

**Establishment of GLP compliant analytical facility at CSIR-IICT to augment biosimilars characterizations in India**

**CSIR-Indian Institute of Chemical Technology (CSIR-IICT)**

**Environmental and Health Risk Management Plan**

**1. Institutional Arrangements**

<b>Requirements</b>	<b>Current Status</b>	<b>Mitigation Steps</b>
Institutional Bio-Safety Committee (IBSC)	Not applicable as the project does not involve in any biological organisms for analytical characterizations	Not applicable as the project does not involve in any biological organisms for analytical characterizations
EHS Team	Team in place for EHS review to look after all EHS related compliances and activities.	EHS team provides training on all safety aspects to employees and mock drills are conducted in regular intervals.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	As per OECD principles and/ NGCMA procedures	The back-up data server will always be maintained for data storage. The waste generated will be disposed off as per the written procedures and policies complying to OECD principles and NGCMA procedures.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	As per OECD principles and/or NGCMA procedures	The SOPs will be prepared to environment compliance with respect to chemical spillage handling and wastage segregation. All safety measure is in place in the institute and safety committee is continuously monitoring the safety aspects of the institute.
General Safety and Storage	Procedures and equipment's are in-place as per institute policies and procedures.	Procedures and equipment's are in-place as per institute policies and procedures.

## 2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk	Running of diesel generators during power failures	Project implementation will not cause any adverse air pollution
Water Pollution and Waste water treatment	Minimal Risk	As the characterizations are at microscale and the samples will be returned to the client after certain retaining period, the impact is very less.	The procedures and policies will be laid down to dispose the solvents and chemicals.
Chemical waste	Solvents use for LC-MS/MS may pose minimal risk	Solvents use for LC-MS/MS may pose minimal risk	The mechanism to dispose chemical waste is already in implementation at the institute.
Biological Waste	Minimal Risk	Project implementation will not cause any adverse biological waste.	The mechanism to award contract to a third party qualified waste disposer to dispose of biological waste is already in implementation at the institute.
Heavy metals	Project implementation will not cause any adverse heavy metal waste.	Project implementation will not cause any adverse heavy metal waste.	The solvents and consumables will be used of mass spectrometric grade and/or analytical grade, hence the heavy metals waste generation is very minimal and the mechanism is already in place to dispose of these along with other chemicals.
Radiation Waste	Minimal Risk	Project implementation will not cause any	Project implementation will not cause any

		adverse radiation waste.	adverse radiation waste
Electronic Waste	Minimal Risk	Project implementation will not cause any adverse electronic waste	All the disposed instruments will be auctioned as per the institute policies and procedures.
Hazardous and C&D Waste	Minimal Risk	Project implementation will not cause any adverse hazardous and C & D waste.	Will be handed over to authorized third party.
Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation will not cause any adverse destruction/alteration of surrounding ecosystem.	Project implementation will not cause any adverse destruction/alteration of surrounding ecosystem

### 3. 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	Power fluctuations Minimal Risk	May damage the instruments Heat Hazards	All the high-end instruments are connected to back-up power systems (UPS) in order to maintain the smooth functions and prevent loss of the data. BSL-2 lab practices for occupational safety and Training of Manpower will be followed.
Chemical hazards, including fire and explosions	Minimal Risk	May affect the laboratory environment	The hazardous chemicals especially organic solvents will be stored in the fire-proof cabins.
Pathogenic and biological hazards	Minimal Risk	Project implementation does not create any adverse pathogenic	Project implementation does not create any adverse pathogenic

		and biological hazards	and biological hazards
Radiological hazards	Minimal Risk	Project implementation does not create any adverse Radiological hazards	Project implementation does not create any adverse Radiological hazards
Electronic Waste	Minimal Risk	Project implementation does not create any adverse electronic waste.	All the electronic waste the auctioned through global tender for their safe disposal.
Hazardous and C&D Waste	Minimal Risk	Project implementation does not create any adverse Hazardous and C&D Waste.	As per the institute policies and procedures
Noise	Minimal Risk	Project implementation does not create any adverse Noise pollution.	The vibration free environment is already in place for high-end analytical equipment's.
Process safety	Minimal Risk	Engineering and equipment maintenance shall be undertaken as per SOPs.	As per the institute policies and procedures. Moreover, GLP practices for occupational safety and Training of Manpower will be followed

#### 4. 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	The mechanism already in place and safety and Swachh Bharat committee under the guidance of Director, CSIR-IICT is looking after it.	The mechanism already in place and safety and Swachh Bharat committee under the guidance of Director, CSIR-IICT is looking after it.
Emergency preparedness and participation of local authorities and potentially affected communities	All safety measures and equipment's are in place at the institute to combat any emergency situation.	Safety and security officer will monitor the impact and take mitigation measures.	All employees are already instructed to immediately reach to the designated open

			places if any accidents arises in the laboratory.
<p>In case your organization already has <b>EHS guideline</b>, please summarise the same. Also, share details of the <b>EHS Officer/ Contact Person</b> of the organization. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.</p>			

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