

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

Proposal entitled: "Development of potential anti-cancer biotherapeutic bi-specific nanobody"

1. Institutional Arrangements

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| (i) | Brief description of the proposed activity The project is aimed at developing protein therapeutics aimed at treating cancer. This will require molecular biology, biochemistry, molecular biophysics and microbiology-based experiments. The work will be carried out in the lab of the project investigator. | | | | |
| (ii) | List of environment related regulatory clearances required for the activity. No additional environment related regulatory clearances are required for the proposed activity. | | | | |
| Institutional Arrangement | | | | | |
| | Area of Risk | Yes | No | Details | Proposed Plan |
| 1. | Is there a designated full-time staff for Environment Health and Safety (EHS) issues? | | No | There are notified committees looking into various aspects. issues. CoA is the overall incharge for safety and he reports to the Director. | Nil, as there are already laid down guidelines to address various issues related to EHS. |
| 2. | Does the EHS staff handle the following? | | | | |
| | 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 | | All incidents and accidents are reported to the administration for maintaining the record and taking remedial and preventive steps for future. In house training is provided annually. Environment Management Framework compliance for Innovate in India Project will be |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| | | | | | followed. |
| 3. | Is there a reporting structure in place regarding EHS issues? | Yes | | The various committees submit their recommendations as per their sphere of activity for final decision. | The existing system is working satisfactorily and there is no proposal to amend the same at present. |
| 4. | Are regular EHS trainings provided to staff? | Yes | | Frequency: Annually | Training calendars shall be prepared for employees. Training will be provided as and when required to all staff. |
| 5. | Institutional Bio-Safety Committee (IBSC) | Yes | | IBSC available | Regular review meetings will be conducted. |
| 6. | Ethics Committee (EC) | Yes | | EC available | Meetings and reviews will be scheduled and regularly carried as per the GoI guidelines. |
| General Occupational Health and Safety | | | | | |
| | Area of Risk | Yes | No | Details | Proposed Plan |
| 7. | Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)? | Yes | | | SOPs and formats to record any accidents, hazards, and other emergencies will be structured. |
| 8. | Are the following in place? | | | No separate register is maintained however, each accident is recorded in the individual case file. | Register will be maintained for ensuring provisions of such requisites. |
| | Chemical spill kits | Yes | | | |
| | Eye wash | Yes | | | |
| | Shower stations | Yes | | | |
| | First Aid Kit | Yes | | | |
| | Fire Extinguishers | Yes | | | |
| | Register of accidents and injuries | | No | | |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| 9. | Are proper signage and storage system in place? | Yes | | The Emergency safety flyers with all the relevant contact number are displayed in all the working area. | 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.) | Yes | | | |
| | Are flammable materials appropriately stored to prevent fire hazards? | Yes | | All details are printed on a sheet with visible fonts size and placed located at strategic locations for easy accessibility and readability. | |
| 10. | Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventors, etc. in place and regularly maintained? | Yes | | | Facilities will be maintained and upgraded with the activities increased. |
| 11. | Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place? | Yes | | | Preventive measures with all precautions will be put in place as and when required during the project. |
| 12. | Are regular mock drills conducted for emergency preparedness and safety? | Yes | | Frequency (type wise): six monthly | Will ensure that this process will be regularly followed. |
| 13. | Are staff provided with OHS training? | Yes | | Periodic training exercises are carried out. | Will ensure that this process will be regularly followed. |
| Biomedical Waste (BMW) | | | | | |
| | Area of Risk | Yes | No | Details | Proposed Plan |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| 14. | Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee? | Yes | | Small animals, lab waste, microbiological waste etc. | Biomedical waste will be sent to PCB authorized facility. |
| 15. | Is there trained staff to handle biomedical waste in the grantee? | Yes | | Daily | Staff will be trained on biomedical waste policies. |
| 16. | Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee? | Yes | | | Authorizations 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 | | Yellow | The biomedical waste will be segregated at the point of generation and will be stored in suitable containers. |
| | | | | Red | |
| | | | | White | |
| | | | | Blue | |
| 18. | Is the bar code system for the segregated waste in place? | Yes | | System is in place | Bar coding will be regularly updated as per policy guidelines. |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| 19. | Is the biomedical waste being sent to an authorized common BMW facility? | Yes | <p>Name and address of CBMWF: Alliance Envirocare Company Private Limited 1st and 2nd Floor, PLOT NO. 182/9, PHASE I , INDUSTRIAL AREA, CHANDIGARH 160002</p> <p>Distance from facility: About 7 km</p> <p>Frequency and Mode of transport: Daily</p> <p>Who transports: Alliance Enviro care</p> | The vendor's contract shall be renewed on time to ensure this practice is being followed throughout the Project. |
| 20. | Does the grantee have an in-house BMW treatment facility? | | No | Reason: It is outsourced |
| | 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: Autoclaving | Will ensure that this process will be regularly followed. |
| 22. | Is the liquid waste checked for active cells before sending to treatment plant? | | No | |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| 23. | Are necessary waste pre-treatment equipment in place? | Yes | <p>List of equipment (autoclaves, shredders, incinerators, etc.): Several autoclaves are installed in the institute</p> <p>Details of waste pre-treatment: The microbiological waste generated is autoclaved</p> | The autoclave shall be periodically qualified as per the maintenance schedule. |
| | Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)? | Yes | | |
| 24. | Are chlorinated plastic gloves and bags phased out in the grantee? | Yes | We don't use chlorinated plastic gloves | Will ensure that this process will be regularly followed. |
| 25. | Are grantee's personnel involved in handling BMW provided with regular training? | Yes | <p>Frequency: Biannually</p> <p>Trainer: Nodal Officer Biomedical waste (Dr Neeraj Khatri)</p> | The personnel are well trained and regularly handle BMW |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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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? | | No | | We will conduct medical examination and immunization |
| 27. | Is a daily register for biomedical waste maintained including accident reporting record? | Yes | | | This practice would be followed with constant review and updation. |
| 28. | Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)? | Yes | | | Annual reports on BWM will be submitted to SPCB as per the requirement |

Hazardous Waste (HW)

| | Area of Risk | Yes | No | Details | Proposed Plan |
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| 29. | Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee? | | No | Project implementation will not cause Hazardous waste, | If Hazardous waste is generated it will be managed as per Hazardous waste rules 2016 |
| 30. | Is there trained staff in the facility to identify and handle hazardous waste? | Yes | | | This will be regularly practiced. Newly recruited staff shall be trained. |
| 31. | Does the grantee have authorization from SPCB for hazardous waste? | | No | No Hazardous waste is generated in our activity | Authorizations will be obtained if required |
| 32. | Is there a secure location for storage of HW with proper signage? | Yes | | No Hazardous waste is generated in our activity | We will arrange proper storage facilities when required |
| | 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? | | No | No Hazardous waste is | Will continue to dispose of |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| | Is the disposal facility in house? | | No | generated in our activity | the hazardous wastes to authorized disposal facility throughout the Project if generated |
| | Is the disposal facility external/outsourced? | | No | | |
| 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? | | No | No Hazardous waste is generated in our activity | We will maintain the register when required |
| 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 | E waste is not generated in the project | If E waste generated it will be managed as per E – Waste Rules 2016 |
| 36. | Has the grantee obtained SPCB authorization on e-waste? | | No | E waste is not generated in the project | Authorizations will be obtained if required |
| 37. | Does the grantee channelize the e-waste to authorized recycling or disposal facility? | Yes | | E waste is not generated in the project | All the batteries are purchased on buy back basis to ensure recycling and proper disposal |
| 38. | Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place? | | No | E waste is not generated in the project | |
| 39. | Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts? | | No | E waste is not generated in the project | |
| 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 | E waste is not generated in the project | |
| 41. | Does the grantee maintain a record of collection, storage, sale and transport of e-waste? | | No | E waste is not generated in the project | |
| 42. | Does the grantee submit annual reports on e-waste to SPCB? | | No | E waste is not generated in the | |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| | | | | project | |
| 43. | Is there accident reporting and records in place? | Yes | | | |
| 44. | Are PPEs available to staff? | Yes | | | The stock status of PPE will be regularly monitored and procurement will be done in time to avoid any situation of stock out. |
| 45. | Is the grantee involved in manufacture of batteries? | | No | | |
| 46. | Does the grantee generate battery waste? | | No | | |
| 47. | Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center? | Yes | | Name and address of battery waste receiving entity: | All the batteries are purchased on buy back basis to ensure recycling and proper disposal |
| 48. | In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries? | | No | | |
| Community Health and Safety and risk mitigation | | | | | |
| | | Yes | No | Details | Proposed Plan |
| 49. | Safety Transportation Management System (for transport Of hazardous material) | Yes | | There is already procedure in place and the existing institutional hazards are transported in dedicated Biohazard vehicle. Bins used to transport Biohazardous materials will be identified by clearly mentioning 'BIOHAZARD MATERIAL' and send out | Will follow the same for the project activities. |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| | | | | from facility only after decontamination as per SOP | |
| 50. | Emergency preparedness and participation of local authorities and potentially affected communities | Yes | | Security officials are situated at the department entrance and well as there is a central security system. Inside and outside of the facility the emergency contact numbers, like Fire brigade, police, ambulance, Institutional security officers, etc are placed. Periodic mock drills for emergency preparedness are conducted with participation of local administration including police department, hospitals etc. The institutional security officer will be informed in case of any emergency. | The local community health workers and community leaders will be informed about any issues that can affect the community. The Emergency Preparedness plan will be executed as per the SOP in place. |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

| 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 | | P32, Tritium, S35 radioisotopes are used. | The work proposed in the Project will not involve usage of any radioactive material. |
| | Does the grantee have appropriate radioactive material and waste storage and disposal system in place? | Yes | | Describe: We have radioactive pit and disposal system. Periodically radioactive material is disposed as per AERB guidelines | Periodically radioactive material will be disposed off as per AERB guidelines. |
| | Are radioactive warning signs in place? | Yes | | Significant sign boards in place. | Will maintain those boards with proper signs and warnings wherever required. |
| 52. | Is the lab/room air regularly checked for microbial contamination? | Yes | | Air sampling is done as and when required for specific facilities | Register with any and all the updates will be done in the register maintained by the Management. |
| 53. | Are there any odor control measures in place? | Yes | | We have chemical/fume hoods where radioactive material is handled | Periodic checks will be done if required |
| 54. | Are fume hoods and exhausts regularly checked and maintained? | Yes | | | Periodic checks will be done if required |
| 55. | Does the grantee use DG set > 15 KVA? | Yes | | | DG sets will be regularly monitored and maintained as per norms. |
| | 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 | | | Necessary compliance will be taken when required. It will be ensured that segregation rules are followed. This will be maintained and monitored. |

Environmental Health Risk Management Plan (EHRMP)

CSIR-Institute of Microbial Technology

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| 57. | Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.) | | No | | STP is planned to be installed in near future as per the NGT guidelines. Will be implemented when needed |
| | Are there sludge management and cut off drains in place for wastewater? | | No | | Will be implemented when needed |
| 58. | Are necessary provisions for noise cancellation in place? | | No | | Not required as the noise levels are within permissible limits |
| 59. | Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises? | Yes | | Residential colonies Distance from premises: Within 100 m | Local Self Government Body of the region and other government departments shall be involved in such instances. |
| 60. | Are there any buffers, fire vehicle routes in the grantee's premises? | Yes | | Fire vehicle movement routes available | Will ensure proper maintenance of these as per requirements in 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.