

## Live attenuated Tetravalent Dengue Vaccine Development

### Indian Immunologicals Limited

#### Environmental and Health Risk Management Plan

##### 1. Environmental Impact and risk mitigation

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Air Pollution	The proposed facilities are already designed and equipped for handling air pollution for the additional activity	Nil	Continuous monitoring of air quality and other systems in place.
Water Pollution and Waste water treatment	The proposed facilities are already designed and equipped for handling waste water pollution for the additional activity	Nil	Continuous monitoring of waste water quality post treatment and other systems in place.
Chemical waste	Very negligible chemical waste is generated and system in place to treat the chemical waste	Nil	Continuous internal safety audits in place
Biological Waste	The proposed facilities are already designed and equipped for Biological waste (Both liquid and solid) for the additional activity	Nil	Continuous internal safety audits in place

##### 2. Occupational Health and Safety and risk mitigation

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Heat Hazards	Nil	Nil	All the personnel handling pure steam, black steam and uF

			water systems are well trained.
Chemical hazards, including fire and explosions	Nil	Nil	All the employees are well trained as per the specific job requirements. Safety manual in place
Pathogenic and biological hazards	Exposure to the Dengue vaccine strains	Nil. The vaccine strains handled are attenuated and have already gone to clinical trial stage in humans and found to be safe.	All the employees are well trained as per the specific job requirements. Biosafety manual in place
Process safety	Process safety will be established prior freezing the final production process as per regulatory norms	Nil	Will be reviewed by SME's, IBSC members and internal safety officer.

### 3. Community Health and Safety and risk mitigation

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Safety Transportation Management System (for transport of hazardous material)	All procedures in place for transportation of Biological materials as per national/ international regulatory norms	Nil	Procedures in place for accidental spill over of biologicals and chemicals
Emergency preparedness and participation of local authorities and potentially affected communities	No risk anticipated	Nil	However, Onsite emergency preparedness plan in place in case of any emergency situation. Based on the situation system in place for intimating to the local authorities and effected communities

**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.**