

# Environmental Health Risk Management Plan (EHRMP)

## National Chemical Laboratory (NCL)

**Proposal entitled:** "Development of the affordable chromatography resin for preparative and analytical purification of the therapeutic proteins"

### 1. Institutional Arrangements

- (i) Brief description of the proposed activity
- (ii) The proposed project activity will be focused on cloning and expression of Protein A and its immobilization on various resin bead matrix.
- (iii)
- (iv) List of environment related regulatory clearances required for the activity.
- (v) Currently, we have the permission from state pollution control board and we are in process of renewing the permissions for the same.

#### **Institutional Arrangement**

| <b>Area of Risk</b> |   | <b>Yes</b> | <b>No</b> | <b>Details</b>  | <b>Proposed Plan</b>  |
|---------------------|---|------------|-----------|---|---|
| 1.                  | Is there a designated full-time staff for Environment Health and Safety (EHS) issues? |            | No        | The appointment of this person is in progress and will be updated to BIRAC soon.            | The Organization will comply with the norms and requirements of the Pollution Control Board.  |
| 2.                  | Does the EHS staff handle the following?  |            |           | EHS staff handles the mentioned responsibilities  | List of consents and regulatory clearances will be monitored.   |
|                     | Occupational Health and Safety  | Yes        |           |   |   |
|                     | Waste Management  | Yes        |           |   |   |
|                     | List of consents and regulatory clearances  |            | No        |   |   |
|                     | Record keeping of accidents and procedures  | Yes        |           |   |   |
|                     | EHS trainings for staff   | Yes        |           | Any other:  |   |
|                     | Environment Management Framework compliance for Innovate in India Project             | Yes        |           | Environment Management Framework compliance for Innovate in India Project is being followed |   |
| 3.                  | Is there a reporting structure in place regarding EHS issues?                         |            | No        | Describe:   | Reporting structure regarding EHS issues will be implemented. A proper reporting structure will always be ensured during the course of project. |
| 4.                  | Are regular EHS trainings provided to staff?  | Yes        |           | Frequency:  | EHS trainings programs will be conducted on regular basis.  |
| 5.                  | Institutional Bio-Safety Committee (IBSC)   | Yes        |           | Institutional Bio-Safety Committee (IBSC) is in place                                       | Relevant approvals with proper renewals will be   |

# Environmental Health Risk Management Plan (EHRMP)

## National Chemical Laboratory (NCL)

|    |                       |     |  |                                   |  |
|----|-----------------------|-----|--|-----------------------------------|--|
|    |                       |     |  |                                   | taken.   |
| 6. | Ethics Committee (EC) | Yes |  | Ethics Committee (EC) is in place | Renewal of registration will be ensured before the expiry. |

### **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 |    | SOP are displayed in each laboratory         | SOPs and protocols will be maintained for any new activity included in the work. |
| 8. | Are the following in place?  |     |    | Mentioned equipment's & systems are in place | Organization will maintain a proper regulation of these requisites.              |
|    | Chemical spill kits  | Yes |    |  |  |
|    | Eye wash   | Yes |    |  |  |
|    | Shower stations  | Yes |    |  |  |
|    | First Aid Kit  | Yes |    |  |  |
|    | Fire Extinguishers   | Yes |    |  |  |
|    | Register of accidents and injuries   | Yes |    |  |  |

|     |   |     |    |   |  |
|-----|---|-----|----|---|--|
| 9.  | Are proper signage and storage system in place?   | Yes |    | All the mentioned Systems are available and in place      | MSDS Signages and its's storage system will be reviewed frequently   |
|     | Display of Material Safety Data Sheet (MSDS) where relevant   | Yes |    |   | Emergency Contact numbers will be reviewed frequently  |
|     | 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 |    |   | Signages across the facility will be monitored frequently  |
|     | 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 | List: At present there is smoke detector only at laminar. | Will ensure that the other safeguards are maintained as and when needed with proper measures during the Project. |
| 11. | Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?                            |     | No | List:   |  |
| 12. | Are regular mock drills conducted for emergency preparedness and safety?  | Yes |    | Frequency (type wise):                                    | This will be followed as per the schedule prepared by the regulating office.                                     |
| 13. | Are staff provided with OHS training?   | Yes |    | Describe: OHS training provided to staff                  | We will provide this training for all staff  |

# Environmental Health Risk Management Plan (EHRMP)

## National Chemical Laboratory (NCL)

|                               |  |            |           |   |   |
|-------------------------------|--|------------|-----------|---|---|
|                               |  |            |           |   | recruited in the project and include in the annual plan.  |
| <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? |            | No        | <p>If No, provide a list of all waste produced in the facility.</p> <p>List of waste generated in the facility: Cell culture broths, plastic wares like used tips, falcon tubes, cotton swabs, chemical containers etc.</p> | <p>We are working with nonpathogenic microorganism and do not generate the biomedical waste.</p> <p>If Biomedical waste Generated it will managed as per Bio-Medical Waste Management Rules, 2016</p> |
| 15.                           | Is there trained staff to handle biomedical waste in the grantee?  |            | No        |   | We do not generate the biomedical waste.  |
| 16.                           | Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?            |            | No        |   | We do not generate the biomedical waste.  |
| 17.                           | Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?       |            | No        | Yellow  | We do not generate the biomedical waste.  |
|                               |  |            |           | Red   |   |
|                               |  |            |           | White   |   |
|                               |  |            |           | Blue  |   |
| 18.                           | Is the bar code system for the segregated waste in place?  |            | No        |   | We do not generate the biomedical waste.  |

## Environmental Health Risk Management Plan (EHRMP)

|     |  |     |    |   |  |
|-----|--|-----|----|---|--|
| 19. | Is the biomedical waste being sent to an <b>authorized</b> common BMW facility?  |     | No |   | We do not generate the biomedical waste. |
| 20. | Does the grantee have an in-house BMW treatment facility?  |     | No | Reason:   | We do not generate the biomedical waste. |
|     | Is the treatment facility own (individual)?  |     | No | Authorization:  |  |
|     | Is the treatment facility a shared facility in an industrial park?   |     | No | Distance of nearest CBWM from facility:<br><br>Types of treatment:      |  |
| 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:<br><br>Autoclaving                                  | Compliance calendar shall be maintained. |
| 22. | Is the liquid waste checked for active cells before sending to treatment plant?  | Yes |    | liquid waste checked for active cells before sending to treatment plant | Routine checks will be done.             |
| 23. | Are necessary waste pre-treatment equipment in place?  |     | No | List of equipment (autoclaves, shredders, incinerators, etc.):          | We do not generate the biomedical waste. |
|     | Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?   |     | No | Details of waste pre-treatment:   |  |
| 24. | Are chlorinated plastic gloves and bags phased out in the grantee?   |     | No |   | We do not generate the biomedical waste. |

# Environmental Health Risk Management Plan (EHRMP)

## National Chemical Laboratory (NCL)

### **Hazardous Waste (HW)**

|     | Area of Risk  | Yes | No | Details  | Proposed Plan   |
|-----|---|-----|----|--|---|
| 25. | Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee? |     | No | <p>If Yes, provide a list of hazardous waste produced in the facility</p> <p>If No, provide a list of all waste produced in the facility.</p> <p>Cell culture broths, plastic wares like used tips, falcon tubes, cotton swabs, chemical containers etc.</p> | <p>We do not generate the Hazardous waste</p> <p>If Hazardous waste generated it will be managed as Hazardous Waste Rules, 2016</p> |
| 26. | Is there trained staff in the facility to identify and handle hazardous waste?              |     | No |  | We do not generate the Hazardous waste. Will ensure that a proper trained staff is employed as and when needed to handle this.      |
| 27. | Does the grantee have authorization from SPCB for hazardous waste?                          |     | No |  | <p>We do not generate the Hazardous waste</p> <p>If Hazardous waste generated we will obtain authorization.</p>                     |

### **E-Waste and Batteries**

|     | Area of Risk   | Yes | No | Details | Proposed Plan   |
|-----|--|-----|----|---------|---|
| 26. | Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment? |     | No |         | We do not generate the E waste.   |
| 27. | Has the grantee obtained SPCB authorization on e-waste?  |     | No |         | We do not generate the E waste. In case we produce e-waste in future would apply for proper regulatory approvals and authorization. |

## Environmental Health Risk Management Plan (EHRMP)

|     |  |  |   |   |   |
|-----|--|--|---|---|---|
| 28. | Does the grantee channelize the e-waste to <b>authorized</b> recycling or disposal facility?   |  | No                                      | Name and address of disposal facility/<br>recycler:<br><br>Inhouse or outsourced Facility : | We do not generate the E waste.   |
| 38. | Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?  |  | No                                      | Describe:   | We do not generate the E waste  |
| 39. | Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?  |  | NO Since we do not generate the E-waste | We are following this practice  | We do not generate the E waste  |
| 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 do not generate the E waste  |
| 41. | Does the grantee maintain a record of collection, storage, sale and transport of e-waste?  |  | No                                      |   | We do not generate the E waste  |
| 42. | Does the grantee submit annual reports on e-waste to SPCB?   |  | No                                      |   | We do not generate the E waste  |
| 43. | Is there accident reporting and records in place?  |  | No                                      |   | We do not generate the E waste  |
| 44. | Are PPEs available to staff?   |  | No                                      |   | We do not generate the E waste. Will ensure proper PPE is provided with proper stock maintained at the Institute. |
| 45. | Is the grantee involved in manufacture of batteries?   |  | No                                      |   | We do not generate the E waste  |
| 46. | Does the grantee generate battery waste?   |  | No                                      |   | We do not generate the  |

**Environmental Health Risk Management Plan (EHRMP)**

|  |  |            |           |                |  |
|--|--|------------|-----------|----------------|--|
|  | <b><u>National Chemical Laboratory (NCL)</u></b>   |            |           |                | E waste                                |
| <b>Community Health and Safety and risk mitigation</b> |  |            |           |                |  |
|  |  | <b>Yes</b> | <b>No</b> | <b>Details</b> | <b>Proposed Plan</b>                   |
| 47.  | Safety Transportation Management System (for transport Of hazardous material)                      |            | No        |                | We do not work with hazardous material |
| 48.  | Emergency preparedness and participation of local authorities and potentially affected communities |            | No        |                | We do not work with hazardous material |

# Environmental Health Risk Management Plan (EHRMP)

## National Chemical Laboratory (NCL)

| Other |   |     |    |  |   |
|-------|---|-----|----|--|---|
|       | Area of Risk  | Yes | No | Details  | Proposed Plan   |
| 49.   | Is the lab/room air regularly checked for microbial contamination?  |     | No |  | Will conduct regular check- ups to curb this activity.  |
| 50.   | Are there any odor control measures in place?   |     | No |  | Proper odour control measures will be put in place as and when required during the Project.   |
| 51.   | Are fume hoods and exhausts regularly checked and maintained?   | Yes |    | Fume hoods and exhausts regularly checked and maintained   | We do not work with radioactive materials. These fume hoods are for chemicals other than radioactive substances. The existing fume hood will be maintained properly throughout. |
| 52.   | Does the grantee use DG set > 15 KVA?   | Yes |    |  | At present we do not monitor DG sets for emissions.   |
|       | Does the grantee have consent for DG > 15 KVA?  |     | No |  |   |
|       | Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?   |     | No |  |   |
| 53.   | 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? |     | No | Describe<br>At present we are following the solid and plastic waste in compliance to Solid Waste Management given by Pune Municipal Corporation. | At present we are following the solid and plastic waste in compliance to Solid Waste Management given by Pune Municipal Corporation.  |
| 54.   | Is wastewater treated separately by the grantee?<br>(Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)                    |     | No | Types of wastewater:<br><br>Treatment of waste water:<br>None<br><br>Chemical management in wastewater treatment                                 | At present we are following the liquid waste management given by Pune Municipal Corporation.  |



## Environmental Health Risk Management Plan (EHRMP)

### National Chemical Laboratory (NCL)

|     |   |     |    |   |  |
|-----|---|-----|----|---|--|
|     |   |     |    | plants: None  |  |
|     | Are there sludge management and cut off drains in place for wastewater?   |     | No |   | At present there is no sludge management for wastewater.   |
| 55. | Are necessary provisions for noise cancellation in place?   |     | No | Describe: No noise is being generated while carrying on the Project activities. | Will ensure that proper noise cancellation in place in future as and when needed.                            |
| 56. | Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises? |     | No | Describe:<br><br>Distance from premises:  | There any no settlements, water bodies, cultivated land, or any other eco-sensitive areas near our premises. |
| 57. | Are there any buffers, fire vehicle routes in the grantee's premises?   | Yes |    | Fire vehicle routes are available   | Will maintain these facilities throughout 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.**