Production of affordable biopharmaceuticals: Ranibizumab as a case study

Indian Institute of Technology, Delhi

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	We have valid IBSC constitution membership	Periodic biosafety audits are conducted by IBSC as per current biosafety guidelines
EHS Team	Team in place for EHS review to look after all EHS related compliances and activities.	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.	Biowaste generation & disposal records maintained	Maintaining records for biomedical waste segregation and waste disposal. Maintaining records for hazardous waste segregation and waste disposal
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	SOP for handling & usage of laboratory chemicals, Chemical MSDS & spill kits available for handling spillage, Segregated storage for acids & solvents	SOP for handling & usage of laboratory chemicals, Chemical MSDS & spill kits available for handling spillage, Segregated storage for acids & solvents
General Safety and Storage	Emergency exit boards, signages, available of PPEs at place of work, fire extinguishers with status tag, spill containment trays for liquid storage, charge dissipation through grounding etc.	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	Running of diesel generators during power failures	Project implementation will not cause any adverse air pollution
Water Pollution and Waste water treatment	Minimal Risk.	All the laboratory waste is handled by the effluent treatment plant and there is no release of waste water into municipal drainage	IIT Delhi has an efficient sewage treatment and waste water utilization policy.
Chemical waste	Minimal Risk	Chemical waste is disposed as per the biosafety guidelines	Chemical waste is disposed as per the biosafety guidelines
Biological Waste	Minimal Risk	Project implementation will not cause any adverse biological waste.	IBSC approval will be taken and biological waste will be disposed according to BSL-2 guidelines.
Heavy metals	Minimal Risk	Project implementation will not cause any adverse heavy metals use	Project implementation will not cause any adverse heavy metals use
Radiation Waste	Minimal Risk	Project implementation will not cause any adverse radiation waste	Project implementation will not cause any adverse radiation waste.
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation will not cause any adverse destruction/alteration of surrounding ecosystem waste	IBSC approval and GLP practices will be followed.

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Minimal Risk	Heat Hazards	BSL-2 lab practices for occupational safety and Training of Manpower will be followed.
Chemical hazards, including fire and explosions	Minimal Risk	Chemical hazards, including fire and explosions	BSL-2 lab practices for occupational safety and Training of Manpower will be followed.
Pathogenic and biological hazards	Minimal Risk	The project involves handling BSL-2 protein components	BSL-2 lab practices and GLP practices for occupational safety and Training of Manpower will be followed.
Radiological hazards	Minimal Risk	Project implementation aspects will not cause any adverse radiological hazards.	BSL-2 lab practices and GLP practices for occupational safety and Training of Manpower will be followed.
Noise	Minimal Risk	Project implementation aspects will not cause high noise level.	Project implementation aspects will not cause high noise level.
Process safety	Minimal Risk	Engineering and equipment maintenance shall be undertaken as per SOPs.	BSL-2 lab practices and GLP practices for occupational safety and Training of Manpower will be followed.

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)	Minimal Risk	Clinical samples will be transported to laboratories	SOPs is in place and training for clinical sample transportation will be provided.
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal Risk	Localised	Institutional policies and procedures for emergency preparedness

In case your organization already has **EHS guideline**, please summarise the same.
If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion**.**

IIT-Delhi has organized waste collection and disposal procedures. The institutional IBSC is operational for project approvals and inspection. Fire exit signs are placed and regular fire drills and trainings are conducted. Manpower training is part of the management process.

Clinical Trial Risk Management Plan (if applicable) – Not applicable to this 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.