

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

Proposal entitled: Immunotherapy of COVID infected patients using therapeutic antibodies from Human or Equine sources

- (i) Brief description of the proposed activities:
- a. To collect Convalescent sera from individuals who have recovered from COVID-19 and purify immunoglobulin G, IgG at large scale
 - b. Conduct clinical trials in patients using these preparations in CoV patients
 - c. To clone, express and purify Covid antigens and Immunize horses with CoV antigens and purify high titers of equine hyper immunoglobulin against COVID-19 for the treatment of COVID infected patients.
2. List of environment related regulatory clearances required for the activity. Pollution Control Board approval, Consents and approvals for HW and BMW management obtained from State pollution control board

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?	✓		Environmental Safety team: Mr. A. Murali Krishna (Asst. Manager), J.Kranthy (Executive) 4 operator level personnel	In case of additional requirements in future we will recruit the personnel as per the requirements.
2.	Does the EHS staff handle the following?			CFO (Consent for Operations) obtained	VBPL plans to implement Environment Management Framework for Innovate in India project. For other parameters like Occupational Health and Safety, Waste management, EHS trainings, VBPL will increase the capacity if need arises in the future.
	Occupational Health and Safety	✓		EHS staff maintains documentation for procedures and accidents. Regulatory clearances as per Hazardous waste and Biomedical waste rules are obtained and available.	
	Waste Management	✓			
	List of consents and regulatory clearances	✓			
	Record keeping of accidents and procedures	✓			
	EHS trainings for staff	✓			

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

	Environment Management Framework compliance for Innovate in India Project		✓		
3.	Is there a reporting structure in place regarding EHS issues?	✓		For reporting EHS issues reporting structure is in place as per SOP No.: EHS-SOP-011	VBPL will implement the existing plan for monitoring the EHS issues.
4.	Are regular EHS trainings provided to staff?	✓		Frequency: Quarterly	Regular trainings are provided to all staff. As and when new employees join the organization EHS training is provided. VBPL will increase the team size of EHS if need arises in the future.
5.	Institutional Bio-Safety Committee (IBSC)	✓		IBSC is already constituted and regular meetings take place with Dr. Lakshmi Narsu as the Chairman.	IBSC meetings will be continued in the future at regular intervals
6.	Ethics Committee (EC)	✓		Ethics committee is constituted with Dr. Ashok Kumar Setty as the Chairman and is registered with CPCSEA	Ethics committee meetings will be continued in the future to monitor the ethics parameters involved in the project.
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.)?	✓		Standard Operating Procedures are prepared for accidents, Hazards and other emergencies In case of accidents, hazards and other emergencies we have SOPs in place for First	VBPL will keep following the standard operating procedures for accidents, Hazards and emergencies to be better prepared for prevention of such incidents. VBPL will upgrade its safety systems if the need arises in future

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

				Aid Procedure (SOP No.: SOP-CF-HS-002), Handling of spillage (Sop No. SOP-CF-HS-007), SOP for Fire extinguisher (SOP-CF-HS-010), Reporting accident/incident SOP No.(SOP-CF-HS-011)SOP for Safety Operations: SOP-CF-HS-008	(due to increased manpower, additional suites and facilities etc.).
8.	Are the following in place?			We have spill control kit, eye wash and body wash showers, First aid kits, Fire extinguishers and Register of accidents and injuries. Personal protective equipment is provided to personnel while working.	VBPL will augment the capacities as per the needs due to an increased employee strength, and Register of installation of additional facilities etc., Sufficient number of first aid kits, eye washers, chemical spill kits will always be maintained. Register of accidents and injuries will be maintained.
	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?	✓		Yes. We have signage and storage system across the facility, MSDS sheets, displayed emergency number in critical places	MSDS, emergency numbers and procedures, signages will aid in safe work environment and will be increased as per the facility requirements. For storage of flammable materials and solvents systems will be upgraded as and when the need arises.
	Display of Material Safety Data Sheet (MSDS) where relevant	✓			
	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical Places	✓		In case of emergencies Personnel emergency evacuation plan (SOP No. SOP-CF-HS-003) shall be followed.	
	Signage across the facility (labs, storage, hazardous areas, etc.)	✓		VBPL has signage across the factory	

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

				premises. Flammable material and Solvent storage is appropriate.	
	Are flammable materials appropriately stored to prevent fire hazards?	✓		Flammable materials are handled under fume hoods.	
10.	Are smoke detectors, fire alarms, automatic safety/shut-off systems, overflow preventors, etc. in place and regularly maintained?	✓		List: Manual Fire alarm call points are defined (SOP No. SOP-CF-HS-003), Fire Hydrant system is in place Safety relief valve and rupture disc to pressurized vessels are in place	Automatic Fire alarm system has been proposed for implementation across the factory premises. The current safety systems are maintained on regular basis.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	✓		List of available measures: Fume Hoods, Exhaust vent and Chimney Bio safety cabinets Air handling Units Inhouse disposal (Kill tank) Pathogens/vectors Handling of hazardous, flammable chemicals and solvents is done under fume hood. SOP No.:SOP-U2-MB-025 for Operation and cleaning of decontamination autoclave and Disposal of Bio waste SOP for Safety operations for Fume	The existing control measures for air emissions, high operating temperatures, pathogens/vectors etc., will be continuously monitored to maintain the safety parameters. VBPL has proposed a Plan for control measures for VOC

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

				hoods and other control measures is given in SOP No.: SOP-CF-HS-008	
12.	Are regular mock drills conducted for emergency preparedness and safety?	✓		Frequency (type wise): Once in six months for Fire safety, Laboratory Safety, Spills, Evacuation	We have a proposed plan to conduct mock drills more frequently at factory premises.
13.	Are staff provided with OHS training?	✓		In-house training is provided to each employee/staff of the company Occupational Health center is operational in factory premises	We plan to keep providing OHS training to all the other staff regularly and ensure that they are well trained to attend any kind of task in the present and near future thereby they can mitigate any kind of environmental and health risk.
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?	✓		Biomedical waste of Plasma and Blood Products is managed as per the Bio Medical waste management rules. Biomedical waste is treated as per SOP No.:SOP-CF-HS-013 Records are maintained and procedures are followed/outsourced as per the requirement regularly for	Biomedical waste management rules will be continuously followed and waste will be monitored regularly for an effective management.

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

				generation, treatment and storage of such waste.	
15.	Is there trained staff to handle biomedical waste in the grantee?	✓		We have trained all the staff responsible for transfer and handling biomedical waste	EHS team will continue to provide regular training to all stakeholders of the project to handle the biomedical waste generated. Newly recruited staff will also be trained upon joining
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	✓		We have obtained authorization from Telangana Pollution control board, Zonal Office, Hyderabad CFO Order No: 846-RR-II/TSPCB/ZOH/TS-iPASS/CFO/2020-85	VBPL will keep following the best in class methods for pollution control. We will make sure that the guidelines are followed and continuous monitoring takes place for the same.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	align="center">✓		Yellow	
				Red	✓
				White	
				Blue	
18.	Is the bar code system for the segregated waste in place?		✓	Currently manual system is followed	Plan is proposed to implement Barcode system

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

19.	Is the biomedical waste being sent to an authorized common BMW facility?	✓		<p>Name and address of CBMWF: Maridi Bio Industries Pvt.Ltd, Survey Number 63/1, Kagaz Maddur Village, Narsapur Mandal, medak District, Hyderabad</p> <p>Distance from facility: Around 18 km</p> <p>Frequency and Mode of transport: Biomedical Waste Van, Every three months</p> <p>Who transports: Transport facility is provided by the vendor</p>	Agreement available, In case of Additional requirements, Frequency of Bio-medical waste disposal will be increased to required level as per the project requirements
20.	Does the grantee have an in-house BMW treatment facility?	✓		Reason: Bulk BMW is outsourced to vendor mentioned above.	Currently the Biomedical waste is outsourced and we plan to continue the same.
	Is the treatment facility own (individual)?	✓		Chemical	
	Is the treatment facility a shared facility in an industrial park?	✓		<p>Disinfection measures are followed In-house SOP-U1-S6-063</p> <p>Distance of nearest CBWM from facility: ~18 Km</p> <p>Types of treatment: Incineration</p>	
21.	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending	✓		Types of treatment: Decontamination of lab waste, chemical waste, microbial	Pre-treatment of microbiological waste and chemical liquid waste will

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

	totreatment facilities according to guidelines prescribed in BWM, 2016 regulations?			waste using decontamination autoclave Sterilization and disinfection is conducted in respective facilities	be continued as per the current procedures before sending it to treatment facilities.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	✓		Liquid waste is checked and treated as per SOP-U1-S6-063 for liquid biowaste handling Procedures to inactivate/remove active cells are included in the manufacturing strategies for plasma-derived products.	Will continue to segregate treated and untreated material to prevent cross contamination. Removal and Inactivation of active cells will be monitored through in process and continuous monitoring of plasma and plasma derived products.
23.	Are necessary waste pre-treatment equipment in place?	✓		List of equipment: Decontamination autoclaves, Kill tank	Future plan of installing an incinerator for treatment of BMW in factory premises.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	✓		lab waste, chemical waste, microbial waste is pre-treated using decontamination autoclave	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		✓	Only Disposable rubber and nitrile gloves and Disposable bags (HDPE material) are used	We have phased out toxic chlorinated gloves and bags from our facility and doing so we safeguard health risk.
25.	Are grantee's personnel involved in handling BMW provided with regular training?	✓		Frequency: Every 3 months Trainer: Mr.A. Murali Krishna	Regular training will be given to all the personnel and all the stakeholders will be trained to handle BMW.

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

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: General health checkups are performed once in a year. Vaccination is provided to staff involved in handling BMW	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?	✓		VBPL has maintained a register (for BMW including accident reporting record as per RGT (SOP-CF-HS-013/RGT-01) for Transportation and Disposal of bio hazardous waste (Format No. SOP-CF-HS-013-F01-00)	VBPL will continue to maintain the BMW register including accident reporting records as per the standard operating procedures defined.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	✓		Submitted to Telangana State Pollution Control Board (FORM-IV)	The annual report submission will be continued to ensure effective handling of BMW as per the rules and for the prevention of adverse events.

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?	✓		At present only ETP sludge is generated as Hazardous waste	Minimal amount of HW is generated which is outsourced to government authorized vendor after pre-treatment in the facility.

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

30.	Is there trained staff in the facility to identify and handle hazardous waste?	✓		We have trained the staff in-house for transfer and handling hazardous waste as per SOP-CF-HS-001	All the stakeholders involved directly are trained to handle and identify HW. New personnel will also be trained before getting part of the project implementation team.
31.	Does the grantee have authorization from SPCB for hazardous waste?	✓		Yes, VBPL has obtained from Telangana State Pollution Control Board CFO Order No: 846-RR-II/TSPCB/ZOH/TS-iPASS/CFO/2020-85	Guidelines will be followed continuously and reports will be submitted to SPCB to maintain the authorization status.
32.	Is there a secure location for storage of HW with proper signage?	✓		Civil structure Platforms, Isolated rooms from critical installations/movement areas, spill control kits Hazardous Waste is sent to treatment facility once in three months	Existing Secure locations for storage of HW will be monitored and maintained properly. If need arises, the capacity and area will be increased as required. The frequency of sending hazardous waste will be increased as per the quantity generated during and after process.
	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?	✓		Outsourced to Authorized disposal facility:M/s HWM Project (TSDF), Dundigul (V), Rangareddy District	The disposal facility is government authorized and VBPL will continue to monitor the process and quality standards offered by the outsourcing authority.
	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	✓		Register is maintained for waste generation records (FORM 3) and	Register and manifest system will be continuously

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

	transport of hazardous waste from the grantee to treatment facility?			Online Manifest system in place	followed and maintained.
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?		✓	E-waste is not generated as the area of working and Industry is Bio-Pharmaceuticals	Project implementation does not create any adverse Electronic Waste
36.	Has the grantee obtained SPCB authorization on e-waste?		✓	Not obtained as not required	Project implementation does not create any adverse Electronic Waste
37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?		✓	Project implementation doesnot create any adverse Electronic Waste	Project implementation does not create any adverse Electronic Waste
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓	E-Waste is not generated	Project implementation does not create any adverse Electronic Waste
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		✓	Project implementation doesnot create any adverse Electronic Waste	No generation of E waste
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?		✓		E-Waste is not generated during project implementation
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		✓	No generation of E waste	No generation of E waste

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

42.	Does the grantee submit annual reports on e-waste to SPCB?		✓	Not required as the Project implementation does not create any adverse Electronic Waste	Project implementation does not create any adverse Electronic Waste
43.	Is there accident reporting and records in place?		✓	Not applicable since there is no E-Waste Generation	Not applicable
44.	Is the grantee involved in manufacture of batteries?		✓	VBPL does not manufacture batteries	Not applicable since project doesn't require the manufacture of batteries
45.	Does the grantee generate battery waste?		✓	Not applicable since batteries are not manufactured	Not applicable since there is no E-Waste Generation
46.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?		✓	Name and address of battery waste receiving entity:	Not applicable due to reasons cited in above rows

Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
47.	Safety Transportation Management System (for transport Of hazardous material)	✓		Available and followed as per MSDS	Govt. Authorized Transporter is only allowed to handle waste.
48.	Emergency preparedness and participation of local authorities and potentially affected communities	✓		On-site and Off-site emergency plans exist	In place On Site Emergency Plan covering all local authorities and essential contacts

Other					
	Area of Risk	Yes	No	Details	Proposed Plan

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

49.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		✓	No use of radioactive material and Project implementation does not create any radioactive waste	Radioactive substances are not used currently and will not be used in the coming months in our R&D. Therefore any risk to environment and health is NIL.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		✓	Describe: No generation of radioactive material	As the radioactive waste is not generated and we do not plan to manufacture any radioactive material/related substances in near future, waste storage systems are not currently available in factory premises
	Are radioactive warning signs in place?		✓	Project implementation does not create any radioactive waste	Project implementation does not create any radioactive waste
50.	Is the lab/room air regularly checked for microbial contamination?	✓		Periodical evaluations done by microbiology department	Continuous evaluation of Lab/room air will be performed in near future also.
51.	Are there any odor control measures in place?		✓	At present no generation of odoriferous substances	If the need arises due to odor generation, control measures will be implemented
52.	Are fume hoods and exhausts regularly checked and maintained?	✓		Yes. Periodical maintenance and regular checks performed	Regular checks and maintenance of fume hoods will be continued till the requirements persist.
53.	Does the grantee use DG set > 15 KVA?	✓		Permissions have	Consents for use of DG

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

	Does the grantee have consent for DG > 15 KVA?	✓		been obtained from TSPCB (500KVA and 1010 KVA capacities available)	sets are obtained from TSPCB and guidelines will be followed regularly at all levels. Emissions from Boilers and DG sets will be continuously monitored.
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	✓		Emissions from boilers and DG sets are regularly monitored and are within prescribed PCB 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?	✓		Proper waste disposal process is followed and waste is managed as per Waste Management SOP No. SOP-CF-HS-001	Proper waste disposal process will be followed and compliance monitoring will be continued as per the rules of Waste management.
55.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	✓		Effluent and Sewage is treated separately Treatment types: pretreatment of ETP and sent to PETL treatment of sewage at STP and used for Gardening	VBPL plans to continue to treat the waste separately as per the current procedures followed.
	Are there sludge management and cut off drains in place for wastewater?	✓		ETP sludge is treated as Hazardous waste and sent to authorized facility for disposal Sludge beds and cut off drains are in place at ETP	VBPL's defined ETP plant procedures will be continued to be followed for best sludge management practices
56.	Are necessary provisions for noise cancellation in place?	✓		Ear muffs and ear plugs are available.	Project stakeholders will be provided with Acoustic enclosures and Noise surveys will be done frequently

Environmental Health Risk Management Plan (EHRMP)

Virchow Biotech Private Limited

57.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	✓		VBPL is situated in Industrial Area	Due to positioning of factory premises in Industrial area, VBPLs premises is free from any settlement of eco sensitive land and water bodies. Due to environmental friendly policies of VBPL, care will be taken in future if such need arises.
58.	Are there any buffers, fire vehicle routes in the grantee's premises?	✓		Yes, Emergency evacuation systems available	In case of Fire and related incidents personnel in the premises will be evacuated as per the procedure mentioned in SOPs
COVID Precautions & Guidelines Implementation					
59.	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?	✓		SOP for Biomedical Waste was revised for handling of COVID waste during April 2020 and is already implemented as per SOP-U1-S6-063	We will keep following the guidelines issued by CPCB/SPCB/GoI for COVID waste generation and as per the SOP-U1-S6-063
60.	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	✓		Guidelines issued by ICMR/GoI are followed inside the factory premises to contain the spread of COVID-19	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.