

**Vcare Biolabs Private Limited**

**Proposal entitled:** "Development and Validation of Protein-L Affinity Resin"

**1. Institutional Arrangements**

<p>(i) <b>Brief description of the proposed activity</b> Protein L is present at the surface of the <i>Pepto streptococcus magnus</i> strains. It is a 76 kDa protein containing five highly homologous, consecutive extracellular immunoglobulin binding domains. These B domains are responsible for the protein interaction with Ig kappa light chains. Protein L will bind to almost all antibody classes. Genetic engineering the Protein L gene into E. coli and expressed the gene with high titer using high cell density fermentation strategies in a soluble form. The soluble form of protein L will be captured by purification strategies without compromising recovery and yields. The purified protein L will be used to conjugate to the resin surface by two steps i) Activation of resin by oxidation ii) conjugation of protein L by reductive amidation. The protein L resin will be further characterized for its binding efficacy, particle size and leachability.</p> <p>(ii) List of environment related regulatory clearances required for the activity.</p> <ul style="list-style-type: none"><li>Consent for establishment &amp; Consent for Operation. No other approvals are required as the facility is located in industrial estate.</li></ul>				
<b>Institutional Arrangement</b>				
Area of Risk	Yes	No	Details	Proposed Plan
1. Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes		Mr. N. Venu We have full time designated staff for EHS	The EHS staff will be responsible for Environment Health and Safety (EHS)
2. Does the EHS staff handle the following?			EHS staff shall handle OHS, waste management, record keeping, required regulatory clearance, training etc	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 Innovate in India Project	Yes			We will comply to Environment Management Framework compliance for Innovate in India Project
3. Is there a reporting structure in place regarding EHS issues?	Yes		EHS in charge shall report to project in charge	Policy will be developed and maintained
4. Are regular EHS trainings provided to staff?	Yes		Frequency: 6 months	Trainings will be conducted
5. Institutional Bio-Safety Committee (IBSC)	Yes		IBSC is in place	

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6.	Ethics Committee (EC)		No	We are not conducting any animal studies	Authorization will be obtained if required
<b>General Occupational Health and Safety</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
7.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes		SOP in place SOP No. QA014 We shall not use any radioactive materials in our lab.	Employees will be trained on the SOP  Display of Procedures at prominent places in the site will be ensured.
8.	Are the following in place?			All the standard	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		procedure are in	
	Eye wash	Yes		place for chemical	
	Shower stations	Yes		spills, eye wash,	
	First Aid Kit	Yes		showers, first aid	
	Fire Extinguishers	Yes		kits, fire	
	Register of accidents and injuries	Yes		extinguishers etc are in place	

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9.	Are proper signage and storage system in place?	Yes		All the signage, storage, MSDS, display of emergency numbers are displayed and all flammable materials appropriately stored to prevent fire hazards.	These would be regularly updated/ replaced while carrying out maintenance.  Display of emergency numbers and procedures will be ensured.
	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 stored to prevent fire hazards?	Yes			
10.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained?		No		We shall install smoke detectors, fire alarms as and when need arises during the Project.
11.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		All the measuring systems are in place	Room temperatures shall be monitored daily, weekly monitoring of facility shall be done for pathogens etc.
12.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): every six months	Mock drills will be conducted
13.	Are staff provided with OHS training?	Yes		Describe: We have SOP for OHS and shall impart training for all of our employees once in 6 months	Training will be provided at every six months interval
<b>Biomedical Waste (BMW)</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
14.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		We are handling E.Coli and yeast cells in our facility. After completion of fermentation process the broth shall be centrifuged and pellet shall be collected. The cell pellet shall be	BMW generated will be treated adhering to Bio-Medical Waste Management Rules, 2016.

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				collected and autoclaved at 121°C for 15 minutes.									
15.	Is there trained staff to handle biomedical waste in the grantee?	Yes		Trained man power is available	Will plan for the training as and when needed during the ongoing Project.								
16.	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes		Yes, State pollution control board	Authorization will be renewed from time to time								
17.	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		<table><tr><td>Yellow</td><td>Yes</td></tr><tr><td>Red</td><td></td></tr><tr><td>White</td><td></td></tr><tr><td>Blue</td><td></td></tr></table>	Yellow	Yes	Red		White		Blue		All the biomedical waste is segregated in Yellow colour bags
Yellow	Yes												
Red													
White													
Blue													
18.	Is the bar code system for the segregated waste in place?		No		We shall request Medicare to supply bar coded bags and implement as soon as possible								

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19.	Is the biomedical waste being sent to an <b>authorized</b> common BMW facility?	Yes	<p>Name and address of CBMWF: Medicare Environmental Management Pvt. Ltd, Sy. No. 619, Isnapur (V), Patancheru (M), Medchal (D)</p> <p>Distance from facility: About 15 Kms</p> <p>Frequency and Mode of transport:  Weekly twice / Road</p> <p>Medicare by there own vehicle</p>	Timely renewal of the vendors contract shall be done. The existing mechanism shall be followed throughout the Project with the authorized common BMW facility.
20.	Does the grantee have an in-house BMW treatment facility?	No	Reason: We shall be generating very low quantities which shall be sent to Medicare	Will ensure that the contract with the outsourced vendor is renewed within timelines.
	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?	Yes	<p>All the procedures are in place</p> <p>Types of treatment: Autoclave at 121°C for 15 minutes</p>	The existing procedures in adherence to the BMW, 2016 Regulations will be followed. Compliance calendar shall be maintained.
22.	Is the liquid waste checked for active cells before sending to treatment plant?	Yes	Procedure is in place to monitor active cells	Routine checks will be done.

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			Once in a month	
23.	Are necessary waste pre-treatment equipment in place?	Yes	List of equipment ( Autoclave for decontamination Details of waste pre-treatment: E.Coli and Yeast cultures  All steps are in place	Regular monitoring shall be done.
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?			
24.	Are chlorinated plastic gloves and bags phased out in the grantee?	Yes	We are not using any chlorinated plastic gloves or bags	
25.	Are grantee's personnel involved in handling BMW provided with regular training?	Yes	Frequency: 6 months Trainer: EHS manager	Training shall be imparted every six months throughout the Project.

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26.	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		Frequency of medical examination: Yearly once and immunization with Tetanus.	Medical examination shall be done once in a year
27.	Is a daily register for biomedical waste maintained including accident reporting record?	Yes		Accident reporting record is in place	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)?	Yes		Shall be submitted at appropriate time	Timely submission will be done as per PCB norms.
<b>Hazardous Waste (HW)</b>					
	<b>Area of Risk</b>	<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
29.	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		If Yes, provide a list of hazardous waste produced in the facility  If No, provide a list of all waste produced in the facility.	The oil generated from DG set which is on rental basis will be handover to vendor. The solid waste / effluent shall be hand overed external agencies
30.	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			Trained staff is available for identify and handling hazardous waste
31.	Does the grantee have authorization from SPCB for hazardous waste?	Yes			Renewal and approvals will be done and taken within specified timelines.
32.	Is there a secure location for storage of HW with proper signage?	Yes		Describe how each item is stored – platforms, distances from critical installations/movement areas, spill collectors, gas escape facility, etc.	Hazardous waste shall be sent to external agencies twice in a week or based on availability
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33.	Is the hazardous being send to an <b>authorized</b> disposal facility or user?	Yes		Name and address of facility:	Timely renewal of contract with the PCB Authorized third party will be done for this purpose.
	Is the disposal facility in house?		No		
	Is the disposal facility external/outsourced?	Yes			
34.	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous	Yes		All the applicable registers are in place	Will be maintained throughout the Project.

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	waste from the grantee to treatment facility?				
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	We are not produce any e-waste	
36.	Has the grantee obtained SPCB authorization on e-waste?		No	No e-waste will be generated	if required we shall initiate and get approval from SPCB.
37.	Does the grantee channelize the e-waste to <b>authorized</b> recycling or disposal facility?		No	No e-waste will be generated and	if required we shall follow this
38.	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?		No		
39.	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?		No	We are not manufacturing any electrical or electronic equipments	Based on the need of the project, the usage of hazardous substances will be reduced
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	We are not manufacturing any electrical or electronic equipments	Yes, at appropriate time if any.
41.	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes			We shall maintain all the records if any
42.	Does the grantee submit annual reports on e-waste to SPCB?		No		We shall submit at appropriate time point
43.	Is there accident reporting and records in place?	Yes			All the records shall be maintained
44.	Are PPEs available to staff?	Yes		All the PPEs are in place	Use of PPE will be ensured by daily monitoring by authorized personnel with appropriate provisions for PPE stock.
45.	Is the grantee involved in manufacture of batteries?		No	We are not manufacturing any	
46.	Does the grantee generate battery waste?	Yes		Couple of	Only one or two



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				batteries / year	batteries will be generated
47.	Does the grantee deposit the battery waste to <b>registered</b> recycler/dealer/manufacturer/reconditioner/collection center?	Yes			We shall resend back to suppliers as buy back options
48.	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		No		We are not manufacturing any batteries in our facility
<b>Community Health and Safety and risk mitigation</b>					
		<b>Yes</b>	<b>No</b>	<b>Details</b>	<b>Proposed Plan</b>
49.	Safety Transportation Management System (for transport Of hazardous material)	Yes		External agencies shall come and pickup the materials	Will follow the same for the project activities along with ensuring the contract with the outsourced agency is renewed on time.
50.	Emergency preparedness and participation of local authorities and potentially affected communities	Yes		System is in place	VCARE will ensure that a designated person is appointed who would be responsible for constituting the emergency preparedness team and liaison with local authorities.

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Other					
	Area of Risk	Yes	No	Details	Proposed Plan
51.	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No	We will not be using any radioactive materials	
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	We will not be using any radio active materials	
	Are radioactive warning signs in place?		No	We will not be using any radio active materials	
52.	Is the lab/room air regularly checked for microbial contamination?	Yes		Once in every month	Periodic checks will be done
53	Are there any odor control measures in place?	Yes		AHUs and exhaust system are in place	Periodic cleaning will be done
54.	Are fume hoods and exhausts regularly checked and maintained?	Yes		Once in every six months	Periodic cleaning of exhausts will be done
55.	Does the grantee use DG set > 15 KVA?	Yes		We have on DG set and all the parameters are monitored	Monitoring will be done and approvals will be taken within prescribed timeline
	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			
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		Describe The solid waste shall be collected and stored in separate area and shall disposed to external agencies	Will follow norm given in SPCB consent along with ensuring the consent is renewed on time.
57.	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		All the waste water generated is collected into an neutralization tank and pH of the waste is adjusted to neutral pH and sent to external agencies	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			Systems in place will be regulated and monitored.

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58.	Are necessary provisions for noise cancellation in place?		No	No noise is generated from our facility	Will keep a check on the noise generated and cap them with proper cancellation provisions.
59.	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	No, our lab is located in industrial area	
60.	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes		Our lab is located in industrial area.	Maintenance as per norms will be ensured.

**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.**