**Development of a novel recombinant, low cost, rapidly producible influenza vaccine**

**Mynvax Private Limited**

## Environmental and Health Risk Management Plan

### 1. Environmental Impact and risk mitigation

| Risks | Project Specific Risk | Potential Impact | Mitigation Steps |
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| Air Pollution | Certain experiments involving volatile substances.<br><br>Viruses and other infectious agents that are used in the laboratory may affect personnel | LOW<br><br>MEDIUM. | These experiments are always conduct within a fume hood.<br><br>The BSL1/2 hoods used have appropriate level of containment as required by regulations, including HEPA filters/Viral Burnouts etc |
| Water Pollution and Waste water treatment | The laboratory requires use of clean (RO) water for its activities.<br><br>Various laboratory experiments utilize organic and inorganic acids, enzymes and other chemicals. | LOW | The RO process generates waste water which is drained as grey water into the common drainage system of the Indian Institute of Science.<br><br>After use, these are diluted and drained into a separate tank which is periodically emptied by the Indian Institute of Science's waste management facility/vendor. |
| Chemical waste | Organic and inorganic acids, spent media from cell culture. Polacrylamide gels. Buffers. | LOW | Acids are neutralised and or diluted before disposal to waste treatment plant.<br><br>Spent media from culture will be treated with bleach |

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| | | | before decanting as grey water waste<br>Solid and liquid waste will be treated with bleach and decontaminated by autoclaving |
| Biological Waste | The Company's laboratories are situated within the campus of the Indian Institute of Science Bangalore. The Bio-hazards committee of the Indian Institute of Science and the Institutional Bio-Safety Committee of the Company have reviewed and approved the project. | LOW | All biological waste will be treated/killed/de-activated. The spent media after growth of culture will be treated with bleach before decanting as grey water waste.<br>Solid and liquid waste will be treated with bleach and decontaminated by autoclave.<br>All biological waste material is handled along with IISc's waste handling system. (letter from IISc is attached) |
| Heavy metals | Use of heavy metals is restricted. | LOW because of the very small quantities involved | Use of heavy metals is highly restricted |
| Radiation Waste | There are no radioactive chemicals that are currently being used at the Company | LOW, no radioactive materials currently used. Currently no plans to use during the project. | We do not use radioactive chemicals in the Company. |
| Destruction/alteration of surrounding ecosystem | There is no proposal for construction activity that would destroy or alter the ecosystem in the vicinity of the | LOW | None. |

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| | laboratory of The Company | | |

## 2. Occupational Health and Safety and risk mitigation

| Risks | Project Specific Risk | Potential Impact | Mitigation Steps |
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| Heat Hazards | During the use of autoclave machines and hot air ovens. | MEDIUM | The equipment has inbuilt safety mechanisms to prevent sudden release of pressure (in the case of autoclave). Temperature in the hot air oven is controlled. The laboratory is equipped with fire alarm and fire extinguishers. There is an emergency exit provided to leave the laboratory in the event of heat related incidents. |
| Chemical hazards, including fire and explosions | Chemical hazards including fire and explosions | MEDIUM | The use of concentrated acids is restricted and appropriate safety precautions, such as fume hoods are available for opening and handling these volatile agents.<br>The laboratory is equipped with an emergency exit to leave the premises in the event of fire and explosion in the laboratory.<br>All laboratory personnel wear protective clothing (gloves, masks, safety goggles) while working in the laboratory. The laboratory is equipped |

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| | | | with fire alarm and fire extinguishers. |
| Pathogenic and biological hazards | Spillage of seasonal influenza virus strains and accidental inhalation of these particles. | MEDIUM | Any experiments using pathogenic and biological infectious agents are first submitted to Mynvax's Institutional Bio-Safety Committee as required by the "Rules for Manufacture, Use/Import/ Export & Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, 1989" prescribed by the Department of Biotechnology, Government of India. Approved experiments are handled as per requirement prescribed by the REGULATIONS AND GUIDELINES ON BIOSAFETY OF RECOMBINANT DNA RESEARCH AND BIOCONTAINMENT (2017) issued on 1st April 2018 by the Department of Biotechnology, Ministry of Science and Technology, Government of India.<br><br>Additionally the personnel working in the Company will be protected by annual immunization against human influenza virus. |
| Radiological hazards | Currently the Company is not using any radioactive labelled chemicals. | LOW | |
| Noise | Certain laboratory instruments for instance, instruments | MEDIUM | These instruments are placed in sound proof chambers. The personnel |

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| | for cell lysing (Sonicator) produce elevated noise levels. | | using these instruments are provided with ear-plugs for protection |
| Process safety | Mynvax has a standard operating procedure which is well documented for laboratory practices and safety. All personnel who work at the Company's laboratory have been trained on the Company's laboratory practices. | MEDIUM | All laboratory personnel are subject to an annual medical check-up and are adequately protected by vaccinations against the relevant infectious disease, ie influenza. |

## 3. Community Health and Safety and risk mitigation

| Risks | Project Specific Risk | Potential Impact | Mitigation Steps |
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| Safety Transportation Management System (for transport of hazardous material) | We do not anticipate transport of hazardous materials. At times, we may transport small quantities of infectious seasonal influenza virus strains from our laboratories to third party facilities. | LOW | Prior approvals will be obtained for transport of virus and appropriate safety precaution including packing requirements will be made for such transport. |
| Emergency preparedness and participation of local authorities and potentially affected communities | Fire | HIGH | Fire alarms and smoke detectors are placed in the laboratories. Emergency escape path to the outside of the building is available in the laboratory. Access to Emergency Response services is available<br><br>In case of any spillages, the IBSC will be informed as |

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| | Spillage of infectious seasonal influence virus strains during transport | MEDIUM | per protocol, and remedial measures including decontamination of spillage site by using anti-viral agents will be immediately undertaken. We do not anticipate any adverse impact to either personnel or the environment. The vast majority of strains used will be vaccine strains and/or mouse adapted strains which pose little health hazard to healthy humans. |

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.