Environmental Health Risk Management Plan (EHRMP)

Theragen Biologics Pvt Ltd

Proposal entitled: Development and Pre-clinical Evaluation of A Novel Anti-VEGF Biologic molecule till Investigational New Drug Application Filling to treat Diabetic Retinopathy

1. Institutional Arrangements

(i) Brief description of the proposed activity- Ensuring the relevant safety measures for the facility , labs, processes, waste management , employee training ,environment are in place in line with the Company Policy and monitoring and taking necessary actions by means of various committees instituted for the same .

(ii) List of environment related regulatory clearances required for the activity.- Pollution Control Board Certificate for operating .

Institutional Arrangement

Area of Risk		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	✓		Qualified - Nebosh certified - personnel is in charge.	The EHS personnel will be training the employees half yearly and for the new recruits at the time of induction.
2.	Does the EHS staff handle the following?			Any other:	SPCB approval shall be obtained .
	Occupational Health and Safety	✓			
	Waste Management	✓			
	List of consents and regulatory clearances	✓			
	Record keeping of accidents and procedures	✓			
	EHS trainings for staff	✓			
	Environment Management Framework compliance for Innovate in India Project	✓		Adherence to all the safety precautionary measures as per the regulatory guidelines.	
3.	Is there a reporting structure in place regarding EHS issues?	✓		Describe:: Reporting Matrix with the EHS In Charge & Dept Head depending on the category of incidents with the process modalities in place	As per the policy there is a well defined reporting matrix for the incidents and issues for the various categories .
4.	Are regular EHS trainings provided to staff?	✓		Frequency: Quarterly	Training is given half yearly to all the employees and for

					new joiners at the time of induction .
5.	Institutional Bio-Safety Committee (IBSC)	✓		Comprise of External experts from various reputed institutions &in-house team members	Regular IBSC meetings which is half yearly (as per the DBT norm) is diligently conducted and adhoc meeting based on requirement . Annual IBSC report is submitted yearly to the DBT .
6.	Ethics Committee (EC)		✓	Since we are outsourcing the preclinical activity hence not applicable.	Meetings and reviews will be scheduled and regularly carried as per the Government of India guidelines.
General Occupational Health and Safety					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	✓		SOP for hazards & emergencies are in place.	The SOPs will be reviewed annually , and amendments will be made as per the requirements .
8.	Are the following in place?				To ensure the refill and replacement of the required tools , servicing and accessories through AMC / approved vendors.
	Chemical spill kits	✓			
	Eye wash	✓			
	Shower stations	✓			
	First Aid Kit	✓			
	Fire Extinguishers	✓			
	Register of accidents and injuries	✓			
9.	Are proper signage and storage system in place?				Periodic check of the signages will be done to ensure all the required MSDS & signages are in place .
	Display of Material Safety Data Sheet (MSDS) where relevant	✓			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	✓			
	Signage across the facility (labs, storage, hazardous areas, etc.)	✓			

	Are flammable materials appropriately stored to prevent fire hazards?	✓			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	✓		List: 1.Fire sprinkler 2.Smoke detector	Half yearly inspection of the fire extinguisher & functionality of the fire alarms will be done through AMC .
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	✓		List: 1.Autoclave 2.BSL1 microorganism as per the guidelines. 3. Steam Sterilization for Fermentor. 4. Air compressor.	The AMCs are in place and regular period checks will be done by the vendors.
12.	Are regular mock drills conducted for emergency preparedness and safety?	✓		Frequency (type wise): Fire fighting - Twice in a year	Mock Drills will be done half yearly .
13.	Are staff provided with OHS training?	✓		Describe: Training shall provide to all employee during induction period	Quarterly training will be done along with training for new joiners at the time of induction .
	Biomedical Waste (BMW)				
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	✓		If Yes, provide a list of biomedical waste produced in the facility- **Annexure -I** If No, provide a list of all waste produced in the facility.	The details of the waste produces is shared in Annexure -I and will be modified regularly based on the projects and requirements .
15.	Is there trained staff to handle biomedical waste in the grantee?	✓		Full Time experienced employee in the	The personnel will be given training /refresher training quarterly.

				rolls of the organization		
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		✓			The authorization shall be obtained .
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	✓		Yellow		All biological waste are separately decontaminated in autoclave as per SOP TBL-SOP-134 & disposed off as biohazard waste through authorized agency – GJ Multiclave.
				Red	✓	
				White		
				Blue		
18.	Is the bar code system for the segregated waste in place?	✓		Vendor issues the bar coded bags.		We will be following as per the relevant code system introduced from time to time by the authorities .
19.	Is the biomedical waste being sent to an **authorized** common BMW facility?	✓		Name and address of CBMWF: GJ Multiclave India Pvt Ltd, New No.37, Old No.20, Teachers Colony, Kamarajar Avenue, Adyar, Chennai - 600 020 Distance from facility: 60Kms Frequency and Mode of transport: Twice a week in their own vehicle Who transports? The vendor		We will be continuing with the authorized vendor in future as well .
20	Does the grantee have an in-house BMW treatment facility?		✓	Reason: Since its minimal in quantity &		We will not be treating the BMW in house and will be tying up the authorized
	Is the treatment facility own (individual)?		✓			

	Is the treatment facility a shared facility in an industrial park?		✓	decontamination is done in house in a separate Autoclave & hence not applicable. Authorization: Distance of nearest CBWM from facility: Approximately 60kms away from the facility. Types of treatment: Burying and incineration	vendor for the disposal .
21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?	✓		Microbial strain such as BL21 in use at our facility fall in the BSL-I risk group, as per the RCGM & DBT guideline representing the lowest risk to environment. But, all biological wastes that are generated at the facility (Like after the fermentation) are first treated with chemical agents to ensure kill. Types of treatment: Autoclaving , decontamination, Sterilization	The mentioned process for decontamination will be followed as per the Company SOPs and in future will make amendments or additions in case of a process change and in line with Government regulations.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	✓		The biological waste (after fermentation) is decontaminated by	The mentioned process for the liquid waste treatment will be followed as per the Company SOPs

				the process of sterilization at 121 degree for 30 minutes . After sterilization the broth will be checked on the LB Agar plate to check the microbial growth ,as well with the microscope .	
23.	Are necessary waste pre-treatment equipment in place?	✓		List of equipment (autoclaves, shredders, incinerators, etc.):Autoclave, Incinerators. Details of waste pre-treatment: As mentioned in Point no :22. All biological waste are separately decontaminated in autoclave as & disposed off as biohazard waste through authorized agency – GJ Multiclave (India) Pvt. Ltd, Chennai	The relevant equipment are in place and in future if required we will be procuring the necessary equipment .
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?				
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		✓	Currently not using it	We will be using it in future based on the requirement.
25	Are grantee's personnel involved in handling BMW provided with regular training?	✓		Frequency: Quarterly- Trainer: Vendor	The quarterly training will be done as per the current policy .

26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		✓	Frequency of medical examination: Since none of our BMW is Hazardous and is BSL-1 such vaccination is not required	We will implement the same in case we generate hazardous waste and the same need to be handled.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	✓			Will be maintained as per the process .
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		✓	Yet to receive the PCB and hence not applicable.	SPCB shall be obtained and will submit the report once the certificate is acquired .
Hazardous Waste (HW)					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		✓	If Yes, provide a list of hazardous waste produced in the facility If No, provide a list of all waste produced in the facility. (Same as Annexure- I)	Since we do not generate hazardous waste this is not applicable .
30.	Is there trained staff in the facility to identify and handle hazardous waste?		✓	Since we do not generate hazardous waste this is not applicable .	Since we do not generate hazardous waste this is not applicable .
31.	Does the grantee have authorization from SPCB for hazardous waste?		✓	Since we do not generate hazardous waste this is not applicable .	Since we do not generate hazardous waste this is not applicable .
32.	Is there a secure location for storage of HW with proper signage?		✓	Describe how each item is stored – platforms, distances from critical installations/movement areas, spill	Since we do not generate hazardous waste this is not applicable .
	Are hazardous waste stored for more than 90 days in the grantee's premises?		✓		

				collectors, gas escape facility, etc.	
33.	Is the hazardous being send to an **authorized** disposal facility or user?		✓	Name and address of facility:	Since we do not generate hazardous waste this is not applicable .
	Is the disposal facility in house?		✓		
	Is the disposal facility external/outsourced?		✓		
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		✓	Since we do not generate hazardous waste this is not applicable .	Since we do not generate hazardous waste this is not applicable .
E-Waste and Batteries					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		✓	Project implementation does not cause any adverse electronic waste.	Since we do not generate e-waste this is not applicable .
36.	Has the grantee obtained SPCB authorization on e-waste?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
37.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		✓	Name and address of disposal facility/ recycler: Inhouse or outsourced Facility:	Since we do not generate e-waste this is not applicable
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓	Describe: Since we do not generate e-waste this is not applicable	Since we do not generate e-waste this is not applicable
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable

40.	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
42.	Does the grantee submit annual reports on e-waste to SPCB?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
43.	Is there accident reporting and records in place?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
44.	Are PPEs available to staff?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
45.	Is the grantee involved in manufacture of batteries?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
46.	Does the grantee generate battery waste?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
47.	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioner/collection center?		✓	Name and address of battery waste receiving entity:	Since we do not generate e-waste this is not applicable
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		✓	Since we do not generate e- waste this is not applicable	Since we do not generate e-waste this is not applicable
Community Health and Safety and risk mitigation					
		Yes	No	**Details**	**Proposed Plan**
49.	Safety Transportation Management System (for transport Of hazardous material)		✓	Since we do not generate hazardous waste this is not applicable	Since we do not generate hazardous waste this is not applicable
50.	Emergency preparedness and participation of local authorities and potentially affected communities		✓	Since we do not generate hazardous waste this is not applicable	Since we do not generate hazardous waste this is not applicable

Other					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		✓	Since we do not use any radioactive materials this is not applicable	Since we do not use any radioactive materials this is not applicable
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		✓	Since we do not use any radioactive materials this is not applicable	Since we do not use any radioactive materials this is not applicable
	Are radioactive warning signs in place?		✓	Since we do not use any radioactive materials this is not applicable	Since we do not use any radioactive materials this is not applicable
52.	Is the lab/room air regularly checked for microbial contamination?	✓		Regular checks for microbial load by LB Agar plates	The checks as per SOP will be followed in future as well .
53	Are there any odor control measures in place?	✓		Proper air exhaust system in place & usage of Laminar Airflow .	The Control measures as per SOP will be followed in future as well .
54.	Are fume hoods and exhausts regularly checked and maintained?	✓		Regular checks & AMC in place for fumehood & LAF .	The periodic half yearly checks will be done in future as well.
55.	Does the grantee use DG set > 15 KVA?	✓		Presently we have 250 KVA under warranty , and is regularly maintenance .	The maintenance will be done half yearly through AMC in future .
	Does the grantee have consent for DG > 15 KVA?	✓			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	✓			
56.	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	✓		Describe: Executed an exclusive agreement with GJ Multiclave for disposing solid & plastic waste. SOPs for waste disposal in place (	The Agreement shall be renewed annually .

57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		✓	Types of wastewater: Treatment of wastewater: Chemical management n wastewater reatment plants:	ETP plant construction process.
	Are there sludge management and cut off drains in place for wastewater?		✓	Sludge is not produced as part of the process & hence not applicable.	Sludge is not produced as part of the process & hence not applicable
58.	Are necessary provisions for noise cancellation in place?		✓	Describe: The process doesn't generate any noise and hence not applicable . Sound proof rooms for fermentation utilities)	The process doesn't generate any noise and hence not applicable . Sound proof rooms for fermentation utilities)
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	✓		Describe: Canal Distance from premises: 100 mts	Canal is a public space
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	✓		The facility is located in the Industrial Estate in line with the required norms.	The current routes will be maintained and no change in infrastructure will be made .

Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.

Annexure - I

Details of Effluent/solid wastes - Theragen Biologics Pvt ltd			
Department	**Types of waste**	**Waste non hazardous**	**Amount/month**
USP	Effluent	Fermentation broth: culture cells, medium, Ammonia, Isopropyl alcohol, Sybr green, antibiotics	120L of fermentation broth and wash effluent, hazardous: negligible.
	Solid wastes	Microplates, Pipette tips, plastic microcentrifuge tube, broken glasswares, single use syringes & filters, blotting papers, tissue papers, aluminium foil, Falcon tubes, nitrile gloves, Agar media plates, agarose gels	All degradable, Plastic wares; 2kg,
DSP	Effluent	Phosphate Buffers, PMSF, Acids, NaOH solution, Triton x100, SDS, Tween 20, cell lysate supernatant, Bradford reagent, B-mercaptoethanol, Isopropyl alcohol	Cell lysate : 120L, wash effluent: 30L hazardous chemicals: negligible
	Solid wastes	Cell debries, polyacralamide gel,Microplates, Pipette tips, plastic microcentrifuge tube, broken glasswares, single use syringes & filters, filter papers, blotting papers, tissue papers, aluminium foil, Falcon tubes, nitrile gloves	All degradable, Cell debries: 12kg, Gels: 500gm, plastic wares: 2kg
Bio-analytical	Effluent	VEGF, Accentrix,Acetonitrile, Methanol, TFA, TMB substrate, H2SO4, Tween 20, Endotoxin lysate and Endotoxin std, lal reagent,	Acetonitrile: 2L, other non-hazardous (TFA, acids): negligible
	Solid wastes	Microplates, Pipette tips, plastic microcentrifuge tube, broken glasswares, single use syringes & filters, filter papers, blotting papers, tissue papers, aluminium foil, Falcon tubes, nitrile gloves	All degradable, Plastic wares; 5kg
Cell Based Assay lab	Effluent	culture media,	cell media, cell debries, supernatant: 2L, hazardous: negligible
	Solid wastes	culture cells, sterile pipetts, falcons, T25, T75, eppendorf	All degradable, plastic wares: 500g
Monthly effluent generation = 274 Ltrs **Monthly solid waste generation = 22 Kgs**			