"Development and Characterization of Golimumab biosimilar clone."

GeNext Genomics Pvt Ltd

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	**IBSC in place, quarterly meeting is arranged and for every new project IBSC approval is required**	**Timely meeting**
EHS Team	**Once in a year training is given to all the employee for EHS by consultant**	**Increase frequency of training**
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	**All the document is stored as GLP compliances, a backup of document is maintained monthly. The SOP Number is EHS_SOP_GNG_V3**	**PMO will have internal audits as well as external audits**
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	**All SOP are revised and authorized by audit team**	**For NBM we will have initial and midterm audit**
General Safety and Storage	**Process defined and SOP maintained**	**We will have audits**

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Not applicable as we are working with cell lines which cannot escape in Air.	Not applicable as we are working with cell lines which cannot escape in Air.	Not applicable as we are working with cell lines which cannot escape in Air.
Water Pollution and Waste water treatment	Untreated effluent will cause ground water contamination.	Ground water contamination will be caused if there is leakage of untreated effluents.	The company has well designed neutralization SOP for waste water to treat the chemical waste as per

			environmental safety norms of India.
Chemical waste	Moderate Risk	Soil and Ground water contamination due to release of untreated chemical waste	The company has well designed neutralization SOP for waste water to treat the chemical waste as per environmental safety norms of India.
Biological Waste	Risk of Escape of recombinant microbes to environment	Escape of recombinant microbes to environment	All biological waste are decontaminated by autoclaving before discharge to ETP. We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes.
Heavy metals	Minimal Risk	Project implementation will not create any adverse heavy metal waste.	No heavy metal containing material is in use
Radiation Waste	Minimal Risk	Project implementation will not create any adverse radiation waste.	No radioactive material is in use
Electronic Waste	Minimal Risk	Project implementation will not create any adverse electronic waste	We work with biological material which do not pose electronic waste.
Hazardous and C&D Waste	Minimal Risk	Project implementation will not create any adverse Hazardous and C&D Waste.	Closed operation in GLP Like facility with proper precaution.

Destruction/alteration of surrounding ecosystem	Untreated effluent will cause Ground water contamination	Untreated effluent will cause Ground water contamination	The company has well designed neutralization SOP for waste water to treat the chemical waste as per environmental safety norms of India.

3. Occupational Health and Safety and **risk mitigation**

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Minimal Risk	We work in ambient temperature of 24ºC in cell culture and protein purification	We work in ambient temperature of 24ºC in cell culture and protein purification
Chemical hazards, including fire and explosions	Moderate Risk	Handling of Hazardous chemical can affect user	Proper GLP training is done for handling of Hazardous chemical
Pathogenic and biological hazards	The project does not involve pathogenic organism however for Recombinant Microbes RCGM approval will be considered	The project does not involve pathogenic organism however for Recombinant Microbes RCGM approval will be considered	The project does not involve pathogenic organism however for Recombinant Microbes RCGM approval will be considered
Radiological hazards	Minimal Risk	Project implementation will not create any adverse Radiological hazards	No radioactive work will be done for the project
Electronic Waste	Minimal Risk	Project implementation will not create	Project implementation will not create any

		any adverse Electronic Waste	adverse Electronic Waste
Hazardous and C&D Waste	Minimal Risk	Project implementation will not create any adverse Hazardous and C&D Waste	Project implementation will not create any adverse Hazardous and C&D Waste.
Noise	Minimal Risk	Project implementation will not create any adverse noise pollution.	Project implementation will not create any adverse noise pollution.
Process safety	Mishandling may lead to accident	There will be Injuries to the user	All necessary action is taken for smooth and safe process. **Process-based audit will be conducted**

4. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Accidental spillage harvest / material contains recombinant microbes (GMOs)	Escape of recombinant microbes to environment	All the work would be processed in closed GLP facility.
Emergency preparedness and participation of local authorities and potentially affected communities	Accidental spillage harvest / material contains recombinant microbes (GMOs) Fire/explosion	Infection to immune compromised people comes in contact of recombinant microbes Casualties	We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes We operate in a closed system GLP/GMP facility. All biological and hazardous wastes are decontaminated by autoclaving before discharge to ETP. We have well established fire fighting system, alarms, emergency

			system. Our employees are gone through compulsory fire frightening training
In case your organization already has **EHS guideline**, please summarise the same. Also, share details of the **EHS Officer/ Contact Person** of the organization. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.**			

Clinical Trial Risk Management Plan (if applicable): Not applicable as scope is clone development.

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.