Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL)

(A Govt. Of India Undertaking)

Project Risk Management Plan

To comply with DBT, World Bank & BIRAC's mission to promote innovation and self-sufficiency in the biotechnology sector while striving to reduce any social and environmental risks in its activities M/s. Bharat Immunologicals and Biologicals Corporation Limited BIBCOL), Fund Recipients for the proposal entitled "**Plasma fractionation process for the production of albumin, immunoglobulin and other products for therapeutic uses"** has identified the following risks related to Project, Environment (including occupational health and community) and during conduct of clinical trials (if applicable). Risk mitigation measures are being taken by self as defined in the following annexures:

i) Annexure 1: **Project Implementation Risk Management plan:** identifies project monitoring mechanisms, complaint redressal mechanism and describes the mitigation measures being implemented for the programme components based on the identified risks. Institutional arrangements in order to implement safeguard parameters, methods for periodical review, monitoring strategy and grievance redressal mechanism are described in this annexure.

ii) Annexure 2: **Environmental and Health Risk Management Plan:** Compliance to corresponding legislations, Good practices in research and development methods, including while use of animals will be followed. We have referred to the Environment, Occupational Health and Safety Management Framework (EMF) document while preparing this annexure. Facility-specific occupational health and safety hazards have been identified based on risk assessment using established methodologies. The Community health and safety impacts related to handling and storage of solid, liquid and gaseous substances have been evaluated and accordingly mitigation measures will be implemented during project implementation. Impacts due to significant exposures to workers and potentially to surrounding communities, depending on quantities and types of accidentally released chemicals and biologicals have been thoroughly evaluated and addressed.

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Annexure 1

Project Implementation Risk Management Plan

1. Project Risk Management:

Risk	Mitigation Measures	Monitoring parameters
Technical		
Breach of any license terms and termination of license agreement (if applicable)	Not applicable.	Not applicable.
Scientific failure that product will not reach the market.	The technology provider (NII) shall be involved in developing the process, its optimization and scale up at 1 litre scale at NII transfer of technology to BIBCOL. NII has rich experience in protein purification and characterization.	Product specifications (quality check by National Institute of Biologicals and yield). In stage –I, BIBCOL shall arrange plasma to ensure project viability, Based on the yield obtained at NII, BIBCOL shall make a business plan & project a scale at which the product will have a margin of profit.
Project Non-Progress	Performance reports and Periodical reviews. The reports shall include the product development progress, and planned activities for next six months.	Milestone charts and performance reports. In addition to this quarterly reviews and progress report shall be generated, as the company is listed in stock exchange.
Manpower risk and backup plan and turnaround time to recruit an alternate person	The appointment letters to selected candidates shall have notice period of 3 months and if required the existing staff shall be placed to cover the turnover time for the recruitment. Selected candidates will be kept in panel for future requirements.	Notice for resignation or/quit or long absence from work. BIBCOL has sufficient qualified and experienced scientist who can take up the job quickly.
Social		

Failure to meet affordability	Affordability of process/ product comes from cost of process/product and if is high, the steps will be taken to improve the process / Scale up/ Capacity enhancement. The vision & mission of BIBCOL is to provide albumin and Immunoglobulins to Indian population at affordable price in subsequent stages.	1. Monitoring Cost of process development/ production and pricing in the market to ensure affordability. 2. Based on the yield obtained at NII, BIBCOL shall make a business plan and project a scale at which the product will have a marginal profit.
Gender non-representation	BIBCOL is an equal opportunity employer and efforts will be made to give preference to female candidates in an appropriate proportion. However, Government of India policy shall be followed in reservation.	Meritorious women candidates will be given equal opportunity. The number of applications received from female candidates, shortlisted candidates and selected candidates is monitored to ensure minimal gender disparity.
Employment generation	The project is expected to generate employment opportunity to at least 2 people in current stage and 10 to 15 people subsequently in stage 2 of the project.	Recruitment process. Quarterly review of the database will be done by the management & the database will be updated.
Financial		
Miss-utilization of funds	Purchases shall be made through Purchase Committee following Purchase Policy and Payment process through Internal Audit. Separate head and bank account shall be created for the project.	Auditor Report (external), Financial Statement, and Internal Auditor Report to monitor utilization of funds.
Non-repayment of existing loans. Risk of being listed as NPA.	There is no long term loan and only working capital loan is taken against confirm order.	Default in timely repayment and monthly bank report

Adverse audit findings	Payment shall be made through Internal Audit and on recommendations of committee which shall be constituted for this specific project.	Periodical Audit report as well as annual statutory audit done by external auditors as per norms.
Late disbursal of funds from NBM	BIBCOL will be able to manage the project as the financial implication is very less.	Fund Flow Statement and periodical update of project progress including fund flow from NBM & monthly review of budget to foresee the requirements.
Data Management		
Loss of Data	Access to critical data shall be restricted to authorized persons only and back up of data shall be maintained.	Data monitoring & data back-up shall be maintained.
Miss-utilization of Data	Access to critical data shall be restricted to authorized persons only and for this BIBCOL/NII has a SOP No: 05/QA/033 for maintaining data integrity.	Data monitoring & antivirus for system protection.
Procurement		
Irregularity in procurement	BIBCOLhas procurement policy based on GFR of Govt. of India and purchases shall be made by following the policy	Audit report and observations of Internal Audit.
Failures during vendor validations processes.	Shall develop list of reputed brands/supplier of specific equipment and chemicals with the help of consultant and existing vendors.	No Timely response, technical disqualification at the time of technical evaluation of bids.
Lack of vendor databases	Support from consultant and other similar industry. A database of vendors is maintained for the most of requirements.	Vendor list database is periodically updated.

Legal		
IP conflict regarding use of technology	This has been addressed in MOU/agreement in between NII and BIBCOL, which has been already submitted to BIRAC	Reporting of conflict
Non-compliance to regulatory framework for conduct of study	1. Permission of procuring plasma from SBTC, Lucknow, its storage and processing for fractionation, testing of purified products for R&D. 2. The application shall be made to regulatory authority and required approval shall be obtained.	Inspection report will be complied, if applicable.
Termination of license	Not applicable	Not applicable
Dispute with outsourcing agency	The clause of Arbitration/dispute resolution shall be incorporated in the agreement if outsourcing is required.	Any disputes between the parties shall be resolved by mutual discussion.
Change of entity status due to statutory non-compliance	BIBCOL is Govt. of India Undertaking and we do not see any change in entity status.	Any non-compliance obscured is reported to the board & necessary corrective action is taken, all statutory compliance shall be complied with so that there is no change is entity status.
Preclinical and Regulatory		
Delay in approval by the competent authority (eg. IAEC, CPSCEA)	Help of Ministry shall be taken and all pre-requisites for getting approvals shall be strictly followed. If applicable	Monthly and quarterly progress report will be made & all pre-requisites for getting approval shall be complied with. If applicable

Unavailability of animals to conduct study.	Not required at current stage	Not applicable
GLP Compliance	A consultant shall be hired for detailed designing and establishing the Lab facility.	Responsibility of the hired consultant to get the GLP certificate from the Regulatory Authority.
Animal welfare/Loss of animal during the study period	Not required at the current sage	Not applicable
Inconclusive study	Product is well established and available in the market.	Product specifications

2. Complaint Redressal:

Internal Grievance/ Complaint Redressal	**Mechanism/ Mitigation**
Employees	Insurance policy is under place for all the employees which is covered by the Organization. We have a commitment to an open culture for reporting any unlawful conduct at work under whistle belier policy'
Women Employees	Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act? Yes, There is women Harassment Cell at BIBCOL where complains against women harassment are addressed, if any
Vendors/ Partners	Vendors/Partners can raise RTI or Complaint to the Management which are addressed as the organization is a Government of India Undertaking (PSU) company.
Customers	Customers are free to raise RTI or Complaint to the Management which are addressed as the organization is a Government of India Undertaking (PSU) company.

3. Project Monitoring Mechanism:

	Monitoring Mechanism	**Strategy**
1	Financial Audit Reports on monitoring Fund utilization, Fund re-appropriation	Annual statutory audit as per companies act and CAG will be done Company audits? Yes
2	Internal Technical Reviews	Periodicals progress report.

4. Impact of the project:

- **Affordability:**

  How funding from NBM will impact: affordability of the product(s) – cost of product with/without NBM funding, product availability/ affordability under National missions, technology licensing to MSMEs/ start-ups. Please share the cost sharing ratio,

  1. Funding from NBM will help in reduction of production cost as the depreciation cost on equipments will be negligible.

  2. License is non exclusive.

- **Social:**

  Use of product/ technology, target population, public health programs, availability of product/ technology to MSMEs for further usage, generation of employment among local population.

  1. The proposed process/Technology for the albumin, Immunoglobulin and other therapeutic proteins shall be utilized for scale up and pilot plant facility development in later stages of the project.

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Annexure 2

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	No potential risk	1.Volatile organic compounds (VOCs) and particulates may be emitted from development processes 2. Product development activities are also expected to cause odor nuisance both to the people working within and outside product development area.	1. Under this project, the process will be developed for albumin and immunoglobulin at R&D scale. 2. Decontamination of waste and equipment with chemical methods and autoclaving. 3. Decontamination area by fumigation of proper disinfectant.
Water Pollution and Waste water treatment	Release of raw material, media and chemicals in water.	1.Programme activities and operation of facilities are expected to generate wastewater from laboratory processes, sterilization and facility wash water, etc. 2. Contamination of area, ground water and drains in the plant or surrounding area.	1. Proper control and release of media by authorized person only. 2. Restricted accesses and recording of entry. 3. Proper decontamination of water and media release. 4. Use of sterile drain and proper treatment of effluent before discharge.
Chemical waste	Minimal risk	Non-specific Project implementation will not cause any adverse chemical waste.	Procedure are in place to address spillage etc.
Biological Waste	Empty bags of plasma,	Health hazard	Proper decontamination before disposal at designated place.

Heavy metals	Project implementation will not cause any adverse heavy metals	Project implementation will not cause any adverse heavy metals.	If any risk arises, appropriate measures will be taken.
Radiation Waste	Project implementation will not cause any adverse radiation waste.	Project implementation will not cause any adverse radiation waste	If any risk arises, appropriate measures will be taken.
Destruction/alteration of surrounding ecosystem	Project implementation will not cause any adverse destruction /alteration surrounding.	Project implementation will not cause any adverse destruction /alteration in surrounding ecosystem.	If any risk arises, appropriate measures will be taken.

2. Occupational Health and Safety and risk mitigation

Risks	**Project Specific Risk**	**Potential Impact**	**Mitigation Steps**
Heat Hazards	Autoclave and DHS	Burn due to release of steam or hot air oven	Suitable equipments with safety features and proper training to employees.
Chemical hazards, including fire and explosions	Fire	Burn, destruction of equipment or facility	Fire control system with fire extinguishers and water hydrant system, alarm system, emergency exit and training.
Pathogenic and biological hazards	Exposure to pathogens may occur during isolation and growth of micro-organisms in laboratory.	Including HIV, Hepatitis and malaria parasite,	Management practices are presented Biohazard Policy (No. BIB/QA/007).
Radiological hazards	No risk is associated	Do not anticipate any risk	If any risk arises appropriate measures will be taken.
Noise		Do not anticipate any risk	Laboratory equipments shall be used for this project. We do not anticipate any risk, if there is any, the personnel protection equipment(PPE) will be

			used by the workers
Process safety	Release of virus if present in plasma	Virus inactivation and removal	Highly pure as the product is inject able.

2. Community Health and Safety and risk mitigation

Risks	**Project Specific Risk**	**Potential Impact**	**Mitigation Steps**
Safety Transportation Management System (for transport of hazardous material)	Transport and supply of source plasma without its required testing	Plasma pooling may contaminate the batch.	1. Properly closed containers, labelling, warning and minimal frequency of transportation under qualified and competent personnel. 2. Maintaining of record of plasma.
Emergency preparedness and participation of local authorities and potentially affected communities	Transport and supply of source plasma without its required testing.	Plasma pooling may contaminate the batch	1. Information to the blood bank from where the plasma was collected. 2. Local authorities about the emergency measures.
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**.**			

BIBCOL has Biohazard Policy (No. BIB/QA/007). At NII we follow most of the biohazard policy following good laboratory practice. The main parts of the policy are-

1. Guidelines on equipment and operation for different level of bio-safety.

2. Good laboratory technique and procedure.

3. Chemical, fire and electrical safety in laboratory

4. Safety organization and training.

5. Safety checklist The Summary of the policy is as under –The laboratories are designed according to their design features, constructions and containment facilities and the parameters for bio-safety level requirement.

Under Good laboratory techniques and procedure, clearly defined techniques for the safe handling of specimen in the lab including specimen containers, transport to the laboratory,

opening of package, use of pipetting aids, techniques for avoiding the dispersal of biological materials, techniques for the use of biological safety cabinets, techniques for the care and use of refrigerators, freezers and cold rooms, contingency plan and emergency procedure are mentioned.

The policy clearly defines the equipment related hazards and how to eliminate or reduce the hazard, incompatible chemicals, toxic effects of chemicals, chemicals spillage, compressed and liquefied gases, fire in the laboratory, electrical hazards and waste hazards.

The safety checklist describes the laboratory premises as its cleaning, any defects in floors, walls and roofs, working space, furniture, pest control program etc. The safety checklist includes storage facilities, sanitation and staff facilities, HVAC and lighting, security and fire prevention, personnel protection, health and safety of staff, laboratory equipments and disposal of lab waste.