Environmental Health Risk Management Plan (EHRMP)

Levim Biotech LLP

Proposal entitled: "Development of novel antibody-drug conjugate for treatment of patients harboring KRAS mutation in adenocarcinoma of Non-Small Cell Lung Cancer NSCLC"

1. Institutional Arrangements

(i) Brief description of the proposed activity

The activities in the proposal involve process development & optimization of the ADC construct, laboratory testing & characterization including cell line studies and pre-clinical studies for safety & efficacy which is planned to be outsourced to CROs

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

Clearance from Pollution control board, biomedical waste approval, IBSC & RCGM approvals, CDSCO & state drug control for manufacturing license for test & research-use purposes during the relevant stages

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?	✓		Mr. Murali Ramu is in-charge of taking care of EHS in the Organization.	Regular review meetings will be held quarterly.
2.	Does the EHS staff handle the following?			Any other:	These facilities will be reviewed in EHS review meetings held quarterly.
	Occupational Health and Safety	✓			
	Waste Management	✓			
	List of consents and regulatory clearances	✓			
	Record keeping of accidents and procedures	✓			
	EHS trainings for staff	✓			
	Environment Management Framework compliance for Innovate in India Project	✓			
3.	Is there a reporting structure in place regarding EHS issues?	✓		Describe: yes as per SOP available	Records part of review in EHS review meetings held quarterly. A proper reporting structure will always be ensured during the course of project.
4.	Are regular EHS trainings provided to staff?	✓		Frequency: once every 6 months	EHS training calendar with topics shall be

					put in place.
5.	Institutional Bio-Safety Committee (IBSC)	✓		At least twice in a year & for any application to be made to RCGM/ DBT	IBSC meetings shall be held at least twice a year to review biosafety procedures & provide annual reports to RCGM/DBT
6.	Ethics Committee (EC)	✓			Institutional EC approval shall be sought for obtaining patient biopsy samples for testing. IAEC (animal ethics) committee shall be sought before conducting preclinical studies
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.)?	✓		SOP for handling of accidents & emergencies in place SOP-LVBHR-002 SOP for handling & usage of laboratory chemicals in place. SOP-LVBQA-056	Implementation of SOPs checked during internal audits held once in 6 months
8.	Are the following in place?			Chemical spill kit available. Eye wash provided in labs & media prep area. Various types of fire extinguishers in place with tags. Accident register in place	Safety provisions & records checked during internal audits held once in 6 months
	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?	✓		MSDS made available in Stores & in lab, segregated storage for acids & solvents provided with fire alarm, safety signages put up across facility along	Signage & storage checked during internal audits held once in 6 months
	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	✓			

	Signage across the facility (labs, storage, hazardous areas, etc.)	✓		with emergency exit plan	
	Are flammable materials appropriately stored to prevent fire hazards?	✓			
10.	Are smoke detectors, fire alarms, automatic safety/ shutoff systems, overflow preventors, etc. in place and regularly maintained?	✓		List: Fire alarm, Smoke detector, Fire damper, Emergency interlock unlocking system	They are available & part of maintenance schedule, but separate list shall be prepared.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	✓		List: Biosafety hoods, HEPA filters in AHUs, local exhaust connected to wet scrubber, boiler stack provided	Boiler stack emission (VOC etc.) & HEPA filter integrity shall be checked once in 6 months.
, 12.	Are regular mock drills conducted for emergency preparedness and safety?	✓		Frequency (type wise): Alarm, evacuation & PA system checked	Mock drills shall be conducted at least once a year.
13.	Are staff provided with OHS training?	✓		Describe: Boiler operation as per SOP, Solvent storage & handling, AHU & LAF monitoring & maintenance, PPE usage	EHS training calendar shall cover OHS topics which will be conducted regularly as per schedule.
	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?	✓		Microbiology, biotechnology & other chemical laboratory waste. This is disposed through authorized biomedical waste disposal agency.	Records shall continue to be maintained for biomedical waste storage and disposal through authorized agency. Procedures shall also be reviewed in EHS meetings held quarterly.

15.	Is there trained staff to handle biomedical waste in the grantee?	✓		Trained staff available	Proper training will be provided to the newly appointed staff to pursue this activity.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	✓		Authorisation No: 19BAZ23435107 dated 08/11/2019 granted by Tamil Nadu Pollution Control Board	Proper and timely renewal will be done.
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	✓		Yellow ✓ Red White Blue	Separately labelled bins shall continue to be placed at source for segregation of biomedical waste & bar-coded yellow bags in sealed drums shall continue to be used for storage before disposal
18.	Is the bar code system for the segregated waste in place?	✓		Bags are bar-coded	Bar-coded yellow bags shall continue to be used for storage before disposal to authorized agency
19.	Is the biomedical waste being sent to an **authorized** common BMW facility?	✓		Name and address of CBMWF: GJ Multiclave (India) Pvt. Ltd, S.F.No. 245&247, Thenmelpakkam Village, Chengalpattu Tk, Kancheerpuram Dt, Tamil Nadu Distance from facility: 50 kms	The vendor's contract shall be renewed on time to ensure this practice is being followed.

				Frequency and Mode of transport: Thrice a week in a closed, light motor vehicle Who transports? GJ Multiclave (India) P Ltd	
20.	Does the grantee have an in-house BMW treatment facility?		✓	Reason: Authorization: Distance of nearest CBWM from facility: Types of treatment:	Biomedical waste will be sent to authorized facility Multiclave (India) Pvt. Ltd.
	Is the treatment facility own (individual)?		✓		
	Is the treatment facility a shared facility in an industrial park?		✓		
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?	✓		Types of treatment: Autoclaving using separate decontamination autoclave	The decontamination autoclave shall be periodically qualified as per the maintenance schedule.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		✓	The autoclave is validated & periodically qualified	The decontamination autoclave shall be periodically qualified as per the maintenance schedule
23.	Are necessary waste pre-treatment equipment in place?	✓		List of equipment (autoclaves, shredders, incinerators, etc.): Decontamination autoclave-AUT0002 Details of waste pre-treatment: Autoclaving as per SOP-LVBQC-038	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)?	✓			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	✓		Non chlorinated gloves & Bags are being used	Awareness on avoiding use of chlorinated gloves & bags shall be made in the EHS trainings

25.	Are grantee's personnel involved in handling BMW provided with regular training?	✓		Frequency: On-the-job & once / year Trainer: Representative from QC and Engineering dept	Proper training will be provided to the newly appointed staff to pursue this activity.
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: once in a year conducted	Medical examination for 2020-21 shall be conducted for all employees including personnel handling BMW waste
27.	Is a daily register for biomedical waste maintained including accident reporting record?	✓		Biomedical generation & disposal log is maintained based on generation & decontamination frequency. Record also maintained for accident reporting & investigation as per SOP.	Review of BMW generation and accident reporting records done in EHS meetings held on quarterly basis
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	✓		BMW data submitted in Form IV to PCB	Shall continue to adhere to statutory reporting requirements
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?	✓		list of hazardous waste produced in the facility Spent solvent, filter cake, air filter media, expired products &drugs	Record formats shall be created to capture hazardous waste generation
30.	Is there trained staff in the facility to identify and handle hazardous waste?		✓		Training of staff for hazardous waste shall be done within the year
31.	Does the grantee have authorization from SPCB for hazardous waste?		✓		We shall check & apply for HW authorization with SPCB as necessary

32.	Is there a secure location for storage of HW with proper signage?		✓	Describe how each item is stored – platforms, distances from critical installations/movement areas, spill collectors, gas escape facility, etc.	Secure location shall be identified for storage of HW with proper signage
	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?		✓	Name and address of facility: Effluent Treatment Plant, Ticel Biopark Ltd., CSIR Road, Taramani, Chennai – 600113	Authorized vendors for certain types of hazardous waste which cannot be routed to the ETP shall be identified and authorization obtained
	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 transport of hazardous waste from the grantee to treatment facility?		✓		Records shall be created & maintained for HW and required procedures for transport shall be followed
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?	✓		Types of e-waste generated are non-functional IT equipment like printers, key boards, computer peripherals and batteries of UPS system	Records shall be created & maintained for e-waste generation & disposal
36.	Has the grantee obtained SPCB authorization on e-waste?		✓		We shall check & apply for authorization with SPCB as necessary
37.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		✓	Name and address of disposal facility/ recycler: Inhouse or outsourced Facility:	Authorized e-waste vendor shall be identified and agreement made for disposal
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓	Describe:	Will Ensure that a proper system is put in place and authorization is taken in case the manufacture

					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?		✓		Will practice this in case Levim Biotech LLP engages in 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?		✓		Will comply with this requirement as and when required in future under the Project.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		✓		Separate register shall be framed
42.	Is there accident reporting and records in place?	✓		Accident reporting forms available	Reporting procedure as per SOP shall be followed in case of accidents
43.	Are PPEs available to staff?	✓		Gloves, goggles, aprons, ear muffs, helmet, safety shoes etc. are made available	IPQA shall continue to have daily check on the availability & usage of PPEs in the facility
44.	Is the grantee involved in manufacture of batteries?		✓		
45.	Does the grantee generate battery waste?	✓		Battery waste is mainly from that connected to the UPS which are non-serviceable over time	Authorized e-waste vendor shall be identified and agreement made for disposal of battery waste
46.	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioner/collection center?		✓	Name and address of battery waste receiving entity:	Authorized e-waste vendor shall be identified and agreement made for disposal of battery waste
Community Health and Safety and risk mitigation					
		Yes	**No**	**Details**	**Proposed Plan**

47.	Safety Transportation Management System (for transport Of hazardous material)		✓	Responsibility for transport of hazardous waste lies with authorized agencies.	Will ensure timely renewal of the contract with the outsourced agencies and that proper management is being taken care off by the agencies throughout the project.
48.	Emergency preparedness and participation of local authorities and potentially affected communities		✓	As ours is a facility located in a govt incubator park, this is taken care by the biopark administration	Will ensure that this facility is being maintained by Biopark Administration throughout the Project.
	Other				
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
49.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		✓		
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		✓	Describe:	
	Are radioactive warning signs in place?		✓		
50.	Is the lab/room air regularly checked for microbial contamination?	✓		Cleanrooms & LAFs/ bio safety hoods are checked for environmental monitoring on daily / weekly basis depending on the area classification	Test for microbial contamination shall continue to be carried out on periodic basis as per SOP
51	Are there any odor control measures in place?	✓		Local exhaust systems, fumehoods& PPEs available	Periodic checks will be done and the fumehoods shall be maintained.
52.	Are fume hoods and exhausts regularly checked and maintained?	✓		Fumehoods & exhaust are checked regularly for performance & maintained by the Engineering team	Periodic check shall be carried out as per maintenance SOP
53.	Does the grantee use DG set > 15 KVA?		✓	Boiler stack emission test done once in 6 months	Boiler stack emission shall be
	Does the grantee have consent for DG > 15 KVA?		✓		

	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	✓			checked once in 6 months.
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?		✓	Describe	Segregation of bio-degradable waste & non bio-degradable dry waste (plastic, paper, wood, metal etc. as recyclable & non-recyclable) shall be done & handed to local bodies or authorized recyclers where possible
55.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	✓		Types of waste water: Process & lab drains Treatment of wastewater: Through common effluent treatment plant in the incubator park functioning with PCB authorization Chemical management in wastewater treatment plants:	Maintenance of authorization for operating common effluent treatment plant by the biopark shall be checked periodically.
	Are there sludge management and cut off drains in place for wastewater?	✓		Traps & drain isolation provided	This facility shall be maintained as per the BMW 2016 rules
56.	Are necessary provisions for noise cancellation in place?	✓		Describe: Ear muffs in use in Utility area	Will ensure that this risk does not arise adapting proper existing measures and creating more such measures if required in future.

57.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?	✓		Describe: Wet marshland at Pallikarani Distance from premises: 7 km	Levim Biotech LLP will be taking every measures to ensure that it is not getting polluted by any means by hospital wastes.
58.	Are there any buffers, fire vehicle routes in the grantee's premises?	✓		Buffers & fire vehicle routes are provided in the incubator park based on which Fire License is accorded to the park	Will ensure proper maintenance of these as per requirements in the project.

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.