



# RAJYA VOKKALIGARA SANGHA

No.148, "Nadaprabhu Kempegowda Bhavana" Krishnarajendra Road, Visveswarapuram, Bangalore-560 004  
Ph. : 26676818, 26507629, 26611029 Fax : 080-22423996  
email : vokkaligarasangha-1906@hotmail.com

## PROJECT RISK MANAGEMENT PLAN

To comply with DBT, NBM, World Bank & BIRAC's mission to promote innovation and self-sufficiency in the biotechnology sector while striving to reduce any social and environmental risks in its activities **Rajya Vokkaligara Sangha**, Fund Recipients for the proposal entitled "Establishment of Pneumococcal vaccine immunogenicity evaluation centre at CRL- Kempegowda Institute of Medical Sciences, Bangalore" has identified the following risks related to Project, Environment (including occupational health and community) and during conduct of clinical trials (if applicable). Risk mitigation measures are being taken by **Rajya Vokkaligara Sangha** as defined in the following annexures:

- i) **Environmental and Health Risk Management Plan:** Compliance to corresponding legislations, Good practices in research and development methods, including while use of animals will be followed. We have referred to the Environment, Occupational Health and Safety Management Framework (EMF) document while preparing this annexure. Facility-specific occupational health and safety hazards have been identified based on risk assessment using established methodologies. The Community health and safety impacts related to handling and storage of solid, liquid and gaseous substances have been evaluated and accordingly mitigation measures will be implemented during project implementation. Impacts due to significant exposures to workers and potentially to surrounding communities, depending on quantities and types of accidentally released chemicals and biologicals have been thoroughly evaluated and addressed.

Project implementation site:

Central Research Laboratory, Kempegowda Institute of Medical Sciences, Banashankari 2<sup>nd</sup> Stage, Bangalore 560070; Phone: +91-8026712546; Email: crlkimsb@gmail.com



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## Environmental and Health Risk Management Plan

### 1. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Moderate Risk	<p>Volatile organic compounds (VOCs) are expected from filtration systems. Fugitive emissions are expected from centrifuges, other equipment</p> <p>Small combustion source emissions are also expected from engines for power and heat generation</p>	<p>1.Reducing or substituting the use of solvents and other materials which have a high VOC content, and substitution with products that have lower volatilities</p> <p>2. Implementation of VOC leak prevention and control strategies from operating equipment</p> <p>3. Installation of high efficiency particulate air (HEPA) filters in the heating, ventilating and air conditioning (HVAC) systems to control particulate matter emissions internally and externally as well as to prevent indoor cross contamination</p>
Water Pollution and Waste water treatment	Moderate Risk	<p>Waste water is generated from laboratory processes, chemical streams, sterilization and strippers and facility wash water, etc. The typical pollutants, however include BOD, COD, TSS, solvents, organic and inorganic acids</p>	<p>All liquid waste will be treated in effluent treatment plant (ETP)</p>
Chemical waste	Moderate Risk	<p>Chemical synthesis processing generates wastes containing spent solvents, reactants, spent acids, bases, aqueous or solvent liquors, still bottoms, cyanides and metal wastes in liquid or slurry form, as well as filter cakes which may contain inorganic salts, organic by-products and metal complexes.</p>	<p>Hazardous and non-hazardous industrial wastes should be stored, transported, and managed as described in the relevant sections of the General EHS Guidelines</p>

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Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Biological Waste	Moderate Risk	Fermentation processes may generate spent solids, intermediates, residual products and filter cakes containing mycelia, filter media, and small amounts of nutrients	Potentially pathogenic waste from biotechnology manufacturing should be inactivated through sterilization or chemical treatment before final disposal.
Heavy metals	Minimal Risk	Project implementation aspects will not create any adverse heavy metals waste.	Hazardous and non-hazardous industrial wastes should be stored, transported, and managed as described in the relevant sections of the General EHS Guidelines
Radiation Waste	Minimal Risk	Project implementation aspects will not create any adverse radiation metals waste	Hazardous and non-hazardous industrial wastes should be stored, transported, and managed as described in the relevant sections of the General EHS Guidelines. As indicated in the General EHS Guidelines, the application of these management practices should be documented in a written Hazardous Materials Management Plan
Destruction/alteration of surrounding ecosystem	Minimal Risk	The specific activities could involve handling, storage, transport, and use of organisms and could cause threats to biological diversity due to the controlled or uncontrolled release of the organisms into the environment.	Avoiding or minimizing harm to biodiversity in compliance with applicable legal requirements;

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## 2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Moderate Risk	Heat hazards are expected, when large volumes of pressurized steam and hot water is used operations. This could cause burns due to exposure to steam or direct contact with hot surfaces as well as heat exhaustion.	Measures such as insulation of steam and thermal fluid pipelines, aligning them away from areas of worker access and screening of high temperature areas, etc. shall be implemented to avoid heat hazards
Chemical hazards, including fire and explosions	Moderate risk	The risk of occupational exposure to chemicals in can occur due to inhalation of VOCs from extraction activities; and from fugitive emissions for centrifuges, valves, and manifold stations. Additional sources of inhalation exposures include extraction operations and sterilization activities. Fire and explosion hazards may arise during laboratory activities involving inflammable substances, hazardous materials, etc	To avoid such hazards, preventive measures such as workers training, use of personal protective equipment (PPE), and toxic gas detection systems with alarms, etc. shall be implemented. Fire explosions should be controlled through process safety engineering and controls.
Pathogenic and biological hazards	Minimal Risk	Exposure to pathogens may occur during isolation and growth of micro-organisms in Laboratory	It will be managed to prevent and control worker exposures, according to standard regulatory protocols.
Radiological hazards	Minimal Risk	Radiological hazards may occur if radiological materials are used in product development chain	It will be managed to prevent and control worker exposures, according to standard regulatory protocols.
Noise	Moderate Risk	High noise levels may are expected in due to compressed air, vacuum sources, and ventilation systems, during the biotechnology activities	Specific mitigation and management measures including use of PPEs, shall be adopted to address the issue of high noise levels.

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Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Process safety	Minimal Risk	Engineering and equipment maintenance shall be undertaken as per SOP's	We have process risk assessment and engineering controls.

### 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	Chemical synthesis processing generates wastes.	Hazardous and non-hazardous industrial wastes should be stored, transported, and managed as described in the relevant sections of the General EHS Guidelines. As indicated in the General EHS Guidelines, the application of these management practices should be documented in a written Hazardous Materials Management Plan
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal risk	Localized	Onsite emergency plan, mock drills, communication mechanism to neighbouring centre. Details of the project and information will be shared with appropriate authorities (Pune Municipal Corporation, local community representatives)

In case your organization already has **EHS guideline**, please summarise the same.

Environment, occupational health and safety management framework is being used as reference for implementation of identification, assessment, monitoring, evaluation and compliance to the Occupational Health, Safety and Environmental aspects associated with scientific projects.

Notwithstanding the above other risk (relevant to the project activities) that will be identified in due course shall be addressed as per standard mitigation major monitoring parameters & manner of records keeping shall be accordance to the recommendation of the project monitoring committee on subject experts engaged by BIRAC.

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