DATA SHEET		
HLL LIFECARE LIMITED, CHENNAI		
nne pharmaplan®	REVIVAL OF BCG VACCINE LABORATORY,GUINDY,CHENNAI	
	Dispensing Booth and Sampling Booth	
	PROJECT #:	110729
	EQ. ID #:	BF-DSB 01_BF-DSB02_WG-DSB 01 WG-SMB 01
	DOCUMENT # :	DS/BF-DSB 01_BF-DSB 02_WG-DSB 01 DS/WG-SMB 01

1	**Process requirements**	
1.1	It is used for dispensing media and buffer.	
2	**Technical Specification**	
2.1	Model	cGMP Dispensing booth
2.2	Overall Area (cu. Mm)	vendor to specify
2.3	Working Area (cu. Mm)	BF-DSB 01:900(w) x 600(d) x 1800(h) approx BF-DSB 02:1500(w) x 1800(d) x 1800(h) approx WG-DSB 01:1500(w) x 1800(d) x 1800(h) approx WG-SMB 01: 1500(w) x 1800(d) x 1800(h) approx
2.4	Type & Capacity	Reverse Laminar Air Flow type
2.5	Machine Compliance	EU GMP
2.6	Design	Grade A (Class ISO - 5, as per ISO 14644-1)
2.7	Electrical	230V AC, 1ph, 50 Hz
2.8	Pre Filter	EU- 4 rating, size: vendor to specify
		EU- 7 rating size: vendor to specify
2.9	Filter Rating	EU-4 90% down to 10µ
		EU-7 95% down to 3µ
		EU-14 99.999% down to 0.3µ
2.10	Minipleat HEPA Filter	0.3µm (EU - 14 rating) with frame box
2.11	Exhaust HEPA Filter	0.3µm (EU - 14 rating) with suitable size (Not with a common frame with SS Grill)
2.12	Air flow rate	0.45 m/s ±20% from 6"below the HEPA filter
2.13	Operating Pressure	vendor to specify
2.14	Quantity	Dispensing Booth: 3 Nos. Samplimng Booth: 1 No
3	**Material Of Construction**	
3.1	Dimension	vendor to specify (booth size, Hepa filter frame size etc)
3.2	Body Construction	SS 304, min 240 grit (puffed side panel wall)
3.3	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited
3.4	Coving	SS 304
3.5	Working Table	SS 304, min 240 grit
3.6	MOC Fan	Aluminium
3.7	All welds shall be grounded and smoothened	

4	**Specific requirment**
4.1	Motor Blower shall be statically and dynamically balanced for less vibration and noise level.
4.2	The dead working table with perforation (Capsule Perforation). shall be SS type with zero vibration.
4.3	3 nos. Magnehelic gauge shall be provided (for intermediate-filter, HEPA filter, exhaust filter) exterior to the working area for pressure measurement (pressure drop).
4.4	Dedicated electrical panel for booth (In built).
4.5	2 no. Electrical switch/ sockets shall be provided with SS cladding flushed with dispensing booth walls.
4.6	Soft Touch controller for motor and light
4.7	PVC curtains shall be provided at the front of booth to maintain the air flow pattern. Length of the curtains shall be till 200-300mm above the gorund floor
4.8	Booth shall be provided with fluorescent lamp suitable to provide minimum 400 lux level.

4.9	Audio visual alarm system :a) audio/visual alarm for motor,b) audio alarm system for pressure drop across the filter.
4.10	Dead zone of ceiling area shall be considered as minimum as possible to get maximum laminar flow.
4.11	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
4.12	Preferred make for Motor Blower assembly : Crompton Greaves/ ABB/ GE/ Siemens/EBM-PAPST/Nicotra
4.13	**Approved makes for filters:** a) Camfil farr b) Freudenberg c) AAF
5	**Other requirements**
5.1	Safe Zone shall be defined by the vendor to perform operations.
5.2	Cleaning shall be done maually.
5.3	Vendor to submit detailed fabrication drawing for approval before fabrication. Detailed HEPA Filter fixing Arrangement shall be get approved before fabrication.
5.4	Vendor to provide wall to wall coving for the equipment as well as floor to equipment coving at site
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
7	**Safety requirement**
7.1	Following facilities must be provided to protect personnel and equipment:
7.1.1	Emergency stop function on accessible area.
7.1.2	Noise level below 75 decible.
7.1.3	No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.
7.1.4	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 product remain in a safe condition.
7.1.5	The heat given off by the unit must be stated.
8	**Documents**
8.1	Vendor to submit detailed fabrication drawing for approval before fabrication.
8.2	**Phase 1: Post ordering and prefabrication stage of the equipment**
8.2.1	Functional design specification
8.2.2	Equipment descriptions
8.2.3	Equipment operation steps
8.2.4	List of failure indications and interlocks (as applicable)
8.2.5	Critical list of major component, devices and instruments with their specific functions, specs and data sheets.
8.2.6	GA/ Schematic diagram of the equipment
8.2.7	DQ specification
8.2.8	IOQ specification
8.3	**Phase - 2**
8.3.1	Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user.
8.3.2	System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.
8.4	**Phase - 3**
8.4.1	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.
8.4.2	Shipping checklist.

8.4.3	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.
8.4.4	Operation and maintenance manuals for the bought out items (as applicable).
8.4.5	Drawings: Electrical, instrumentation, final GA drawing etc.
8.4.6	Spare and/ or change parts list with ordering information.
8.4.7	MOC certificates
8.4.8	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
8.4.9	Comprehensive warranty for 1 year after the date of completion.
8.4.10	Types of Lubricant and Lubrication instructions. Food grade certificates.
8.4.11	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**
9.1	*NA*
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

	AFI Approved for Enquiry			AFO Approved for Ordering		
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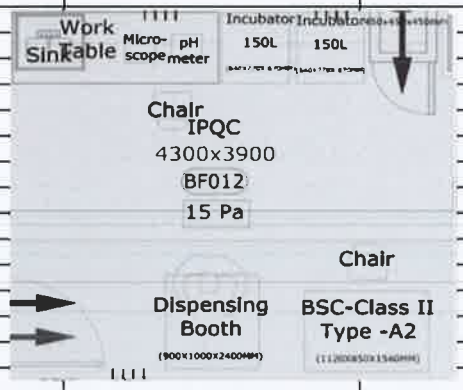
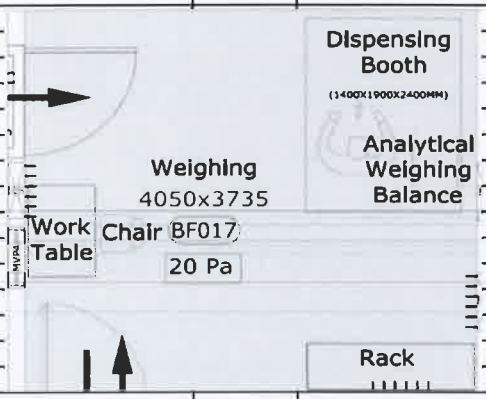
Dispensing Booth and Sampling Booth

PROJECT #:	**110729**
EQ. ID #:	**BF-DSB 01_BF-DSB 02_WG-DSB 01 WG-SMB 01**
DOCUMENT # :	**DS/BF-DSB 01_BF-DSB 02_WG-DSB 01 DS/WG-SMB 01**

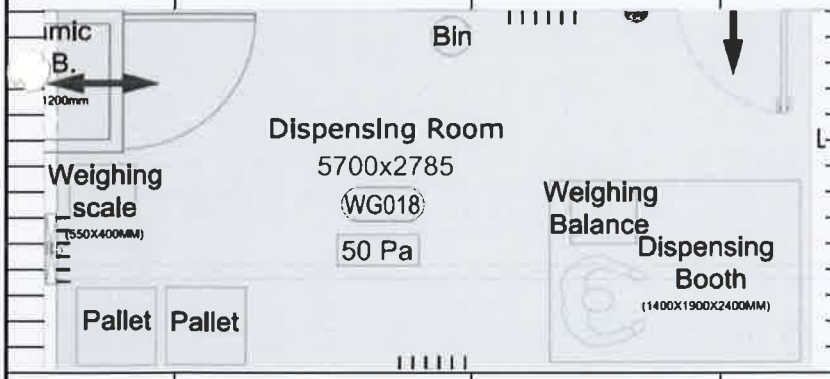
ROOM LOCATION:	**BF-DSB 01**
1	BF012 - IPQC
2	**ROOM DIMENSION:** L(4300mm) X W(3900mm)
3	**FALSE CEILING:** 3000mm
4	**ROOM PRESSURE:** 15Pa



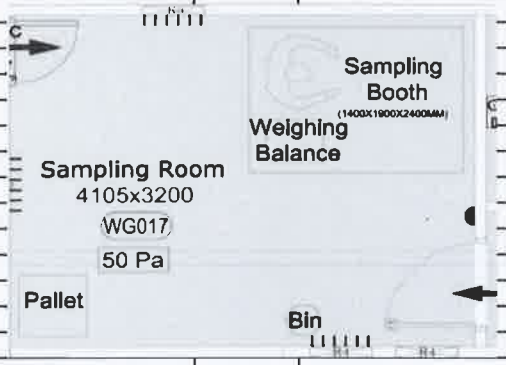
ROOM LOCATION:	**BF-DSB 02**
1	BF017- Weighing
2	**ROOM DIMENSION:** L(4050mm) X W(3735mm)
3	**FALSE CEILING:** 3000mm
4	**ROOM PRESSURE:** 20Pa



ROOM LOCATION:	**WG-DSB 01**
1	WG018 - Dispensing Room
2	**ROOM DIMENSION:** L(5700mm) X W(2785mm)
3	**FALSE CEILING:** 2700mm
4	**ROOM PRESSURE:** 50Pa



ROOM LOCATION:	**WG-SMB 01**
1	WG017 - Sampling Room
2	**ROOM DIMENSION:** L(4105mm) X W(3200mm)
3	**FALSE CEILING:** 2700mm
4	**ROOM PRESSURE:** 50Pa



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