Environmental Health Risk Management Plan (EHRMP)

Datt Mediproducts Pvt. Ltd.

Proposal entitled: A study for safety and efficacy of VELGRAFT containing Human Bone marrow derived Mesenchymal Stem Cell and Mesenchymal stem cell differentiated adipocytes as a skin substitute on wounds of Diabetic Foot Ulcers

1. Institutional Arrangements

i) Brief description of the proposed activity:
Grantee has Class 1000 and 10000 clean room facility for producing cell based product for advance wound management. Clean room has been validated and initial batches of products have been produced for stability studies and preclinical studies. The same facility has been audited by CDSCO which has given the clearance for production of preclinical batches. Grantee has already filled the application for clinical trial approval in CDSCO and waiting for earliest approval.

ii) List of environments related regulatory clearances required for the activity.
Grantee has been already got the NOC and all the necessary approvals from state pollution control board, CPCSEA, Biomedical waste management. Grantee has also followed all the regulatory norms and modified and implement the system as required. Grantee has DSIR recognised centre and also has own stem cell committee and institutional animal ethics committee. Grantee is a ISO 9001-2008 certified company and it has various approvals like CE certification for class 1 and class 2 products, US FDA approvals for class 1 products. Grantee has also successfully defended SODEX audit from European authorities.

		Yes	No	Details	Proposed Plan
Institutional Arrangement					
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		We have a trained full time staff to address Environment Health and Safety related issues. The designated staff regularly provides training to other staff to strictly follow the SOP as per government norms.	The trained EHS staff shall be appointed for the proposed project and he will comply with the norms and requirements of the Pollution Control Committee.
2.	Does the EHS staff handle the following?			Staff has been trained and provide regular training to other staff to strictly follow the SOP.	The concerned staff will be trained as per the Environment Health and Safety (EHS) Rules.
	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	Yes			

	Innovate in India Project				
3.	Is there a reporting structure in place regarding EHS issues?	Yes		Proper record register has been available at HR department.	Review of the register with any and all the updates will be done in the register maintained by the HR Department.
4.	Are regular EHS trainings provided to staff?	Yes		We have a designated staff to provide such kind of trainings on regular basis. Frequency: once in a 6 month or as required	This will be regularly followed by ensuring adherence to the requirements
General Occupational Health and Safety					
5.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		All the desired SOP has been already posted in each department and person has been authorised in each department for concerned activity.	Display of Procedures at prominent places in the site will be ensured.
6.	Are the following in place?			Designated place has been mentioned and marked for all the things as per ISO norms.	Proper equipment will be in place and stock will be maintained as per the Institute's guidelines for Environment Health and Safety (EHS).
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
7.	Are proper signage and storage system in place?			All procedural SOPs are available for the desired requirements. There is a proper display of emergency contact numbers, signage across the facility, storage system and fire escape plan in every department.	These would be regularly updated/ replaced while carrying out maintenance.
	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.)	Yes			
	Are flammable materials appropriately	Yes			

	stored to prevent fire hazards?				
8.	Are smoke detectors, fire alarms, automatic safety/ shutoff systems, overflow preventors, etc. in place and regularly maintained?	Yes		Manufacturing plant has smoke detectors, fire alarms, auto power shut off has been available.	These would be regularly maintained.
9.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/ vectors etc. in place?	Yes		SOP has been available for the all the activities and concerned staff has been trained.	This would be reviewed periodically.
10.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Regular mock drills are conducted for safety measures by Engineering Staff, QA Staff, QC staff HR department and each department representative. Frequency(type wise): Mock drills are conducted jointly at 6 months interval	This will be followed as per the schedule prepared by the Engineering department which will be monitored by an appointed officer.
11.	Are staff provided with OHS training?	Yes		OHS training has been provided by WHO as per norms and trained staff has been given training to other staff in factory premises. A SOP has been available for this and regular yearly audit has been done.	Training includes , manual training materials, which shall be updated and reviewed periodically.
Biomedical Waste (BMW)					
12.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		We have already signed an agreement with government approved vendor and renewed it yearly on contract basis. The authorized personnel collects the biomedical waste from our site on daily basis or as per requirement. Provide a list of biomedical waste produced in the facility: **Animal waste** Experimental animal carcasses, body parts, organs, tissues, including the waste	Outsourced Organisation Biotic waste management Limited, services will be responsible to treat the BMW adhering to Bio-Medical Waste Management Rules, 2016.

				generated from animals used in experiments or animal houses. **Solid Waste:** Items contaminated with blood, body fluids like dressings, cotton swabs and bags containing residual or discarded blood and blood components. **Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps. **Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.		
13.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Training has been given to all the new staff before handling the material.		This on-going process will be followed throughout the Project duration.
14.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		We have got the approval from state pollution control board for complete plant activity.		Timely Certificate renewals will be done.
15.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yellow	Yes	All the generated biomedical waste will be collected as per biomedical waste management plan in
				Red	Yes	

				White	Yes	colour coded polybags and SOP will be placed in each collection and generation point.
				Blue	Yes	
16.	Is the bar code system for the segregated waste in place?	Yes		Bar code system is available at factory site and provided by authorised vendor.		Bar coding will be done as per BMW management act amendment 2018 and will be regularly updated as per policy guidelines.
17.	Is the biomedical waste being sent to an **authorized** common BMW facility?	Yes		Biomedical waste is collected by authorized vendor. Name and address of CBMWF: **Biotic waste Limited, Plot 725, Pace City – II, Sector 37 Industrial Area, Gurugram, Haryana – 122004** Distance from facility: **40 km** Frequency and Mode of transport: **Daily through their vehicle** Who transports: **Biotic Waste Limited**		Renewal will be done as per timelines.
18.	Does the grantee have an in-house BMW treatment facility?		No	Reason: Biomedical waste is collected by authorized vendor. Authorization: Biotic Waste limited Distance of nearest CBWM from facility: 40 km Types of treatment: Animal tissue waste and solid waste		Will be routinely done as per the BMW Rules 2018. This practice will be continued throughout the project
	Is the treatment facility own (individual)?		No			
	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?	Yes		All the biomedical waste has been treated first before sending the vendor for further treatment as per biomedical waste management regulations 2016.	Compliance calendar shall be maintained.
20.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		We pre-treat the liquid waste before mixing with other water waste using non-chlorinated chemicals.	Will follow this practice on route basis before discarding such liquid waste throughout the project.
21.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): Autoclave and shredders Details of waste pre-treatment: Sterilization and effluent treatment plant has been available at factory site and regularly checked and approved by state pollution control board.	Regular monitoring shall be done.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
22.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes		We phased out used chlorinated plastic gloves and bags. All such kind of waste is sent to authorized recyclers.	This process shall be adhered and this practise will be maintained.
23.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Training has been given to personal involved BMS collection only and SOP has been placed in designated place. Frequency: Once in a 6 month or as required Trainer: Dr. Mukesh	This will be a regular process during the project.

				Kumar Dr. Siddharth Pandey	
24.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		There is a proper medical examination of personnel involve in waste handling. Frequency of medical examination: Six month examination has done for each staff and vaccination has been done for staff and workers involved in BMW.	Will be routinely followed and done.
25.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Record register has been available at factory gate and concerned department.	This practice would be followed and checked periodically.
26.	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes		Annual report of biomedical waste has been submitted by registered vendor (Biotic waste limited).	All the biomedical waste generated will be discarded on bar code base system. Post this we will receive the monthly statement of material dispatched from our site by SPCB. Accordingly, the Annual report would be submitted within timelines.
Hazardous Waste (HW)					
27.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		ETP sludge and other hazardous waste has been discarded as per state pollution control board norms and we have already got approval from *SPCB* for this. Pollution control certificate has been already provide.	The collection, treatment and disposal of these hazardous waste generated will comply with the Hazardous Waste Rules 2016
28.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes		Separate staff has been assigned for ETP waste and other waste collection and disposal.	This training shall be given to the respective staff specifically appointed to carry out this activity.
29.	Does the grantee have authorization from SPCB for	Yes		SPCB certificate has been already provided at the	Timely renewals will be done and approvals will

	hazardous waste?			time of application submission.	be taken.
30.	Is there a secure location for storage of HW with proper signage?	Yes		All the waste material has been stored in in designated place nearby ETP plant and back side of store department at separate place marked area.	Proper storage of HW with proper visible signage will be ensured.
	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	We have in-house ETP plant to treat the sludge material at our factory site and after that release waste materials.	Will ensure that this facility is maintained and utilized properly.
	Is the disposal facility in house?	Yes			
	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?	Yes		All the records of waste treatment has been maintained by engineering department.	Engineering Department will continue to maintain the register with frequent review and updates.
E-Waste and Batteries					
33.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes		Grantee has very rare e-waste in the form of computers, keyboard etc.	We will contact any authorize e waste collector nearby our factory site.
34.	Has the grantee obtained SPCB authorization on e-waste?	Yes		We have approvals from sate pollution control board for all industrial waste.	Once contract with the e-waste agency is in place, renewal will be done on yearly basis.
35.	Does the grantee channelize the e-waste to **authorized** recycling or disposal facility?		No		We will contact any authorize e waste collector nearby our factory site.
36.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No		Manufacture will follow the guidelines and maintain the records regularly.
37.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No		Grantee is not involved in manufacturing of electrical and electronic equipments and its parts and will continue to do the same throughout the project

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?	Yes		We have provided all the information as per rule.	Will continue to do the same throughout the project.
39.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		We have all the records of stored e-waste.	This record will be updated and maintained regularly.
40	Does the grantee submit annual reports on e-waste to SPCB?		No	Till now grantee has not solid or discarded any e-waste.	Grantee will contact any nearby e-waste collection centre and maintain all the record as per norms.
41	Is there accident reporting and records in place?		No	There is no accident related with electronic materials has been reported so far at our site.	Accident reporting and recording mechanism will be put in place.
42	Are PPEs available to staff?	Yes		PPEs kit has been provided to designated engineering person/staff to handle the waste materials.	All the required materials will be stocked and maintained by the Engineering department and concerned person/department. Will ensure regular provision under the project.
43	Is the grantee involved in manufacture of batteries?		No		
44	Does the grantee generate battery waste?	Yes		The battery has been not generated as e-waste. As we purchase new batteries used in DG sets and other systems in exchange of old used batteries. In this case, no such battery waste is generated at our site.	Management never discard the batteries directly in environment. For this, we follow our system of exchange of old batteries against the purchase of new batteries. It saves the cost and reduces e-waste.
45	Does the grantee deposit the battery waste to **registered** recycler/ dealer/ manufacturer/ reconditioner/	Yes		All the old batteries have been used for exchange of new purchase of batteries.	All the record will be maintained by concerned department.

	collection center?				
Others					
46.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc.)?		No	Our work does not involve use of any kind of radioactive material in any of our production units.	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	Grantee has not generated any radioactive waste. So does not required any storage and disposal system.	
47.	Is the lab/room air regularly checked for microbial contamination?	Yes		Microbial contamination has been regularly checked in clean room by plate settlement method by registered microbiologist.	System is in place and all the record has maintained.
48.	Are there any odor control measures in place?	Yes		We have proper exhaust system in our production units to assure odor control measures. All clean rooms have AHU system and other areas have facility for fresh air availability.	Periodic cleaning and maintenance will be done
49.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Fume hoods and exhaust are weekly checked by maintenance staff.	Records of fume hood maintenance will be available at concerned departments.
50.	Does the grantee use DG set > 15 KVA?	Yes		Approvals for DG set has been provided by state authorities.	Will ensure maintenance of the DG sets used by the Datt Mediproducts Pvt. Ltd..
	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			
51.	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		On regular basis, solid waste like metallic waste and plastic waste like packing materials send to local authority or kabadiwallas or as per municipal waste collection system. (frequency: 2-3 months)	Will be maintained and monitored by concerned Departments.

52.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		ETP plant has been available at factory site and it is approved and inspected by state pollution control board.	Periodic checks will be done and the treatment plant shall be maintained.
	Are there sludge management and cut off drains in place for wastewater?	Yes		ETP plant has been available at factory site and is approved and inspected by state pollution control board.	This Plant will be periodically checked and maintained to ensure its proper functioning
53.	Are necessary provisions for noise cancellation in place?	Yes		Necessary equipment's has been provided to designated staff and workers employed in this area.	Will keep reviewing the noise generated and cap them according to the existing cancellation provisions.
54.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No		
55.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Fire Vehicles movement route has been available at all the premises.	Will ensure that the premise is well equipped with these essential services.

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.