

Environmental Health Risk Management Plan (EHRMP)

Seagull BioSolutions Private Limited

Proposal entitled: Synthesis and demonstration of efficacy of a novel Active Virosome Vaccine for prevention of COVID-19 infections & its Preclinical characterization

(i) Brief description of the proposed activity

This facility will be used for development and synthesis of vaccines. The facility will be able to handle the products, which will require BSL-2 (biosafety level-2) organisms and related processes. The animal work will be carried at a dedicated vivarium owned by Syngene International. This vivarium is compliant with the guidelines pertaining to using animals for research work. All the animal studies will be reviewed & approved by Institutional Animal Ethics Committee (IAEC).

Please note that no active wild type SARS COV2 virus will be used in our facility as Seagull BioSolutions does not have BSL-3 facility. So only the attenuated measles virus harboring the COV2 spike protein will be used for these experiments, which of course are very safe to handle.

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

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		The Principal Investigator himself acts as the Officer i/c of EHS for Seagull BioSolutions.	Name: Vishwas Joshi
2.	Does the EHS staff handle the following?	Yes			1. All staff are trained before allowing them to start working in the lab by Venture Center. 2. If any employee has a Health Issue, s/he is advised to visit a Doctor & resume duties after securing a Fitness certificate.
	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	Yes			
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Describe: 1. Incidents – are recorded when they occur and appropriate action is taken.	Additionally, Seagull facilities are inspected by EDC(Venture Center) to ensure that appropriate safety precautions are followed. The PI – as part

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					of his duties as EHS incharge, ensures that all recommendations of EDC are implemented.
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: At the time of joining & as and when organized by EDC.	All employees are allowed to work in the laboratory only after they have been well trained by the EHS staff from EDC.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		As per DBT guidelines IBSC will be convened for approvals.	Existing procedures, process and regulatory compliance will be extended and followed as per statutory requirement and internally established processes.
6.	Ethics Committee (EC)		No	All the animal work will be performed by Syngene International. Their ethics committee will be used. No clinical studies are involved in this project.	We do not plan on setting up an Ethics Committee.

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 incidents are reported to the PI (EHS) who takes the necessary action(s)	SOP for accidents shall be implemented.
8.	Are the following in place?		No	All incidences are reported to the PI and his instructions followed.	Only non-hazardous chemicals & bacteria/living cells are used in our facility.
	Chemical spill kits		No		
	Eye wash	Yes			
	Shower stations		No		
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			

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9.	Are proper signage and storage system in place?	Yes			For emergencies, the centrally available numbers with EDC are used.
	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		Seagull Biosolutions	
	Are flammable materials appropriately stored to prevent fire hazards?	Yes		does not store flammable substances at levels greater than 1 bottle (500 mL)	The work involved in our laboratories does not require any flammable substances and hence no risk to anyone. So specific policies are not established.
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?		No		As the lab facility is a single room facility, no fitment of alarms is planned.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	List:	VOCs are not used. So no measure planned. Will incorporate appropriate measures as and when required during the Project.
12.	Are regular mock drills conducted for emergency preparedness and safety?		No	Frequency (type wise):	
13.	Are staff provided with EHS training?	Yes		Describe: Employees are instructed to study the EHS policy 2016 and follow the same.	Training will be imparted on material safety data sheets and on chemical handling to the concerned personnel..
Biomedical Waste (BMW)					
	Area of Risk	Yes	No	Details	Proposed Plan

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14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	No	<p>The following waste is produced:</p> <ol style="list-style-type: none"> Culture of laboratory (safe) strains of bacteria & animal cells Aqueous solutions comprising of non-hazardous chemicals Plastic ware used for culture & experimental purposes 	<p>Only non-hazardous biological material is handled in our laboratories. Additionally all material is autoclaved prior to discarding. Therefore, no additional policy has been defined.</p>								
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes	<p>All the staff is trained by EDC EHS representative before allowing them to work in the labs.</p>	<p>Training will be regularly provided to new staffs recruited to handle biomedical waste.</p>								
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	No	<p>To our knowledge, no polluting substance is generated as a waste in our laboratories.</p>	<p>In future, if any pollution is created due to the activities done by the Company, the Company will ensure proper and timely approvals and authorization from the Pollution Control Board, respectively.</p>								
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	No	<table border="1"> <tr> <td data-bbox="841 1381 948 1436">Yellow</td> <td data-bbox="948 1381 1110 1436"></td> </tr> <tr> <td data-bbox="841 1436 948 1486">Red</td> <td data-bbox="948 1436 1110 1486"></td> </tr> <tr> <td data-bbox="841 1486 948 1537">White</td> <td data-bbox="948 1486 1110 1537"></td> </tr> <tr> <td data-bbox="841 1537 948 1638">Blue</td> <td data-bbox="948 1537 1110 1638"></td> </tr> </table>	Yellow		Red		White		Blue		<p>Solid and Liquid waste is separated. Solid waste is discarded in a central place while liquid waste is autoclaved and let out in the normal drainage.</p>
Yellow												
Red												
White												
Blue												
18.	Is the bar code system for the segregated waste in place?	No	<p>Simple labels are used for labeling of wastes & marking the BioHazard signs</p>	<p>Lab & Waste generated is too small/little to make bar coding cost effective.</p>								

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19.	Is the biomedical waste being sent to an authorized common BMW facility?		No	Name and address of CBMWF: Distance from facility: Frequency and Mode of transport: Who transports?	No Biomedical waste is generated.
20.	Does the grantee have an in-house BMW treatment facility?		No	Reason:	No Biomedical waste is generated. Additionally non-BMW waste generated in our labs is at extremely small scale and treatable quantities of waste are not produced.
	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		All the waste is autoclaved before discarding in the drain.	If some liquids cannot be autoclaved, then they are mixed with 1% Hypochlorite and will be discarded.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		No		All waste is autoclaved irrespective of whether it contains any living cells or NOT.
23.	Are necessary waste pre-treatment equipment in place?	Yes		Dedicated autoclave facility has been provided for by the EDC. This is used.	
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes			
25.	Are grantee's personnel involved in handling BMW provided with regular training?		No		No biomedical waste is generated

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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?		No	Medical examination is only performed in case an employee presents with illness for >3 days.	Appropriate policy will be established in a month's time.
27.	Is a daily register for biomedical waste maintained including accident reporting record?		No	No	Biomedical waste is NOT generated. All the liquid waste is autoclaved/sterilized as a policy and then let out in normal drain. Will ensure proper records are maintained as and when the need arises during the Project.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	No-Biomedical waste is generated. So this submission is not performed.	-Will ensure proper approvals and submissions as and when required adhering to the norms and regulations.

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?		No	<p>If Yes, provide a list of hazardous waste produced in the facility</p> <p>If No, provide a list of all waste produced in the facility.</p> <ol style="list-style-type: none"> 1. Spent culture media 2. Plastic ware used for experiments 3. Small amount (< 500 mL) of alcoholic waste comprising of ~ 30% alcohol or 	<p>We will update the list of waste periodically.</p> <p>The collection, treatment and disposal of these hazardous waste generated will comply with the Hazardous Waste Rules 2016.</p>

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30	Is there trained staff in the facility to identify and handle hazardous waste?		No	Hazardous waste is not generated.	
31	Does the grantee have authorization from SPCB for hazardous waste?		No	Hazardous waste is not generated.	
32	Is there a secure location for storage of HW with proper signage?		No	Describe how each item is stored – platforms, distances from critical installations/movement areas, spill collectors, gas escape facility, etc. Our lab facility is well ventilated & has exhaust fan	Since no HW is generated, a specific area is not required/defined. Not more than 500 ml of Alcohol is stored in the lab at a time. This is stored in open shelf
	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?		No	Name and address of facility:	As no hazardous waste is generated this is not required
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?		No		
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?		No	No HW is generated. All liquid waste is autoclaved/sterilized.	Not required
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 plan is needed
36	Has the grantee obtained SPCB authorization on e-waste?		No		Necessary Authorization will be taken if required

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37	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	No	Name and address of disposal facility/recycler: Inhouse or outsourced Facility:	Would ensure proper channelization for disposal of e-waste is done as and when the need arises during the Project.
38	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?	No	Describe:	Grantee does not manufacture any product
39	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	No		Grantee does not manufacture any product
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		Grantee does not manufacture any product
41	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	No		Grantee does not generate e-Waste
42	Does the grantee submit annual reports on e-waste to SPCB?	No		
43	Is there accident reporting and records in place?	No	So far, there have been no accidents to report.	Will ensure a register is being maintained for the duration of the Project.
44	Are PPEs available to staff?	Yes		Will ensure proper provisions of these as and when required during the Project.
45	Is the grantee involved in manufacture of batteries?	No		Grantee does not manufacture batteries
46	Does the grantee generate battery waste?	No		Grantee does not manufacture batteries
47	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner /collection center?	No	Name and address of battery waste receiving entity:	Not applicable as Grantee does not manufacture batteries

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48	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	No		Not applicable as Grantee does not manufacture batteries
Community Health and Safety and risk mitigation				
		Yes	No	Details
				Proposed Plan
49	Safety Transportation Management System (for transport Of hazardous material)	No		Grantee does not have to transport any material.
50	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		Emergency preparedness Committee in place.
				The EDC provides all needed support. Regular training will be given to the members of the Committee.
Other				
	Area of Risk	Yes	No	Details
				Proposed Plan
51	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?	No		We do not have any plan to use radioactive material in the near future
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?	No		We do not have any plan to use radioactive material in the near future
	Are radioactive warning signs in place?	No		We do not have any plan to use radioactive material in the near future hence not required to put signage
52	Is the lab/room air regularly checked for microbial contamination?	Yes		Laboratory is routinely de-contaminated every 6 months.
				No specific records are kept. This practice can be started if specified at the time of inspection.
53	Are there any odor control measures in place?	No		Grantee does not use any odor generating material
54	Are fume hoods and exhausts regularly checked and maintained?	Yes		This is performed by the House keeping department of EDC on routine basis.
				No separate inspection(s) are performed by Grantee
55	Does the grantee use DG set > 15 KVA?			EDC has installed a DG set and its
	Does the grantee have consent for DG > 15 KVA?			Performed as per the policies of EDC by EDC.

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	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	yes		maintenance and all related compliances are performed by EDC	
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 All wastes are segregated as per Solid waste, liquid and plastic and disposed as per the guideline(s) from EDC.	Register with any and all the updates will be done in the register maintained by the Management.
57	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		No		
	Are there sludge management and cut off drains in place for wastewater?		No	All waste is rendered non-hazardous by sterilization.	Quantities are extremely small. These will be periodically checked and maintained to ensure their proper functioning.
58	Are necessary provisions for noise cancellation in place?		No	Describe: Not Applicable-The ambient noise level is not exceeded in the limit of 75dB	
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?		No		These facilities if required, will be put in place and will be maintained regularly.
COVID Precautions & Guidelines Implementation					
61	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	Yes		COVID (hazardous) waste is not generated in our laboratories.	No specific policy is used other than general disposal policy.
62	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Yes		1. Only authorized personnel is allowed to enter the facility	The use of lab coats, face shields/masks will be used regularly and ensure prevention from any kind of

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			<p>2. All personnel who may be suffering from COVID-19 like symptoms are immediately required to consult a doctor & test themselves for COVID</p> <p>3. All must use lab coats, face shields/masks while in the laboratory.</p>	COVID related work and from its exposure.
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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.