Optimization and scale-up of a high throughout refolding process for production of Insulin Glargine from inclusion bodies of Escherichia coli

Vitane Biologics Pvt. Ltd.

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Accidental escape of recombinant microbes	Recombinant microbes in air	Closed operation in GMP/ GLP facility with proper AHU and terminal HEPA filter which is monitored and maintained on regular basis
Water Pollution and Waste water treatment	Untreated effluent	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	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	Escape of recombinant microbes to environment	All biological waste are decontaminated by autoclaving before discharge to ETP. We follow the

			safety guideline of DBT / RCGM in dealing with recombinant microbes.
Heavy metals	Not applicable	Not applicable	No heavy metal containing material is in use
Radiation Waste	Not applicable	Not applicable	No radioactive material is in use
Destruction/alteration of surrounding ecosystem	Escape of recombinant microbes	Escape of recombinant microbes to environment	We operate in a closed system GLP/GMP facility. Our product is small volume parenteral. We discharge waste generated after proper treatment through our well established effluent treatment plant and do not allow it to go to surrounding environment. So our operation does not destroy or alter the surrounding ecosystem
others	Not applicable	Not applicable	Not applicable

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Operation of boiler	Heat injury to operator	We have trained boiler operator
Chemical hazards, including fire and explosions	Toxic process chemicals	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.

			We have well established fire fighting system, alarms, emergency system. Our employees are gone through compulsory fire frightening training
Pathogenic and biological hazards	Escape of recombinant microbes	Escape of recombinant microbes to environment	All biological waste are decontaminated by autoclaving before discharge to ETP. We follow the safety guideline of DBT / RCGM in dealing with recombinant microbes.
Radiological hazards	Not applicable	Not applicable	No radioactive chemicals are in use
Noise	Not applicable	Not applicable	Not applicable
Process safety	Personnel handling high concentration product	In toxication	Personal protective equipments are in use and operation is in closed system
others	Not applicable	Not applicable	Not applicable

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)	Escape of recombinant microbes to environment	Our product is small volume parenteral. We discharge waste generated after proper treatment through our well established effluent treatment plant and do not allow it to go to surrounding environment. So our operation does not destroy or alter the surrounding ecosystem. Cultures of GMOs are to be held in closed system, which is designed to reduce any chance of escape. However in an emergency or spillage, the culture/spillage/glass wares shall be taken to decontamination autoclave(Autoclave at 121°C for 30 minutes). The waste materials shall be collected into the biohazardous bags and secured by properly closing their mouth with a string. The polybags shall be labeled properly with non-washable ink giving details of the

			biological waste generated with date. These bags shall be sealed and sent for incineration in case of solid and soft waste otherwise the materials are disposed off in drainage in case of liquid waste. Lab ware that has come in contact with the aforementioned waste items/materials (e.g. contaminated plastic pipettes, pipette tips, petri dishes, centrifuge tubes, eppendorf tubes, disposable gloves, and wipes) shall be disinfected by dipping in 0.5% sodium hypochlorite placed in sodium hypochlorite containers at respective laboratories and then transfer to the red plastic bags. For disposal of biohazardous waste above bin lined with red color plastic bags shall be used. The lid must be kept on the container whenever waste is not being actively added to the bag. All well packed biohazardous waste and non infected

			waste shall be handed over to M/s. Medicare Environmental Management Pvt Ltd, Ramky Grandiosa- 13th Floor, Ramky Towers Complex, Gachibowli to incineration in a centralized controlled waste treatment facility Hyderabad-500032
Emergency preparedness and participation of local authorities and potentially affected communities	Accidental spillage harvest / material contains recombinant microbes(GMOs) Fire/explosion	Infection to immune compromised people comes in contact of recombinant microbes Casualties	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 by autoclaving before discharge to ETP. We have well established fire fighting system, alarms, emergency system. Our employees are gone through compulsory fire frightening training
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**.**			