inspection Co-operation Scheme (PIC/S), World Health Organization (WHO) and other relevant regulations and standards both national and international.
- 3.2 The new QC facility is consisting of a Chemistry Laboratory, Biochemistry Laboratory and Microbiology Laboratory. The existing AHU F-3 will supply clean air to Microbiology Laboratory while the AHU F-5 is for Chemistry & Biochemistry Laboratories.
- 3.3 The existing HVAC system shall be re-designed to reduce the energy consumption, safety, ease of maintenance and compatible with fumigation process for all system components.
- 3.4 The existing ducts routes shall be adjusted to meet the updated list of rooms and areas for air to be supplied to. Refer to **Appendix 1**.
- 3.5 The chilled water is to be supplied by central chillers located within the Chiller Plant Room (T208). Where re-heat is required, electric heaters shall be installed.
- 3.6 The HVAC system shall be located at the existing location in the HVAC Plant Room (T201).

4. REQUIREMENTS

4.1 Capacity

- U1 The HVAC system shall be designed and constructed to operate continuously and reliable for 24 hours per day, 7 days per week, 52 weeks per year.
- U2 Air handler components such as coils, humidifiers, dehumidifiers, dampers, fans, motors and filters should be designed and constructed to provide 115% of design capacity to accommodate potential increased demand or future expansion.

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4.2 Performance

U3 All rooms/areas shall be designed with air recirculation concept. Whereby the theoretical rule of thumb shall be 80% recirculation and 20% makeup air but this may vary depends on the room leakages or exhaust capacity. Any rooms that will contribute to contamination or great heat load then the make-up air condition will require a 100% exhaust out air and 100% make up air in.

U4 Total air leakage rate from the AHU casing shall be <0.5% of rated flow at 150% of the design pressure or 50 CFM (1.42 m³/min), whichever is greater.

4.2.1 Air Handler Unit (AHU) / Pre-Air Handler Unit (PAHU)

U5 Removable wall panels shall be made available for removal of large components that would not fit through the AHU access door if it requires.

U6 The panel should be removable with simple hand tools to avoid cutting or sawing and creating a leakage issue after reassembly.

U7 Interior lights shall be installed in the AHU and controlled with a one 6-hour maximum waterproof, light switch timer as a minimum.

4.2.2 Flooring

4.2.2.1 Flooring in AHU should be of sufficient thickness to prevent deformation when walked upon and damage from dropped tools or equipment.

4.2.2.2 The floor shall be designed to have a capacity of 500 kg/m² live load to accommodate the service mechanic working inside the AHU.

4.2.2.3 Flooring should have a non-slip texture for the safety of the person standing within the unit. Floor seams should be sealed to the wall for a watertight floor system.

4.2.2.4 In the event of the interior of the AHU may require cleaning and wash down, a drain opening is fully sealed around its perimeter and fitted with a secured/removable, flush-mounted, airtight cover plate or plug to prevent the entry of contamination during operation shall be made available.

4.2.3 Condensate Pan

U8 The pan should slope to enhance total drainage (minimum 1.5%) with a minimum depth to prevent overflow during normal operation. Its length should extend beyond the coil's downstream face a minimum of 12 inches (30cm) or half the height of the coil, whichever is greater, and a minimum of 6 inches (15cm) beyond its upstream face.

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U9 Each stacked cooling coil should have a drain pan with drainage into the lower coil section. The length of the stacked cooling coil should extend beyond its downstream face of 12 inches (30cm) or half the height of the coil, whichever is greater, and a minimum of 15 inches (40cm) beyond its upstream face.

U10 Condensate drain traps should be tall enough to prevent air movement into or out of the AHU during operating conditions.

U11 Condensate drain pans should not leave puddles. Drain pans should slope a minimum of 1:100 (1%) toward the drain outlet. Connections should be piped through the casing wall and sealed.

4.2.4 Access Door

U12 Doors should be installed on each section of the AHU e.g., coils, filters, fan etc, sufficiently wide to allow entry by the operator for cleaning and maintenance.

U13 Doors should be of a double gasket compression design to minimize leakage.

U14 Each access doors shall be fitted with an instrument test port to allow temperature and pressure readings to be collected without drilling into the casing during air balancing commissioning.

U15 The doors shall be fitted with a clear viewport to allow visual inspection on the interior without opening the access doors.

4.2.5 Fans

U16 Fan pressure performance and construction shall at least meet the AMCA Class II standard.

U17 Fan wheels should be fully welded and non-overloading. Wheels should be both statically and dynamically balanced.

4.2.6 Cooling Coils

U18 The coils should have a maximum average face velocity of 450 fpm (2.29 m/s) to eliminate condensate carry over and optimize heat transfer capacity.

4.2.6.1 The selection of the number of rows, spacing, type of fins, tube sizes and tube staggered layouts to the specified capacities shall be based on the overall plant energy consumption, particularly with blower fan energy consumption.

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U19 Coil piping should have shut off valves and union fittings to facilitate coil removal or repair.

4.2.7 Ductworks

U20 Ductwork should be following SMACNA and the HVCA standards.

U21 Ductwork should be adequately supported to easily carry its weight and insulation along with in-line equipment and controls.

U22 In-line silencers shall be installed ahead of HEPA filters if there is a concern on the noise produced.

U23 Flexible support and connections should be considered if there is a concern about vibration.

U24 If flexible ductwork is required to tie the branch to the terminal air device, its length should be kept to a minimum and should not exceed 3 m.

U25 Duct leaving fans and AHU should be straight, and if elbows are required near the fan, it should not reduce system performance and consume horsepower.

U26 Ductwork should be sealed with approved fire and smoke rated sealant following NFPA 255 or UL 723 or equivalent.

U27 Ductwork should have no more than 1% leakage (with 0% leakage on positive pressure exhaust duct and positive pressure duct carrying hazardous materials).

4.2.8 Dampers and Louvers

U28 The outdoor air intake, return, exhaust and relief dampers should be rated for low leakage to prevent the infiltration of air when the systems are off or during hostile weather conditions.

U29 Low leakage dampers should have vinyl seals that are mechanically attached to the damper blade and jamb seals to prevent leakage around the ends of damper blades.

U30 Damper jackshaft should be extended to the exterior of the AHU casing for actuator mounting.

U31 Outside air inlet velocities should prevent drawing in rain through the louver's free area.

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HVAC System for Quality Control Laboratory**No.: URS-083****Revision No.: 02****Effective Date:** 16 MAR 2022**Page 8 of 16****4.2.9 Diffusers and Registers**

- U32 The devices shall be properly positioned to provide good distribution and a sweeping action of the air from the supply to the return side of the space to deliver uniform air patterns.

4.2.10 Filter Installation

- U33 Filter frames should have closed cell rubberized/neoprene-type gaskets to prevent shedding.
- U34 A separation of at least 1 inch (25 mm) should exist between the filters in the pre-filter section to reduce static pressure drop, increase the performance of the filters and permit pressure measurement between the filters.
- U35 Each filter bank within AHU and ductwork should have a DP gauge to monitor the increase in pressure drop because of loading.
- U36 Permanent downstream media protective screens should be included to prevent physical damage to the filter medium.
- U37 Individual filters in filter banks should be capable of replacement without disruption of adjacent filters.

4.2.11 Air Filtration

- U38 Grade D areas are to be provided with in-plant HEPA (HI 4) protection.
- U39 All AHU shall be fitted with pre-filter (class G3), primary (class G4) and secondary filters (class F8).

4.2.12 Control & Monitoring System

- U40 The system shall be designed to be able to support a wide range of industry platforms and protocols to enable seamless integration with existing equipment, control systems and IT environments especially to the existing EMS in PLS.
- U41 The control system shall provide the following function but not limited to:
- Alarms
 - Independent safety interlock
 - The output of system status
- U42 VFDs shall be installed to control the volume of air delivered.
- U43 All system/equipment control system legends and operator message display configuration will be in English.

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U44 All control system (if any) supplied are to be fully validate-able and following the requirements of current Goods Automated Manufacturing Practice (GAMP).

4.2.13 Label

U45 The ducts shall be labelled with directional arrows and type of air passing through i.e., fresh air supplied air and returned air.

U46 The equipment and instruments ID and specification shall be labelled clearly on the equipment or panel.

4.2.14 Utility & Electrical Specification

4.2.14.1 Utility provided by PLS are as below:

- Oil free compressed dry air: 6-10barg
- Chilled water: supply at 6°C and return at 11°C @ 3barg pressure

U47 Volts: 415/3 Phase, 240/1 Phase. Phase reversal protection must be supplied if there is any chance of damaging the machine if it is run in reverse. Equipment shall be arranged for connection to 3 phase supply with separate N and E.

U48 Junction boxes should be weatherproof and conduit penetrations should be sealed airtight.

U49 Electrical components, wiring and terminals should be tagged. High voltage terminals must be labelled as such. Internal power cabling should be shielded.

U50 Materials and installation methods should comply with NFPA and NEC or the local electrical code.

U51 Symbols and Colours of pushbuttons, lamps, display screens etc. shall follow EN 604171&2: 1999 Graphical Symbols for Use on Equipment.

4.2.15 Material

U52 The interior panel surfaces and joints of AHU should be smooth and continuous, constructed of a material such as aluminium, galvanized steel or stainless steel that can be wiped clean and will not easily rust or corrode.

U53 The cooling coil condensate drain pan should be of 304L SS.

U54 Screws, nuts, washers etc should be corrosion resistant with flexible washers to minimize air leakage in the exterior. Materials that oxidize or promote rust should not be used in the construction of the equipment.

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- U55 Fan wheels should be of aluminium construction to reduce weight and rusting.
- U56 The coil casing and frame shall at least fabricate from 304L SS for a longer lifespan and no rust.
- U57 Supply and general return air ductwork should be constructed of galvanized steel. Stainless steel should be used when corrosion or continual cleaning occur, such as inside of the cleanroom.
- U58 Interior insulation that can add particles or harbour growth is not allowed to be used. A smooth interior is preferred to ensure low friction and low resistance to airflow.
- U59 Dampers should be made of corrosion-resistant materials.
- U60 The diffusers and registers shall be fabricated from stainless steel, to eliminate corrosion and rusting resulting from wash downs with aggressive cleaning agents.
- U61 Pre and final filtration mounting grid systems should be of rigid construction (aluminium or 304L SS) with exposed trim inside of the cleanroom shall be stainless steel.

4.2.13 Maintenance

- U62 Fans and motors shall be provided with vibration sensors to provide early warning and trending of bearing performance.
- U63 Automatic bearing lubricators for fan and motor's bearing shall be installed to increase bearing life and reduce maintenance.
- U64 Sufficient space should be provided for operation and maintenance purpose.
- U65 The chilled water supply and return to/from the HVAC system shall be controlled automatically. Vendor may propose the use of actuated modulating valves or circulator pumps to improve the flow efficiency.

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4.3 GMP Critical Data

U66 Room Classification

Parameters		Room Grade			
		A	B	C	D
Max. limits for particulates $\geq 0.5 \mu\text{m}/\text{m}^3$	At Rest	3,520	3,520	352,000	3,520,000
	In Operation	3,520	352,000	3,520,000	N/D
Max. limits for particulates $\geq 5.0 \mu\text{m}/\text{m}^3$	At Rest	N/A	N/A	2,900	29,000
	In Operation	N/A	2,900	29,000	N/D
Air sample, CFU/m ³		<1	10	100	200

*N/D = Not Defined, N/A = Not Applicable

U67 Room Environment Condition

Room No.	Room Description	Room Grade	Air Change Rate / Hour	Temperature (°C)	RH (%)
Microbiology Laboratory					
L209	Microbiology Laboratory	CNC	≥ 10	<25	<80
L210	Sample Receipt	CNC	≥ 10	<25	<80
L211	Hot, Wash & Decon	CNC	≥ 10	<25	<80
L212	Glassware	CNC	≥ 10	<25	<80
L213	Media Preparation	CNC	≥ 10	<25	<80
L214	MLT	CNC	≥ 10	<25	<80
L215	Incubation	CNC	≥ 10	<25	<80
L216	Personnel Airlock In /Out	CNC	≥ 10	<25	<80
L217	Personnel Airlock In /Out	D	≥ 20	18-24	50-60
L218	Sterility	D	≥ 20	18-24	50-60
Chemistry / Biochemistry Laboratory					
L201	Chemistry Laboratory	CNC	≥ 10	<25	<80
L202	FTIR / Balance & Reference Standard	CNC	≥ 10	<25	≤ 65
L203	AAS / ICP-OES	CNC	≥ 10	<22	<80
L204	Hot & Wash	CNC	≥ 10	<25	<80
L205	Glassware	CNC	≥ 10	<25	<80
L206	Biochemistry Laboratory	CNC	≥ 10	<25	<80
L207	Chemical / Solvent	CNC	≥ 10	<25	<80
L208	Quality Control Corridor	CNC	≥ 10	<25	<80
L220	Fume Hood	CNC	≥ 10	<25	<80
B201	QC Office	CNC	≥ 10	<25	<80

U68 The pressure for the laboratory is positively pressurized to the adjacent areas. The air differential pressure for the same grade area is 5 Pa, whereas different grade area is 15 Pa.

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Room No.	Room Description	Room Grade	Air Flow Direction	Adjacent Room / Passage ID	Differential Pressure (Pa) to the Adjacent Room or Passage ('In Operation Condition')
L216	Personnel Airlock In /Out	CNC	←	L217	15
			→	L209	5
L217	Personnel Airlock In /Out	D	←	L218	5
			→	L216	15
L218	Sterility	D	→	L217	5

U69 Critical instrumentation that is installed shall be calibrated to ensure the reliability of the data that is provided.

4.4 Safety Requirements

- U70 Each secondary AHU must be fitted with a duct mounted smoke detector, which will shut down the individual AHU in the event of an alarm, stopping the fan and closing the dampers on the ductwork distribution system.
- U71 The combined sound emission not to exceed 82 dBA decibels measured under standards established by Malaysian Department Safety and Health (DOSH) and ISO 14644-4.
- U72 Positive pressure sections of the AHU should have doors labelled as such to protect operators if opened during AHU operation.
- U73 Doors should have latch handles located inside of the AHU to prevent personnel from becoming trapped inside of the unit.
- U74 Sections with fans and moving parts should have warning signs, such as 'isolate before entry' affixed to the doors.
- U75 In the event of power failure, the system shall capable to recover / restart automatically without human intervention.

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5. DOCUMENTATION

The following standard documentation shall be provided by the Vendor:

- 5.1 Project timeline
- 5.2 Risk assessment
- 5.3 List of Documentation
- 5.4 Design Qualification
 - 5.4.1 Design Specification
 - 5.4.2 Functional Specification
- 5.5 Installation Qualification (IQ)
 - 5.5.1 IQ protocols
 - 5.5.2 System description
 - 5.5.3 List of system components
 - 5.5.4 Material certificates
 - 5.5.5 Calibration certificates
 - 5.5.6 Ladder diagram
 - 5.5.7 Circuit and wiring diagram
 - 5.5.8 Electronic copies of layout and elevation drawings showing principal dimensions, weights, utility connection points and spatial requirements
 - 5.5.9 Copy of software control program
 - 5.5.10 System Operation & Maintenance manual and spare parts list
- 5.6 Operational Qualification (OQ)
 - 5.6.1 OQ protocols
 - 5.6.2 SOP
 - 5.6.3 Verification report of system functionality
 - Filter installation
 - Motor rotation, speed and amperage verification
 - Operational of dampers, motors, switches, indicators etc
 - Vibration measurement
 - Static pressure and temperature setpoint adjustment
 - VFD adjustment
 - Coil performance

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5.6.4 Testing results and reports.

- Ductwork leak testing
- Safety devise testing
- Air balancing
- Rotating equipment balancing
- Filter integrity testing
- Time delay on differential pressure alarm

5.7 Performance Qualification (OQ)

5.7.1 Testing results and reports should be based on ISO14644.

- Room classification testing
- Room pressurization or airflow direction testing
- Airflow visualization
- Face velocity
- Room particle count test
- Room recovery testing
- Room differential pressure, temperature and relative humidity
- Air change rate
- Microbial count

6. REFERENCES

- PIC/S Guide to Good Manufacturing Practices for Medicinal Products.
- ISPE Heating, Ventilation and Air Conditioning (HVAC).
- ISPE Baseline Pharmaceutical Engineering Guide, Volume 5: Commissioning and Qualification.
- BS EN ISO14644-1:1999: Clean rooms and associated controlled environments – Part 1: Classification and air cleanliness.
- BS EN ISO14644-2:2000: Clean rooms and associated controlled environments – Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.
- ISO 14644-4:2001(E): Cleanrooms and associated controlled environments – Part 4: Cleanrooms and associated controlled environments - Design, construction and start-up.
- ISO 14644-5:2004(E): Cleanrooms and Associated Controlled Environments – Part 5: Cleanroom Operations.
- EN 604171&2: 1999 Graphical Symbols for Use on Equipment.

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- Malaysian Factories and Machinery Act 1967 (Act 139).
- BS EN 2917 Graphical Symbols and Circuit Diagrams for Fluid Power Systems.
- BSI. DISC PD 2000-1 BSI definition of the Year 2000 conformity requirements.
- 4434: 1995 — Specification for Safety and Environmental Aspects in The Design, Construction and Installation of Refrigerating Appliances and Systems

7. ABBREVIATIONS AND TERMINOLOGY

AHU	Air Handler Unit.
AMCA	Air Movement and Control Association.
cGMP	Current Good Manufacturing Practice.
CNC	Clean Non-Classified.
EMS	Environmental Monitoring System.
EU	European Union.
GAMP	Goods Automated Manufacturing Practice
HEPA	High-Efficiency Particulate Air.
HVAC	Heat, Ventilation and Air Conditioning.
HVCA	Heating and Ventilation Contractors' Association.
LAF	Laminar Air Flow.
NEC	National Electrical Code.
NFPA	National Fire Protection Association.
PAHU	Pre-Air Handler Unit.
PIC/S	Pharmaceutical Inspectorate Convention Scheme.
PLS	Pharmaniaga LifeScience Sdn Bhd.
SMACNA	Sheet Metal and Air Conditioning Contractors' National Association.
SOP	Standard Operating Procedure.
URS	User Requirement Specification.
VFD	Variable Frequency Drive.
WHO	World Health Organization.

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8. INDEX OF APPENDICES

- 8.1 KMN/20221/SPL/ACMV/301 – Air Conditioning & Mechanical Ventilation Services (AHU F3 and F3a).
- 8.2 KMN/20221/SPL/ACMV/302 – Air Conditioning & Mechanical Ventilation Services (AHU F5)

9. CHANGE HISTORY

Revision	Approval Date	Changes
00	: 02-Dec-2020	Original.
01	: 04-May-2021	- Remove previous 3.3 and U23 – U25. - Add 4.2.6.1. - Revise list of appendices.
02	: 16 MAR 2022	- Remove B202 HOU Office and others (S201, S203 & S204). - Rename B201 Work Station to QC Office, L208 Quality Control to Quality Control Corridor and L210 Sample Receipt & Store to Sample Receipt.