Biological and Preclinical Testing Facility for Medical for facility for Medical implants, devices and Drug device combination

Palamur Biosciences Pvt. Ltd.

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	A minimal air pollution risk is identified in this project as it is only a testing service and do not generate any specific gaseous pollutant. However, the use of electricity backup generators indeed cause air pollution. Use of incinerators to dispose animal carcass	This is subject to the quality of electricity supply that is available at our facility from the electricity board. Use of diesel-electric generators will potentially cause air pollution. Use of incinerators will cause some air pollution due to smoke.	Use of diesel-electric generators will be kept at minimum and only when essential. In case of planned power cuts, work may be rescheduled. Since inclinator is not allowed at our state all the carcasses will be disposed through pollution control approved agency.
Water Pollution and Waste water treatment	Standard use of any facility where manpower is used will generate typical levels of water pollution. Additionally, water from autoclaves and water used for cleaning animal holding areas will be a source of waste water.	All the waste water generated from the project are collected and treated separately. Waste water will be collected in the underground cement tanks and allowed to settle the sludges. Clear water will be stored in another tank and chlorinated before using for garden purpose.	Treated waste water will be used for gardening purpose and no potential impact are identified. We will comply with the requisite state regulations for waste water management.
Chemical waste	Solvents used in HPLC instruments for analysis. Chemicals used in OT (eg.	All the chemical waste is collected separately and handed over to approved pollution	Proper collection, segregation and storage of chemical waste for disposed by

	Chloroform, formaldehyde, ethanol etc.).	control agencies for the safe disposal. No hazardous or nuclear waste is generated	approved pollution control agencies
Biological Waste	Animal blood, tissues, bones and carcass post experimentation, animal bodies due to natural/ unnatural death in routine operation of the facility, animal droppings and excreta, contaminated food and drinking water used for animals, animal hospital and OT consumables and medical waste.	All the biological waste is collected separately and handed over to approved pollution control agencies for the safe disposal	All the biological waste is collected separately and handed over to approved pollution control agencies for the safe disposal
Heavy metals	Disposable items used in animal testing such as needles, scalpels, blades etc. No implantable devices will be made of heave metals.	All the sharps and other needles are collected separately and handed over to approved pollution control agencies for the safe disposal. These however do not use heavy metals.	All the sharps and needles are disposed by approved pollution control agencies.
Radiation Waste	Non-ionizing radiation may be used in imaging instruments in the facility.	Project implementation will not create any adverse radiation waste.	Project implementation will not create any adverse radiation waste.
Destruction/alteration of surrounding ecosystem	Minimal Risk	Since Palamur Biosciences Private Limited is already operating from a small remote village on a non-agricultural land in an existing building, no destruction/ alteration of surrounding ecosystem is expected.	Project implementation will not create any adverse destruction/ alteration of surrounding ecosystem

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Use of incinerator	Project implementation will not create any adverse heat hazards	Project implementation will not create any adverse heat hazards
Chemical hazards, including fire and explosions	Organic chemicals to be used in analytical instruments and OT.	Chemical burns to people or animals, interruption or stoppage of on-going study, destruction of records.	All the scientists/ care takers are well trained to use personal protective equipment to protect against chemical hazards and all staff are trained in disaster management plan. Special SOPs are followed for the storage and handling of organic solvents and chemicals and in the event of any fire accident.
Pathogenic and biological hazards	Entry of diseased animal into the facility, spread of disease to animals in facility, introduction of contaminated food/ water for animals, spread of zoonotic diseases from animals to outside of facility.	Quarantine and extermination of all infected animals, leading to financial loss and potential interruption/ stoppage of on-going study.	All the scientists/ care takers are well trained to use personal protective equipment to handle pathogenic and biological hazard. Special SOPs are followed and all staff members are trained. All new animals will be examined for disease-free status, animal health will be checked periodically, food and water quality for animals will be checked, animal waste will be treated appropriately, mechanisms to control disease vectors (such as flies, flees, mosquitos, insects etc.) will be implemented.

Radiological hazards	Minimal Risk	Project implementation will not create any adverse radiological hazards.	Project implementation will not create any adverse radiological hazards
Noise	Beagle dogs barking sound (existing animals).	Since they are in air cooled facility with air-tight rooms, the noise level will be minimal.	The scientists/ care takers will monitor the breeding facility to control the noise level. Personal protective equipment such as ear plugs are given to users.
Process safety	Minimal Risk for product development as it is a test facility. Damage of equipment due to mishandling during use/ analysis remains a bigger risk. Accidental death of animals due to negligence of care takers. Medical injuries to care takers by animals.	Damage of test equipment or medical devices due to negligence may lead to financial loss and loss of time.	Proper training of scientists and care takers in animal welfare practices and use of test equipment.

3. 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. Transport of biological and chemical waste for disposal is the most hazardous part, followed by animal transport during procurement.	All chemical and biological waste are being collected by approved pollution control agencies directly through their vehicles.	All chemical and biological waste are being collected by approved pollution control agencies directly through their vehicles.
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal Risk	Palamur Biosciences is already operating with OHS committee which will provide periodic training and audit the work place. In addition to the above they are also inviting the local	Palamur Biosciences is already operating with OHS committee which will provide periodic training and audit the work place. In addition to the above they are also inviting the local

		authorities for periodic safety training	authorities for periodic safety training

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

Palamur Biosciences facility is already operating with EHS guideline and monitored by special OHS committee which will review all potential hazards arising from our facility.

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.