

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

Proposal entitled: Development of Human Monoclonal antibodies to SARS-CoV2 from convalescent patient blood

- (i) Brief description of the proposed activity.

Aim

Development of human monoclonal antibodies to SARS-CoV2 proteins and selection of virus neutralizing antibodies.

Rationale

Monoclonal antibodies as immunotherapeutics have been found effective in the clinical treatment of infectious diseases. Many mAbs against viruses are developed in recent years and some are in clinical pipeline. Neutralization of virus mediated by antibodies is an attractive approach for virus treatment. Hence this proposal aims at development of human monoclonal antibodies with virus neutralizing potential using B cells from COVID-19 convalescent patient blood.

Methodology

In the proposed activity, development of human monoclonal antibodies to SARS-CoV-2 is being carried out through the following steps:

Step 1: Isolation of B cells from convalescent patient blood

Step 2: EBV transformation of B cells

Step 3: Screening of clones secreting SARS-CoV2 specific antibodies

Step 4: Testing of antibodies in virus neutralization assays and selection of neutralizing clones with high avidity

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

(a) Approval from Institutional Biosafety committee (IBSC)

(b) MoU with hospital for collection and transfer of blood from convalescent donors

(c) Approval by Ethics committee of hospital

(d) Agreement with authorized agency for disposal of biomedical wastes

(e) Authorisation awaited, under Bio medical Waste Management Rules, 2016

Institutional Arrangement

Area of Risk		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS)	Yes		Bioklone's Senior Project Manager closely	Will ensure EHS aspects at site.

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

	issues?			monitors the EHS issues.	Will ensure implementation of all EHS procedures.
2.	Does the EHS staff handle the following?			EHS Systems are in place	
	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		Environment Management Framework compliance for Innovate in India Project is being followed	
3.	Is there a reporting structure in place regarding EHS issues?	Yes		EHS staff has regular discussions with Bioklone management regarding EHS issues	
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: Once in three months	Training programs will be conducted as per plan
5.	Institutional Bio-Safety Committee (IBSC)	Yes			Regular meetings being conducted to ensure complete regulatory compliance.
6.	Ethics Committee (EC)		No	Bioklone does not have ethics committee.	For the purpose of collection of blood from convalescent donors, Bioklone has obtained approval of human ethics committee of Chettinad Hospital, Chennai. Blood from donors is collected at blood bank of Chettinad hospital, Chennai after obtaining informed consent from the donors and confirming the suitability of blood donation by the donors.

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

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		<p>Detailed SOPs are maintained for accidents, hazards, and other emergencies.</p> <p>All employees at Bioklone have been given detailed information regarding the same.</p> <p>Periodic discussions are had with the employees to ensure that they are aware of the SOPs.</p>	SOPs and protocols will be developed for any new activity included in the work
8.	Are the following in place?			All the safety aids mentioned are available at various locations	(i) Sufficient quantity of spill kits, eye wash bottles, shower, first aid kit, fire extinguisher in place. (ii) We maintain the register for accident and injuries
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

9.	Are proper signage and storage system in place?	Yes	(i) The proper storage system are available in warehouse according to category of material (ii) MSDS are displayed in storage area. (iii) Emergency contact no is displayed (iv) All the emergency contact numbers like doctor, ambulance, fire and police are being displayed in each department. (v) The safety sign ages are marked at dedicated locations (vi) Flammable materials are appropriately stored in dedicated yard to prevent the fire hazards.	
	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	Smoke detectors, fire alarms are placed at dedicated location as per requirement.	Preventive maintenance is also timely done for all the safety equipments
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	Bioklone does not deal with VOC, air emissions, high operating temperatures,

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

					pathogens/vectors.	
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Once in six months		
13.	Are staff provided with OHS training?	Yes		Describe: All aspects of OHS are discussed with the employees during OHS training which is done once in 3 months.	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		Empty blood bags post recovery of blood into tubes, Tubes with blood pellet, post B cell isolation	We discard our biomedical waste to common biomedical waste treatment facility. This will be followed throughout the Project.	
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Trained staff is available at Bioklone to handle biomedical wastes. He is provided with refresher training once in four months.	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?		No	Authorisation awaited, under Bio medical Waste Management Rules, 2016		
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				

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes	Name and address of CBMWF: GJ Multiclave Distance from facility: 20 Kms Frequency and Mode of transport: Alternate days/ Van Who transports: Agency team	
20.	Does the grantee have an in-house BMW treatment facility?	No	Reason:	We discard/dispose our biomedical waste to common biomedical waste treatment facility
	Is the treatment facility own (individual)?	No	Bioklone disposes its biomedical wastes through an authorized agency and hence Bioklone does not have an in-house BMW treatment facility.	
	Is the treatment facility a shared facility in an industrial park?	No		
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: Steam sterilization	Will follow the system as per the BMW rules 2016
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes	Liquid waste is checked for active cells once in a month, before sending to treatment plant.	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.): Autoclave, Needle dispenser	(i) We treat our biomedical waste by autoclaving it and will continue to do so. (ii) 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: Blood bags, tubes,	

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

				cells and spent media are sterilized in autoclave.	
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?	Yes		Frequency: Once in three months Trainer: A Senior Project Manager with adequate knowledge on handling of BMW	SOPs are in place for handling biomedical waste which would be followed throughout the Project.
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: Once in six months	
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes			
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	Authorisation awaited, under Bio medical Waste Management Rules, 2016	

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	No hazardous waste is being generated at Bioklone	
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	No hazardous waste is being generated at Bioklone	
31.	Does the grantee have authorization from SPCB for hazardous waste?		No	No hazardous waste is being generated at Bioklone	Authorization will be taken if required
32.	Is there a secure location for storage of HW with proper signage?		No		

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

	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		
	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 hazardous waste is being generated at Bioklone	

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	Bioklone does not manufacture electrical or electronic equipment.	A small number of irreparable computer monitors, keyboard, mouse, printer, laptop, small batteries, electronic spares and other lab equipment have been kept aside, at Bioklone. It is proposed to dispose them through an authorized e-waste dealer in early 2021.
36.	Has the grantee obtained SPCB authorization on e- waste?		No		
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		No		Small number of e-wastes have been accumulated at Bioklone till date. It is proposed to dispose these wastes through an authorized e-waste dealer in early 2021.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No		
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No		

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

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		
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes			Since the quantity of e-waste generated at Bioklone is very less, there was no disposal till date. The e-wastes collected so far would be disposed in 2021. Record of e-waste given to authorised recycler or to vendors /OEM would be maintained.
42.	Does the grantee submit annual reports on e-waste to SPCB?		No		
43.	Is there accident reporting and records in place?	Yes			
44.	Are PPEs available to staff?	Yes		Aprons, gloves, head caps, face masks, shoe covers are available.	
45.	Is the grantee involved in manufacture of batteries?		No		
46.	Does the grantee generate battery waste?	Yes			Bioklone generates battery wastes like UPS (used for PC), once in 3-4 years. In addition, small number of batteries (used for AC remotes and wall clocks) are also generated.
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: Yet to finalise the registered dealer	Since the quantity of battery wastes generated so far at Bioklone was very less, there was no disposal till date. The battery wastes would be deposited in 2021 to registered recycler/dealer.

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

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)		No		Will follow if required
50.	Emergency preparedness and participation of local authorities and potentially affected communities		No		Will follow if required

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	Bioklone does not use radioactive materials	Bioklone does not plan to use radioactive materials
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	Bioklone does not use radioactive materials	Bioklone does not plan to use radioactive materials
	Are radioactive warning signs in place?		No	Bioklone does not use radioactive materials	Bioklone does not plan to use radioactive materials
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		Routine agar plate exposure is done in the lab (once in 1-2 months), to check the level of microbial load in the air.	Routine agar plate exposure will be done once in 1-2 months, to check the level of microbial load in the air.
53	Are there any odor control measures in place?	Yes		Processes at Bioklone do not generate substances that cause accumulation of odor in the atmosphere.	Measures will be taken to ensure that there is no accumulation of odor in the atmosphere.
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Performance of fume hoods and exhausts are checked and maintained by service engineers, once in six months.	Performance of fume hoods and exhausts will be checked and maintained by service engineers, once in six months.
55.	Does the grantee use DG set > 15 KVA?		No	Centralised DG set provided by the Biotech Park.	DG stack emissions will be monitored as per CPCB rules
	Does the grantee have consent for DG > 15 KVA?		No	Details of DG are given below-	
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?			<ul style="list-style-type: none"> • DG – 1 No. – 82.5 KV – Kirloskar • DG – 1 No. – 125 KV - Kirloskar • DG – 1 No - 15 KV – Kirloskar • DG – 1 No. - 12 KV – USHA 	

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

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	Municipal solid waste is collected by local municipality Plastic waste is given to authorized recyclers.	Municipal solid waste will be collected by local municipality daily Plastic waste will be given to authorized recyclers, once in a month.
57.	Is waste water treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes	Types of waste water: <u>Process waste:</u> 0.1 klpd from Cell culture spent media <u>Domestic waste:</u> 0.4 klpd Treatment of waste water: Process waste: Sodium hypochlorite and Steam sterilization Chemical management in waste water treatment plants: Sodium hypochlorite	The Treatment will be done as per SEZ rules. Central SEZ facility. Common SEZ has a water treatment and waste water treatment plants.
	Are there sludge management and cut off drains in place for wastewater?	No		There is no sludge generated
58.	Are necessary provisions for noise cancellation in place?	Yes	No noise generating machinery or source including Air Handling Unit is used at Bioklone	All necessary measures will be taken up like acoustic enclosures and hearing protection will be provided to employee working in that area and other noise making area. Also monitoring for noise production will be done.

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

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 movement routes available.	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		(i) All operations pertaining to handling of covid convalescent blood are carried out in BSL2-B2 cabinet at Bioklone. (ii) Stringent SOPS, as per the guidelines of CPCB/SPCB/GoI are in place, for handling, treatment and disposal of COVID waste generated.	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		(i) Provisions have been made at the entrance for hand sanitizer and thermal screening. (ii) Only asymptomatic staff/visitors are allowed to enter. (iii) Employees maintain a minimum distance of 6 feet. (iv) All employees wear face masks. (v) All employees	Preventive measures to contain the spread of COVID-19 will be followed time to time in the future also.

Environmental Health Risk Management Plan (EHRMP)

Bioklone Biotech Private Limited

				<p>practice frequent hand washing with soap or use alcohol-based hand sanitizers.</p> <p>(vi) Respiratory etiquettes are strictly followed.</p> <p>(vii) Employees have been instructed to self-monitor their health and report any illness at the earliest to the Admin manager.</p> <p>(viii) Spitting is strictly prohibited.</p>	
--	--	--	--	--	--

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.