"Development of biosimilar Aflibercept"
Lupin Limited

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Already instituted and routine IBSC meetings are held to monitor the development work with recombinant cell lines.	IBSC meeting to be continued at routine intervals for regular updation
EHS Team	EHS Manager -1 EHS Sr. Executive-1 EHS officer -1 Occupational Health Centre Factor Medical Officer -1 Nurse in all three shifts Environment staff/ ETP -15 Nos	EHS team provides training on all safety aspects to employees and mock drills are conducted in regular intervals.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	Hazardous waste generation and disposal records will be maintained. Biomedical Waste Generation, collection and disposal record will be maintained. Bio contaminated effluent decontamination record will be maintained. Consent to Operate from Maharashtra state pollution control boards is in place. Organization is a member of hazardous and biomedical waste common hazardous waste transport and disposal facility.	Maintaining records and Submitting monthly and annual returns as follows Monthly: 1) Generation, storage and disposal of hazardous waste :Form-3 2) Effluent quality, Ambient Air, Stack monitoring and Hazarduous waste disposal reports submission to sate pollution control board. Yearly: 1) Form-IV: Annual return under Hazardous waste Rule. 2) Form-II: Annual Return under Biomedical waste Management Rule. Form V: Environment Audit Report for financial year.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	We have well established procedure for the following: 1) Operation of Kill tank 2) Procedure For operation of Effluent treatment Plant	**SoP is in place**

	3) Procedure for operation of Reverse Osmosis plant 4) Procedure for operation of Multiple effect evaporator 5) Procedure for operation of Agitated film Dryer 6) Handling and disposal of hazardous Waste 7) Handling and disposal of Biomedical Waste 8) Procedure for spill response 9) SOP for decontamination & disposal of empty glass bottle. 10) Procedure for sample collection at ETP plant Operation of Vials/Syringes/ampules Crusher machines and disposal of waste mass	
General Safety and Storage	**EHSMS:** Having well established Safety systems based on Lupin EHS Polices work to Permit system, Emergency practise Infrastructure for fire protection and fire alarming devices. Online access for MSDS, SAPEHSM for online accident incident reporting and investigation system. **Storage:** PESO Licenced FO and HSD storage tanks. FLP area for storage of flammable solvent inside the building Flameproof cupboards for storage of flammable solvent in QC area.	Procedures and equipment's are in-place.

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk	Environment air pollution through boiler stacks.	Monthly environment monitoring from MoEF Approved laboratory.
Water Pollution and Waste water treatment	Minimal Risk	Environment water pollution.	Zero liquid Discharge plant and consent to Operate authorised from Maharashtra Pollution control board.
Chemical waste	Minimal Risk	Environment contamination with chemical Waste	Authorisation for Govt. Approved Common Hazardous Waste transport, Storage and Disposal Facility (CHWTSDF)

Biological Waste	Minimal Risk	Environment contamination with Biological Waste	Authorisation for Govt. Approved Common Bio Medical Waste transport, Storage and Disposal Facility (CBMWTSDF). In-house facility like decontamination tank and autoclave for disinfection of effluent and waste respectively.
Heavy metals	Minimal Risk	Project implementation will not create any adverse heavy metal waste	Project implementation will not create any adverse heavy metal waste
Radiation Waste	Minimal Risk	Project implementation will not create any adverse Radiation Waste	Project implementation will not create any adverse Radiation Waste
Electronic Waste	Minimal Risk	Environmental pollution	E – Waste being collected and send to Govt. Authorised recycler and disposal agency.
Hazardous and C&D Waste	Minimal Risk	Environment contamination with Hazardous waste	Authorisation for Govt. Approved Common Hazardous Waste transport, Storage and Disposal Facility (CHWTSDF)
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation will not create any adverse Destruction/alteration of surrounding ecosystem	Project implementation will not create any adverse Destruction/alteration of surrounding ecosystem

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

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Minimal Risk	Burn injuries is a possibility	Personal Protective Equipment (PPE), signage and other Engg. Contrrol Heat resistance hand gloves, face shield and apron used for heat protection, caution sinages display and Engineering controls like insulation of hot surfaces provided.
Chemical hazards, including fire and explosions	Minimal Risk	Property loss, damage is a possibility	Chemical handling training, PPE Engg. Designed booths mitigating the exposure safety. First aid firefighting equipment, Fire Hydrant system, fire alarm and fire detection system & Public address system.
Pathogenic and biological hazards	Minimal Risk	There will be Infection and allergies to the persons handling and	Bio safety cabinets. Training and awareness, PPE, health check-up, immunisation programme etc.

		threat to controlled environment	
Radiological hazards	Minimal Risk	Project implementation doesnot create any adverse radiological waste	Project implementation doesnot create any adverse radiological waste
Electronic Waste	Minimal Risk	Project implementation doesnot create any adverse Electronic Waste	Project implementation doesnot create any adverse Electronic Waste
Hazardous and C&D Waste	Minimal Risk	Project implementation doesnot create any adverse Hazardous and C&D Waste	Project implementation doesnot create any adverse Hazardous and C&D Waste
Noise	Occupational Injuries among personnel.	Damage to ear and sensitive tissues.	Noise survey Acoustic enclosure Audiometry test for employees And PPE.
Process safety	Process activities including any use, storage, manufacturing, handling or the on-site movement of hazardous chemicals	Unsafe practices during process operations	Process safety study, Hazop Study, Risk assessment, Engineering controls Regular monitoring on daily basis for the activities carried out during operation
others			

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)	Accident or damage to vehicle and accidental spillage Improper segregation and packing of waste.	Unauthorised disposal may cause illness to the exposed persons and environment pollution	Govt. Authorised Transporter (CHWTSDF) is only allowed to handle waste
Emergency preparedness and participation of local authorities and potentially affected communities	Fire accident is a possibility	Damage to property and persons. Shut down of operations.	In place On Site Emergency Plan covering all local authorities contacts.
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. **EHS contact person : Mr. Sandip Gorad (Manager-EHS)**			