

Production of safe and effective oral cholera vaccine of global GMP standards in India through Industry-Academia partnership to meet India's supply needs

Bharat Immunologicals & Biologicals Corporation Limited (BIBCOL)

Environmental and Health Risk Management Plan

1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Release of Vibrio Cholerae in the environment	Cholera	<ol style="list-style-type: none"> 1. GMP facility. 2. Separate production area. 3. Closed system. 4. BSL 2 facility 5. Decontamination of waste and equipment with chemical method and autoclaving. 6. Decontamination area by fumigation of proper disinfectant
Water Pollution and Waste water treatment	Release of bacteria, fungus and media chemicals in water	Contamination of area , ground water and drains in the plant or surrounding area	<ol style="list-style-type: none"> 1. Proper control and release of seed, culture and media by authorized persons only. 2. Restricted access and recording of entry. 3. Proper decontamination of water, media release. 4. Use of sterile drain and proper treatment of effluent before discharge
Chemical waste	Minimal risk	Non specific Project implementation will not cause any adverse chemical waste.	Procedures are in place to address any spillage etc
Biological Waste	Bacteria, fungus	Health hazard	Proper decontamination before disposal at designated place

Heavy metals	Project implementation will not cause any adverse heavy metals	Project implementation will not cause any adverse heavy metals	If any risk arises, appropriate measures will be taken
Radiation Waste	Project implementation will not cause any adverse radiation waste	Project implementation will not cause any adverse radiation waste	If any risk arises, appropriate measures will be taken
Destruction/alteration of surrounding ecosystem	Project implementation will not cause any adverse destruction/alteration surrounding		If any risk arises, appropriate measures will be taken

2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Autoclave and DHS	Burn due to release of steam or hot air	GMP certified equipment with safety features and proper training to employees
Chemical hazards, including fire and explosions	Fire	Burn, destruction of equipment or facility	Fire control system with fire extinguishers and water hydrant system, alarm system, emergency exit and training,
Pathogenic and biological hazards	Release of bacteria	cholera	Immunization against cholera
Radiological hazards	No risk is associated	Do not anticipate any risk	If any risk arises, appropriate measures will be taken
Noise	Minimal impact	Do not anticipate any risk	Laboratory equipment shall be used for this project, we do not anticipate any risk, if there is any, the protection equipment (PPE) will be used by the workers
Process safety	Release of bacteria	cholera	Immunization against cholera

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)	Seed strain	Outbreak of cholera	Properly closed containers, labelling, warning and minimal frequency of transportation under tight security
Emergency preparedness and participation of local authorities and potentially affected communities	Release of bacteria	Outbreak of cholera	1. Stock of vaccine 2. Mass immunization with the help of local authorities. 3. Information to local authorities about the emergency measures
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.			

BIBCOL has ***Biohazard Policy*** (No. BIB/QA/007). The main parts of the policy are –

1. Guidelines on equipment and operation for different level of bio-safety.
2. Good laboratory technique and procedure.
3. Chemical, fire and electrical safety in laboratory
4. Safety organization and training
5. Safety checklist

The summary of the policy is as under -

The laboratories are designated according to their design features, constructions and containment facilities and the parameters for bio-safety level requirement.

Under Good Laboratory techniques and procedures, clearly defined technique for the safe handling of specimens in the lab including specimen containers, transport to the laboratory, opening of package, use of pipettes and pipetting aids, techniques for avoiding the dispersal of biological materials, technique for use of biological safety cabinets, techniques for the care and use of refrigerators, freezers and cold rooms, contingency plans and emergency procedures are mentioned.

The Policy clearly defines the equipment related hazards and how to eliminate or reduce the hazard, incompatible chemicals, toxic effects of chemicals, chemical spillage, compressed and liquefied gases, fire in the laboratory, electrical hazards and waste hazards.

The safety checklist describes the laboratory premises as its cleaning, any defects in floors, walls and roofs, working space, furniture, pest control program etc. The safety checklist includes storage facilities, sanitation and staff facilities, HVAC and lighting, security and fire

prevention, personnel protection, health and safety of staff, laboratory equipments and disposal of lab waste.