Environmental Health Risk Management Plan (EHRMP)

Lab Iconics Technologies LLP

Proposal entitled: "Development of quality management system electronic platform for Biopharmaceutical Industry"

1. Institutional Arrangements

(i) Brief description of the proposed activity - This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry,
Objective 1: Deployment of low-cost Laboratory Information Management System LIMS Platform **Objective 2:** Deployment of low-cost Electronic Laboratory Notebook ELN Platform. **Objective 3:** Development of Backup Software.

(ii) List of environment related regulatory clearances required for the activity. – This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence it does fall under the ambit of environment related regulatory clearances/consents/Authorization from state pollution control board/ Ministry of environment, forest and climate change.

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?		✓	The company is not involved in any manufacturing but software development. For the scope of the activities a dedicated EHS person is not required	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry. The company is under white category. A consultant will be hired on need basis.
2.	Does the EHS staff handle the following?			Any other:	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence it does not fall under the ambit of EHS requirements.
	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:	This project is to Develop IT Platforms

					for Quality Management System in Biopharmaceutical Industry, hence it does not fall under the ambit of EHS requirements.
4.	Are regular EHS trainings provided to staff?		✓	Frequency:	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence it does not fall under the ambit of EHS requirements.
5.	Institutional Bio-Safety Committee (IBSC)		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence it does not fall under the ambit of EHS requirements.
6.	Ethics Committee (EC)		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence it does not fall under the ambit of EHS requirements.
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.)?		✓	No hazardous chemicals are however used the company office except market available cleaning solutions.	The applicant will however develop the in-house SOPs for such an event.
8.	Are the following in place?			First Aid and fire extinguishers are placed in the office premises.	Due to the nature of the work undertaken at the company office chemical spill related risks are not applicable but first aid and fire extinguishers are in place. We will have documentation for periodic quality check
	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?			Display of emergency numbers is available.	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence these risk are not applicable.
	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.)		✓		
	Are flammable materials appropriately stored to prevent fire hazards?		✓		
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?	✓		Office space is in a with these standard safety features	Ours is an office space, and it is standalone building with Ground Floor and First Floor with safety measures inbuilt which will be regularly maintained.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		✓	Not applicable as not manufacturers of biotherapeutic product	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence these risk are not applicable.
12.	Are regular mock drills conducted for emergency preparedness and safety?		✓	Frequency (type wise):	Ours is an office space, and it is standalone building with Ground Floor and First Floor with safety measures inbuilt.
13.	Are staff provided with OHS training?		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk is not applicable.
	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?		✓	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable.	Our facility is office infrastructure, hence no hazardous / bio medical waste is generated, expect limited stationaries waste.

15.	Is there trained staff to handle biomedical waste in the grantee?		✓			This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable
16.	IIas the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		✓			This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?		✓	Yellow Red White Blue	 	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable
18.	Is the bar code system for the segregated waste in place?		✓			This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable

19.	Is the biomedical waste being sent to an **authorized** common BMW facility?		✓	Name and address of CBMWF: Distance from facility: Frequency and Mode of transport: Who transports?	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable
20.	Does the grantee have an in-house BMW treatment facility?		✓	Reason: Authorization: Distance of nearest CBWM from facility: Types of treatment:	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable
	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:	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence no laboratory waste is generated.
22.	Is the liquid waste checked for active cells before sending to treatment plant?		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk is not applicable
23.	Are necessary waste pre-treatment equipment in place?		✓	List of equipment (autoclaves, shredders, incinerators, etc.): Details of waste pre-	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence this risk is not applicable.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?		✓		

				treatment:	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence this risk is not applicable.
25.	Are grantee's personnel involved in handling BMW provided with regular training?		✓	Frequency: Trainer:	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence this risk is not applicable.

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:	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence this risk is not applicable.
27.	Is a daily register for biomedical waste maintained including accident reporting record?		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence this risk is not applicable.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		✓		This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry and ours is an office space, hence this risk is not applicable.
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?		✓	This project is to Develop IT Platforms for Quality Management System in Biopharmaceutical Industry, hence this risk of bio medical waste is not applicable.	Our facility is office infrastructure, hence no hazardous / bio medical waste is generated, expect limited stationaries waste.
30.	Is there trained staff in the facility to identify and handle hazardous waste?		✓		Our facility is office infrastructure, and no hazardous waste is generated, hence training is not applicable.
31.	Does the grantee have authorization from SPCB for hazardous waste?		✓		Our facility is office infrastructure, and no hazardous waste is

					generated, hence authorization for SPCB is not applicable.
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.	Our facility is office infrastructure, and no hazardous waste is generated, hence this risk is not applicable.
	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:	Our facility is office infrastructure, and no hazardous waste is generated, hence this risk is not applicable.
	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?		✓		Our facility is office infrastructure, and no hazardous waste is generated, hence this risk is not applicable.

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?		✓		Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste is generated during the project it will be disposed through authorized agencies.
36.	Has the grantee obtained SPCB authorization on e-waste?		✓		Our facility is office infrastructure, and as such no e-waste is generated, hence not applicable.
37.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		✓	Name and address of disposal facility/ recycler : Inhouse or	Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste will be disposed through authorized agencies as specified by Government and as

				outsourced Facility:	per rules.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		✓	Describe:	Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste will be disposed through authorized agencies. Hence this risk is not applicable.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		✓		Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste will be disposed through authorized agencies. Hence this risk is not applicable.
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?		✓		Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste will be disposed through authorized agencies. Hence this risk is not applicable.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		✓		Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste will be disposed through authorized agencies. Hence this risk is not applicable.
42.	Does the grantee submit annual reports on e-waste to SPCB?		✓		Our facility is office infrastructure, and as such no e-waste is generated. However, if any e-waste will be disposed through authorized agencies. Hence this risk is not

					applicable.
43.	Is there accident reporting and records in place?		✓		Our facility is office infrastructure, and as such no e-waste is generated. Hence this risk is not applicable.
44.	Are PPEs available to staff?	✓		General PPEs like face shield, masks, Gloves, Safety Goggles, are available	Proper provision will be maintained in stock of the required PPEs throughout the Project.
45.	Is the grantee involved in manufacture of batteries?		✓		Our facility is office infrastructure, and as such no battery waste is generated. Hence this risk is not applicable.
46.	Does the grantee generate battery waste?		✓		Our facility is office infrastructure, and no battery waste is generated.
47.	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer/reconditioner/collection center?		✓	Name and address of battery waste receiving entity:	Any battery waste generated from inverters would be returned to authorized battery suppliers.
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		✓		Our facility is office infrastructure, and as such no battery waste is generated. Hence this risk is not applicable.
Community Health and Safety and risk mitigation					
		Yes	**No**	**Details**	**Proposed Plan**
49.	Safety Transportation Management System (for transport Of hazardous material)		✓		Our facility is office infrastructure, no hazardous material is generated or transported, hence this risk is not applicable.
50.	Emergency preparedness and participation of local authorities and potentially affected communities		✓		Our facility is office infrastructure, no hazardous material is

					generated or transported, hence this risk is not applicable.
Other					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		✓		Our facility is office infrastructure, no radioactive material is used hence this risk is not applicable.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		✓	Describe:	Our facility is office infrastructure, no radioactive material is used hence this risk is not applicable.
	Are radioactive warning signs in place?		✓		Our facility is office infrastructure, no radioactive material is used hence this risk is not applicable.
52.	Is the lab/room air regularly checked for microbial contamination?		✓		Our facility is office infrastructure, hence this risk is not applicable.
53	Are there any odor control measures in place?		✓		Our facility is office infrastructure, hence this risk is not applicable.
54.	Are fume hoods and exhausts regularly checked and maintained?		✓		Our facility is office infrastructure, hence this risk is not applicable.
55.	Does the grantee use DG set > 15 KVA?		✓		Our facility is office infrastructure, and DG set is not used, hence this risk is not applicable.
	Does the grantee have consent for DG > 15 KVA?		✓		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		✓		
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?		✓	Describe	Our facility is office infrastructure, and no solid waste is generated.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		✓	Types of wastewater: Treatment of wastewater: Chemical management in wastewater treatment plants:	Our facility is office infrastructure, and no liquid or chemical waste is generated.

	Are there sludge management and cut off drains in place for wastewater?		✓		Our facility is office infrastructure, hence this risk is not applicable.
58.	Are necessary provisions for noise cancellation in place?		✓	Describe:	Our facility is office infrastructure, hence this risk is not applicable.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		✓	Describe: Distance from premises:	No, Our facility is stand-alone building inside a gated community, hence this risk is not applicable.
60.	Are there any buffers, fire vehicle routes in the grantee's premises?		✓		Our office premises is stand-alone building and it has access for fire engine, with 2 way road of about 60 ft wide in front and open to sky in all the 4 sides with wider space and hence, these requisites are not needed.

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.