Establishment of National Repository of GMP Cell Lines for Biopharmaceutical Products NRGCBIO at CSIR-Institute of Microbial Technology

CSIR-Institute of Microbial Technology

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Institutional Bio-Safety Committee is in place and working	Institutional Bio-Safety Committee is in place and working
EHS Team	EHS Team is in place and working	EHS Team is in place and working
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	Records related to the below risks (whichever is applicable) is kept at central documentation facility in administration department of the institute.	The validity and availability of the document shall me monitored periodically and proactive action taken to mitigate if there is any forseable risks
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	The GMP facility related SOPs will cover the mitigation steps of these risks	The adherence to SOPs will be ensured by dedicated personal and committee
General Safety and Storage		

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk	Project implementation will not cause any adverse air pollution.	SOP for management of various type of wastes (wherever applicable) will be prepared and implemented. The personal involved in the activities will be trained with the respective SOP and training records will be maintained.
Water Pollution and Waste water treatment	Minimal Risk	Project implementation will not cause any adverse water pollution	
Chemical waste	Minimal Risk	Project implementation will not cause any adverse chemical waste.	
Biological Waste	Minimal Risk	There will be biological waste of blood samples and Viruses	
Heavy metals	Minimal Risk	Project implementation will not cause any adverse heavy metal waste.	

Radiation Waste	Minimal Risk	Project implementation will not cause any adverse radiation waste	
Electronic Waste	Minimal Risk	Project implementation will not cause any adverse Electronic Waste	
Hazardous and C&D Waste	Minimal Risk	Project implementation will not cause any adverse Hazardous and C&D Waste	
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation will not cause any adverse destruction/alteration of surrounding ecosystem waste	

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Minimal risk . The heat hazards is associated with the use of autoclave and steam lines.	Minimal risk . The heat hazards is associated with the use of autoclave and steam lines.	All the piping will be insulated with insulating materials. The heat and cold insulated gloves will be used while unloading the materials from autoclave and -80 freezers, respectively.
Chemical hazards, including fire and explosions	Exposure with chemicals like NaOH, Ammonia, acids and bases etc will pose moderate risk.	Exposure with chemicals like NaOH, Ammonia, acids and bases etc	Periodic trainings for mitigation of various types of hazards will be organized. The chemicals will be dispense in designated fume hoods. Personal Protective Equipments (PPE) kits will be available in the facility at visible places. The fire extinguishers and suppression systems will be in place in the facility. SOP for use of chemicals and toxic reagents (if applicable) are available and will be customized as per GMP facility and implemented.

Pathogenic and biological hazards	Exposure of personals with pathogenic bacteria used in the process	Exposure of personals with pathogenic bacteria used in the process	The cGMP facility will be made as per BSl2 standard. All the operation related to the handling of pathogenic microbes will be performed in Biosafety cabinate with personals having the proper gowning to prevent any contact with body parts. The gown used in during the activities will be single used and autoclaved after operation. The personals working in the facilities will be vaccinated. Periodic health check-up of personals involve in the operation will be conducted. The Biological wastes will be sterilized by autoclaving and discarded as per existing SOP.
Radiological hazards	Minimal Risk	Project implementation aspects will not cause any radiological hazards.	Project implementation aspects will not cause any radiological hazards.
Electronic Waste	Minimal Risk	Project implementation aspects will not cause Electronic Waste.	Project implementation aspects will not cause high Electronic Waste.
Hazardous and C&D Waste	Minimal Risk	Project implementation aspects will not cause Hazardous and C&D Waste.	Project implementation aspects will not cause Hazardous and C&D Waste. .
Noise	Minimal Risk	Project implementation aspects will not cause high noise level.	Project implementation ts will not cause high noise level.

Process safety	Minimal Risk	Engineering and equipment maintenance shall be undertaken as per SOPs.	The entry exit SOP will be followed by all the personals working in GMP facility. Primary and secondary gowning will be implemented for the persons working in the process. Biometric access will be implemented for Entry-exit. As a precautionary measure at a particular time atleast 2 persona should be present in the GMP facility. Facility will be equeped with Unauthorized entry will not be allowed. The chemical and biological wastes will be discarded in designated bins. Cold rooms, -80 and other freezers will be equipped with alarm systems. Personals working in the particular process will be trained with the procedure.

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)	Spilling of Biological Hazards, Improper packaging and sterilization	Minimal	The safe transportation of Biological waste materials will be ensured by SOP. There is already procedure in place and the existing institutional hazards are transported in dedicated Biohazards vehicle. Bins used to transport Bihardous materials will be identified by clearly mentioning 'BIOHAZARD MATERIAL' and send out from facility only after decontamination as per SOP

Emergency preparedness and participation of local authorities and potentially affected communities	Medical and fire emergency	Minimal	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 contant numbers, like Fire brigade, police, ambulance, Institutional security officers, etc will be placed. Periodic mock drills for emergency preparedness will be conducted. SOP will followed for every operation in . The institutional security officer will be informed and in case of any emergency.
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**.**			

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.