Andhra Pradesh Med Tech Zone

Proposal entitled: Covid MedTech Manufacturing & Development Strategy CoMMAND Strategy

- i) Brief description of the proposed activity: Assembly and Manufacturing of Medical Devices / Equipment
- ii) List of environments related regulatory clearances required for the activity. Pollution Control Board Clearance Certificate and Environmental Clearance Certificate Obtained.

		Yes No	Details	Proposed Plan
	Institu	itional A	Arrangement	
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Y	available. Two Technical Assistants, One Safety Officer, and One Head (QC)	Monitoring in every month will be conducted
2.	Does the EHS staff handle the following? 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	Y Y Y Y Y Y Y Y Y Y	EHS staff handle all the mentioned responsibilities Environment Management Framework compliance for Innovate in India Project is being followed	responsibilities Environment Management Framework compliance for Innovate in India Project will be followed through out the project
3.	Is there a reporting structure in place regarding EHS issues?	Y	Reporting structure in place regarding EHS issues	Will continue to follow and maintain the reporting structure of EHS.
4.	Are regular EHS trainings provided to staff?	Y	Frequency: Once in every quarter	EHS trainings

					programs will be conducted on regular basis.
5.	Institutional Bio-Safety Committee (IBSC)		N		
6.	Ethics Committee (EC)		N		
	General Occu	pati	onal	Health and Safety	
7.	Are there Standard Operating	Y		Standard Operating	SOPs and protocols
	Procedures for accidents,			Procedures are in place	will be maintained for
	hazards, and other emergencies			1	any new activity
	(chemical spills, heat hazards, fire				included in the work
	hazards, radioactive hazards etc.)?				
8.	Are the following in place?	Y		Mentioned equipment's &	Equipment's will be
	Chemical spill kits	Y		systems are in place	checked, monitored,
	Eye wash	Y]	replaced and
	Shower stations	Y		1	maintained well
	First Aid Kit	Y		1	through out the project
	Fire Extinguishers	Y			
	Register of accidents and injuries	Y			
9.	Are proper signage and storage system in place?	Y		All the mentioned Systems are available and in place	Proper equipment will be in place and stock
	Display of Material Safety Data	Y			will be maintained as
-	Sheet (MSDS) where relevant			_	per the guidelines for
	Display of emergency numbers	Y			Environment Health
	and procedures (Person to				and Safety (EHS)
	Contact, Doctor, Ambulance, Fire				enacted by the
	Emergency, Police) displayed in all critical places				legislature.
	Signage across the facility (labs,	Y		1	
	storage, hazardous areas, etc.)				
	Are flammable materials	Y			
	appropriately stored to prevent				
	fire hazards?			1 1	
10.	· · · ·	Y		smoke detectors, fire	smoke detectors, fire
	automatic safety/shutoff systems,			alarms, automatic	alarms, automatic
	overflow preventors, etc. in place and regularly maintained?			safety/shut	safety/shut
	regularly maintained?			off systems are in place and regularly maintained	
11	Are there control measures for VOC	V		•	regularly maintained
11.	Are there control measures for VOC, air emissions, high operating	Y		Control measures for VOC, air emissions, high	
	temperatures, pathogens/vectors etc. in			operating temperatures,	these measures as and
	place?			pathogens/vectors are in	when required.
	pruce.			place	
12.	Are regular mock drills conducted for	Y		Frequency (type wise):	regular mock drills will
	emergency preparedness and safety?	-		Every month	be conducted for

13.	Are staff provided with OHS training?	Y		OHS training provided to staff	emergency preparedness and safety We will provide such training for all staff recruited in the project
	Biome	dical	Wa	ste (BMW)	
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Y		Micro Biological Plates, Cultured Tubes, Left Over Media, Expired Kits.	Any BMW generated will be treated adhering to Bio-Medical Waste Management Rules, 2016.
15.	Is there trained staff to handle biomedical waste in the grantee?	Y		Trained staff available to handle biomedical waste	Regular training and review will be done for the staff involved in this.
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Y		Authorizations obtained	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?	Y		Yellow Red White Blue	This is an ongoing process which will be followed throughout the Project.
	Is the bar code system for the segregated waste in place?	Y			Will ensure a proper system is in place adhering to BMW Act during the Project.
19.	Is the biomedical waste being sent to an authorized common BMW facility?	Y		Name and address of CBMWF: Vashishtha Environ Care Distance from facility: 12 Kms	Biomedical waste will be sent to an authorized common BMW facility throughout the Project.
20.	Does the grantee have an in-house BMW treatment facility? Is the treatment facility own (individual)?		N N	BMW is sent to Authorized vendor.	Will ensure that the contract with the outsourced vendor is renewed within

	Is the treatment facility a shared facility in an industrial park?		N		timelines.
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?	Y		Autoclave	Will be done as per BWM 2016. Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Y			Routine checks will be done.
23.	Are necessary waste pre-treatment equipment in place?	Y		1 1	Regular monitoring shall be done.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Y		Autoclaves (Make Equitron), Shredders	
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Y		and bags phased out	chlorinated plastic gloves and bags will not be utilized in future also
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Y			This will be a regular process during the project.
26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Y			medical examination will be provided to personnel involved in BMW waste handling and they will be provided with relevant immunization like Hepatitis B and Tetanus quaterly
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Y			This register will be maintained for the entire duration of the Project.
28.	Are annual reports on BWM submitted to SPCB as per required form (see Bio- Medical Waste Rules 2016)?	Y			Timely submission will be done as per PCB norms.

	Haza	rdous	s W	aste (HW)	
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?		N	In our activity we do not generate the Hazardous waste	If case any hazardous waste is generated as per rules it will be
30.	Is there trained staff in the facility to identify and handle hazardous waste?		N	In our activity we do not generate the Hazardous waste	followed. As and when required a separate staff will be recruited and trained to treat and handle the hazardous wastes.
31.	Does the grantee have authorization from SPCB for hazardous waste?		N	In our activity we do not generate the Hazardous waste	NecessaryAuthorizationsbe taken if required.
32.	Is there a secure location for storage of HW with proper signage? Are hazardous waste stored for more		N N	In our activity we do not generate the Hazardous waste.	
	than 90 days in the grantee's premises?				
33.	Is the hazardous being send to an authorized disposal facility or user? Is the disposal facility in house? Is the disposal facility		N N	In our activity we do not generate the Hazardous waste	
34.	external/outsourced? Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?		N	In our activity we do not generate the Hazardous waste	
	E-W	'aste a	and	Batteries	
35.	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?		N	In our activity we do not generate the E-Waste and Batteries	
36.	Has the grantee obtained SPCB authorization on e-waste?			In our activity we do not generate the E-Waste and Batteries	Necessary Authorizations will be taken if required.
37.	Does the grantee channelize the e- waste to authorized recycling or disposal facility?			In our activity we do not generate the E-Waste and Batteries	As and when the need arises proper system will be put in place during the project.
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		Ν	In our activity we do not generate the E-Waste and Batteries	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?	N	In our activity we do not generate the E-Waste and Batteries	Will practice this in case 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?	N	In our activity we do not generate the E-Waste and Batteries	Will comply with this requirement as and when required in future during the Project.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	N	In our activity we do not generate the E-Waste and Batteries	
42.	Does the grantee submit annual reports on e-waste to SPCB?	N	In our activity we do not generate the E-Waste and Batteries	
43.	Is there accident reporting and records in place?	N	In our activity we do not generate the E-Waste and Batteries	
44.	Are PPEs available to staff?	N	In our activity we do not generate the E-Waste and Batteries	
45.	Is the grantee involved in manufacture of batteries?	N	In our activity we do not generate the E-Waste and Batteries	
46.	Does the grantee generate battery waste?	N	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.
47.	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditio ner/collection center?		In our activity we do not generate the E-Waste and Batteries	
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and	N	In our activity we do not generate the E-Waste and Batteries	

	ensure collection of old batteries?		
	Community Healt	h ano	d Safety and risk mitigation
49.	Safety Transportation Management System (for transport of hazardous material)	Y	
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Y	
		C	Others
51.	Is the lab/room air regularly checked for microbial contamination?	Y	The will be routinely monitored.
52.	Are there any odor control measures in place?	Y	Periodic cleaning will be done
53.	Are fume hoods and exhausts regularly checked and maintained?	Y	Preventive maintenance plan will be put in place.
54.	Does the grantee use DG set > 15 KVA?	Y	Will ensure maintenance of the DG
	Does the grantee have consent for DG > 15 KVA?	Y	sets used by the Company during the
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?	Y	Project.
55.	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?	Y	Greater VisakhapatnamThis process will be Municipal Corporationcarried on throughout (GVMC) is regularlythe project clearing Dry Waste products
56.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Y	AMTZ have its own This treatment shall be Sewage Treatment Plant, maintained with proper and Water Treatment Plant. checks and balances. after treatment it is being used for Green (Land Scaping)
	Are there sludge management and cut off drains in place for wastewater?	Y	Will ensure that they are maintained throughout to treat the wastewater.
57.	Are necessary provisions for noise cancellation in place?	Y	Necessary equipment's has Will keep reviewing been provided to designated the noise generated and staff and workers employed cap them according to in this area. the existing

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				cancellation provisions.
58.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		N	
59.	Are there any buffers, fire vehicle routes in the grantee's premises?	Y		Will ensure that the premise is well equipped with these essential services.
	COVID Precaution	ns &	Gui	delines Implementation
60.	Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed?		N	COVID waste is not generated in our activity
61.	SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed?	Y		Taking the preventive measures

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.