Environmental Health Risk Management Plan (EHRMP)

Inochi Care Private Limited

Proposal entitled: Multi Therapeutic Wound Healing Technology: Scale up and clinical evidence generation to bring the technology closer to market

1. Institutional Arrangements

i) Brief description of the proposed activity:

To facilitate the faster healing of these wounds, we have developed a novel and indigenous multi therapeutic wound healing technology which utilizes combined approach to provide negative pressure wound therapy and oxygen in combination to target multiple underlying biomechanisms favourable for wound healing. This indigenous novel technology reduces the time and cost of healing these wounds. The functional prototype has been successfully built and tested in bench top testing in the lab set up. The feasibility clinical studies have also been done along with the usability study in the hospital settings. Through the current grant, we will complete the design for manufacturing and pilot manufacture the units of device in ISO 13485 certified facility. The device will be tested for safety and EMC (electromagnetic compatibility) compliance testing and certification from an accredited lab as per the ISO 60601 standards. This will be followed by clinical performance evaluation to evaluate the efficacy of the device randomised controlled study of 120 subjects at 3-4 hospital/ medical institute sites at different geographical locations in India. The results of the clinical testing would be compiled and published in peer reviewed journal. This will establish safety and generate clinical evidence for the indigenously developed wound healing technology to advance commercialization of the technology and bring it closer to the market.

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

1. No hazardous material is used in the whole manufacturing process or any individual component
2. During the manufacturing: Manufacturing will be done at ISO certified facility with all the environment policies and pollution board approvals.
3. During the clinical study: The disposables like canister and dressings need to be disposed of as per the biomedical waste disposal guidelines. The disposal processes and framework are already in place in the hospitals targeted for clinical study. No health risk as device already tested extensively. Further it will be used under the supervision of expert healthcare providers.

None of the in-house activity (including design and development, bench testing, quality assurance, data analysis, assembly of the units, simulation studies, clinical data analysis, software and algorithms, firmware development) has any biomedical or involvement of any hazardous chemical or material. In future, if any of the activities need Environmental policies or permissions, it will be done by approaching the concerned authorities and guidelines.

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?		No	In house activities are limited to design and development and do not involve any kind of hazardous materials. The prototyping and	In future, if any of the activities need Environmental policies or permissions are required, it will be done by approaching the concerned authorities and

				manufacturing processes will be conducted through partners with certified manufacturing facilities and established EHS processes.	guidelines. Full time EHS staff with appropriate experience will be hired in that case.
2.	Does the EHS staff handle the following?			No dedicated EHS staff. Members of the team handle following duties: 1. Standard Operating and Safety procedures and user manuals for prototyping equipment in the facility are maintained 2. List of consents and regulatory clearances required throughout the project is maintained 3. Record of accidents or injuries at work are recorded 4. New employees/ interns are given an safety instructions during induction	In future, if any of the activities need Environmental policies or permissions, it will be done by approaching the concerned authorities and guidelines. Full time EHS staff with appropriate experience will be hired in that case.
	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		No		
3.	Is there a reporting structure in place regarding EHS issues?	Yes		All work activities and concerned issues if any are recorded in logbooks maintained for different activities	This will be regularly followed and ensure adherence to the requirements.
4.	Are regular EHS trainings provided to staff?		No	Since at this stage of work in the company, the current activities do not carry any major Environment Health and Safety risks	In future as the scope of activities carried out in the company broadens, either a Qualified person to handle EHS will be hired, or appropriate training for team members will be arranged as per the requirement.
General Occupational Health and Safety					
5.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive	Yes		None of the activities involve use of harmful chemicals or radioactive or hazardous material or chemical. Standard Operating	Similarly, new SOPs and protocols will be maintained for any new activity included in the work

	hazards etc.)?			procedures are in place for all kind of equipment used, prototyping and bench testing or other activities done.	
6.	Are the following in place?			The required things as per the work activity like first aid kit, antiseptic and sanitizer, emergency contact numbers list (ambulance, fire, police) is available	Register will be maintained for ensuring provisions of such requisites.
	Chemical spill kits		No		
	Eye wash		No		
	Shower stations		No		
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
7.	Are proper signage and storage system in place?			MSDS and SOP and User manuals are kept in place Display of emergency contact numbers is provided on the board Appropriate storage for all kind of materials used in work	Facilities will be upgraded with the activities increased.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			
	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.)				
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			
8.	Are smoke detectors, fire alarms, automatic safety/shutoff systems, overflow preventors, etc. in place and regularly maintained?	Yes		Available in the total building where office situated	Facilities will be upgraded with the activities increased.
9.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?		No	No such activity is done in the in-house work	
10.	Are regular mock drills conducted for emergency preparedness and safety?		No	Safety precautions are followed with use of equipment	As the team size and scope of activities in the company increases, appropriate

					emergency and safety trainings will be conducted
11.	Are staff provided with OHS training?	Yes		Safety and precautions instructions are provided to staff handling a particular equipment.	We will provide such training for all staff recruited in the project and include in the annual plan.
Biomedical Waste (BMW)					
12.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		Biomedical waste generated during clinical studies will be disposed through the hospital biomedical waste disposal system The Biomedical waste generated during clinical validation will be – disposable items like dressing patch and canister with wound fluid/exudates.	The disposal processes and framework already in place will carried forward by the respective hospitals targeted for clinical study (Collaborators of this project).
13.	Is there trained staff to handle biomedical waste in the grantee?		No	Biomedical Waste will be handled by trained staff (nurses, technicians, ward boys) at the partner hospitals where clinical studies will be conducted There is no biomedical waste generated in the company premises	No Clinical Trial will be conducted at the premises of the Company. Clinical Trials and their regulatory mechanisms will be ensured by the respective hospitals acting as Collaborators under this Project. The Collaborators will ensure that proper approvals and disposals of any waste generated is treated as per existing applicable laws.
14.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?		No	The current activities carried out in company premises do not require authorization from Pollution Control Boards. The manufacturing processes will be outsourced to certified facilities having the required authorization	No Clinical Trial will be conducted at the premises of the Company. Clinical Trials and their regulatory mechanisms will be ensured by the respective hospitals acting as Collaborators under this Project. The Collaborators will ensure that proper approvals and disposals of any waste generated is treated as per existing applicable laws.

15.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?		No	No Biomedical waste is generated in the company premises However, The Biomedical waste in the hospital premises where clinical study will be conducted segregates biomedical waste into infectious and non-infectious waste, plastic or non-plastic, recyclable, sharp waste into suitable red, yellow, blue and black containers	The respective hospitals being the Collaborators to this project will ensure proper disposal of any waste generated is done as per existing and applicable laws.
16.	Is the bar code system for the segregated waste in place?		No	No hazardous waste generated in company premises	
17.	Is the biomedical waste being sent to an **authorized** common BMW facility?		No	No biomedical waste generated in company premises	This will be taken care by the respective Hospitals acting as Collaborators in this Project.
18.	Does the grantee have an in-house BMW treatment facility?		No	Reason: No biomedical waste generated in company premises	This will be taken care by the respective Hospitals acting as Collaborators in this Project.
	Is the treatment facility own (individual)?				
	Is the treatment facility a shared facility in an industrial park?		No		
19.	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	No microbial or chemical waste generated in company premises	This will be taken care by the respective Hospitals acting as Collaborators in this Project.
20.	Is the liquid waste checked for active cells before sending to treatment plant?		No	No microbial or chemical waste generated in company premises	This will be taken care by the respective Hospitals acting as Collaborators in this Project.
21.	Are necessary waste pre-treatment equipment in place?		No	No biomedical waste generated in company premises	This will be taken care by the respective Hospitals acting as Collaborators in this Project.
	Do the equipment adhere to prescribed norms by State Pollution Control Board		No		

	(SPCB)?				
22.	Are chlorinated plastic gloves and bags phased out in the grantee?		No	No biomedical waste generated in company premises	This will be taken care by the respective Hospitals acting as Collaborators in this Project.
23.	Are grantee's personnel involved in handling BMW provided with regular training?		No	No biomedical waste generated in company premises	
24.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?		No	No biomedical waste generated in company premises	
25.	Is a daily register for biomedical waste maintained including accident reporting record?		No	No biomedical waste generated in company premises	
26.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?		No	No biomedical waste generated in company premises	
Hazardous Waste (HW)					
27.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		No	None of the in-house activity (including design and development, bench testing, quality assurance, data analysis, assembly of the units, simulation studies, clinical data analysis, software and algorithms, firmware development) has any biomedical or involvement of any hazardous chemical or material. The main kind of waste generated is routine paper waste, or plastic bottles etc which are disposed of as per municipal corporation waste collection system.	In future, if any of the activities need Environmental policies or permissions, it will be done by approaching the concerned authorities and guidelines

28.	Is there trained staff in the facility to identify and handle hazardous waste?		No	Activities carried out in company do not create hazardous waste	
29.	Does the grantee have authorization from SPCB for hazardous waste?		No	Activities carried out in company do not create hazardous waste	
30.	Is there a secure location for storage of HW with proper signage?		No	Activities carried out in company do not create hazardous waste	
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
31.	Is the hazardous being send to an **authorized** disposal facility or user?		No	Activities carried out in company do not create hazardous waste	
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?		No		
32.	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	Activities carried out in company do not create hazardous waste	
E-Waste and Batteries					
33.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		No	All of the equipment in the facility is newly procured and is within usable and serviceable life. Manufacturing generating any e-waste is done at ISO certified facility of partnering vendors with all the procedures and environment policies and pollution board approvals.	As the equipment approach end of life, authorized E-Waste disposal centres will be approached. The list of authorized centres will be obtained from Govt. sources, for eg **http://greene.gov.in/wp-content/uploads/2019/09/2019091881.pdf**
34.	Has the grantee obtained SPCB authorization on e-waste?		No	No e-waste is generated at the company premises	Company will obtain the authorization from SPCB as and when the need arises.
35.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		No	No e-waste is generated at the company premises	Will select an authorized vendor authorized and listed by the Government to channelize any e-waste generated in future.

36.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No	The company is in product development stage and production has not started yet.	Appropriate authorization will be obtained before moving to mass production stage.
37.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	Yes		All of the components selected for the product are RoHS compliant	Will ensure that the products are RoHS compliant in future.
38.	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	All components used are RoHS compliant The product is still in Development/DFM stage and user documentation are being prepared	Product User Documentation will be prepared after DFM. RoHS information about product and constituents will be incorporated.
39.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?		No	No e-waste is generated at the company premises	
40	Does the grantee submit annual reports on e-waste to SPCB?		No	No e-waste is generated at the company premises	
41	Is there accident reporting and records in place?		No	No e-waste is generated at the company premises	
42	Are PPEs available to staff?	Yes		Safety glasses, cut resistance gloves, disposable gloves etc. are available	The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out.
43	Is the grantee involved in manufacture of batteries?		No		
44	Does the grantee generate battery waste?		No	The batteries procured in the early stages of development are within their service life.	As the batteries approach end of life, authorized E-Waste disposal centres will approached for their disposal. The list of authorized centres will be obtained from Govt. sources, for eg http://greene.gov.in/wp-content/uploads/2019/09/2019091881.pdf

45	Does the grantee deposit the battery waste to **registered** recycler/dealer/manufacturer /reconditioner/collection center?		No	The batteries procured in the early stages of development are within their service life.	As the batteries approach end of life, authorized E-Waste disposal centres will approached for their disposal. The list of authorized centres will be obtained from Govt. sources, for eg http://greene.gov.in/wp-content/uploads/2019/09/2019091881.pdf
Others					
46.	Is the lab/room air regularly checked for microbial contamination?	Yes		Office AC filters are regularly serviced for routine maintenance. No direct or indirect microbiology work is done in the office	Periodic checks will be done
47.	Are there any odor control measures in place?	Yes		Office is adequately ventilated. Room-freshener sprays available in the premises Activities performed in the premises do not generate odor or fumes	Periodic cleaning will be done
48.	Are fume hoods and exhausts regularly checked and maintained?		No	No fume hoods required. Portable fume extractors used at soldering station have disposable filters.	Periodic checks will be done and fume extractors will be maintained.
49.	Does the grantee use DG set > 15 KVA?		No		No DG set use is planned for this project
	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		
50.	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		Solid and Biodegradable waste are segregated at source Authorized waste picker by municipal corporation collects waste from the total building where office situated	It will be ensured that segregation rules are followed. This will be maintained and monitored by an authorized Committee.
51.	Is wastewater treated separately by the grantee?		No	No chemical, culture or coolant waste generated at	Will provision such a facility if required for the

	(Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)			the premises	project.
	Are there sludge management and cut off drains in place for wastewater?		No	No liquid waste is generated through the current activities	
52.	Are necessary provisions for noise cancellation in place?		No	No heavy equipment in the facility. All equipment and hand tools operate within the acceptable noise limits	Will keep a check on the noise generated and cap them with proper cancellation provisions.
53.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No		
54.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		The building which houses the office is accessible by roads on two sides and an alleyway broad enough for cars on the third side.	Will ensure cleared for fire safety including vehicle routes throughout 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