

Environmental Health Risk Management Plan (EHRMP)

Syngene International Limited

Proposal entitled: “Synthesis and demonstration of efficacy of a novel Active Virosome Vaccine for prevention of COVID-19 infections & its Preclinical characterization”

(i) Brief description of the proposed activity

This facility will be used for development and synthesis of vaccines. The facility will be able to handle the products, which will require BSL-2 (biosafety level-2) organisms and related processes. The animal work will be carried out in a dedicated vivarium which is compliant with the guidelines pertaining to using animals for research work. For all animal work approvals will be taken from Institutional Animal Ethics Committee (IAEC). Please note that no active wild type SARS COV2 virus will be used in our facility as do not have BSL-3 facility, so only the attenuated measles virus harboring the COV2 spike protein will be used for these experiments, which of course are very safe to handle.

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

| Syngene International Limited (Biocon park) | | | |
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| Existing Environmental consents | | | |
| 1 | Water & Air consent | No : A-303115 | 30.06.2021 |
| 2 | Hazardous waste authorization | No:309364 | 30.06.2021 |
| 3 | Plastic waste authorization under Brand Owners | No: PCB/WMC/2359/PLS/2017/H753 | 23.11.2021 |
| 4 | Bio medical waste authorizations | KSPCB/RO-Anekal/Addendum-BMW Authorization/Syngene/2019-20/541 | Lifetime validity |

Institutional Arrangement

| Area of Risk | Yes | No | Details | Proposed Plan |
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| 1. Is there a designated full-time staff for Environment Health and Safety (EHS) issues? | Yes | | EHSS team consists of 30 full time staffs to manage EHSS operations. | The full time staff will ensure safety of the personnel and other EHS related risks/issues. |
| 2. Does the EHS staff handle the following? | | | | THE EMS in place will ensure that the management |

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| | Occupational Health and Safety | Yes | | | of environment is done and practiced by the staff effectively in mitigating any environmental and health related issues. |
| | Waste Management | Yes | | | |
| | List of consents and regulatory clearances | Yes | | | |
| | Record keeping of accidents and procedures | Yes | | | |
| | EHS trainings for staff | Yes | | Environmental management system (EMS - ISO 14001:2018) is in place. | |
| | Environment Management Framework compliance for Innovate in India Project | | | | |
| 3. | Is there a reporting structure in place regarding EHS issues? | Yes | | Describe: Incident reporting system available online which can be accessed by all the employees. Incident reporting & investigation S/EHSS/SOP/015 | The incident reporting system will be followed regularly and made accessible to the staff. This will make our work area safe. |
| 4. | Are regular EHS trainings provided to staff? | Yes | | Frequency: Monthly As per in house procedure (S/EHSS/SOP/026 Planning & organizing EHSS training programs) | The in house training programs shall be continued and held regularly for staff awareness. |
| 5. | Institutional Bio-Safety Committee (IBSC) | Yes | | As per DBT guidelines Syngene has IBSC for reviewing biological materials and projects. | IBSC meetings will be continued in the future at regular intervals |
| 6. | Ethics Committee (EC) | Yes | | IRB, ICH-GCP and ICMR guidelines for clinical subject, research projects are followed. | Ethics committee meetings will be continued in the future to monitor the ethics parameters involved in the project. |
| General Occupational Health and Safety | | | | | |
| | Area of Risk | Yes | No | Details | Proposed Plan |

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| 7. | Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? | Yes | | <p>I) Incident reporting & investigation S/EHSS/SOP/015.</p> <p>II) Onsite emergency plan is available which is approved by Directorate of factories, and Emergency response procedure (S/EHSS/SOP/005) is available .</p> <p>III) Lab safety procedure (S/EHSS/SOP/017) is available.</p> | Incident reporting systems and investigations are in place as per the SOP's and are being followed at Syngene regularly. Our trained staff will ensure the incidents don't occur. |
| 8. | Are the following in place? | | | All the emergency gadgets are available at facility and periodic monitoring is carried out as per internal procedure. | The Standard Operating Procedures, which are in place will be useful to mitigate any kind of injury to the staff. These SOP's will be a useful guide while working in the lab. |
| | Chemical spill kits | Yes | | | |
| | Eye wash | Yes | | | |
| | Shower stations | Yes | | | |
| | First Aid Kit | Yes | | | |
| | Fire Extinguishers | Yes | | | |
| | Register of accidents and injuries | Yes | | <p>1. Operation and Maintenance of Emergency Eye washer & Shower S/EHSS/SOP/009</p> <p>2. Operation and Maintenance of Spill control Kit S/EHSS/SOP/006</p> <p>3. Usage and maintenance of First Aid box S/EHSS/SOP/001</p> <p>4. Operation and Maintenance of Fire Extinguishers S/EHSS/SOP/005</p> <p>5. . Incident reporting & investigation S/EHSS/SOP/015</p> | |

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| 9. | Are proper signage and storage system in place? | Yes | | I) Proper signages are in place as per standards. II) All safety data sheets available for all the chemicals in use. We are also using <i>Chemwatch software</i> SDS management. III) Emergency numbers are displayed as per Emergency response procedure (S/EHSS/SOP/005). IV) All the flammable materials are stores in flame proof cabinets as per compatibility. | The proper signage's in place will lead the staff to safer places in any kind of emergency and the MSDS will be used to tackle any kind of chemical hazards. |
| | 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? | Yes | | List: I) Fire Suppression System S/EHS S/SOP/029 II) Operation and Maintenance of Fire Extinguishers /EHSS/SOP/005 III) S/EHSS/SOP-60 Safety and maintenance control of fire hydrant overhead system IV) S/EHSS/SOP-07 Fire alarm service procedure | The SOP's are available to ensure the healthiness of fire protection systems and will be followed throughout the Project. |
| 11. | Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place? | Yes | | List: Engineering controls like fume hood , scrubbers , and bio safety cabinets are in place. Work place | The SOP will be followed. |

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| | | | | monitoring is carried out as per (S/EHSS/SOP/062) INDUSTRIAL HYGIENE MANAGEMENT procedure | |
| 12. | Are regular mock drills conducted for emergency preparedness and safety? | Yes | | Frequency (type wise): Mock drills are conducted every month for the identified scenarios. Emergency Preparedness And Response S/EHSS/SOP/010 | Mock drills will be continued every month to ensure worker/staff safety. |
| 13. | Are staff provided with OHS training? | Yes | | All employees are trained on OHS as per Standard Operating Procedures (S/EHSS/SOP/026) Planning and organization EHSS Trainings. | The staff will be trained regularly to ensure that they are given complete training to handle any accidents/incidents. |
| 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? | Yes | | List of bio medical waste: i) Human Anatomical Waste ii) Animal anatomical waste iii) Expired discarded medicines, . iv) Microbiology Biotechnology and other clinical laboratory waste and etc., | The proposed plan is to dispose any kind of biomedical waste as per the rules. |
| 15. | Is there trained staff to handle biomedical waste in the grantee? | Yes | | Employees handling | Training in handling bio |

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| | | | | bio medical wastes are trained on bio medical waste management as per(S/EHSS/SOP/004 – handling of solid and liquid waste) procedure. | medical waste will be continued further. | | | | | | | | |
| 16. | Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee? | Yes | | Life time bio medical waste authorization in place (KSPCB/RO-Anekal/Addendum-BMW Authorization/Syngene/2019-20/541) | Will keep following the best in class methods for pollution control. We will make sure that the guidelines are followed and continuous monitoring takes place for the same. Timely renewals and proper approvals will be taken. | | | | | | | | |
| 17. | Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers? | Yes | | <table border="1"> <tr> <td>Yellow</td> <td>Yes</td> </tr> <tr> <td>Red</td> <td>Yes</td> </tr> <tr> <td>White</td> <td>Yes</td> </tr> <tr> <td>Blue</td> <td>Yes</td> </tr> </table> | Yellow | Yes | Red | Yes | White | Yes | Blue | Yes | The practice of bio medical waste segregation will be continued. |
| Yellow | Yes | | | | | | | | | | | | |
| Red | Yes | | | | | | | | | | | | |
| White | Yes | | | | | | | | | | | | |
| Blue | Yes | | | | | | | | | | | | |
| 18. | Is the bar code system for the segregated waste in place? | Yes | | Bar code system is followed as per bio medical waste management rules. | The bar coding system as per the biomedical rules will be followed. | | | | | | | | |

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| 19. | Is the biomedical waste being sent to an authorized common BMW facility? | Yes | | <p>Name and address of CBMWF: M/s. Maridi Eco Industries Pvt Ltd No 1/37& 1/38. Gabbadikaval Village 35th Mile stone, Kanakapura Road Bangalore-112.</p> <p>Distance from facility: 30KM</p> <p>Frequency and Mode of transport: Daily basis through dedicated transport vehicle.</p> | The BWM that we generate is sent to SPCB authorized facility and sending the waste will be continued. This will help in mitigating environment and health risk. |
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| | | | Who transports? M/s. Maridi Eco Industries Pvt Ltd | |
| 20. | Does the grantee have an in-house BMW treatment facility? | | No | The BWM that we generate is sent to SPCB authorized facility and sending the waste will be continued. This will help in mitigating environment and health risk. |
| | 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 | Types of treatment: Autoclaves and chemical treatment (10% Hypochlorite solution as per BMW rules 2016) decontamination procedures | The treatment techniques used currently will be followed in the future also. |
| 22. | Is the liquid waste checked for active cells before sending to treatment plant? | Yes | Liquid wastes are decontaminated before sending to treatment plant . (Autoclaves and chemical treatment -10% Hypochlorite solution as per BMW rules 2016) | Decontamination procedures in place will be followed that will ensure safe working environment in our laboratories. |
| 23. | Are necessary waste pre-treatment equipment in place? | Yes | List of equipment (autoclaves, shredders, incinerators, etc.):Autoclaves& Bio kill systems Details of waste pre-treatment:Autoclave method and 10% Hypochlorite solution as | Pre-Treatment will be done by decontamination by our staff regularly. Existing systems will be maintained. |
| | Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)? | Yes | | |

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| | | | | per BMW rules 2016 | |
| 24. | Are chlorinated plastic gloves and bags phased out in the grantee? | Yes | | Non Chlorinated bags are used across the site. | As non-chlorinated bags are used there is no harm to environment and health. |
| 25. | Are grantee's personnel involved in handling BMW provided with regular training? | Yes | | Frequency: Monthly refreshers Trainer:EHSS Officer | Regular training will be given to all the personnel and all the stakeholders will be trained to handle BMW. |
| 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: Annually. As per "Annual/Half Yearly Health Checkups/EHSS/SOP/046" Yes , Immunization are provided to people handling BMW | The health check up will be followed in the future also. |
| 27. | Is a daily register for biomedical waste maintained including accident reporting record? | Yes | | As per Handling Of Liquid and Solid Waste S/EHSS/SOP/004 | SOP for handling of liquid and solid waste will be followed. |
| 28. | Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)? | Yes | | Annual report is submitted to state pollution control board as per prescribed timelines. | The annual report submission will be continued to ensure effective handling of BMW as per the rules and for the prevention of adverse events. |
| 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? | Yes | | List of hazardous waste produced in the facility : Spent solvents,process residue wastes, Process sludge ,spent carbon ,Off spec products, Date expired products, used spent oil, | Will be sending the hazardous wastes to PCB authorized agency. |

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| | | | | spent catalyst. | |
| 30. | Is there trained staff in the facility to identify and handle hazardous waste? | Yes | | Trained staffs are engaged in the activity and all process are handled as per SOPs. | Training in handling hazardous waste will be continued so our staff will be competent enough to handle HW. |
| 31. | Does the grantee have authorization from SPCB for hazardous waste? | Yes | | Hazardous waste Authorization in place valid upto 30.06.2021. | Guidelines will be followed continuously and reports will be submitted to SPCB to maintain the authorization status with timely renewals and authorization. |
| 32. | Is there a secure location for storage of HW with proper signage? | Yes | | Hazardous wastes (Liquid & Solid) are collected in dedicated leak proof containers & segregation done based on compatibility & as per hazardous waste categorization. (Hazardous waste handling rule 2016) and disposed within 90 days of generation. | Storage of hazardous waste in dedicated leak proof containers will be followed. |
| | 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? | Yes | | Name and address of facility: E Nano Incintech (Hazardous waste incineration) Plot No.342/B, 2 nd phase , 2 nd sector , harohalli industrial area, Kanagapura, ramnagara district. | Syngene will continue to monitor the process and quality standards offered by the outsourcing authority. |
| | Is the disposal facility in house? | No | | | |
| | Is the disposal facility external/outsourced? | No | | | |

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| 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? | Yes | - | Manifest system followed as per hazardous waste handling rules 2016. | Register and manifest system will be continuously followed and maintained. |
| 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? | Yes | | Generated E-wastes like Personal computers, Electrical & electronic equipments. | e-waste generated will be managed as per rules. |
| 36. | Has the grantee obtained SPCB authorization on e-waste? | | No | Not applicable since we are not bulk consumers as per e-waste management rule. | |
| 37. | Does the grantee channelize the e-waste to authorized recycling or disposal facility? | Yes | | Name and address of disposal facility/ recycler: E-Parisaraa pvt ltd., 30 – P3, Karnataka Industrial Area Development Board, Dabaspet Industrial Area, Bangalore Rural District, Pin:, Karnataka 562111 | |
| 38. | Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place? | | No | We are not the manufacturer of electrical or electronic equipment. | No proposed plan is required. |
| 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 the manufacturer of electrical or electronic equipment. | No proposed plan is required. |
| 40. | Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to | | No | | |

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| | Reduction in Hazardous Substances in the product user documentation? | | | | |
| 41. | Does the grantee maintain a record of collection, storage, sale and transport of e-waste? | Yes | | Records are maintained | Maintenance of records will be continued. |
| 42. | Does the grantee submit annual reports on e-waste to SPCB? | Yes | | Submitted on annually as per prescribed timelines. | Annual submission as per prescribed timeline will be taken up and continued to SPCB. |
| 43. | Is there accident reporting and records in place? | Yes | | Incident reporting & investigation S/EHSS/SOP/015. | In future also incident reporting and investigation records will be maintained. |
| 44. | Are PPEs available to staff? | Yes | | Existing procedures, process in place | The existing procedures in place will be followed and reviewed from time to time. |
| 45. | Is the grantee involved in manufacture of batteries? | | No | | We don't manufacture batteries nor intend to manufacture. |
| 46. | Does the grantee generate battery waste? | Yes | | Batteries from UPS are returned to suppliers | |
| 47. | Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/re-conditioner/collection center? | Yes | | Name and address of battery waste receiving entity: M/s. Sri ponni industries, No.24, 4th Phase, Bommasandra Industrial Area, Bangalore – 560099. | Any kind of battery waste will be sent to the authorized recycler. |
| 48. | In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries? | Yes | | Handed over to authorized vendor only | Current process will be followed throughout the project. |
| Community Health and Safety and risk mitigation | | | | | |
| | | Yes | No | Details | Proposed Plan |
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| 49. | Safety Transportation Management System (for transport Of hazardous material) | Yes | | Complying to hazardous waste management and transboundary rules 2016 | Compliance to the hazardous waste rules will be followed. |
| 50. | Emergency preparedness and participation of local authorities and potentially affected communities | Yes | | Emergency preparedness in place to mitigate the potential hazardous situations. | The emergency preparedness plan will be implemented properly to avoid any kind of emergencies. |

| Other | | | | | |
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| | Area of Risk | Yes | No | Details | Proposed Plan |
| 51. | Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)? | Yes | | We have AERB registered RSO onsite and specific labs are approved for the use of radioactive materials by the Radiation Safety Division (RSD) at AERB. | |
| | Does the grantee have appropriate radioactive material and waste storage and disposal system in place? | Yes | | Proper storage and disposal systems in place. | |
| | Are radioactive warning signs in place? | Yes | | Appropriate warning signages are provided. | The presence of appropriate warning signages will help the staff to identify and move to a secure place in any kind of emergency. The signages will be properly maintained regularly. |
| 52. | Is the lab/room air regularly checked for microbial contamination? | Yes | | Indoor air quality monitored as per S/EHSS/SOP/062) INDUSTRIAL HYGIENE MANAGEMENT procedure. All labs working with live organisms have fumigation cycles followed periodically. | Continuous evaluation of Lab/room air will be performed in near future also. |
| 53 | Are there any odor control measures in place? | Yes | | Fume hoods, scrubbers are in place. | Cleaning and maintain records |
| 54. | Are fume hoods and exhausts regularly checked and | Yes | | As per preventive maintenance schedule they are regularly | The in place maintenance schedule |

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| | maintained? | | | checked and maintained. | will be used to regularly check and maintain fume hoods and exhausts. |
| 55. | Does the grantee use DG set > 15 KVA? | Yes | | | |
| | 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: all types of wastes are segregated as per the Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016 | Proper waste disposal process will be followed and compliance monitoring will be continued as per the rules of Waste management. |
| 57. | Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.) | Yes | | Types of wastewater: Effluent & Sewage Treatment of wastewater: Treated in ETP (ZLD) & STP maintained by Biocon limited. Chemical management in wastewater treatment plants: chemicals are used as per the characteristic of effluent in the treatment process. | Syngene plans to continue to treat the waste separately as per the current procedures followed. |
| | Are there sludge management and cut off drains in place for wastewater? | Yes | | Effluent collection tank sludge was Sent to TSDF facility for disposal. | Sending sludge to the TSDF for disposal is being done regularly so that no toxic sludge lies in the facility premises. |
| 58. | Are necessary provisions for noise cancellation in place? | Yes | | Describe: Acoustic enclosures provided for all the noise emitting equipments and periodic noise monitoring in place. | Project stakeholders will be provided with Acoustic enclosures and Noise surveys will be done frequently. |

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| 59. | Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises? | | No | | |
| 60. | Are there any buffers, fire vehicle routes in the grantee's premises? | Yes | | Fire tender movement road is available around the building | The available routes will ensure free follow of vehicles in any kind of emergency. |
| COVID Precautions & Guidelines Implementation | | | | | |
| 61 | Guidelines of CPCB/SPCB/GoI for Handling, Treatment, and Disposal of COVID Waste Generated is whether being followed? | Yes | | Guidelines are being followed | |
| 62 | SOP on preventive measures to contain spread of COVID-19 issued by ICMR/GoI from time to time is whether being followed? | Yes | | Preventive measures are being followed | |

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.