

Environmental Health Risk Management Plan (EHRMP)

Cadila Healthcare Limited

Proposal entitled: “Development of a DNA Vaccine against novel Coronavirus (SARS-CoV-2)”

(i) Brief description of the proposed activity

The aim of the proposal activity is to seek funds to support the development of ZyCoV-D Vaccine and to conduct the phase I/II clinical trial in healthy individuals.

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

- Gujarat Pollution Control Board (GPCB) clearance
- Petroleum and Explosives Safety Organization (PESO) license
- Factory License
- Biomedical waste (BMW) authorization
- Boiler certificate

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		Goonjan Tanna Manager Pratik Chaudhari Associate Manager Neel Pandya Executive	Will ensure EHS aspects at site. Will ensure implementation of all EHS procedures.
2.	Does the EHS staff handle the following?			Any other:	We have SOPs/Guidelines for OHS, waste management. We have all valid licenses – CTO, PESO, Fire NOC etc. - We have a system for accident management and its records. - Will impart need based training to all the staff whenever required.
	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			
	Environment Management Framework compliance for Innovate in India Project		No		
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Describe: EHS personnel reports to Plant	- EHS department reports to Plant Head and also reports to CEHS

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				Head.	head.
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: Monthly	Yes we provide need based training.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		IBSC committee has been functional since 2002.	Regular meetings to ensure complete regulatory compliance.
6.	Ethics Committee (EC)	Yes		We have Ethics Committees in place for both animal and human study as per NDCT Rules 2019.	Regular meetings to ensure complete regulatory compliance.

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		All SOPs/Guidelines are as per ISO-45001 standards	Yes we have all SOPs/Guidelines and are as per ISO-45001 standards. SOPs and protocols will be maintained for any new activity included in the work
8.	Are the following in place?	Yes			- Sufficient quantity of spill kits, eye wash bottles, shower, first aid kit, fire extinguisher in place. - We maintain the register for accident and injuries Yes we have all SOPs/Guidelines are as per ISO-45001 standards
	Chemical spill kits	Yes		All	
	Eye wash	Yes		SOPs/Guidelines	
	Shower stations	Yes		are as per ISO-	
	First Aid Kit	Yes		45001 standards	
	Fire Extinguishers	Yes		All	
	Register of accidents and injuries			SOPs/Guidelines are as per ISO-45001 standards All SOPs/Guidelines are as per ISO-45001 standards	

9.	Are proper signage and storage system in place?	Yes		- Signages are placed wherever required.	We displayed emergency numbers and proper signage as and where required for the Project. Dedicated storage area for
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes		- Storage system are according to the storage condition	
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes		- MSDS are	

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	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes		available and easily accessible.	explosive chemicals will be maintained properly.
	Are flammable materials appropriately stored to prevent fire hazards?	Yes		- Emergency contact details are displayed and available - Storage system are according to the storage condition and all flammable material are stored as per requirement.	
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	Yes		List: Fire Hydrant system in place Fire Alarm System In place	- We have SOP for Operation and Maintenance of Fire Extinguishers - Preventive maintenance is also timely done for all the critical Equipments/machineries.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	NA		List:	- Environment monitoring is conducted on periodic basis to ensure environmental compliance.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Mock Drill - Six monthly	- We conduct mock drills on half yearly basis.
13.	Are staff provided with OHS training?	Yes		Describe: Training given on monthly basis	- We have planner and will impart the training accordingly.
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		If Yes, provide a list of biomedical waste produced in the facility - Animal Carcass - Media waste - Egg waste - Waste from QC	- We discard our biomedical waste to common biomedical waste treatment facility. This will be followed throughout the Project.

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				(microbiology) - Soiled Waste - Waste Sharps If No, provide a list of all waste produced in the facility.		
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes			We have a training planner and will impart the training accordingly	
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes			We have valid authorization for Biomedical waste which will be renewed with proper approvals within timelines.	
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow	Yes	We have SOP for segregation of biomedical waste. The SOP is reviewed regularly.
				Red	Yes	
				White	Yes	
				Blue	Yes	
18.	Is the bar code system for the segregated waste in place?	Yes			- Common biomedical waste treatment facilitator has started the bar code..	
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		Name and address of CBMWF:E-coli waste management Pvt Ltd Distance from facility: 1.5 KM Frequency and Mode of transport: Alternate Days Who transports?- CBMWF	Yes, we discard/dispose our waste to common biomedical waste treatment facility.	

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20.	Does the grantee have an in-house BMW treatment facility?		No	Reason:	- We treat our biomedical waste by autoclaving it and continue to do so. - We discard/dispose our biomedical waste to common biomedical waste treatment facility
	Is the treatment facility own (individual)?		No	Authorization:	
	Is the treatment facility a shared facility in an industrial park?		No	Distance of nearest CBWM from facility: Types of treatment:	
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: Autoclaving done	- We treat our biomedical waste by autoclaving it and will continue to do so. - We discard/dispose our biomedical waste to common biomedical waste treatment facility. - Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Sodium hypochlorite treatment followed by Autoclaving before releasing it for Disposal	- We take proper steps whenever such kind of waste is generated.
23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.):	- We treat our biomedical waste by autoclaving it and will continue to do so. - We discard/dispose our biomedical waste to common biomedical waste treatment facility
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment:	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes			Yes, non-chlorinated plastic gloves and bags are phased out. So, no environmental and health risk.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Monthly/Half Yearly Trainer:	- SOP are in place for handling biomedical waste which would be followed throughout the Project.

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			Department SOPs/EHS	
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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: As per the requirement	- Vaccination is provided to biomedical waste handler - The frequency of medical checkups will be increased and vaccination will be continued for all the personnel getting involved in BMW handling.
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Register in place	We have the entry of all the disposal made to common biomedical waste facility
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		Annual reports prepared	We will keep submitting the annual report to SPCB as per authorization and timeline.

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		<p>If Yes, provide a list of hazardous waste produced in the facility</p> <ul style="list-style-type: none"> - ETP Sludge - MEE Salt - Spent Oil - Spent Solvent - Spent Carbon - Waste and Residues - Discarded containers - Off specification products - Expired drugs/medicines <p>If No, provide a list of all waste produced in the facility.</p>	- We maintain the records of hazardous waste disposal and dispose the same as per our valid CTO and continue in the near future.

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30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			- Trained staff will be handling the hazardous waste.
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes			- Valid CTO mentioning the details of hazardous waste is and will always available
32.	Is there a secure location for storage of HW with proper signage?	Yes		Describe how each item is stored – platforms, distances from critical installations/movement areas, spill collectors, gas escape facility, etc. Separate storage area for waste	- We have separate storage area for hazardous waste and timely disposal of the same is done.
	Are hazardous waste stored for more than 90 days in the grantee’s premises?	Yes			
33.	Is the hazardous being send to an authorized disposal facility or user?	Yes		Name and address of facility: M/s. Saurashtra Enviro Project Private Limited	- We dispose the hazardous waste to PCB approved vendor only.
	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			- We will maintain records of hazardous waste and manifest system is strictly followed whenever the hazardous waste is disposed.

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?	Yes		Sent to E-waste recycler	- We will dispose the e-waste to registered recycler only
36.	Has the grantee obtained SPCB authorization on e-waste?	Yes			- We have taken membership from E-waste recycler/dismantler and will ensure its renewal within timelines.

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37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and address of disposal facility/ recycler: M/s Pruthvi E-waste Ahmedabad Inhouse or outsourced Facility:	- M/s Pruthvi E-waste Ahmedabad; we dispose and will be disposing our waste to PCB approved vendor.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Describe:	We maintain records of E-waste and timely submission of annual report is done.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No		We do not manufacture any electrical and electronic Equipments.
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		We do not manufacture any electrical and electronic Equipments.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes			We maintain the records of e-waste
42.	Does the grantee submit annual reports on e-waste to SPCB?	Yes			Annual report is and will be submitted timely.
43.	Is there accident reporting and records in place?	Yes		We have a system for accident reporting and its records.	The records for reporting will be updated and maintained.
44.	Are PPEs available to staff?	Yes		PPEs are provided as per the hazard identification.	The stock status of PPE will be regularly monitored and procurement is done in time to avoid any situation of stock out.
45.	Is the grantee involved in manufacture of batteries?		No		We do not manufacture batteries instead we buy batteries from dealers and discard in safe manner as per Pollution control boards norms.
46.	Does the grantee generate battery waste?	Yes		We discard the used/waste batteries to authorized recycler	We will continue to practice this throughout the Project.

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47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?	Yes		Name and address of battery waste receiving entity: M/s S K Metals, Rajkot Gravita India Ltd. Rajastan	We dispose/discard our battery waste to registered recycler
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No		We dispose/discard our battery waste to the registered recycler.

Community Health and Safety and risk mitigation

		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		We provide form 9 to the vendor while transporting of hazardous waste	Safely Transported by PCB authorized agency
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		We have onsite and emergency plan to ensure emergency situations are be handled safely.	On site emergency Plan maintained

Other

	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	We will not be using any radioactive material for this study	Plan will not be applicable as we won't be doing any radiolabeled study.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	We will not be using any radioactive material for this study	Plan will not be applicable as we won't be doing any radiolabeled study.
	Are radioactive warning signs in place?		No	We will not be using any radioactive material for	Plan will not be applicable as we won't be doing any

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				this study	radiolabeled study.
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		We have SOP for environment monitoring	Environment monitoring is be performed as per the frequency mentioned in the SOP
53	Are there any odor control measures in place?	Yes		We place odor controller wherever required	Regular cleaning and records are maintained.
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Preventive Maintenance is done for fume hoods	Preventive Maintenance is done as per frequency mentioned in the SOP
55.	Does the grantee use DG set > 15 KVA?	Yes		Monitoring done on monthly basis	Monitoring done on monthly basis through NABL approved Lab
	Does the grantee have consent for DG > 15 KVA?	Yes			
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Yes			
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		Describe: Sent to GPCB approved vendor	We have registration under Plastic waste management rules and solid waste is disposed to approved vendor
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Effluent from process Domestic waste from offices Treatment of wastewater: Effluent Treatment Plant Reverse Osmosis Plant and Multiple Effect Evaporator And Membrane Bioreactor Facility Chemical management in wastewater treatment plants: We are using Chemicals in waste water treatment as and when required	We have in-house effluent treatment plant in the premises to treat the waste water.
	Are there sludge management and cut off drains in place for wastewater?	Yes		All the drains are connected to ETP for treatment of waste water	Procedures will be continued to be followed for best sludge management practices.
58.	Are necessary provisions for noise cancellation in place?	Yes		Describe: Acoustic enclosures provided to DG sets	All DG sets are provided with acoustic enclosures and hearing protection is

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				provided to employee working in that area and other noise making area Also we carry out monthly monitoring for noise
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	Yes	We have storage of water for firefighting and also we have route in which fire vehicle can reach Will ensure cleared routes for fire safety including vehicle routes throughout the project.
COVID Precautions & Guidelines Implementation				
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes	Yes	We disposed all the waste as per government guidelines. We will keep following the guidelines issued by CPCB/SPCB/GoI for COVID waste generation.
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes	Yes	We follow the guidelines provided by government. We maintain social distancing, we provide sanitizers to all workers, PPE compliance is checked. Preventive measures to contain the spread of COVID-19 will be followed time to time in the future also.

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.