

"Clone Development for Biosimilar Ramucirumab."

Enzene Biosciences Limited

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	IBSC Committee approved by RCGM for monitoring biosafety at Enzene is in place	Any incident occurs in the facility shall be communicated to IBSC and further intimated to RCGM. Periodic biosafety audits are conducted by IBSC as per current biosafety guidelines
EHS Team	Internal EHS committee to monitor premise and personnel safety is in place.	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.	The waste generated are disposed as per required guidelines through an approved vendor from Pollution control board.	Documents and records are well maintained for compliance of EHS activities
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	We have SOP in place	Sop for waste disposal (No. ENZ/CRA/SOP/008.03).
General Safety and Storage	Procedures and equipment's in place	First aid kits & Spill kits are available. ➤ Displayed warnings and sign boards in all areas.

		<ul style="list-style-type: none"> ➤ Displayed emergency contact numbers in all relevant areas. ➤ Providing fire proof racks for chemical storage. ➤ Providing external training on first aid & fire fighting
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1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Accidental escape of recombinant microbes will create low risk	Escape of Recombinant microbes in air	Closed operation in controlled facility with proper AHU and HEPA filter which is monitored and maintained on regular basis
Water Pollution and Waste water treatment	Untreated effluent will create moderate risk	Ground water contamination	The company has well designed Effluent Treatment Plant (ETP) to treat the chemical waste as per environmental safety norms of India.
Chemical waste	Toxic process chemicals will create moderate risk	Soil and Ground water contamination	The company has well designed Effluent Treatment Plant (ETP) to treat the chemical waste as per environmental safety norms of India.

Biological Waste	Escape of recombinant microbes will create moderate risk	Escape of recombinant microbes to environment	All biological waste are decontaminated by autoclaving before discard. We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes.
Heavy metals	Minimal Risk	Project implementation will not create adverse heavy metal waste	Project implementation will not create adverse heavy metal waste
Radiation Waste	No Risk	No radioactive material will be used during Project implementation hence there will be no adverse Radiation Waste	Project implementation will not create adverse Radiation Waste
Electronic Waste	Minimal Risk	Project implementation will not create adverse electronic Waste	We have vendors identified to dispose this type of waste
Hazardous and C&D Waste	Minimal Risk	Project implementation will not create adverse Hazardous and C&D Waste	Project implementation will not create adverse Hazardous and C&D Waste
Destruction/alteration of surrounding ecosystem	Escape of recombinant microbes	Escape of recombinant microbes to environment	We operate in a closed controlled system facility. Our product is small volume parenteral. We discharge waste generated after proper treatment

			and approved vendor by pollution control board.
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2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Operation of autoclave may create moderate risk	Heat injury to operator	Proper training is provided to the Operator
Chemical hazards, including fire and explosions	Toxic process chemicals may create moderate risk	Health hazards to the persons handling, Soil and Ground water contamination	The chemical waste is disposed as per environmental safety norms of India. We have well established fire fighting system, alarms, emergency system. Our employees are gone through compulsory fire frightening training.
Pathogenic and biological hazards	No pathogenic strains will be handled. Escape of recombinant microbes	Escape of recombinant microbes to environment	All biological waste are decontaminated by autoclaving. We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes (http://thsti.res.in/pdf/IBG.pdf) We have SOP of waste disposal in place (SOP No. ENZ/CRA/SOP/008.03)
Radiological hazards	No risk	Project implementation will not create adverse Radiological Waste	Project implementation will not create adverse Radiological Waste
Electronic Waste	Minimal risk	Project implementation will not create adverse electronic Waste	We have vendors identified to dispose this type of waste

Hazardous and C&D Waste	Minimal risk	Project implementation will not create adverse Hazardous and C&D Waste	Project implementation will not create adverse Hazardous and C&D Waste
Noise	We do not have any instrument which generate high decibels	Project implementation will not create adverse Noise pollution.	Project implementation will not create adverse Noise pollution.
Process safety	Personnel handling biological material and product	Exposure to recombinant strains and In toxication	Personal protective equipments are in use and operation is in closed controlled system

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)	Accidental spillage harvest / material contains recombinant microbes (GMOs) may pose moderate risk.	Escape of recombinant microbes to environment	Any transfer of biological material if required will be done through expertise shipper and under safety norms
Emergency preparedness and participation of local authorities and potentially affected communities	Accidental spillage harvest / material contains recombinant microbes (GMOs) may pose moderate risk.	The strains used in facility are non-pathogenic and Casualties in case of fire	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

	<p>Fire/explosion may pose moderate risk</p>		<p>by autoclaving before discharge to ETP. We have well established firefighting system, alarms, emergency system. Our employees are gone through compulsory fire frightening training</p>
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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.

All the activities related to handling of recombinant strain shall be conducted as per Biosafety Manual of RCGM. The host system and the vector elements are well known and hence do not pose any risk to environmental health.

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Clinical Trial Risk Management Plan (if applicable): This section is not applicable as project scope is only till 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.