Setup of a world class, flexible cGMP Biologics Pilot facility catering to Clinical Grade Drug Substance and Drug product requirements of customers for Human Clinical Trials and early commercial batches

Shilpa Medicare Ltd.

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	From Diesel Generators (75kva x 3 nos) and boiler	Particulates in air	Volatile organic compounds – we do not use Organic solvents in our processes and have replaced them with aqueus processes. In analytical / QC rooms that still use small amounts of solvents, the raw material and the equipments/processes that use these are stored/used at 22 Deg C and this is already incorporated into our design – thereby reducing chances of formation of VoC. We have also have provided for local ventilation hoods for control of point emissions. All storages for such material is segregated and connected to catalytic converters or wet scrubbers. Particulates – All our processes are with aqueus medium thereby minimising chances of particulate formation. Buffer preparation areas are segregated from process areas via separate air handling units and buffer salts are handled inside negative pressure LAF. Such units are also connected to wet scrubbers where required to ensure dust from the facility is minimised. Staff operating in these areas are not exposed to particulates and in addition are supplied with sufficient face masks and gloves in order to ensure minimised exposure. All buffer salts that we use in our process are not hazardous unless ingested directly. Each process area has segregated Air Handling unit and ducts that contains

			multiple filters including terminal HEPA filters for capture of any particulate matter, even from air. Combustion source Emmissions – We have proposed to setup 2+1 standby 750 KVA diesel generation sets at the facility to provide backup power. We have also gone in for a 33 KVA HT line connection to the site to ensure uninterrupted high quality power 24/7/365 days. The generator sets are being provided only as a backup. Based on data available from HESCOM today, the downtime for maintenance of the 33KVA line in a year is about 24 hrs and is expected that this is the time for which the generator sets are expected to run during the year. The generator sets are from Cummins with autostarters and autosynchronisation panels for optimal utilisation of diesel. A common 30m stack is provided for these generator sets – this is in full compliance with the PCB requirements and the particulates from these gensets will be well within prescribed limits. The units will be maintained and inspected at regular intervals by our dedicated maintenance and engineering team of 30 staff. .
Water Pollution and Waste water treatment	Stream containing cells, cell debris Streams containing salt buffers, but no cells.	Ground water pollution	The liquid waste from the facility is segregated into 2 streams at the point of generation itself a) Streams that contain cells, cell debris – this is first chemically treated (Example - with Sodium hypochlorite, Hydrogen Peroxide etc) before being sent to the High temperature Automated Kill tank facility for high temperature treatment by wet steam for 45minutes. Post confirmation of complete destruction of cells (via sampling/testing confirmation), the treated sludge is discharged into the ETP for further treatment with other

			liquid wastes at the initial fully enclosed hold tank. b) Streams that contain buffers, but no cells – Example from the downstream processing stream and fill-finish streams are sent directly to the ETP hold tank for normalisation of pH in a automated mode. Such liquid is then sent for poly electrolyte treatment and electrocoagulation unit operations that can operate in continuous fashion if required. Deodorisation also takes place at this step. All aggregates that settle are removed from the process, dried through a centrifuge and air dryer before being sent to solid waste storage as bricks c) The remaining liquid containing mainly salts are then sent through a series of RO membrane filters to recover as much water as possible, before the salt enriched solution is sent to the forced circulation MEE.
Chemical waste	Salt containing buffers	Ground water contamonation	The processes that we follow do not contain any organic solvents. The salt buffers are sent to the ETP from the unit via a closed loop system and are subjected to electro-coagulation, a series of RO filtration steps, before being subject to Multiple Effect Evaporation step. The condensate from the MEE is recovered and reused, while the buffer salts are segregated as salt cakes and sent to Authorised Land Fills (run by Ramky Enviro Engineers) through a official tieup with the agency.
Biological Waste	Cells and cell debris	Potential for ground water contamination	All cell lines (CHO-S, CHO-K1 etc) in use at our facility fall in the BSL-I risk group, representing the lowest risk to environment. But, all biological wastes that are generated at the facility (Ex – from the fermentation) are first treated chemical agents to ensure kill.

			As a part of our commitment to ensure complete treatment on par with global standards, the chemically killed biological waste is then sent to a fully automated 21CFR-P11 compliant 500L kill tank facility for high temperature treatment by wet heat for 45minutes. Samples from this Kill tank are tested for any live cells by our microbiology QC team before the sludge is sent our Effluent treatment facility for further treatment to reduce the BoD and CoD to below mandatory limits. The single use bags used in the process are subjected to pyrolysis to ensure full treatment and energy recovery with no waste being discharged to the environment
Heavy metals	None	None	Not applicable
Radiation Waste	None	None	Not applicable
Destruction/alteration of surrounding ecosystem	Very low	None	The facility is located in a designated Karnataka Industrial Areas Development Board industrial area at Belur, Dharwad District, with all the required clearances to setup the facility. There are no forests or historical monuments in 10km radius around the industrial area. Similarly there are no running water bodies in the industrial area or in a radius of 10km from the industrial area. The designated land is surrounded by other industries (Heavy and Engineering industry). Incidentally, when the company took over the 11 acre of industrial land, there was no green cover of any sort on this land. As a part of our facility site master plan, we are committed to populate atleast 35% of the land area with trees and green cover. The facility being setup is designed as a zero liquid discharge facility. The

			facility with its emphasis on single use technologies and continuous production technologies enables us to reduce the footprint of the facility by approximately 40% when compared to peer facilities of similar capacities, thereby reducing the enery requirements also. This enables low carbon foot print. Plans are afoot to tie-up with solar and wind energy generators to ensure that the electricity supply is supplemented with as much environment friendly sources of power generation. Over and above this, single use items will be subject to pyrolysis (initial tests on suitability already done with very encouraging results) and energy recovered from this process recycled into our process. Therefore plastic wastes will not be sent to landfills. The company already has produced copies of CFE from the PCB (that covers the Water, Air, noise and solid wastes) to the visiting due-diligence committee. The company shall also have the facility approved by the GEAC and CDSCO on mechanical completion of the facility being achieved. The company already has a Institutional Biosafety Committee that meets atleast thrice a year. We report no safety or environment incidence thus far. Copies of other licenses required, including (a) labour license, (b) GST registration , (c) Karnataka State Fire & Emergency Services, (d) Directorate of Factories, Boilers, Industrial Safety & Health have been provided to the Due Diligence committee during the visit to site. The company also undertakes to apply for and obtain any

			other required license/permission which may not form part of this list, but is required for the startup and operations of the plant, such as the CFO from the PCB.
others			

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Diesel storage for generators and boiler	Potential for fire and explosion	a) Floating roof insulated tanks surrounded by Dyke b) The tanks are ringed by automated fire fighting piping with heat sensors. The fire fighting unit is in ready charged mode all the time c) All steam lines and lines with temperature higher than 40 Deg C are insulated – as a saferty precaution d) KSFES, Inspectorate of factories and Boilers approval for the plan already in place. Copies verified by Due Diligence committee. PESO approval will be taken where required on setup
Chemical hazards, including fire and explosions	VoC	Air pollution	We do not use Organic solvents in our processes and have replaced them with aqueus processes. In analytical / QC rooms that still use small amounts of solvents, the raw material and the equipments/processes that use these are stored/used at 22 Deg C and this is already incorporated into our design – thereby reducing chances of formation of VoC. We have also have provided for local ventilation hoods for control of point emissions. All storages for such material is segregated and connected to catalytic converters or wet scrubbers.

Pathogenic and biological hazards	Cells and cell debris	Ground water contamination	All cell lines (CHO-S, CHO-K1 etc) in use at our facility fall in the BSL-I risk group, representing the lowest risk to environment. But, all biological wastes that are generated at the facility (Ex – from the fermentation) are first treated chemical agents to ensure kill. As a part of our commitment to ensure complete treatment on par with global standards, the chemically killed biological waste is then sent to a fully automated 21CFR-P11 compliant 500L kill tank facility for high temperature treatment by wet heat for 45minutes. Samples from this Kill tank are tested for any live cells by our microbiology QC team before the sludge is sent our Effluent treatment facility for further treatment to reduce the BoD and CoD to below mandatory limits. The single use bags used in the process are subjected to pyrolysis to ensure full treatment and energy recovery with no waste being discharged to the environment
Radiological hazards	None	None	Not applicable
Noise	Generator sets, compressors	Noise pollution	All generators come in CSPCB regulations compliant insulated casing that reduce noise levels to below 65 dB Similarly we have gone in for Copeland oil free screw compressors that are low noise and additionally come inside noise proof enclosures to further reduce the sound. All utilities that generate sound are kept separately outside in the utilities section to further reduce impact of any noise
Process safety	Cell lines with virus, adventitious agents	Infections to personnel handling the cell lines	We use only BSL-I cell lines sourced from authorised cell banks (CHO-K1, CHO-S, CHO-DG44) which are tested for no adventitious agents. All cell lines coming into the facility are kept isolated until tested again for any adventitious agent, contaminant.

			Use of BSL-II hoods in our cell culture facility ensures minimum exposure of personnel to cell lines EHS and QA departments ensure that only fully trained personnel handle cell lines. All such personnel are trained and certified before being allowed to use cell lines. The cell lines and cell debris are subjected to chemical kill treatment and then heat kill treatment in a dedicated 21CFR P-11 compliant kill tank connected to the facility to ensure that at no point any cell line comes in direct contact with the environment outside the CMC facility
others			

3. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	We only use aqueous solvents in our processes (We have substituted all organic solvents). Hence there is no impact from use of large scale organic solvents	No impact	We make no use of any organic solvents in our processes. Hence this risk is mitigated
	Acid and bases, Liquid Nitrogen	Fire, Fumes, burns, cold burns to personnel handling if handled improperly	Direct usage of stock solution in our process with the use of the ILC for buffer preparation ensures we minimise direct contact of personnel with acids or bases. All acids and bases are stored in temperature controlled storage with fume vents that are connected to scrubbers. LN2 storage is in temperature controlled vacuum insulated double walled tanks with pressure sensors and level sensors to ensure no breakage of tanks happen due to overpressurisation. LN2 is made up automatically in these LN2 tanks All personnel handling raw material and buffer preparation are provided with safety gloves, safety goggles and masks for minimising any effect of contact with acids and bases, LN2 The facility design also has taken into account, eye wash basins and showers at strategic locations where the personnel could come in contact with acids and bases

			All employees are given documented, full fledged training on handling raw material including acids and bases (driven through SOPs) and this program is driven by the EHS and QA department A medical doctor is available at site to attend to any accidents despite all precautions being taken with first aid kits, drugs required to treat burns and an ambulance available at short notice The company has tieups with local doctors and hospitals for treatment of it staff
Emergency preparedness and participation of local authorities and potentially affected communities	Dangerous gaseous emissions, VOC emissions, fire rated/Explosive material storage	The unit is located inside a designated industrial area We do not use any volatile chemicals or organic solvents in our processes. Diesel used for diesel generator sets are can be dangerous in case of vapour build up, especially during summers	Even for very small amounts of solvents used in analytical procedures, we store them in temperature controlled solvent cupboards connected to strippers to ensure removal of all VOCs. PESO approvals sought for all tanks that store material that pose fire hazard or explosion risk. All such tanks come with vacuum insulation, floating roof and pressure sensors and vents to ensure removal of any buildup. These tanks are located in dykes to ensure that there is no spread of the diesel in case of any leaks. Automated Foam firefighting equipments / hoses with heat sensors surround the tank to ensure that there is no spread of fire even in case of any untoward incident

			All tanks are connected with lightning arrestors, multiple chemical earthings to ensure that fire is not caused by electrical / static charge buildup Personnel evacuation procedures in forms of SOPs are already available. Training shall be imparted to all staff working at site on emergency procedures and processes. Emergency numbers such as local fire-station, Hospitals, Police are with the EHS. Designated EHS staff are responsible for escalating calls to emergency / regulatory bodies including the local DC office in case of any accidents. The company records air, water and noise pollution levels on a ongoing basis and posseses data from the time of acquisition of the land. Hence this data (including wind direction, speed, particulates) shall be used to form basis for emergency evacuation plan including staff from the factory as well as any neighbouring facilities in case of any eventualities. The plan has already received approval from KSFES Regular training of staff on first aid and emergency procedures driven by the EHS department shall ensure continued preparedness.
In case your organization already has **EHS guideline**, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.**			

Governance model

Areas	**Monitoring Parameters**

Procurement Policy	**Procurement policy and documentation in place** Short description of the Procurement policy – ✓ Post development of a URS for a technology package by the bioprocess and Engineering team, atleast 3 vendors are identified (where available. In case of proprietary technology, like the ATF appropriate documented justifications are available). ✓ URS is shared with the identified vendors with RFQs based on the URS. ✓ Technical and Commercial bids are evaluated for suitability along with technology suitability (by Bioprocess team, QA and Engineering Groups), Technology package Price offered, terms of service/warranty/CMC/AMC included in the offer, payment terms, time for delivery at site (ie. Until Site Acceptance Test), market feedback on the technology package proposed by the vendor at other customer location. ✓ Gradation of the vendors offering based on the above terms are done and sent to Corporate office for final commercial negotiations with L1 and L2 vendors. ✓ Based on the attractiveness of terms of the final commercial offers, we select the final vendors.
Vendor Evaluation and Supply Chain Management	**Vendor evaluation SOP in place at SML. QA drives this initiative at SML with help from operations and purchase personnel. Checklist for vendor evaluation available. Evaluation criteria includes – Quality and EHS apart from regulatory compliance practices** **Supply chain management –** ✓ The facility is designed with a separate GMP warehouse, wherein the consumables required for the pilot facility are entered, stored, dispensed ✓ A significant portion of our raw material is today imported. We recognise the timelines required to indent, purchase, procure such raw material is between 30 and 45 days. ✓ Hence, the warehouse is designed with an intent to store 3 months worth of raw materials and finished products in temperature controlled conditions as the case may be – this is to ensure that there are no disruptions in operations at any given time due to shortage of raw materials. At the same time this ensures that the shelf life of the inventory is maintained at optimal levels and no wastage occurs on account of non-usage of raw materials. ✓ We also have tieups with cold chain transporters and couriers to ensure that the transport of temperature sensitive material across borders goes on smoothly with no disruption or rejects. All material will be transported in conditions that are acceptable to GMP warehousing. ✓ While inventory management is today carried out with Tally, SAP ERP with supply chain and finance modules will be implemented at the facility once

	the facility is commissioned in line with all other SML facilities that currently run on these modules. ✓ Only qualified vendors (local and abroad) will form part of the supply chain – the facilities of these vendors will be inspected periodically by our Quality assurance personnel. SOPs and protocols for such inspection and qualification of vendors is already in place. Secrecy agreements with all qualified vendors shall form part of the practice ✓ Where-ever feasible, material from 2-3 potential vendors will be evaluated, facilities inspected, prices negotiated based on long term supply contracts and only then finalised. ✓ Once the SAP system is in place, the indenting, approval of the indents, Purchase orders, material receipt, inventory management, inventory dispense, re-ordering, vendor payments, material rejects etc will be online with requisite controls at every step. ✓ Barcoding / RFID based tracking systems are also being implemented as a part of our supply chain requirements at various SML units. The same will be implemented at this pilot facility once the unit is stabilized operationally. ✓ SML has a Best practices team that will be responsible for such activities. ✓ A similar process will be followed with finished goods where full traceability shall be ensured till customer site. **Requirement of cold chain facilities** ✓ Some of the raw materials (Ex – Cell culture media, chromatography resins, enzymes), cells and finished goods require transport and storage under cold conditions. ✓ Hence the facility is designed with Room temperature holds, 2-8 Deg C holds, -20 Deg C hold and -80 Deg C holds for raw material as well as finished products – at the warehouse, inprocess and finished goods storage. In addition, the company is also investing in a temperature controlled freeze-thaw unit from Sartorius to ensure that the quality of the material is not compromised on account of non-validated freeze thaw methods. ✓ We also have tieups with cold chain transporters and couriers to ensure that the transport of temperature sensitive material across borders goes on smoothly with no disruption or rejects. All material will be transported in conditions that are acceptable to GMP warehousing. Recording of temperatures during the transport of the material will be available to SML at any time. This will form part of the documentation.
Manpower Recruitment Policy	o Manpower recruitment policy – Attached as Annex - 1 o Subcontract or outsourcing policy – Not applicable to this project. o Sustainability model – ✓ SML Biologics Unit, has a dedicated HR group consisting of 3 nos dedicated staff for hiring manpower required for the biologics unit

	✓ As described earlier, planning for a position to be filled starts 6 months prior to the actual requirement at site by the Department Head and has to be as per the approved budgeted Organogram for that year. ✓ Based on statistical model that we have developed, for every posting atleast 50 nos candidates need to be interviewed over a period of 1-2 months from date of indent. ✓ A recruitment team consisting of the dept head (indentor), senior technical personnel from same department and HR representative carry out the interview. The shortlisted final 3 candidates are again interviewed by the Department Head and the CSO. ✓ 2 candidates are offered the position and normally one nos joining the organisation in the required time. ✓ Employee referrals get the highest weightage and consultants get the lowest weightage based on our experience.
Subcontract and Outsourcing model	Not applicable. In case a customer wants clone development, media optimisation, process development and analytical services at laboratory scale that are not part of the current BIRAC-NBM funded facility, SML will cater to this requirement from its existing R&D facility.
Internal Monitoring Mechanism	✓ The Business Head (BH) and Chief Scientific Officer (CSO) are responsible for driving all Biologics operations & business at SML. The Quality Head reports to the BH and CSO. ✓ The BH drives the revenue operations/sales/finance/legal, while the CSO is responsible for all technical operations at site. ✓ The Plant Operations Head (POH) reports to the CSO while the Finance Head (FH) and Legal Manager (LM) reports to the BH ✓ The Finance Head monitors the payment schedules and collections on each project and monitors the budgeted amount versus actual spent on each project in terms of (a) Consumables (b) Manpower allocation (c) Overheads ✓ The Legal Manager's responsibility is the ensure that the project is carried out within the ambit of the signed agreement. In case of any disputes of legal nature including terms of agreement, it is the responsibility of the LM to come up with relevant solutions. ✓ The POH drives all site manufacturing and utilities operations. His responsibility is to ensure timely delivery of the project based on the timelines agreed to with the customers and in accordance with the quality parameters agreed upon, ✓ The Internal Managing Committee (IMC) consists of the following senior personnel at SML Biologics Unit that meet once a week at pre-scheduled

	time and date – (a) Business Head (b) Chief Scientific Officer (c) Quality Head (d) Plant operations Head and (e) Finance Head (f) Legal Manager. ✓ This committee reviews each project on a weekly basis and ensures progress of project, optimises resources allocated to the project, maintaining the financial viability of the project without compromising on the quality of output. This committee is also responsible for ensuring customer satisfaction and taking operational decisions that ensure operational excellence. ✓ Internal decisions on capacity enhancement or facility enhancement shall be under the purview of the IMC.
For Oversight by NBM-BIRAC **1. Implementation Governance model** – Checks on fund utilization - Checks on Technical side **2. Sustainability and Differential Costing Model** **3. Trainings** (to be provided to identified segment – BIRAC grantees, academia, start-ups, SMEs)	BIRAC monitoring committee to have the authority to review the costing charged to identified segment (BIRAC grantees, academia, SMEs, Start-ups) **Checkpoint for fund utilization –** SML, Biologics Division (Previously called Navya Biologicals Pvt Ltd) has been a recipient of DBT / BIRAC funds thus far. Based on this, we have a strong understanding of the requirements. We are open to setup a dedicated account for utilization of funds for this project. Incase we have already paid advances for through existing accounts for purchase of long lead items, we will make available the necessary documentary/payment proof for these to be included as part of the project (Most documents are already sent). Fund utilisation statements along with the bank statement will be made available to NBM-BIRAC at the end of every 6 months and on annualised basis, verified by our chartered accountant. Similarly NBM-BIRAC can nominate a committee or chartered accountant to verify such expenses and invoices. All invoices will be made available to NBM-BIRAC in scanned format. The original copies of these invoices and bank statements along with corresponding utilisation certificates will be made available to the monitoring committee. **Checkpoints on technical side –** SML has already committed to the timelines of implementation of the project via a GANTT chart. In addition, the same is reflected as Objectives and Milestones with deliverables in the proposal (Ref - BT/NBM0008/01/17). We will make available to NBM-BIRAC the technical progress reports along with photos of the facility at the end of every 6 months. The monitoring committee will have BIRAC nominee to monitor the progress of the project through its monitoring committee. **For the infrastructure funded by NBM-BIRAC, we will have a joint monitoring committee consisting of 3 SML appointees (Technical, Commercial and Financial). NBM-BIRAC shall also appoint same number of monitoring committee members. This committee will meet once in 6 months to resolve any outstanding governance, technical and any**

requirements unique to the infrastructure funded by NBM-BIRAC.

Sustainability and Differential Costing model -

Services: Commitment on reserved/preferred service time and differential costing for categories of SMEs, Start-ups, public institutions etc.

We offer 3 different models of engagement based on the customer type -

a) **Case 1 - SML typical model with own existing customers is based on Transfer pricing mechanism prevalent in the pharma industry**
    i. This involves use of SML IP and process, regulatory filings
    ii. Hence the pricing is based on
        1. Market demand, linked to retail price of the final product
        2. Extent of use of SML IP
        3. Geographies in which the product is sold and the pricing mechanisms in those markets
        4. Typically packaged offering that involves, IP/Development/non-GMP scaleup/Engineering batches/GMP batches for API generation/Fill-finish batches and regulatory filings in markets of interest.
        5. Milestone payments are involved in this business model

b) **<u>Case 2 – What we intend to offer to BIRAC fundees - SML model with BIRAC fundees / Academic researchers for Contract manufacturing only</u>**
    i. Will be based on a Cost + model, with segregation between fixed and variable expenses being made transparent in the beginning. Plus component will include a margin of 10-15% above actual costs incurred.
    ii. Each service offering is segregated based on the customer need –
        b. Development
        c. Non-GMP scaleup and Engineering batches
        d. GMP batches for API generation
        e. Fill – finish batches
        f. Stability data generation and regulatory filing
        g. Formulation studies and filling studies

h. No milestone payments involved.

i. Case 3 – A joint development model for select projects that are of mutual interest to SML and BIRAC fundee - SML model with BIRAC fundees / Academic researchers for joint development

Will be based on a Shared Cost model, with segregation between fixed Cost shall be equitably apportioned for all facility users or projects received and variable expenses being made transparent in the beginning

i. SML will being in its process development, manufacturing and regulatory experience
ii. Partner expected to bring in discovery expertise, initial laboratory process
iii. Commercialization model will be based on shared IP and commercial rights
iv. This model will be on case specific basis only.

j. Lower margins for Cases 2 and 3 will be offset by the higher margins offered to commercial customers (non-BIRAC funded companies) in Case 1. <u>This will ensure viability of the business</u>

k. SML will target both BIRAC and non-BIRAC funded startups, established companies and institutions as potential customers for this service. <u>BIRAC funded projects will be given preference over non-BIRAC funded projects</u>.

The potential customers can also write in directly into a dedicated website for the facility that outlines their requirements and needs. The Business Manager to whom the query is forwarded to will reply to the customer.

Model after 3 years –

The facility will continue to cater to a mix of BIRAC fundees and SML customers (local and international) in the same format as replied earlier.

a) BIRAC fundees will be catered to on a "Cost Plus model" while SML will continue to cater to its own customers (national / international) through its existing CMO pricing model or on its existing transfer price model.
b) On select projects where SML and BIRAC customer have common interests, co-development of molecules may be feasible with shared commercial rights - that will be decided on case to case basis mutually.

Any further additions to the infrastructure that may be required at this point due to expanding market or evolving regulatory requirements with respect to biologics shall be addressed through the management cum monitoring

committee mechanism mentioned in point (2) above and discussions with NBM-BIRAC.

Revenue Generation model: Towards corpus creation for this facility and its continual existence.

- Please project for 5 years beyond the grant/project duration

Head / year	0	1	2	3	4	5	6	
	Implementation period				Post implementation			
OPEX (Rs Lacs)								
Consumables cost pa		135	232	334	443	608	783	1
Overheads including water / electricity etc per batch		420	433	446	459	473	487	5
Manpower		168	185	203	224	246	271	2
Total		**723**	**849**	**983**	**1125**	**1326**	**1540**	**1**
Maintenance & Technology upgradation costs pa		36	42	49	71	97	125	1
Grand Total of expenses pa		**759**	**892**	**1032**	**1196**	**1424**	**1665**	**1**
REVENUES (Rs Lacs)								
Revenue pa		**360**	**618**	**891**	**1180**	**1621**	**2087**	**2**
Difference in cash flows (Rs Lacs)		**-399**	**-274**	**-141**	**-16**	**197**	**422**	**7**
Funds available for further expansion (Rs Lacs)				**-71**	**-8**	**99**	**211**	**3**

Assumptions
Maximum number of batches feasible from this facility per annum - 25 nos
Inflation in consumable costs - 3% per annum (data based on average increase in consumable prices over last 5 years)
Any additional requirement in funding will be borne by SML

- **Minimum percentage corpus that is expected to be generated once the services start**

✓ We have made the facility and infrastructure sufficiently future proof in terms of technology and regulatory requirements by including the latest technologies such as the ILC, the ATF perfusion unit, modular chromatography units, single use fermentation units that can accommodate the latest technologies trends for atleast the next 3-4 years.

✓ We expect this unit to be net cash flow positive and EBT positive within 3 years of operations.

✓ Typically, in the normal course of business, we re-invest about 5-7% per annum of revenues (equivalent to 25%-28% of profits) from each of our units in technology upgradation and maintenance. The same will be done with this unit and we will not revert to BIRAC-NBM for additional funding

	once the initial funds are invested. ✓ The higher margins derived from commercial and foreign customers will be used to even out the lower margins from BIRAC funded customers. Increasing business volumes from existing SML customers and BIRAC funded customers will drive viability and profitability of the business going ahead. ✓ Once we find that the business offtake is higher than the capacity of the unit, SML will, through its own cash flows invest in further capacities or add on capacities with compromising interests of the BIRAC fundees requirements **Basic Training Programs shall be provided to customers from institutions, BIRAC funded startups on** **a) Basic GMP requirements,** **b) data integrity and documentation in GMP setting** **c)** Safety and environment practices programs by our inhouse EHS department **after one year of the facility being started up.** **Results for services of pre facility shall be made online and the fund recipient website will provide details of the services, estimates and list of users especially start-ups,SMEs etc**