Product development and Occupational Health, Safety and Environmental requirements as relevant for the programme

DBT and BIRAC are committed to environmental sustainability by upholding numerous good practices throughout their pursuit of fulfilling their mandate including:

- Protect the environment and to continual improvement in the management of Programme activities;
- Ensure better compliance with applicable regulations, and reducing adverse impacts on people and the environment from the Programme operations;
- Promote adoption of Good Industry Practices (GIP), Good Laboratory Practices (GLP) and best practices in I-3 Programme activities;
- Integrate economic and environmental considerations in the decision-making process;
- Capacity Building of the Biotechnology stakeholders towards sustainability consciousness;
- Exercising monitoring as a quality control tool for determining whether study activities are being carried out as planned, so that deficiencies can be identified and corrected; and
- Pursue environmental goals in a cost effective manner and to preserve culture of sustainability.

In line with these commitments, due risk assessment and mitigation strategies have been proposed for the National Biopharma Mission I-3 Programme that will be integrated into the entire implementation chain. Additionally for facilities, a detailed governance model should be provided with the required information under the different heads:

1. **Affordability:**
   a. **How will the funding from NBM impact the cost of proposed facility?**
      i. NBM proposes to contribute Rs 2200 lacs to the setup of the pilot facility, while SML proposes to contribute Rs 1984.50 lacs to the setup of the pilot facility in the form of equipments, manpower and consumables to qualify the plant.
      ii. NBM and SML will share the cost of equipments for the 200L pilot in the ratio of 52.58::47.42
      ii. Additionally Cost of Setup of the facility including land, building, electricity, water, WFI, utilities connections, clean room panelling/ HVACs, EMS/BMS, clearances etc will be borne 100% by SML. The value of this is Rs xxxx lacs. Progress is on track thus far.
   b. **Cost with/without NBM funding, please give the cost sharing ratio.**

Consolidated Budget		
		Rs. (in lakhs)
a	**TOTAL CONTRIBUTION BY APPLICANT**	1984.50
a	**TOTAL SUPPORT REQUESTED UNDER BIRAC**	2200.00
	(I) GRANTS-IN-AID	2200.00
b	**TOTAL COST OF THE PROJECT**	**4184.50**
c	**TOTAL COST OF THE PROJECT (IN WORDS):**	**Four Thousand One Hundred Eigthy-Four Lakhs and Fifty Thousands**

Summary –

i. NBM-BIRAC contributes 52.58% of the cost of project as defined by the goals

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ii. Shilpa Medicare Ltd (SML) contributes 47.42% of the cost of the project as defined by the goals and approved by the SAG
iii. In addition to the above SML on its own is investing Rs xxxx lacs towards setup of facility including land, building, electricity, water, WFI, utilities connections, clean room panelling/ HVACs, EMS/BMS, clearances etc

2. Social Impact of the project:

a. **Area of application** –

The Need / Pain point - Biosimilars & Biologics are likely to be the therapies of choice over the next decade for a majority of Indian patients provided they are available in cost effective manner. India has significant number of biosimilars and biologics in development at various R&D laboratories Commercial & Academic presently.

But most independent commercial or academic R&D laboratories do not have access to high quality cGMP CMC facilities to produce clinical grade biologics to help progress their products through Human Clinical Trial.

Therefore a significant proportion of the Indian biologics pipeline today is stuck at the entry to clinical stage programs. Lab to commercial scale manufacturing is largest gap in India today. The facility designed by NBPL, along with its multi-functional team caters to this fast growing requirement.

Our solution - Setup and run a world class contract mammalian cell culture based Biologics CMC facility including fill-finish facility for generation & supply of clinical grade drug substance and Drug product to conduct human clinical studies that is capable of complying with international cGMP norms.

Capacities – 1x200L disposable mammalian bioreactors with option to run perfusion process along with one downstream facility that ensures optimum capacity utilization. Fill & Finish facility will consist of isolator based filling unit that can handle upto 40 units per minute of both, PFS and vials, as the case may be. Additionally, the design includes lyophilizer into the fill & finish facility.

b. Target population and analysis of demand versus supply –

I - National relevance

A) Patient burden - India has the largest patient population for a Diabetes (65million), Autoimmune disorders - Arthritis (15million)/Psoriasis (16 million), Macular Degeneration (13 million).
India also has the fastest growing cancer patient pool (More than a million new cases of cancer diagnosed each year). Biologics have made the most impact in these three areas so far.
Biosimilars and later novel biologics are likely to emerge as therapies of choice for Indians for auto-immune disorders, diabetes and oncology provided these drugs are made available to Indians on a high quality, cost effective platform. This is not the case today. **Market penetration of these drugs in India is estimated at lower than 1 percent. SML's goal through our efforts including**

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this project is to help in increasing the market penetration of these highly effective drugs atleast to 8% over the next 5 years.

B) India now has quite a few startups/players doing laboratory scale development of biopharmaceuticals. But unlike with Chemistry based molecules, biosimilars are significantly more challenging to produce in terms of technology and cost, especially at pilot and production scales.

Following are reasons for limited impact of these highly effective drugs on Indian patients today -

i. Significant number of players at R&D stage, but relatively low competition on the market since few players are able to graduate from laboratory through clinic & commercialization
ii. Few integrated cross functional teams in the country with experience and understanding of scaleup of biologics processes from laboratory scale through to manufacturing scale, design of facility, regulatory requirements and setup of QA processes that are required.
iii. Limited availability of facilities to actually carry out the scaleup and transfer studies/batches due to high capital intensity of such facility apart from significant operational costs this increases the already long gestation period for development of such products and are stuck at the laboratory scale. Most projects therefore are abandoned.

II - Business imperatives - India as a potential key producer and exporter of biosimilars to the global markets -

Despite issues listed in I- A and I- B above, the industry views Biosimilars & Biologics as the next big opportunity estimated ~$12 Billion pa over the coming decade, especially with key product worth 60 billion in sales per annum patents expiring over the next 3-5 years. Exports of cost effective biologics from India to the global markets will be a key growth driver both for companies involved as well the making these therapies available in a cost effective manner to the local market through economy of scales being achieved.

III - Recognising all the above drivers, Navya and now through its amalgamation with Shilpa Medicare Ltd brings on the table the following –

a) An integrated biology, bioprocess, analytical and engineering team that can visualise, scaleup processes developed at Lab scale to industrial scale with proven track records.
b) Quality assurance processes that make the process and product robust / reliable and audit worthy by regulatory agencies
c) Teams with Experience in technology transfer and manufacturing that can complement the technology development teams. d Strong operational experience with ability to deal with global regulatory requirements

c. Availability of product/ technology to MSMEs or start-ups –

Our target customer segments are -

1 – Biopharmaceutical startups funded by BIRAC

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2 – Academics & Institutions funded by BIRAC
3 - Biopharmaceutical startups, Institutions and companies that are not funded by BIRAC, but in need of CMC services

Customer profiles will include the following –

- Start-ups / Companies / Institutions with clinical stage leads that need to generate clinical grade material (Bulk formulated API)
- Start-ups / Companies / Institution with clinical stage leads that need to generate filled-finished material for human clinical trials – Phase I, II and abbreviated Ph III PFS / vials (Liquid format) / vials (Lyophilised format)
- Start-ups / Companies / Institutions having laboratory scale processes and now looking for a partner to carry out non-GMP scale up studies to generate material for formulation development and filling
- Start-ups / Companies / Institutions having laboratory scale processes and now looking for a partner to carry out non-GMP scale up studies to generate bulk non-GMP formulated API and filled product to carry out stability studies – Long term, accelerated and degradation studies
- Start-ups / Companies / Institutions intending to tieup with SML for co-development of molecules where early work is already completed by them
- Global startups with early stage leads that want to partner with Indian company for co-development of molecules with shared commercial rights with SML retaining part of the geographic rights including India

Shilpa Medicare Ltd will aggressively markets its Development and Clinical Manufacturing services to all the above groups

d. Generation of employment among local population

The facility being setup will provide employment to approximately 150 nos personnel mainly drawn from local areas of Hubli-Dharwad, Sirsi, Belgaum, Davangere, Kolhapur, Karwar, Gadag in the areas of –

a) Bioprocess development and production
b) Maintenance and Engineering

Apart from this, the experienced senior bioprocess personnel originally from Hubli-Dharwad or surrounding areas, but presently employed in Metros like Bangalore, Pune, Mumbai and Hyderabad have shown a keen interest in relocating back to Hubli-Dharwad if suitable employment opportunities are available.

Such a unit will also create indirect employment opportunities for additional 250-300 people through ancillary unit requirements, ancillary services requirements.

3. Employment:

a. Current number of employees in R&D/product development team – We currently have 52 nos R&D personnel in the R&D and MSAT team. This team is being expanded to 70 nos by December 2018.
Apart from the above, we currently employ 21 nos Projects and Engineering staff for execution of the project and 11 nos Quality Assurance and Quality Control staff to ensure Quality assurance processes and procedures are in place by the time the

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facility is ready for commissioning. SML is a strong believer in Quality by Design and elements of this are incorporated in our processes even at the planning and execution stage of the project

b. Additional recruitment planned under the program –

As a part of the program, we intend to / are recruiting 60 nos additional staff for –

a) Bioprocess
b) Quality Assurance
c) Fill-Finish

Of this total number, 7 managerial staff remuneration is funded by NBM-BIRAC contribution to the project

c. **Current number of women employees**

22nos of the 52 R&D staff are women. In addition, the Principal Applicant is also a woman and was the founder & director of Navya Biologicals Pvt Ltd (now part of Shilpa Medicare Ltd). As a internal guideline, we strive to have atleast 33% female staff of total staff in R&D, if not more.

d. Current number of PH/ST/SC/OBC/lower economic class employees

Of the 52 nos R&D staff presently employed,
PH – 1 nos
ST/SC – 0 nos
OBC – 9 nos
Lower Economic classes - 26

e. Skill development programs for existing employees.

SML Biologics unit holds the following programs for employees and staff on regular basis –

a) Quality Assurance and documentation training programs – hosted by the Quality Assurance staff to ensure that the documentation and quality assurance practices are on par with the industry and regulatory requirements. These sessions include GLP and GMP case studies based on Form 483 issued, resolution strategies for these points and how we can implement the same at our facility if need be.
b) Analytical Skill development programs conducted by vendors – in HPLC handling and data interpretation by Shimadzu & Waters, Chromatography systems handling and data interpretation, DoE sessions from GE Healthcare, Fermentor handling, scaleup studies, DoE software data interpretation by Sartorius
c) Safety and environment practices programs by our inhouse EHS department
d) We are now starting managerial skills development program – a requirement as the organisation continues to grow.
e) We also hold Orientation program every month for new employees to introduce them to the SML culture, goals and introduce them to the basic processes.

4. Complaint Redressal

Is there a complaint redressal policy for employee welfare?

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- ✓ Yes, SML has a complaint redressal forum which is conducted by the HR Department where employees are free to voice their concerns. Issues related to employee welfare (Food, transport, healthcare, insurance, attendance, personal requirements) are addressed here.
- ✓ For complaints that have implications on major policy matters of the company, HR Department in turn involves the management on coming up with resolutions.
- ✓ Ethical concerns, if any, are to be addressed at the same forum and the management is directly involved with any such issues on Ethics, Safety and Environment.
- ✓ In addition, the company also has a sexual harassment policy and committee in place to address any issues faced by the female staff at the facility. The management is directly involved with functioning of this committee and female staff is encouraged to report any potential threats. We are proud to have had a zero incident record so far on this count.

Risk Management and Risk Mitigation plans

The applicant should provide Risk Management and Risk Mitigation plans under the following domains with reference to the project funded by NBM:

- **Societal**
  - **Expansion plan and its impact on the society**

The facility being setup will provide employment to approximately 150 nos personnel mainly drawn from local areas of Hubli-Dharwad, Sirsi, Belgaum, Davangere, Kolhapur, Karwar, Gadag in the areas of –

a) Bioprocess development and production
b) Maintenance and Engineering

Apart from this, the experienced senior bioprocess personnel originally from Hubli-Dharwad or surrounding areas, but presently employed in Metros like Bangalore, Pune, Mumbai and Hyderabad have shown a keen interest in relocating back to Hubli-Dharwad if suitable employment opportunities are available

Facility - The facility being setup is 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. 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 is also setting up a comprehensive system for treatment of liquid and bio wastes from the facility that includes

a) Fully automated kill tank with capacities that are 2x of the actual requirement
b) ETP that can treat up 40000L of liquid wastes from the facility per day and includes Multiple Effect evaporators to recover and reuse all the water from the process.
c) Condensate from the MEE will be recycled back into the raw water tank after running it through a RO facility – our dependence on fresh raw water from the municipality is greatly reduced with this.

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d) Rain water harvesting unit is being implemented to supplement our sources of water and reduce dependence on municipal water units.
e) Similarly, even our chillers used in HVAC / Central air conditioning are Air cooled chillers and not water cooled chillers – another step in reducing dependence on water.
f) The company has developed processes that does not employ organic solvents hence reducing the amount of VoC emitted from the facility. Despite this the company has already made provisions to capture any VoC, particulates and treat them / recycle them appropriately at the ETP
g) The company will have standby Diesel Generator sets which will employ the latest low emission engines and automation technologies. In addition stack at a height of 30m is being built at site, which is in accordance with the PCB requirements for air pollution. Electrostatic / mechanical dust separators will be employed in case we handle any dust generating materials/solids.
h) Double redundant electrical power backup is being designed in order to ensure that the facility or process does not shut down inadvertently at any time. Additionally 33KVA dedicated power line is being brought into the facility from the near sub-station. This will reduce the amount of electrical power outages.
i) Rain water harvesting technology is being employed to regenerate ground water sources within the facility. Our dependence on municipality water will be minimised.
j) Regular testing of water, soil and air shall be carried out at site by NABL approved third party laboratory to ensure that we do not affect the local environment adversely. We will continue to hunt for, and upgrade to any latest, best in class technologies that help track and reduce emissions from the site.
k) The facility is located in a KIADB industrial area with all the required clearances to setup the facility. The clearances required to run the facility will also be applied for and taken once the setup of the facility is complete. 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.

- **Environmental: Impact of the project on the environment in terms**
  - **air pollution –**

    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

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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 –**
  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** – 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 – 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

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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.

- **radiation waste –** we have no radiation wastes

- **heavy metals –** we do not have heavy metal wastes being generated from our processes or any of our raw material does not contain heavy metals.

- **Destruction/alteration of surrounding ecosystem –**
  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

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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.

- **Financial**
  - Financial Audit findings – All documents required for financial due diligence were presented and verified by NBM-BIRAC representative onsite. Explanations sought were also provided to the auditor.
  - List of creditors to the company – Please refer Annex 3 for the top 10 creditors
  - Details of existing loans –
    For SML Biologics Unit (Formerly Navya Biologicals Pvt Ltd)
    SBIRI Loan BT/I/623/21-B12/2009 – Rs xxxx lacs as on 31st March 2018
    BIPP Loan BT/BIPP0542/17/11 – Rs yyyy lacs as on 31st March 2018. One further tranche of loan repayment of Rs zzzz lacs is made after this date in June 2018 as scheduled.
    For SML – List of charges as available on MCA site was made available in the application and to the Due Diligence team. Attached again as Annex - 2
  - Whether the company/ sister concern/ parent company is listed as NPA by any financial institution - No
  - Whether the company/ sister concern/ parent company has filed for insolvency/ bankruptcy - No
  - Contingency/ backup fund availability in case on late disbursal of funds from NBM. – SML generates enough free cash flows from its present operations to cover any delays in disbursals from NBM-BIRAC. Hence there will be no delays in the implementation timeline, as is evident from our ongoing activities at site and the advance payments already done for long lead items.
- **Technical**
  - Technical capability in terms of manpower, infrastructure, IP –
    - ✓ The company employs 52 R&D, MSAT manpower with 8 PhDs, 34 MTEchs, Other being MSc or BE in Biotechnology as on date.
    - ✓ The company has been a previous recipient of BIRAC projects/grants and these have been successfully implemented at our site – and have been recognised by BIRAC as amongst the most innovative
    - ✓ The company specialises in development of
      - platform technologies for expression of "difficult-to-express proteins", Glycosylated proteins
      - pathway engineered cell lines for improved protein expression altered glycosylation patterns
      - proprietary media components to enhance expression of proteins in mammalian cell culture
      - Continuous high density bioprocess platforms for glycosylated proteins and fusion proteins.
      - The company has filed for 4 nos bioprocess platform patents, including PCT applications.
  - Project consultants – XXXX Consultants
  - Manpower risk and backup plan and turnaround time to recruit an alternate person
    - ✓ The company has furnished its Organogram and has a well established recruitment, bi-annual performance evaluation policy for all its staff at all hierarchial levels.

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- ✓ This also helps the company plan its expansion and manpower requirement 6 months in advance. The company keeps track of the number of candidates interviewed every month, as against actual hired and joined. Hence this helps us create a statistical model to ensure sufficient pipeline of candidates for an advertised position.
- ✓ We have also identified critical technical positions in the organogram where redundancy is required and have always hire atleast 2-3 candidates for such positions to ensure continuity even in case of any turnover
- ✓ All methods / processes are converted to SOPs to reduce dependence on single person. Each technical SOP is independently field evaluated by 2-3 operations personnel (apart from the QA staff). This also ensures that the quality of results obtained is not determined by a single person.
- ✓ In critical areas / processes, videos of the process/method are made to ensure that it is available to successive designated staff. This process also ensures that the training efforts for newly joined staff is reduced.
- ✓ Clear professional career path is laid out to staff at the time of interviews and during the initial orientation program to ensure that employee is clear about career growth path at SML Biologics Unit.
- ✓ For candidates in critical positions with super-specialised technical assignments, apart from bonds, we also have a incentivisation program to ensure that the staff retention is high.

- **Details on collaborations or any pre-existing engagements**
  Not applicable for this program or application. SML through its other established units in Raichur and Jadcherla has a number of partnerships with national and international pharmaceutical companies. We will leverage on these well established business relationships when required.
- **Contractual arrangements with employees under the project.**
  - ✓ All staff at the facility are covered under individual secrecy/confidentiality agreement that forms part of the initial hiring agreement.
  - ✓ All new staff joining afresh from institutes and experienced staff in identified critical functions are also covered by bonds and non-compete agreements
  - ✓ The company shall make available to all staff at the time of joining the company - a written framework of governance, ethics and business conduct that the company follows and all staff will be governed and judged by the same. Refresher courses will be held by the HR Group at the company every 6 months on the same
  - ✓ Personnel will be hired at the facility with adequate background check and all such records shall be maintained by the company
  - ✓ A separate Safety Heath Environment policy and document shall be in possession of all staff and the staff will be adequately trained on these policies/procedures/actions, by a dedicated SHE Department
  - ✓ Project specific secrecy agreements are signed with customers on a need basis. Under this the company as well as the staff working on such projects are individually included as part of the secrecy agreement with liability clauses included to ensure customer interests are protected.

- **Legal (**Please mention wherever applicable**)**
  - **IP conflicts regarding use of technology**

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Not applicable. None so far.

- **Agreements with any technology partners such as licensing etc.**
  - ✓ We presently have commercial in-licensing agreements on certain proprietary vectors / vector elements.
  - ✓ Similarly we are covered under a R&D license on proprietary CHO cell line. We can make available this cell line to a customer with prior intimation to the licensor. We can develop a process or product using such a license. Incase a customer wants to commercialise any products which use the same cell line, the customer can independently approach the same cell line licensor for a commercial license at the time of commercialisation of the product.
  - ✓ We are currently negotiating a commercial license for another proprietary CHO cell line with the licensor. This too, shall be made available to customers on a need basis.
  - ✓ IN addition, we also have a third adherent CHO cell line that does not carry any license terms with it.
  - ✓ SML Biologics Unit has also developed its own set of proprietary vectors and elements that can form a part of the CMO project proposal.
- **Sub-licensing agreement –**
  - ✓ AS mentioned above, we can either work with a customer cell line (if the customer has already licensed the cell line from the licensor) or offer the CMO services from our range of proprietary cell lines that are covered either by R&D license or commercial license as the case may be, with intimation to the licensor.
  - ✓ The customer can then directly negotiate with the licensor for a commercial licence at the time of commercialisation of a product using that proprietary cell line OR enter into a sub-license arrangement with SML for the cell line.
- License management policy to avoid foreclosure or termination.
  All licenses negotiated by SML or being negotiated by SML with third party licensor are –
  - ✓ Perpetual
  - ✓ Carry a clause that clearly states that in case of the licensor closing down, or being sold to a third party or merging with the third party, the terms of license will not change at the hands of the new owner.

  Similarly incase SML outlicenses its proprietary technology platforms to any customer, it will be on perpetual non-exclusive basis with same terms as above in case of merger or sale of the unit. Therefore the customer will not suffer even in case of any eventuality.
- The license clause should be irrevocable license clause – Yes, outlined above.

Governance Model

- **Procurement Policy**
  - **Procurement policy document -Yes**, available as a SOP at SML. Can be made available.

    Short description of the Procurement policy –

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- ✓ 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, 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 CFT 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 protocols** – Yes available as a SOP at SML. Can be made available. QA drives this initiative at SML Biologics Group.
- **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 X 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.
✓ 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.
✓ Barcoding 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.

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- **Requirement of cold chain facilities**
  - ✓ Some of the raw materials, cells and finished goods require transport and storage under cold conditions.
  - ✓ Hence the facility is designed with controlled temperature 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 infrastructure 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**
  - Manpower recruitment policy – Attached as Annex - 1
  - Subcontract or outsourcing policy – Not applicable to this project.
  - 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.

- **Sustainability model -** Please address the following**:**
  - **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 -
    - ✓ **Case 1 - SML typical model with own existing customers is based on Transfer pricing mechanism prevalent in the pharma industry**
      - This involves use of SML IP and process, regulatory filings
      - Hence the pricing is based on
      - Market demand, linked to retail price of the final product
      - Extent of use of SML IP
      - Geographies in which the product is sold and the pricing mechanisms in those markets

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- 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.
- Milestone payments are involved in this business model

✓ **<u>Case 2 – What we intend to offer to BIRAC fundees - SML model with BIRAC fundees / Academic researchers for Contract manufacturing only</u>**

- 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.
- Each service offering is segregated based on the customer need –
  - Development
  - Non-GMP scaleup and Engineering batches
  - GMP batches for API generation
  - Fill – finish batches
  - Stability data generation and regulatory filing
  - Formulation studies and filling studies
  - No milestone payments involved.

✓ **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 and variable expenses being made transparent in the beginning

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

✓ **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>**

✓ **SML will target both BIRAC and non-BIRAC funded startups, established companies and institutions as potential customers for this service. BIRAC funded projects will be given preference over non-BIRAC funded projects.**

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.

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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.

- **Training:** Minimum frequency of training, with minimum no. of women/socially backward, SC/ST etc.
  - ✓ Training for SML staff on quality, process, new technologies, technology upgradation, career growth, managerial requirements is part of routine Standard Operating Procedure and will be followed every month.
  - ✓ We also have a dedicated EHS department to impart training on First-Aid, Environment and Safety aspects every 3 months. Records of such trainings will be made available to regulatory bodies.
  - ✓ All levels of staff, regardless of their backgrounds will be subject to these training and brain storming sessions.

- **Sub-contract or outsourcing model** (if such component is part of proposal) – 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.

- **Implementation governance model:**
  - 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.

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- 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 NBM-BIRAC shall also 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.

- Handling of client complaints if any –

- ✓ A dedicated Business Manager (BM) shall be in charge of all business correspondence with the customer until the end of the project. All correspondance and information exchange of proprietary information with customers will be covered under a Confidentiality agreement. All staff at the facility shall also be covered under individual secrecy/confidentiality agreement that forms part of the initial hiring agreement.
- ✓ On signing of a contract, the Organisation chart and issue escalation-resolution chart/protocol will be made available to each customer. At this point, a Technical Project Manager (TPM) who works alongside the Business Manager (BM) for resolution of issues, redressal of complaints from customers - for each project shall be ensured.
- ✓ The TPM is accountable for actions taken within the facility and for customer data/material received and sent. Each TPM shall have a technical team for execution of the project
- ✓ Internally, the TPM reports to the Plant Operations Head (POH) for scheduling / rescheduling of runs operations and resource requirements.
- ✓ A Quality Manager (QM) shall be allocated to each project with details of deliverables as agreed with each customer.
- ✓ The BM, the TPM, the QM shall form a Resolution Committee (RC) for interfacing with the client on regular basis (At pre-determined timelines that are captured as part of the project agreement) to update the customer on the progress of the project, send out project progress and technical report to customer at predetermined intervals and to flag any operational issues that are brought up.
- ✓ In case of issues that need intervention from the management (Quality, Pricing) this will be escalated by the RC to the Internal Monitoring Committee (IMC) described in the next section. The RC and if issue is unresolved, then IMC will be responsible for resolving any pending customer complaints.

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- ✓ Such customer complaints, details and action taken shall be logged and made available if required to the Steering committee setup by SML & NBM-BIRAC for projects that are carried out in the facility funded by NBM-BIRAC

- 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.

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

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

Head / year	0	1	2	3	4	5	6	7	8
	Implementation period				Post implementation period				
OPEX (Rs Lacs)									
Consumables cost pa		135	232	334	443	608	783	1021	1218
Overheads including water / electricity etc per batch		420	433	446	459	473	487	502	517
Manpower		168	185	203	224	246	271	298	327
Total		**723**	**849**	**983**	**1125**	**1326**	**1540**	**1820**	**2062**
Maintenance & Technology upgradation costs pa		36	42	49	71	97	125	163	195
Grand Total of expenses pa		**759**	**892**	**1032**	**1196**	**1424**	**1665**	**1983**	**2256**
REVENUES (Rs Lacs)									
Revenue pa		**360**	**618**	**891**	**1180**	**1621**	**2087**	**2722**	**3247**
Difference in cash flows (Rs Lacs)		**-399**	**-274**	**-141**	**-16**	**197**	**422**	**739**	**991**
Funds available for further expansion (Rs Lacs)				**-71**	**-8**	**99**	**211**	**370**	**495**

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

- **Project Monitoring (Please mention detail within each)**

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- Internal audits' reporting –

  SML is a listed company with strong financial processes and cash flows in place The company has already made investments in land, setup of new building, utilities and infrastructure for this project. The company has also placed orders for equipment with long lead times along with advance payments.

  The company already has a 22 member strong project execution team at the site as on date which is well diversified with experienced personnel from Pharmaceutical Project Management, Engineering and process backgrounds.

  In addition, the company has employed a dedicated Quality Assurance and Quality control team of 10 experienced personnel at the start of the setup of the project to ensure adherence to all international standards and regulatory requirements.

  The company has also made available the list of staff who are dedicated to setup of the facility.

  In addition the company has invested in MS Project based project tracking modules. SML also has a dedicated site accounting and inventory management team to ensure no slip-ups or wrong doing in payments made. The purchase process is managed well through vendor evaluation through Commercial Bid Analysis and Technical Bid analysis of vendors to ensure that the company gets the best prices in the market without sacrificing on the quality.

  The company has produced a GANTT chart at the time of application that outlines each step involved in setup of the plant and thus far, the project is on track.

  Logistics and supply chain is also looked after by a small but dedicated team of 3 staff who are responsible for all site logistics to ensure supply of material to site in time.

  All documentation required for proof of setup, purchase, commissioning, qualification, validation is now in place.

  The company has recently hired a dedicated Finance Head to evaluate existing financial processes and strengthen it further.

  The finance and project management teams will ensure that the site progress is reported to BIRAC every 6 months. The team also reports to the IMC presently every week. Weekly and monthly progress reports are being presented to the IMC currently in addition to sending the same to BoD of SML at Raichur, who are also tracking the progress of the project.

  The company also has a well managed hiring process plan for commissioning of the plant

- **Internal Technical reviews**

  The technical project setup is headed by Chief Manager Projects. For purpose of execution and fixing responsibility to ensure execution, the project is split into packages and package owners are assigned to head and execute each package. The package owner has a small team of 3-4 staff to ensure evaluation and execution of the project, track execution timelines. All execution timelines

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and progress feedback into the main GANTT chart that has the execution timelines for the project.

The Project Coordinator is responsible for ensuring all reports come back in time, GANTT chart kept updated and all vendors invoices, scrutiny and payments are done on time to ensure smooth flow of the project. Issues with vendors are handled jointly by the PC and the purchase team.

The updated GANTT chart along with physical site progress is evaluated by the Business Head every week. The Business Head in turn reports to the Managing Director of the company every week on the site progress, issues faced/resolved and upcoming plans.

- **Is there a core team which does quality monitoring and review? If yes, what is the team strength?**
  Yes, the IMC as described earlier keeps track of the quality monitoring. The Quality Head reports to the Business Head and the CSO.

  The QH has a team strength of 10 nos QA staff as on date to ensure quality monitoring, setup of documentation, creation of SOPs, development of Quality Management System, review URS and Design Qualification, carry out Factory Acceptance Test, Site Acceptance Test, Installation Qualification, Operation Qualification, Process Qualification. This team is now being expanded to about 18 staff to ensure that we have enough oversight on the project.

  Additionally, SML through its Units at Raichur, Hyderabad and Jadcherla already has a Corporate Quality Group of close to 120 staff that have both, API and filling experience and have exposure to regulatory audits of most geographies including India FDA, USFDA, PMDA, EMA, ANVISA etc. We draw from this pool of experienced resources as and when required to ensure that the latest trends in regulatory requirements are incorporated in to our design and execution.

  Similarly, the Plant heads of all SML plants (5 nos) meet once a month to review technologies at use in different plants and share experiences with new technologies, issues in implementation, resolution to these issues.

b. How is the progress/no progress reported from the above reviews?

As mentioned above, the GANTT chart in MS Project is the primary source of tracking of the project execution.

The GANTT chart is kept updated on a real time basis and we are in a position to drill down to the last detail on progress of each package, issues if any, package owners reasons for delays (if any), resource utilisation, additional resources required. The PC is responsible for ensuring coordination across different package owners, vendors, Purchase dept and Finance Departments to ensure smooth execution of the project.

As described earlier, weekly meetings are held internally to monitor the progress of the project, resolve vendor issues, track payments made/pending,

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any logistical issues. The weekly meeting is headed by the Business Head who in turn reports to the Managing Director of SML.

c. How is troubleshooting done in case of no-progress?

The constantly updated GANTT chart highlights the timeline and Critical Path for execution of the project. Any changes in timeline or the critical path flags the PC and the Chief Manager Projects, who in turn flag the Business Head in case there is a delay of more than 3 days on any package.

Incase the delay is within the set time line of three days and normally this happens due to Logistics issues, the purchase manager along with the PC work together to ensure delivery of items in time.

In case the delay is due to reasons that other than logistics and are technical or financial in nature, the Business Head is brought in to resolve the matter along with the CM Projects and the Finance Head. A report of this is also sent to Corporate Office Raichur to ensure full project traceability and accountability.

Critical Vendor meetings are held every week two days after the weekly project meeting by the CM Projects, Project Coordinator and the Purchase manager to ensure timely execution of the project.

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