Environmental Health Risk Management Plan (EHRMP)

M/s Gennova Biopharmaceuticals Limited

Proposal entitled: **"Therapeutic antibodies for COVID-19"**

1. Institutional Arrangements

(i) Brief description of the proposed activity

- Process development and scale up for the production of neutralizing antibodies from stable cell-lines
- Production of neutralizing antibodies in cGMP for clinical studies
- Characterization of cGMP product
- Stability of neutralizing antibodies in cGMP
- Preclinical studies in relevant animal model
- Efficacy testing in the challenge model
- Site selection and recruitment of healthy volunteers for Phase I
- Site selection and establishment criteria for patients for Phase II studies
- Phase I dose escalation and safety
- Phase II safety and treatment outcome in terms of reduction in viremia, reduction in hospitalization time and recovery

(ii) List of environments related regulatory clearances required for the activity.

Authorizations from SPCB is available

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?	Yes		Full-time EHS Staff in place – meeting 3 - 5 times a year	Regular review meetings will be held quarterly.
2.	Does the EHS staff handle the following?	Yes		Team of at least 3 Persons with their roles defined o EHS Manager (Controlling overall EHS function, evaluating clients proposals) o EHS	Expansion of the exiting EHS team for the project as required will be done.
	Occupational Health and Safety	Yes			
	Waste Management	Yes			
	List of consents and regulatory clearances	Yes			
	Record keeping of accidents and procedures	Yes			
	EHS trainings for staff	Yes			

				Executive (Environment specialist)	
	Environment Management Framework compliance for Innovate in India Project		No		Environment Management Framework compliance for Innovate in India Project
3.	Is there a reporting structure in place regarding EHS issues?	Yes		EHS Officers (Day-to-day Monitoring of EHS activities)	A proper reporting structure will always be ensured during the course of project.
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: Twice in a year	EHS training calendar with topics shall be put in place and provided yearly.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		Meetings are scheduled as per the requirements.	IBSC meetings are held as per the requirements.
6.	Ethics Committee (EC)	Yes		EC is in place to handle our COVID-19 vaccine project.	Meetings are held as per the requirements.
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.)?	Yes		SOP for handling & usage of laboratory chemicals.	Implementation of SOPs checked during internal audits held once in 6 months
8.	Are the following in place?			Chemical spill kit available. Eye wash provided in labs & media prep area. Various types of fire extinguishers in place with tags. Accident register in place	Safety provisions & records checked during internal audits held once in 6 months.
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			

9.	Are proper signage and storage system in place?	Yes		MSDS made available in Stores & in lab, segregated storage for acids & solvents provided with fire alarm, safety signages put up across facility along with emergency exit plan.	
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		List: every lab has these detectors List available	
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		List: every lab has these detectors	micro
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Twice in a year	
13.	Are staff provided with OHS training?	Yes		Tainting record available	
	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?	Yes		Biomedical waste –Rat blood sample in EDTA tube 0.5ml (Ethyl diamine tetra acetic acid tube) (Waste send to the Govt. approved facility Life secure enterprises for disposal purpose)	Records shall continue to be maintained for biomedical waste storage and disposal through authorized facility. Procedures shall also be reviewed in EHS meetings.
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Trained staff available	Proper training will be provided to the

					newly appointed staff to pursue this activity.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		MPCB consent available	Proper and timely renewal will be done.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow: Yes Red: White: Blue:	Separately labelled bins shall continue to be placed at source for segregation of biomedical waste & bar-coded yellow bags in sealed drums shall continue to be used for storage before disposal
18.	Is the bar code system for the segregated waste in place?	Yes		Colour code containers and polybag available	Bar-coded yellow bags shall continue to be used for storage before disposal to authorized agency
19.	Is the biomedical waste being sent to an **authorized** common BMW facility?	Yes		Name and address of CBMWF: Life secure Enterprises, Talegaon Dabhade, Pune -410507 Distance from facility:10 Km Frequency and Mode of transport: weekly / fortnightly Who transports? Life secure Enterprises authorized vehicles	The vendor's contract shall be renewed on time to ensure this practice is being followed throughout the Project.

20.	Does the grantee have an in-house BMW treatment facility?		No	Reason: we have send BMW to Govt. Approved facility Authorization: Life secure Enterprises Distance of nearest CBWM from facility: 10 Km Types of treatment: Incineration	Biomedical waste will be sent to authorized facility Life secure Enterprises.
	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?	Yes		Types of treatment:	Micro
22.	Is the liquid waste checked for active cells before sending to treatment plant?				
23.	Are necessary waste pre-treatment equipment in place?	Yes		Autoclaves, shredders, incinerators, etc.): Details of waste pre-treatment:	The decontamination autoclave shall be periodically qualified as per the maintenance schedule maintained and monitored by th Micro Department.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?				
24.	Are non-chlorinated plastic gloves and bags phased out in the grantee?	Yes		We are not using any type of chlorinated gloves and bags	Awareness on avoiding use of chlorinated gloves & bags shall be made in the EHS trainings
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Every three months Trainer: Prashant Rane	Proper training will be provided to the newly appointed staff to pursue this activity.

26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		Frequency of medical examination: Twice in year	
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Available	
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes			
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?	Yes		1.Spent organic solvent 2.Discarded drugs 3. Used oil	Procedures will be followed as per the guidelines.
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes		MPCB consent available	Authorizations will be Renewed from time to time
32.	Is there a secure location for storage of HW with proper signage?	Yes		1. Spent organic solvent Discarded drugs and Used oil we are stored separately in storage room. 2. We are sending hazardous waste before 90 days to Govt. approved facility	
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		

33.	Is the hazardous being send to an **authorized** disposal facility or user?	Yes		Name and address of facility: MEPL, Ranjangaon Pune-412220	
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?	Yes			
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?	Yes		Manifest available	
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?		No	No substantial electrical waste is generated in the lab	
36.	Has the grantee obtained SPCB authorization on e-waste?		No	No substantial electrical waste is generated in the lab	Necessary Authorizations will be taken if required.
37.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		No	No substantial electrical waste is generated in the lab	
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	No substantial electrical waste is generated in the lab	
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	No substantial electrical waste is generated in the lab	
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?		No	No substantial electrical waste is generated in the lab	
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	No substantial electrical waste is	

				generated in the lab	
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	No substantial electrical waste is generated in the lab	
43.	Is there accident reporting and records in place?	Yes		Available	
44.	Are PPEs available to staff?	Yes		Available	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?		No		
46.	Does the grantee generate battery waste?	Yes			
47.	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioner /collection center?	Yes		Nirnay electronics Pune	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No		
Community Health and Safety and risk mitigation					
		Yes	**No**	**Details**	**Proposed Plan**
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		We are sending hazardous waste materials in Govt. approved vehicle	
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		We are having Onsite emergency plan	
Other					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	we don't use radioactive material	

	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	we don't use radioactive material	
	Are radioactive warning signs in place?		No	we don't use radioactive material	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes			Periodic checks will be done
53	Are there any odor control measures in place?	Yes		AHU available	
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes			Periodic checks will be done
55.	Does the grantee use DG set > 15 KVA?		No	We are on lease (Scope in Emcure)	DG sets emissions will be regularly monitored as per CPCB norms if procured
	Does the grantee have consent for DG > 15 KVA?		No		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		
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?	Yes		We are sending solid and plastic waste to Govt.approved vendor	It will be ensured that segregation rules are followed
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		We have separate ZLD plant (zero liquid discharge) We are on lease (Scope in Emcure)	
	Are there sludge management and cut off drains in place for wastewater?	Yes			
58.	Are necessary provisions for noise cancellation in place?	Yes		Ear plug and ear muff are available in noise area	Preventive measures will be taken for reducing noise levels if generated
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No		

60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire vehicle routes are available	
COVID Precautions & Guidelines Implementation					
61.	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		We do not generate neither use any COVID sample. However we use GoI of a gene of SARS-CoV-2 and its disposable is detailed in previous sections.	
62.	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes			

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.