DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan®

REVIVAL OF BCG VACCINE LABORATORY,GUINDY,CHENNAI

Mobile Laminar Air Flow (Horizontal Type)

PROJECT #:	110729
EQ. ID #:	FG-MLF 01-03
DOCUMENT # :	DS/FG-MLF 01-03

1	**Process requirements**		
1.1	Mobile LAF trolley will be used to transfer half stoppered vials from filling station to Lyophilizer and lyo trays/ stoppers from autoclave to filling station and transport of bungs & seals from autoclave to filling room under class 100.		
2	**Technical Specification**		
2.1	Model	cGMP LAF Trolley	
2.2	Type	Grade A (ISO 5)	
2.3	Overall Dimension (mm)	FG-MLF 01 FG-MLF 02 FG-MLF 03	Not to exceed (1150mm x705mmx1900mm) (D×WxH)
2.4	Purpose	Mobile LAF trolley will be used to transfer autoclaved trays and frames from the autoclave unloading area to the casseting station under class 100	
2.5	Facility Details	Door Dimension (clear area) (W x H) m	1.5m x 2.1m
2.6	Type & Capacity	a)Uni-directional positive type b)Double Stage filtration c)Horizontal air flow d)Front and back sides shall be covered and side should be openable type (for loading and unloading material)	
2.7	Pre- Filter	To trap large particle in the inflow air, protecting against damage and prolonging HEPA filter life. EU - 6 Efficiency >95% Size: 5 µ	
2.8	HEPA Filter	H-14 Efficiency >99.997% Size: 0.3 µ	
2.9	UV light	UV light with Hour meter The light minimum hour life should be 5000 hr & light emitted shall be short-wave UV radiation with a peak at 253.7 nm (UV-C) for germicidal action. The hour meter should be able to be manually re-set.	
2.10	Air flow rate	0.45 m/s ±20% from 6" away from the filter	
2.11	Quantity	3 nos	
2.12	Electrical Requirement	Power Consumption: ***Vendor to specify***	
2.13		220-230 V, 50 Hz Single phase Battery back up with inverter for atleast 2 hours.	
3	**Material Of Construction**		
3.1	Body Construction	SS 304 , min 240 grit	
3.2	Support Stand	SS 304 , min 240 grit	
3.3	Coving	SS in built	
3.4	Working Shelves	SS 304	
3.5	MOC Fan	Aluminium	
3.6	Safety Cabinet door	UV protected safety glass with SS handles	
3.7	Wheels	Non shedding Teflon/Nylon with lockable castor wheels.	
3.8	All welds shall be ground finish		

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4	**Specific requirment**
4.1	LAF shall comply Class 100 (Grade A as per ISO standard)
4.2	Direct Drive centrifugal blowers for vibration free operations
4.3	1 no.- magnehelic gauge to be provided to monitor the differential pressure across the HEPA filter
4.4	Soft touch controls for blower and light
4.5	Spacer to be provided to maintain minimum distance between HEPA and the load
4.6	Inner chamber to accommodate 9 trays of 1000 mm x 700 mm (vendor to confirm) in the configaration of 2x5
4.7	Double door with hinged joint.
4.8	LAF shall be provided with tear drop light fitting suitable to provide minimum 300 lux level
4.9	Battery back up with inverter for atleast 2 hours along with chargeable point. So that LAF can work on battery as well as direct electrical supply
4.10	HEPA filter shall have an efficiency of 99.997 % when tested with DOP.
4.11	Pre-filters should be easily detachable for periodic cleaning.
4.12	Fully automatic AC / DC changeover system.
4.13	Lighting through diffusers with switch control.
4.14	Sleeving for accommodating the pre filters.
4.15	Side access panel for final filters and blowers.
4.16	LED display for motor operation.
4.17	Battery shall be kept closed with self roll able wire min 6 metre length to be provided in proper and secure enclosure
4.18	Adjustable shelfs (min 5 Nos) shall be provided.
4.19	Preferred make for Motor Blower assembly : Crompton Greaves/ ABB/ GE/ Siemens/EBM-PAPST/Nicotra
4.20	Approved make for filter: Camfil Farr / AAF / Freudenberg
5	**Other requirements**
5.1	Lockable Castor wheels shall be provided
5.2	Cleaning shall be done manually.
5.3	All bolts, nuts shall be of dome type of SS304 material
5.4	Vendor to give code numbers for each component
5.5	There shall be no crevices, so as to avoid dust accumulation
5.6	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. motors, filters, etc.
5.7	The design shall be maintenance friendly for the ease of replacement of filters
5.8	All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants
5.9	The heat given off by the unit must be stated (inside the room).
5.10	**Failure mode detection** **A.** Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process: a) Blower motor overload. b) Emergency stop activated. c) LAF blower is stop. **B.** Following condition need only notification to operator for procedural control: a) Differential pressure across the HEPA filter not within the limit
5.11	The following test to be conducted at site during qualification 1. air velocity test 2. Filter Integrity Test 3. Flow Visualization Test (videography) 4. Non viable Particle Count 5. Recovery Test 6. Lux Level 7. Sound Level
6	**Regulatory guidelines / standards**
6.1	ISO 14644 – 1 (For Cleanliness Class)
6.2	ISO 14644 – 3 (For HEPA filter integrity testing & Velocity testing)
6.3	EU-GMP-Guideline Part 1, Annexes 1, 11 & 15
6.4	Schedule M of Indian Drugs and Cosmetics Act
6.5	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs

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7	**Safety requirement**
7.1	Emergency stop function on accessible area.
7.2	Noise level below 75 decible.
7.3	Appropriate closure of all the rotating parts.
8	**Documents**
13	Vendor to submit detailed fabrication drawing for approval before fabrication.
8.1	**Phase 1: Post ordering and prefabrication stage of the equipment**
8.1.1	Functional design specification containing:
8.1.2	Equipment descriptions
8.1.3	Equipment operation steps
8.1.4	List of failure indications and interlocks (as applicable)
8.1.5	Critical list of major component, devices and instruments with their specific functions, specs and data sheets.
8.1.6	GA/ Schematic diagram of the equipment
8.1.7	DQ Specification
8.1.8	IOQ specification
8.2	**Phase - 2**
8.2.1	Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user.
8.2.2	System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.
8.3	**Phase - 3**
8.3.1	Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user at least 15 days before the delivery equipments for the engineering check of the documents.
8.3.2	Shipping checklist.
8.3.3	Operation and maintenance manuals; preventive maintenance instruction & schedule for equipment major component as well as the operating system. Control system operation manual. Cleaning procedures to be provided.
8.3.4	Operation and maintenance manuals for the bought out items (as applicable).
8.3.5	Drawings: Electrical, instrumentation, final GA drawing etc.
8.3.6	Spare and/ or change parts list with ordering information.
8.3.7	MOC certificates for all product contact surfaces.
8.3.8	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
8.3.9	Comprehensive warranty for 1 year after the date of completion.
8.3.10	Types of Lubricant and Lubrication instructions. Food grade certificates.
8.3.11	The Vendor shall provide start-up services through successful completion of the site acceptance test. The site acceptance test will be a repeat of the factory integration test performed at the Vendor's facility.
9	**Timelines**
	NA
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

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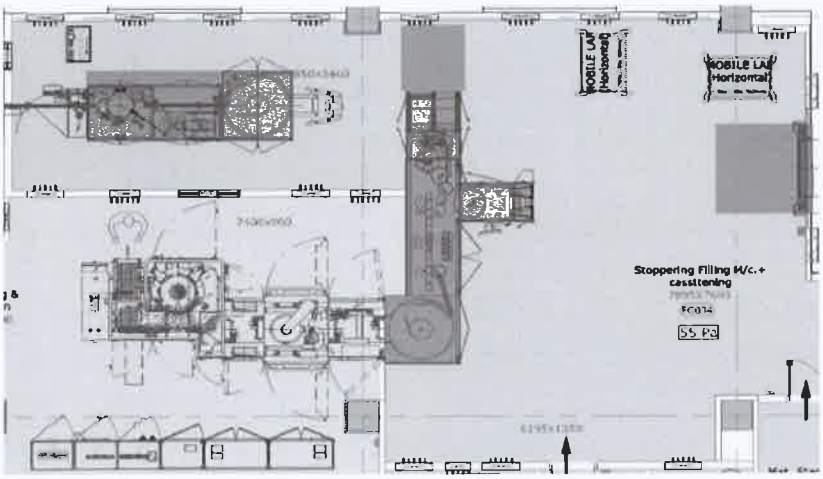
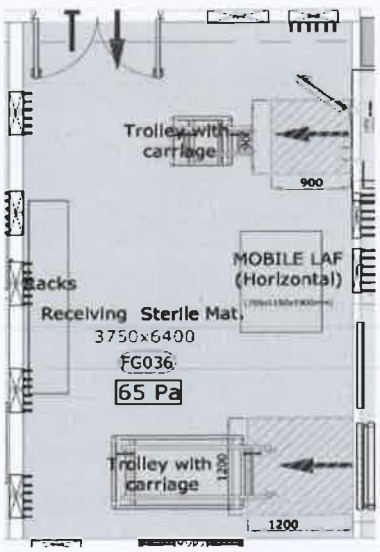
ROOM LOCATION:	FG034
1	Stoppering Filling M/c+Cassetting
2	**ROOM DIMENSION:** 7895 mm x 7695 mm 6850 mm x 3460 mm 6195 mm x 1350 mm 6535 mm x 2345 mm
3	**FALSE CEILING:** 3000mm
4	**ROOM PRESSURE :** (55)Pa



ROOM LOCATION:	FG034
1	Receiving sterile Mat.
2	**ROOM DIMENSION:** 3750 mm x 6400 mm
3	**FALSE CEILING:** 3000mm
4	**ROOM PRESSURE :** (65)Pa



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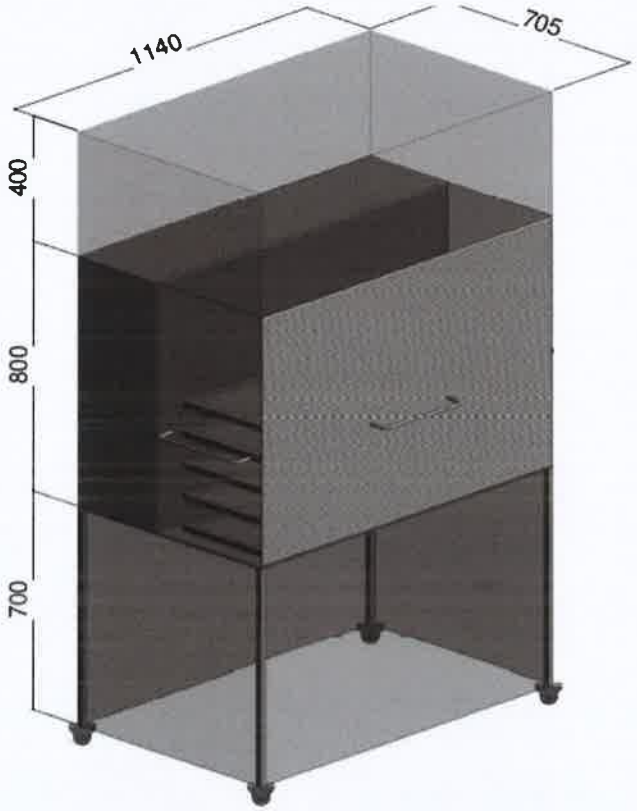

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