

Environmental Health Risk Management Plan (EHRMP)

Indian Immunologicals Limited

Proposal entitled: "Development of Recombinant Human anti Rabies Monoclonals for Post exposure Prophylaxis of Rabies"

1. Institutional Arrangements

(i) Brief description of the proposed activity Process development and scale up activity for the production of monoclonal antibodies, formulation development and testing for post exposure prophylaxis of Rabies dog bites (ii) List of environment related regulatory clearances required for the activity. Authorization for generation, segregation, collection and storage of bio-medical waste from Telangana 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?	Yes		Dedicated staff is available for Safety and Environment, total 6 members company employees and 8 members contract manpower	The training to the staff will be given in every 12months. EHS will be managed by well-established department. Safety and training department already in place. All new staff will be trained as a part of the induction program
2. Does the EHS staff handle the following?			Any other: Plant is certified with Health and safety Management System (ISO 45001:2018) and Environmental Management System (ISO 14001:2015).	These activities of ESH will be regulated as per the Company's guidelines for Environment Health and Safety (EHS).
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		All legal and statutory requirements belongs to EHS are being complied as per defined frequency.	
3. Is there a reporting structure in place regarding EHS issues?	Yes		Describe: Meetings, Inspections and Audits. Reporting structure In Place	A proper reporting structure will always be ensured during the course of project.
4. Are regular EHS trainings provided to staff?	Yes		Frequency: conducted based on work place	Training calendars shall be prepared for employees. Training

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				hazards and training need assessment, i.e. Safety induction trainings, Tool Box Talks, On Job Safety trainings & Class room trainings for employees and contract manpower in every month	will be provided as and when required to all staff.
5.	Institutional Bio-Safety Committee (IBSC)	Yes		IBSC meeting will be conducted at least twice in a year. All projects involving recombinant work and pathogenic organisms will be reviewed and approved by IBSC	Regular review meetings will be conducted.
6.	Ethics Committee (EC)	Yes		All experiments involving animals will be reviewed by IAEC and CPCSEA as applicable All clinical trials will be reviewed and approved by respective institutions as applicable	Meetings and reviews will be scheduled and regularly carried as per the GoI guidelines.
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		a. SOP is available to report incident and accidents b. On Site Emergency Plan (OSEP) is available to handle any potential emergency situations. Emergency Response Team is available and they have undergone safety trainings on OSEP.	SOP will be made available to report incidents and accidents Onsite emergency plan will be put in place to handle any potential emergency situations. Trained response teams availability will be ensured
8.	Are the following in place?			Total fire extinguishers 205	Fire extinguishers, spill kits, showers, First aid
	Chemical spill kits	Yes			

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	Eye wash	Yes		available, Body	kits, eye wash stations will be ensured
	Shower stations	Yes		showers stations 8	
	First Aid Kit	Yes		No, Eye wash	
	Fire Extinguishers	Yes		bottles 18	
	Register of accidents and injuries	Yes		Locations, chemical spill kits are available at process blocks including R & D, engineering and warehouse.	
9.	Are proper signage and storage system in place?	Yes		Safety signage are placed, Storage System in Place and MSDS available	Safety signages and MSDS will be ensured at respective places.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes		Emergency Ph. numbers were displayed at 24 locations in the plant, Flammable liquids are storing based on their flash points in godowns and tank yards.	
	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: 90 Smoke detectors & 10 Heat detectors, 21 Duct detectors, 22 MCP units are available, Fire Hydrant system is also placed.	Presence of smoke detectors, fire alarms and automatic safety/shutoff systems will be ensured.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		List: Being done by third party on monthly basis	Control measures will be ensured
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Once in six months	This will be followed and done as per schedule.
13.	Are staff provided with OHS training?	Yes		Describe: All new employees will go through EHS training and refreshing courses are conducted at least once in a year. Project Specific trainings are imparted as applicable	Ensure to provide required OHS training to all the employees involved in the project
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?	Yes		<p>If Yes, provide a list of biomedical waste produced in the facility Used needles, syringes, Sharps & Animal Carcass post neutralization studies</p> <p>If No, provide a list of all waste produced in the facility.</p>	We have an agreement with third party Medicare for disposal of Biomedical waste and will ensure to have the agreement during the course of the project
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		All personnel working on the projects are trained for handling biological waste as applicable	Will ensure that this trained staff will be available throughout the Project.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		We have obtained authorization from Telangana State pollution control board	Renewal of Authorizations will be obtained
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yell <input checked="" type="checkbox"/>	The biomedical waste will be segregated at the point of generation and will be stored in suitable containers
				Red <input checked="" type="checkbox"/>	
				Whi <input checked="" type="checkbox"/>	
				Blue <input checked="" type="checkbox"/>	
18.	Is the bar code system for the segregated waste in place?		No		Will be implemented at the earliest
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Yes <input checked="" type="checkbox"/>		<p>Name and address of CBMWF: All animal waste post challenge studies, disposable lab ware, filter Cartridges will be sent to MEDICARE Pashamylaram Industrial Area, Isnapur, Patancheru,</p>	The vendor's contract shall be renewed on time to ensure this practice is being followed throughout the Project.

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				Medak District, Telangana Distance from facility: 30 Kms Frequency and Mode of transport: Twice in a week as per the requirement. Dedicated vehicle from the vendor Who transports? Vendor – Medicare	
20.	Does the grantee have an in-house BMW treatment facility?	Yes		Reason:	Needles, disposable lab ware, Catridges etc. were disinfected in-house by steam sterilization and passed onto third party Medicare. Spent media post sterilization/Disinfection with validated disinfectant will be sent to the centralized kill tank facility
	Is the treatment facility own (individual)?	Own		Authorization:	
	Is the treatment facility a shared facility in an industrial park?			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: All lab waste, microbiologic al waste and chemical liquid waste pre-treated are pre- treated with validated disinfectants before storing and sending to treatment facilities (Kill tank) according to guidelines	Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Testing methods in place	Routine checks will be done.

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23.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): We have dedicated autoclaves for disinfection in R & D labs and animal houses	The decontamination autoclave shall be periodically qualified as per the maintenance schedule.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes		Details of waste pre-treatment: lab waste, spent media microbiological waste and chemical liquid waste pre-treated are pre-treated with validated disinfectants before storing and sending to treatment facilities (Kill tank)	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		To some extent where ever applicable	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: At least once in year & as per the requirement Trainer: Biosafety Officer	Personnel involved in handling BMW will be provided with regular training
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: All employees are screened	All personnel involved in handling BMW will be provided with relevant immunizations

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				for medical examination once in a year. All employees involved will be vaccinated as applicable and monitored for antibody titres.	
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Daily register maintained. Accident reporting SOP in place.	Registers will be maintained
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes			Annual reports on BWM will be submitted to SPCB as per the requirement
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	-	If Yes, provide a list of hazardous waste produced in the facility a. ETP Sludge b. ATFD Salt c. Waste Oil d. Biomedical waste	Proper handling and disposal of hazardous waste will be followed as per Hazardous Waste Rules, 2016
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			Regular Training of newly recruited staff for hazardous waste shall be done within the year.
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes			Will ensure timely renewals and proper authorization as and when required during the Project.
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.	All the hazardous wastes will be cleared on monthly basis.
	Are hazardous waste stored for more than 90 days in the grantee's premises?	-	No		

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				<p>Separate pathway is provided for personnel movement which are away from critical installation</p> <p>a. ETP sludge & ATFD Salt is kept in polythene bags under designated place under shed and secured and are away from critical installation</p> <p>Waste oil is kept in drums in a designated place and are away from critical installation</p>	
33.	Is the hazardous being send to an authorized disposal facility or user?	Yes		Name and address of facility: Hyderabad Waste Management Project, a unit of Ramky Enviro Limited	Will ensure during the course of the project
	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		Register maintained	Will ensure maintenance of the register during the course of the project
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		e-waste-Cables/wires, CFL Lights and Misc.-Waste	Will ensure the proper disposal of the e-waste, Cables/wires, CFL Lights and Misc.-Waste
36.	Has the grantee obtained SPCB authorization on e-waste?		No		Will obtain it as and when required as per the existing regulations and SPCB guidelines.

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37.	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Z Enviro Industries Pvt Ltd. H.no. 8-2-686/pd/b5, Prime dwelling apartment, MLA colony, Banjara Hills Road no-12, HYD-34	Will ensure to channelize the e-waste to third party during the course of the project.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Describe:	
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 don't undertake any manufacture of electrical and electronic equipment and its parts.	
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		Records in place	Continue to keep the records in place
42.	Does the grantee submit annual reports on e-waste to SPCB?		No		Will submit such reports if required and needed during the Project.
43.	Is there accident reporting and records in place?	Yes		Reporting & Records in Place	Will continue during the course of the project
44.	Are PPEs available to staff?	Yes		All employees are provided with PPEs as applicable	PPE's will be made available to the staff during the course of the project
45.	Is the grantee involved in manufacture of batteries?		No		--
46.	Does the grantee generate battery waste?	Yes		The e-waste generated -Cables/wires, CFL Lights and Misc.-Waste	Will ensure the proper disposal of the e-waste as per e-waste Management Rules.
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/re-conditioner/collection center?	Yes		Z Enviro Industries Pvt Ltd. H.no. 8-2-686/pd/b5, Prime dwelling apartment, MLA colony, Banjara Hills Road no-12, HYD-34	Will continue to handover to the third party

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48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?	Yes			Old batteries will be collected as per Battery Management Rules 2000
Community Health and Safety and risk mitigation					
		Yes	No	Details	Proposed Plan
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		SOP in place	This process will be followed periodically (Twice in a year) with proper checks and balances with the BMW agency.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		SOP in place for escalation procedure as per the severity	Frequent training programme will be conducted and given to the employees of IIL to handle the emergency situation as per the SOP.

Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Is the lab/room air regularly checked for microbial contamination?	Yes		We monitor both viable and non-viable particle counts in the lab area	Periodic checks will be done
52.	Are there any odor control measures in place?	Yes		SOP in place for decontamination procedure	Periodic cleaning will be done following the decontamination procedure.
53.	Are fume hoods and exhausts regularly checked and maintained?	Yes		All fume hoods and exhaust are regularly checked and validated	Periodic checks and maintenance will be done.
54.	Does the grantee use DG set > 15 KVA?	Yes			Proper checks and maintenance of the DG Set and Boilers will be done.
	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			
55.	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		Plastic wastes are segregated and will be handed over to recycler third party Sri Sai Traders, Plot No. 14, Sai Bab Nagar Colony, Prakash Nagar, Kukatpally, Hyderabad	Will ensure to continue the services during the course of the project.

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				Solid waste ETP sludge & ATFD salt dispose to be handed over to authorized vendor Hyderabad waste Management project (A Unit of Ramky Enviro Engineers Limited) Survey No. 684/1, Dundigal Village, Gandimaisamma Mandal, Medak District, Telangana	
56.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Treatment of wastewater: Chemical management in wastewater treatment plants: Waste water generated from labs are treated in ETP, whereas the cultures coming from restricted area are treated by Thermal treatment followed by secondary treatment at ETP.	Maintenance of Treatment plant shall be done.
	Are there sludge management and cut off drains in place for wastewater?			Process drains are connected by underground pipeline to ETP	This facility shall be maintained as per the BMW 2016 rules
57.	Are necessary provisions for noise cancellation in place?	Yes		Describe: DG sets are provided with silencers and acoustic enclosures are in place to keep the noise within the acceptance limits	Will ensure that this risk does not arise adapting proper existing measures and creating more such measures if required in future.
58.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	Describe: Distance from premises:	
59.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire vehicle routes are available in the premises	Will ensure proper maintenance of these as per requirements