Environmental Health Risk Management Plan (EHRMP)

Omnibrx Biotechnologies Private Limited

Proposal entitled: "Development of MiniBRx single use bioreactor system: high-throughput affordable platform for process Development & QbD studies of biopharmaceutical"

1. Institutional Arrangements

(i) Development and manufacturing of Single use bioreactors involves three basic steps:
1) Manufacturing of plastic components and part using Plastic injection molding process.
2) Assembly of Single-use bioreactor vessels and controller systems.
3) Quality related in process and lot release testing of the product.

(ii) There are no environment related regulatory clearances required for the manufacturing activity of single use bioreactors. We are not manufacturing any plastics. We are just molding the plastic resin and there is no plastic waste generated during our manufacturing processes. However, we will apply to obtain White Category certificate from GPCB (Gujarat 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?		No		EHS policies will be drafted and dedicated full-time staff will be hired to ensure the compliance of EHS policies for and during the Project.
2.	Does the EHS staff handle the following?			Appointed EHS staff handle all the mentioned responsibilities	Appointed EHS staff will handle all the mentioned areas through out the project. Environment Management Framework compliance for Innovate in India Project will be followed
	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			SOPs and formats to record any incidents and EHS issues will be structured as a part of EHS policy
4.	Are regular EHS trainings provided to staff?	Yes		Frequency: 6 months	As a part of EHS policy Regular EHS trainings will be provided to staff

5.	Institutional Bio-Safety Committee (IBSC)		No	Our product is an equipment and machinery. We are not using any biohazard material and there is no biohazard related operations and issues in our manufacturing processes	No IBSC required at this moment. If required in future, we will take necessary action and approvals whenever required.
6.	Ethics Committee (EC)	Yes		Internal ethics committee is constituted	Code of conduct and ethics policy will be drafted soon
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		OHSAS 18001:2007 Occupational Health and Safety Management Certification will be obtained soon.	SOPs and formats to record any accidents, hazards, and other emergencies will be structured as a part of OHSAS policy
8.	Are the following in place?			Our manufacturing process and any other production process does not involve use of any hazardous chemical compounds.	Fire safety management and register to record accident and injuries will be in place as a part of OHSAS policy. Proper equipment will be in place and stock will be maintained as per the guidelines for Environment Health and Safety (EHS) enacted by the legislature.
	Chemical spill kits		No		
	Eye wash		No		
	Shower stations		No		
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
9.	Are proper signage and storage system in place?	Yes		Implementation of quality management system according to ISO 9001 guidelines. All the material storage and signage systems are in place including the signage across the facility as a part of ISO 9001 quality management policy.	Proper equipment will be in place and stock will be maintained as per the guidelines for Environment Health and Safety (EHS) enacted by the legislature.
	Display of Material Safety Data Sheet (MSDS) where relevant		No		
	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 preventers, etc. in place and regularly maintained?		No		Our manufacturing process does not involve use of any inflammable chemicals.

11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No		Our manufacturing process does not involve use of any volatile toxic chemicals.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): 6 months	Mock drills for emergency will be done as a part of OHSAS policy
13.	Are staff provided with OHS training?	Yes		Describe: 6 months	We will provide such training for all staff recruited in the project OHSAS 1800:2007 Occupational Health and Safety Management Certification will be obtained soon.
	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?		No	Our facility does not generate biomedical waste. Waste produced in the facility include: - Plastic injection molding waste. - Packaging material and other paper waste	General waste including plastic waste will be handed over to municipal waste collection agencies for its disposal.
15.	Is there trained staff to handle biomedical waste in the grantee?		No	We are currently manufacturing bioreactor and its control system. We do not have any operation generating biomedical waste in entire manufacturing process.	In case of any biomedical waste generation happens in future, we will provide the training to the assigned staff with establishment of procedures to handle such biowaste material and ensure that handling of biomedical waste is done as per regulatory norms.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		No	There is no biomedical waste generated in our facility and hence, the requirement of authorization from SPCB is not required.	The amount of waste produced will be regularly monitored and authorization from GPCB will be sought as and when such a requirement is created. Necessary Authorizations will be taken if required
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?		No	Yellow Red White Blue	If our facility starts generating biomedical waste in future, then the related waste material will

						be categorized and staff will be trained before carrying out of the operation. Moreover, the required resources and defied procedure will be in place and ensured that defined procedure is followed.
18.	Is the bar code system for the segregated waste in place?		No	Our facility do not generate any kind of biomedical waste and hence no bar code system is required to segregate biomedical waste.		If biomedical waste is generated in future, we will adopt the bar code system for easy segregation and handling of waste.
19.	Is the biomedical waste being sent to an **authorized** common BMW facility?		No	Our facility do not generate biomedical waste and hence no need to send it to BMW facility.		If any kind of biomedical waste generated in future, we will sent it to authorized BMW facility.
20.	Does the grantee have an in-house BMW treatment facility?		No	Our facility do not generate biomedical waste and hence no BMW facility required.		If any kind of biomedical waste generated in future, we will sent it to authorized BMW facility. We may have in-house biomedical treatment facility if required as a part of any regulatory compliance.
	Is the treatment facility own (individual)?		No			
	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?		No	Types of treatment: Our facility do not generate biomedical waste and hence no BMW facility required.		In future, in case the biomedical waste is generated in our facility, all the lab waste, microbiological waste and chemical liquid waste will be pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations
22.	Is the liquid waste checked for active cells before sending to treatment plant?		No	Our facility do not generate biomedical waste and hence no checking for active cells required.		None of the manufacturing operations of bioreactor and control system involves active cell. However, in future, if the same is required, we will establish procedure to check the active cells after decontamination treatment before sending to BMW facility.

23.	Are necessary waste pre-treatment equipment in place?		No	Waste pre-treatment equipments are not required since our facility is not generating any biomedical waste.	If biological material handling is required in future operations at site, then we will ensure that the qualified equipments, are in place to perform the pre-treatment of biomedical waste before disposal.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?		No		
24.	Are chlorinated plastic gloves and bags phased out in the grantee?		No	No chlorinated plastic gloves and bags required since our facility is not generating any biomedical waste.	In case of handling of chlorinated gloves, bags or any other similar material in future, we will phase out them as per regulatory guidelines.
25.	Are grantee's personnel involved in handling BMW provided with regular training?		No	Frequency: No frequency required since there is no biomedical waste generation. Trainer: No Trainer required since there is no biomedical waste generation.	In future if our facility generates biomedical waste, sufficient training will be imparted to the relevant staff to handle BMW by authorized trainers.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		No	Frequency of medical examination: No medical examination is required since there is no biomedical waste generation.	In future if our facility generates biomedical waste, the staff, who will handle the biomedical waste, will be immunized periodically as per the regulatory requirements.
27.	Is a daily register for biomedical waste maintained including accident reporting record?		No	No register is required since there is no biomedical waste generation.	In future if our facility generates biomedical waste, we will register all biomedical waste related activities in it, maintain and review for improvement of established procedure.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	No annual reports are required since there is no biomedical waste generation.	We will prepare and submit the annual report to SPCB as per required form if biomedical waste handling activities are carried out at our facility.
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	OmniBRx facility does not generate any kind of hazardous waste.	No hazardous waste materials are being generated at site, e.g. used oil from DG. If such material produced or handled at site, then detailed risk assessment report will be prepared in advance and the detection and control measure will be in place to reduce the risk probability number of each risk as per Hazardous waste rules 2016.
30.	Is there trained staff in the facility to identify and handle hazardous waste?		No	No trained staff is required since there is no hazardous waste generation.	In future, if any hazardous waste is generated, the assigned staff will be trained to identify and handle hazardous waste.
31.	Does the grantee have authorization from SPCB for hazardous waste?		No	No authorization is required since there is no hazardous waste generation.	We will obtain the required permits from GPCB for handling of hazardous waste if required in future. Necessary Authorizations will be taken if required
32.	Is there a secure location for storage of HW with proper signage?		No	No secure location for storage is required since there is no hazardous waste generation.	In future if our facility generates hazardous waste, dedicated locations with all required safety signages will be allotted for storage of hazardous waste.
	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	Name and address of facility: Our facility does not generate hazardous waste and hence no need to send it to authorizedHW facility.	If our facility generates hazardous waste in future, contract with authorized disposal facility will be done for disposal of hazardous waste as per statutory norms.
	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 need to maintain registers since there is no hazardous waste generation in our facility.	If our facility generates hazardous waste in future, registers will be maintained for recording of all details of activities for hazardous waste generation, treatment

					and transport and will be periodically reviewed.
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	No e-waste, electrical or electronic and IT waste will be generated during manufacturing of bioreactors in our facility.	If our facility generates e-waste in future, we will take appropriate action to comply the rules mentioned in the e-waste rules 2016.
36.	Has the grantee obtained SPCB authorization on e-waste?		No	No authorization is required since there is no e-waste generation in our facility	We will obtain necessary permissions and authorizations in case in future our facility generates ant e-waste.
37.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		No	No need to channelize the e-waste since there is no e-waste generation in our facility	If our facility generates e-waste in future, we will take appropriate action to channelize the e-waste to authorizedrecycling or disposal facility
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	Describe: No EPR-authorization is required since there is no e-waste generation in our facility	If our facility generates e-waste in future, we will take appropriate action to implement extended producer responsibility system and EPR – authorization.
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	No need for reduction in the usage of hazardous substances required since there is no e-waste generation in our facility	We do not practice in the usage of hazardous substances in manufacturing of bioreactors. If the said practice is required, practice will be aligned to the e-waste rules 2016.
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	No need for detailed information on the constituents required since our product is only assembled in our facility and no electrical parts are manufactured in our facility. Also, there is no e-waste generation in our facility	If our facility generates e-waste in future, we will declare the confirmation to reduction in hazardous substances in product user documents in case of usage of such substance in manufacturing operations.

41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	No need to maintain a record of collection, storage, sale and transport of e-waste since there is no e-waste generation in our facility.	If our facility generates e-waste in future, we will maintain record of collection, storage, sale and transport of e-waste in register
42.	Does the grantee submit annual reports on e-waste to SPCB?		No	No need to submit annual reports since there is no e-waste generation in our facility.	If our facility generates e-waste in future, we will prepare annual report on e-waste, which will be submitted to SPCB.
43.	Is there accident reporting and records in place?		No	No need to record accident reporting since there is no e-waste generation in our facility.	In case of accident happenings at manufacturing site, accident report will be prepared and it will be recorded as per defined procedure.
44.	Are PPEs available to staff?		No	PPEs are not required since there is no e-waste generation in our facility.	If our facility generates e-waste in future, the required PPEs will be made available to the staff.
45.	Is the grantee involved in manufacture of batteries?		No	We are not involved in manufacturing of batteries	We do not involve in manufacturing of batteries.
46.	Does the grantee generate battery waste?		No	There is no battery-waste generated in our facility.	If our facility generates battery-waste in future, it will be handled as per Battery management rules 2000.
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/ re conditioner /collection center?		No	No need to deposit the battery waste to registered recycler since There is no battery-waste generated in our facility.	If our facility generates battery-waste in future, the used batteries will be deposited to registered recycler
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No	There is no battery-waste generated in our facility.	If our facility generates battery-waste in future, we will comply the rules mentioned in Battery management rules 2000 for proper handling and disposal.
Community Health and Safety and risk mitigation					
		Yes	**No**	**Details**	**Proposed Plan**

49.	Safety Transportation Management System (for transport of hazardous material)		No	There is no need for Safety Transportation Management System since there is no hazardous-waste generation in our facility.	In future, if any hazardous waste is generated, A contract mentioning safe transportation of hazardous material will be done and it will be transported safely to disposal site.
50.	Emergency preparedness and participation of local authorities and potentially affected communities		No	There is no need for Emergency preparedness since there is no hazardous chemicals and any other items are used or generated in our facility.	In future, if any hazardous waste is generated, concerned local authorities will be immediately communicated in case of any emergency related to handling or transport of hazardous material
Other					
	Area of Risk	**Yes**	**No**	**Details**	**Proposed Plan**
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	There are no radioactive materials being used in our facility.	In future if required to use radioactive material in our facility we will take all the necessary actions as per the regulations.
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	There are no radioactive materials being used in our facility.	In future if required to use radioactive material in our facility we will take all the necessary actions as per the regulations.
	Are radioactive warning signs in place?		No	There are no radioactive materials being used in our facility thus no signs are required.	In future if required to use radioactive material in our facility we will take all the necessary actions as per the regulations. All warning signs will be used if radioactive material usage is required.
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		The classified production area (clean rooms) is regularly checked for bioburden load and microbial contamination according to the ISO 14664 guidelines	Microbial contaminant load is checked every six months during routine clean room qualification procedures.
53	Are there any odor control measures in place?		No	No odor control measures are required since we do not use or produce any odor generating material in	Necessary control measures will be put in place as and whenever required.

				our facility.	
54.	Are fume hoods and exhausts regularly checked and maintained?		No	None of the fume generating materials are being used in manufacturing operations. No fume hoods and exhausts are required since it is not required in our facility.	If any operation requires usage of such materials, the fume hood and required exhausts system will be installed and maintained.
55.	Does the grantee use DG set > 15 KVA?		No	No DG set is being used in our facility	In future, in case of usage of boiler or DG sets, the emission from such equipment will be monitored on defined frequency and will be ensured that such emissions do not exceed their predetermined limits.
	Does the grantee have consent for DG > 15 KVA?		No		
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?		No		
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		OmniBRx follow the plastic and solid waste disposal procedures complying to Solid Waste Management Rules, 2016 & Plastic Waste Management Rules, 2016	Dedicate team recruited will handle the solid and plastic waste disposal procedures
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)		No	No separate wastewater treatment is required. Our factory generates only domestic wastewater from the activities like floor cleaning, washing of utensils, and toilets. The wastewater is disposed directly in local sewage system.	In future, if our facility generates any kind of hazardous wastewater, we will take appropriate actions as per the regulatory requirements.
	Are there sludge management and cut off drains in place for wastewater?		No	No sludge management is required since there is no hazardous wastewater generation.	If required in future, the provision for sludge management and cut off drains will be made for required regulatory compliances.
58.	Are necessary provisions for noise cancellation in place?		No	No noise cancellation is required since there is no noise generating materials used in our facility.	In case of generation noise beyond permissible limits, we will provide the noise cancellation earcups to our staff. In addition to that, we will ensure that noise does

					not affect the surrounding community.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	There are no settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises	Appropriate actions will be taken in case if any settlements, water bodies, cultivated land, or any other eco-sensitive areas are required in our facility.
60.	Are there any buffers, fire vehicle routes in the grantee's premises?		No	No Fire tender movement route is available since we do not used any inflammable materials in our facility.	In future, if required, fire tender movement route will be defined whenever required.

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.