Environmental Health Risk Management Plan (EHRMP)

M/s **Tergene Biotech Private Limited**

Proposal entitled "**Development of an Affordable, Asia specific 15 valent Pneumococcal Polysaccharide - CRM197 Protein Conjugate Vaccine**"

1. Institutional Arrangements

(i) Brief description of the proposed activity:

The project is intended for manufacturing of Pneumococcal Conjugate Vaccine. Research and development laboratories are part of the facility. The Unit will be provided with necessary infrastructure, instrumentation, etc. Qualified and experienced scientists are available with supporting staff work for R&D. Analytical laboratory with instrumentation and wet laboratories are designed to support the research work.

Pneumococcal Conjugate Vaccine is a biological (bio-technology) product and made from variety of natural resources, viz., soya bean casein digest, yeast extract, D-glucose, vitamins, etc. The vaccine is then formulated with excipients and preservatives, before filling into final containers i.e. vials.

(ii) List of environments related regulatory clearances required for the activity.
a. CFO issued by the state PCB for the above-mentioned activity.
b. No GEAC approvals are required, as there is no genetically modified organism used in the activity.

Institutional Arrangement

		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	✓		The biotech park (MN Science Park) in which our facility is located has dedicated staff for EHS	Will ensure that a full-time staff for EHS issues is always in place throughout the Project. The Staff will strictly follow the Biosafety guidelines. Regular review meetings will be held quarterly.
2.	Does the EHS staff handle the following?			Mentioned equipments & systems are in place	These facilities will be reviewed in EHS review meetings held quarterly.
	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	✓		-	
3.	Is there a reporting structure in place regarding EHS issues?	✓		Reporting to Plant Head & Corporate EHS team	A proper reporting structure will always be ensured during the course of project.
4.	Are regular EHS trainings provided to staff?	✓		Frequency: Every 1 year	EHS training calendar with topics shall be put in place with regular scheduled trainings throughout the project.
5.	Institutional Bio-Safety Committee (IBSC)		✓	No Genetically Modified Organisms	

				(GMO) are involved in the process.	
6.	Ethics Committee (EC)		✓	No Animal models are used and Clinical Trial sites will have their own EC.	
General Occupational Health and Safety					
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	✓		EHS Manual and SOPs available	Will continue to enforce the EHS manual throughout the Project.
8.	Are the following in place?			Mentioned equipments & systems are in place	Safety provisions & records checked during internal audits held once in 6 months.
	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?	✓		-	Signage & storage checked during internal audits held once in 6 months
	Display of Material Safety Data Sheet (MSDS) where relevant	✓		MSDS available	
	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.)	✓		Signages available	
	Are flammable materials appropriately stored to prevent fire hazards?	✓		Stored in dedicated areas with labels	
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	✓		Hooters, Smoke Detectors & Heat Detectors	These would be regularly maintained with periodical checks.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	✓		Stack monitoring and Ambient Air Quality	This would be reviewed periodically.
12.	Are regular mock drills conducted for emergency preparedness and safety?	✓		Frequency: Once a year	Mock drills for emergency will be done as per schedule and EHS policy.
13.	Are staff provided with OHS training?	✓		Describe: Fire-fighting training, Biomedical Waste management, On site emergency management, First aid training	We will provide such training for all staff recruited in the project and include in the annual plan. -
Biomedical Waste (BMW)					
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	✓		List of biomedical waste produced in the facility	Will be updating this list regularly and will ensure

				1. Bio-process Effluents. 2. Environmental Media Plates. 3. Lab waste 4. Bacterial cultures used in QC and Production	disposal as per BWM Rules, 2016.
15.	Is there trained staff to handle biomedical waste in the grantee?	✓		Biomedical waste handling trained staff available	Staff will be trained on biomedical waste policies.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	✓		PCB has given Biomedical waste category in CFO itself.	Monitoring team will submit six monthly data and renewal will be done annually.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	✓		Yellow ✓ Red White Blue	The biomedical waste will be segregated at the point of generation and will be stored in suitable containers
18.	Is the bar code system for the segregated waste in place?	✓		We are following bar code system	Bar coding will be regularly updated as per policy guidelines.
19.	Is the biomedical waste being sent to an **authorized** common BMW facility?	✓		Name and address of CBMWF: M/s. Sattva Global Services Pvt Ltd, Plot No.36/B, Biotech Park, Phase III, Karakapatla(V), Mulugu (M), Siddipet Dt. Distance from facility: 15 Kms Frequency and Mode of transport: Based on the BMW generation frequency and normally within 48 hours it is cleared by road. Who transports:	The vendor's contract shall be renewed on time to ensure this practice is being followed throughout the Project.

				M/s. Sattva Global Services Pvt Ltd	
20.	Does the grantee have an in-house BMW treatment facility?		✓	Reason: Authorization Distance of nearest CBWM from facility Types of treatment:	Whatever BMW generated will be treated by the outsourced agency throughout the project.
	Is the treatment facility own (individual)?		✓		
	Is the treatment facility a shared facility in an industrial park?		✓		
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?	✓		Types of treatment: Decontamination by Autoclaves and Chemical Inactivation	Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	✓		SOP in place	Routine checks will be done.
23.	Are necessary waste pre-treatment equipment in place?	✓		List of equipment: Autoclaves Details of waste pre-treatment: Chemical Inactivation	The autoclave shall be periodically qualified as per the maintenance schedule.
	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?	✓		Non-chlorinated bags are used.	-
25.	Are grantee's personnel involved in handling BMW provided with regular training?	✓		Frequency: 1 Year Trainer: MN Park	Personnel involved in handling BMW will be provided with regular training
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: Once in a year	This practice will be checked periodically and its compliance shall be ensured.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	✓		Register for Biomedical waste generation is maintained including accident reporting record as per BMW 2016 guidelines.	This practice would be followed with constant review and updation.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	✓		PCB has given Biomedical waste category in CFO itself. No separate BMW authorization is issued.	Annual reports on BWM will be submitted to SPCB as per the requirement

				Biomedical waste details are submitted in Form IV as per CFO.	
Hazardous Waste (HW)					
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 1. No Hazardous waste generated 2. BMW 3. Process Effluents 4. Plasticwares & Labwares 5. General Waste	Record formats shall be created to capture hazardous waste generation, if they are generated in future.If No, provide a list ofall waste produced in the facility.
30.	Is there trained staff in the facility to identify and handle hazardous waste?		✓	-	As and when required will recruit and train a staff for the same.
31.	Does the grantee have authorization from SPCB for hazardous waste?		✓	-	Will plan and apply for proper approvals as and when required under this project.
32.	Is there a secure location for storage of HW with proper signage?		✓	Describe how each item is stored – Will be stored in a separate room with labels, distant from critical installations and proper ventilation.	As and when required appropriate labeling and demarcation of these items will be done to ensure proper precautions when handling these items as provided in Hazardous Waste Rules, 2016.
	Are hazardous waste stored for more than 90 days in the grantee's premises?		✓	-	-
33.	Is the hazardous being send to an **authorized** disposal facility or user?		✓	Name and address of facility:	Will ensure a proper facility is in place as and when the need arises.
	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?		✓	-	Will maintain the register with frequent reviews to be done by assigned staff as and when required in future throughout the Project.

E-Waste and Batteries					
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		✓	E-waste not generated till now. In future, whenever generated, it will be disposed as per the E-waste management rules	-
36.	Has the grantee obtained SPCB authorization on e-waste?		✓	-	Will obtain it as and when required as per the existing regulations and SPCB guidelines.
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:	-
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓	Describe:	-
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		✓	-	-
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?		✓	-	-
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		✓	-	-
42.	Does the grantee submit annual reports on e-waste to SPCB?		✓	The park is submitting reports to PCB	Will ensure that this activity is followed throughout the Project.
43.	Is there accident reporting and records in place?	✓		Accident reporting forms available	Reporting procedure as per SOP shall be followed in case of accidents
44.	Are PPEs available to staff?	✓		PPE kits available for staff.	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		✓	-	-
46.	Does the grantee generate battery waste?		✓	No Battery waste generated are till date. When they are generated,	Will ensure disposal through authorized re-sellers through buyback scheme as and when

				will disposed to authorized re-sellers through buyback scheme	required.
47.	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/ reconditioner/collection center?		✓	Name and address of battery waste receiving entity: Will be disposed to authorized recycler	Will ensure a proper facility is in place as and when the need arises.
Community Health and Safety and risk mitigation					
48.	Safety Transportation Management System (for transport Of hazardous material)	✓		TREM Cards are given to the hazardous waste transport vehicles	This process will be followed periodically with proper checks and balances.
49.	Emergency preparedness and participation of local authorities and potentially affected communities	✓		On site Emergency plan.	Propose to have mock drill with fire department.
Other					
50.	Is the lab/room air regularly checked for microbial contamination?	✓		Cleanrooms & bio safety hoods are checked for environmental monitoring on daily / weekly basis depending on the area classification.	Test for microbial contamination shall continue to be carried out on periodic basis as per SOP
51.	Are there any odor control measures in place?	✓		Local exhaust systems, fumehoods & PPEs available	Periodic checks will be done and the fumehoods shall be maintained.
52.	Are fume hoods and exhausts regularly checked and maintained?	✓		Fumehoods & exhaust are checked regularly for performance & maintained by the Engineering team	Periodic check shall be carried out as per maintenance SOP
53.	Does the grantee use DG set > 15 KVA?		✓	The Park has a common DG which is operated and maintained by the park	The Common DG set will be maintained by park.
	Does the grantee have consent for DG > 15 KVA?		✓		-

	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		✓		-
54.	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?	✓		Municipal solid and plastic wastes are sent to authorized third party M/s. Hyderabad Integrated Municipal Solid Waste Management Project (HIMSW) through the Park	Proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016 will be followed.
55.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		✓	Types of wastewater: Wastewater (Process effluents) is not treated separately by the grantee. The wastewater is collected and sent to CETP through the Park. Treatment of wastewater: -NA- Chemical management in wastewater treatment plants: -NA-	-
	Are there sludge management and cut off drains in place for wastewater?		✓	-	-
56.	Are necessary provisions for noise cancellation in place?		✓	Describe: There is no noise pollution generated by our activity	Will ensure that this risk does not arise adapting proper existing measures and creating more such measures if required in future.
57.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		✓		-
58.	Are there any buffers, fire vehicle routes in the grantee's premises?	✓		Fire tender movement access available.	Will ensure proper maintenance of these as per requirements in the project.