

An Integrated approach to create globally compliant PDL and cGMP manufacturing facilities for mammalian cell line based recombinant therapeutics

Gennova Biopharmaceuticals Limited

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	<ul style="list-style-type: none"> • In place – meeting 3 - 5 times a year 	IBSC is in Place.
EHS Team	<ul style="list-style-type: none"> • Team of at least 3 Persons with their roles defined <ul style="list-style-type: none"> ○ EHS Manager (Controlling overall EHS function, evaluating client’s proposals) ○ EHS Executive (Environment specialist) ○ EHS Officers (Day-to-day Monitoring of EHS activities) 	<ul style="list-style-type: none"> • Expansion of the exiting EHS team for the project as required will be done.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	<ul style="list-style-type: none"> • List of Reports <ul style="list-style-type: none"> ○ Daily Reports ○ Monthly Reports • Statutory compliance Planer and tracking sheet • Regulatory compliances reports • e-reports 	<ul style="list-style-type: none"> • Documents to be prepared as per GLP requirement.
SOPs related to Environment Compliance e.g. Chemical spillage handling, waste segregation etc.	<ul style="list-style-type: none"> • List of EHS SOP’s in place • Monitoring Records available 	<ul style="list-style-type: none"> • SOP is in place
General Safety and Storage	<ul style="list-style-type: none"> • EHS SOP’s for storage, Handling and Transportation • Use of PPE’s 	EHS policy is in place.

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	<ul style="list-style-type: none"> Emissions from Steam Boiler, D.G. set, Vents from Fume hoods 	<ul style="list-style-type: none"> Low Release of emissions in to the environment 	<ul style="list-style-type: none"> Compliance with pollution control board norms
Water Pollution and Waste water treatment	<ul style="list-style-type: none"> Industrial Effluents Domestic Effluents Effluent treatment plant 	<ul style="list-style-type: none"> Low Contamination of water risks 	<ul style="list-style-type: none"> Effluent treatment plant and recycling of water, Zero liquid discharge plan in accordance with PCB norms
Chemical waste	<ul style="list-style-type: none"> Minimal risk 	<ul style="list-style-type: none"> Project implementation does not cause any adverse chemical waste 	<ul style="list-style-type: none"> Project implementation does not cause any adverse chemical waste
Biological Waste	<ul style="list-style-type: none"> Solid and liquid, Biomedical wastes. Inactivation Heat as well as chemical, Incineration 	<ul style="list-style-type: none"> Low 	<ul style="list-style-type: none"> Contract with Govt. approved agencies for solid waste incineration after proper decontamination
Heavy metals	<ul style="list-style-type: none"> Minimal Risk 	<ul style="list-style-type: none"> Project implementation does not cause any adverse heavy metal waste 	<ul style="list-style-type: none"> Project implementation does not cause any adverse heavy metal waste
Radiation Waste	<ul style="list-style-type: none"> Minimal Risk 	<ul style="list-style-type: none"> Project implementation does not cause any adverse radiation waste 	<ul style="list-style-type: none"> Project implementation does not cause any adverse radiation waste
Electronic Waste	<ul style="list-style-type: none"> E-waste collection and destruction policy 	<ul style="list-style-type: none"> Low 	<ul style="list-style-type: none"> Contract with competent agencies for disposal
Hazardous and C&D Waste	<ul style="list-style-type: none"> Collection and destruction policy in place <ul style="list-style-type: none"> ETP Sludge Discarded & expired drugs Spent oil 	<ul style="list-style-type: none"> Low Spillage leading to soil and water contamination 	<ul style="list-style-type: none"> Maximum usage of non-hazardous construction materials. Timely disposal through

	<ul style="list-style-type: none"> ○ Off specification products ○ Spent solvent 		<p>competent agencies</p> <ul style="list-style-type: none"> ○ Contract with Govt. approved agencies for collection and disposal
Destruction/alteration of surrounding ecosystem	<ul style="list-style-type: none"> ● NA - as the land has been curated and provided by Gujrat Industrial Development Corporation (GIDC). 	<ul style="list-style-type: none"> ● Land has been curated and provided by GIDC 	<ul style="list-style-type: none"> ● Land has been curated and provided by GIDC.
Others			

3. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	<ul style="list-style-type: none"> ● Steam, WFI 	<ul style="list-style-type: none"> ● High 	<ul style="list-style-type: none"> ● Training to users will be conducted ● Use of PPE, Engineering controls
Chemical hazards, including fire and explosions	<ul style="list-style-type: none"> ● Solvents, chemical storage and handling 	<ul style="list-style-type: none"> ● Low ● Accidental spills of chemicals 	<ul style="list-style-type: none"> ● Use of Chemical storage cabinets, fire detectors and extinguisher infrastructure ● MSDS training
Pathogenic and biological hazards	<ul style="list-style-type: none"> ● BSL-1 ● Biological material waste will create minimal risk. 	<ul style="list-style-type: none"> ● Low 	<ul style="list-style-type: none"> ● Use of bio containment cabinets, ● Training to Employees
Radiological hazards	<ul style="list-style-type: none"> ● Project implementation does not cause any radiological hazard 	<ul style="list-style-type: none"> ● NA 	<ul style="list-style-type: none"> ● NA
Electronic Waste	<ul style="list-style-type: none"> ● Electronics (PCBs, CPUs, Monitors, electronic instruments) 	<ul style="list-style-type: none"> ● Low 	<ul style="list-style-type: none"> ● Proper disposal procedure to be followed
Hazardous and C&D Waste	<ul style="list-style-type: none"> ● Construction material such as debris and unused materials 	<ul style="list-style-type: none"> ● Low 	<ul style="list-style-type: none"> ● Proper disposal procedure to be followed
Noise	<ul style="list-style-type: none"> ● Instrument 	<ul style="list-style-type: none"> ● Low 	<ul style="list-style-type: none"> ● Personal protective equipment

			<ul style="list-style-type: none"> • Use of acoustic panels wherever applicable
Process safety	<ul style="list-style-type: none"> • Material Handling 	<ul style="list-style-type: none"> • Low • Human injury • Damage to the facility 	<ul style="list-style-type: none"> • HAZOP Report • Regular inspection and monitoring of equipment.

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)	<ul style="list-style-type: none"> • Construction material • Spent solvents • Disinfected bio-waste 	<ul style="list-style-type: none"> • Low • Solvent spillage 	<ul style="list-style-type: none"> • SOP's, in place • Training to users • Contract with Govt. approved agencies for disposal
Emergency preparedness and participation of local authorities and potentially affected communities	<ul style="list-style-type: none"> • Fire 	<ul style="list-style-type: none"> • High • Human health and environment 	<ul style="list-style-type: none"> • Regular Fire and safety evacuation drill • Emergency alarm system, exits signs and functional exit doors • NOC from fire department • SOP's and training

In case your organization already has **EHS guideline**, please summarise the same. Also, share details of the **EHS Officer/ Contact Person** of the organization. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.

ENVIRONMENT, HEALTH AND SAFETY POLICY

We at Gennova Biopharmaceuticals Limited committed to:

- Provide Safe and Healthy workplace for our employees and demonstrate world class leadership in Environment, Health and Safety (EHS) Management.

We recognize:

- Health and Safety in workplace are fundamental and ethical values that are necessary requirement to be taken into account in company's management.

To achieve this Gennova will:

- Comply with all applicable statutory and other requirements of EHS and shall review the same at regular intervals.
- Strive to achieve continual improvement in EHS performance where practicable by setting achievable objectives and targets.
- Provide proactive and effective Occupational Health and Hygiene programs to avoid ill Health.
- Investigate all incidents, even of near miss or minor nature and implement the recommendations to avoid injury to the employees.

- Take full cognizance of EHS considerations in project planning and decision making by conducting Safety Evaluations, Safety Audits and Risk Assessment.
- Develop and maintain appropriate emergency response procedure and contingency plans.
- Assess and seek to minimize the impact of business activities on the Environment and communities in which its operations are located.
- Prevent pollution by eliminating or reducing as far as practicable all emissions to the Environment with reduction at source as the first priority.
- Develop and maintain appropriate systems for conservation of energy and other natural resources.
- Continual efforts to reduce, recycle and reuse of wastes.
- Provide the suitable human resources and necessary tools to implement and control the Health and Safety system.
- Involve and ask for suggestions from employees with regards to Safety in workplace.
- Ensure all employees are informed and duly trained to carry their tasks in full compliance with Health and Safety guidelines.
- Motivate, involve and empower employees to participate and implement EHS related activities for achieving the highest standards and consider EHS performance of individuals for their career advancement.
- Disseminate the culture of accident prevention and safety amongst customers and suppliers to support EHS initiatives.

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Not Withstanding the above, other risks (related to 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.

Check-list for Environmental and Health Risk Management Plan

Institutional Arrangement					
		Yes	No	Details	Proposed Plan
1.	Is there a designated full-time staff for Environment Health and Safety (EHS) issues?	Yes			Currently we have staff, but we will recruit more staff as per the need for the new proposed facility.
2.	Does the EHS staff handle the following?			Any other:	The new recruits will be trained for all of these activity. YES 1) OHC available 2) MEPL - Govt. Approved Facility 3) Regulatory clearance –time to time done. 4) SOPs available 5) EHS training record available 6) Env. Monitoring done every quarterly
	Occupational Health and Safety	Yes			
	Waste Management	Yes			
	List of consents and regulatory clearances	Yes			
	Record keeping of accidents and procedures	Yes			
	EHS trainings for staff	Yes			
	Environment Management Framework compliance for Innovate in India Project	Yes			
4.	Is there a reporting structure in place regarding EHS issues?	Yes		Describe:	As per company organogram
5.	Are regular EHS trainings provided to staff?	Yes		Frequency: Quarterly	In future will be continues as per training calendar
General Occupational Health and Safety					
6.	Are there Standard Operating Procedures for accidents, hazards, and other emergencies (chemical spills, heat hazards, fire hazards, radioactive hazards etc.)?	Yes			Shall be implemented through EHS SOP's
7.	Are the following in place?	Yes			Shall be procured more in new facility and kept in place as per approved plan
	Chemical spill kits	Yes			
	Eye wash	Yes			
	Shower stations	Yes			
	First Aid Kit	Yes			
	Fire Extinguishers	Yes			
	Register of accidents and injuries	Yes			
8.	Are proper signage and storage system in place?	Yes			Shall also be implemented in the new project.
	Display of Material Safety Data Sheet (MSDS) where relevant	Yes			

	Display of emergency numbers and procedures (Person to Contact, Doctor, Ambulance, Fire Emergency, Police) displayed in all critical places	Yes			
	Signage across the facility (labs, storage, hazardous areas, etc.)	Yes			
	Are flammable materials appropriately stored to prevent fire hazards?	Yes			
9.	Are smoke detectors, fire alarms, automatic safety/shut off systems, overflow preventers, etc. in place and regularly maintained?	Yes		List:	As per approved by DISH (Directorate of Industrial safety and Health)
10.	Are there control measures for VOC, air emissions, high operating temperatures, pathogens/vectors etc. in place?	Yes		List:	Fume hood with filters or scrubber provision can be made as per process requirement, for high temperatures heat insulation shall be done, no pathogens/vectors shall be handled in project. However, these conditions are not the usual conditions required for bio-manufacturing.
11.	Are regular mock drills conducted for emergency preparedness and safety?	Yes		Frequency (type wise): Twice in a year. Fire, spillage, electric, toxic chemical	It will also be a part of Onsite emergency plan
12.	Are staff provided with OHS training?	Yes		Describe: Firefighting training. Lab safety, PPE, MSDS	Training calendar will be in place
Biomedical Waste (BMW)					
13.	Is there generation of biomedical waste (as described in Bio-Medical Waste Management Rules, 2016) in the grantee?	Yes		If Yes, provide a list of biomedical waste produced in the facility If No, provide a list of	Spent Media in Microbiology lab, Blood sample used in QC lab for test, used syringes, Bio contaminated cotton swab

				all waste produced in the facility.	
14	Is there trained staff to handle biomedical waste in the grantee?	Yes			EHS person shall be responsible
15	Has the grantee obtained authorization from State Pollution Control Board /Pollution Control Committee?	Yes			Shall be complied
16	Is the biomedical waste segregated at point of generation in the facility and stored in suitable containers?	Yes		Yello	Shall be complied
				w	
				Red	
				White	
Blue					
17	Is the bar code system for the segregated waste in place?	Yes			Shall be complied
18	Is the biomedical waste being sent to an authorized common BMW facility?	Yes		<p>Name and address of CBMWF: Life secured services Talegaon Pune</p> <p>Distance from facility: 15 KM</p> <p>Frequency and Mode of transport: As and when required</p> <p>Who transports? Life secured services Talegaon Pune</p>	Shall be complied
19	Does the grantee have an in-house BMW treatment facility?		NO	Reason: Since the qty will be very negligible hence shall be outsourced to authorized agencies.	In future may be planned if quantities are high enough.
	Is the treatment facility own (individual)?		NA		
	Is the treatment facility a shared facility in an industrial park?		NA		

				Authorization: Distance of nearest CBWM from facility: 15KM Types of treatment:	
20	Are lab waste, microbiological waste and chemical liquid waste pre-treated before storing and sending to treatment facilities according to guidelines prescribed in BWM, 2016 regulations?	Yes		Types of treatment: Sterilization	Necessary infrastructure e.g sterilizer, kill tank is considered in project plan.
21	Is the liquid waste checked for active cells before sending to treatment plant?	Yes		Sampling shall be done and will be routed through kill tank	Shall be complied
22.	Are necessary waste pre-treatment equipment in place?	Yes		List of equipment (autoclaves, shredders, incinerators, etc.): Details of waste pre-treatment: Zero liquid discharge plant facility in place	Necessary infrastructure e.g sterilizer, kill tank is considered in project plan. Shall be implemented
	Do the equipment adhere to prescribed norms by State Pollution Control Board (SPCB)?	Yes			
23	Are non-chlorinated plastic gloves and bags phased out in the grantee?	Yes			Shall be complied
24	Are grantee's personnel involved in handling BMW provided with regular training?	Yes		Frequency: Quarterly Trainer: EHS Dept. Head	It is part of EHS job responsibility
25	Are medical examination provided to personnel involved in BMW waste handling and are they provided with relevant immunization like Hepatitis B and Tetanus?	Yes		Frequency of medical examination: once in a year	Yearly medical checkup plan shall be in place
26	Is a daily register for biomedical waste maintained including accident reporting record?	Yes			Shall be complied

27	Are annual reports on BWM submitted to SPCB as per required form (see Bio-Medical Waste Rules 2016)?	Yes			Shall be complied
Hazardous Waste (HW)					
28	Is there generation of hazardous waste (as per Hazardous Waste Rules, 2016) in the grantee?	Yes		If Yes, provide a list of hazardous waste produced in the facility 1) Spent Organic Solvent 2) Spent Oil 3) Discarded drugs 4) ETP sludge If No, provide a list of all waste produced in the facility.	Shall be complied
29	Is there trained staff in the facility to identify and handle hazardous waste?	Yes			Shall be handled by EHS person
30	Does the grantee have authorization from SPCB for hazardous waste?	Yes			Shall be a Part of consent
31	Is there a secure location for storage of HW with proper signage?	Yes		Describe how each item is stored – platforms, distances from critical installations/movement areas, spill collectors, gas escape facility, etc. As per approved by DISH (Directorate of Industrial safety and Health)	Shall be implemented as per SPCB norms
	Are hazardous waste stored for more than 90 days in the grantee's premises?		No		
33	Is the hazardous being send to an authorized disposal facility or user?	Yes		Name and address of facility: MEPL- Maharashtra Enviro Power Ltd. Ranjangaon MIDC Taluka- Shirur Pune- 412220	Shall be outsourced to authorized agencies
	Is the disposal facility in house?		NO		
	Is the disposal facility external/outsourced?	Yes			

34	Is a register maintained on production and treatment, and a manifest system followed for transport of hazardous waste from the grantee to treatment facility?	Yes			Shall be complied
E-Waste and Batteries					
35	Does the grantee generate e-waste, produce or manufacture electrical and electronic equipment?	Yes			Shall be outsourced to authorized agencies for disposal
36	Has the grantee obtained SPCB authorization on e-waste?	Yes			Shall be maintained as per SPCB consent
37	Does the grantee channelize the e-waste to authorized recycling or disposal facility?	Yes		Name and address of disposal facility/recycler: Nirnay Electronics Pune Inhouse or outsourced Facility: Outsourced	Shall be maintained as per SPCB consent
38	Does the manufacturing grantee have Extended Producer Responsibility system and EPR-authorization in place?	Yes		Describe:	Shall be maintained as per SPCB consent
39	Does the grantee practice reduction in the usage of hazardous substances in the manufacture of electrical and electronic equipment and its parts?	Yes		Reduction by optimum uses	Shall be maintained as per SPCB consent
40	Does the grantee provide detailed information on the constituents of the equipment and their components/spares and declaration of conformation to Reduction in Hazardous Substances in the product user documentation?	Yes			Shall be maintained as per SPCB consent
40	Does the grantee maintain a record of collection, storage, sale and transport of e-waste?	Yes		Send to Govt approval vendor for disposal	Shall be maintained as per SPCB consent
41	Does the grantee submit annual reports on e-waste to SPCB?		No	Govt approved vendor	Will check with SPCB and if needed we will submit the report

				submit the report	
42	Is there accident reporting and records in place?	Yes		As per SOP	Shall be complied
43	Are PPEs available to staff?	Yes		As per SOP	Shall be complied
44	Is the grantee involved in manufacture of batteries?		No		N/A
45	Does the grantee generate battery waste?	Yes		Mainly from power back up devices	
46	Does the grantee deposit the battery waste to registered recycler/dealer/manufacturer/reconditioner/collection center?	Yes		Name and address of battery waste receiving entity: Nirnay Electronics Pune	Shall be handed over to authorized agencies
47	In case of manufacturing, does the grantee comply to Battery Management Rules 2000 and ensure collection of old batteries?		NA		NA
Other					
48	Does the grantee use any radioactive materials (isotopes tracers, radiation equipment, etc)?		No		NA
	Does the grantee have appropriate radioactive material and waste storage and disposal system in place?		No	Describe:	NA
	Are radioactive warning signs in place?		NA		NA
49	Is the lab/room air regularly checked for microbial contamination?	Yes		As per SOP	Air Sampling shall be done as per SOP
50	Are there any odor control measures in place?		No	No objectionable odour is generated in the premises	Will implement if needed
51	Are fume hoods and exhausts regularly checked and maintained?	Yes		It will be maintained as per Preventive maintenance plan	
52	Does the grantee use DG set > 15 KVA?	Yes		Permission from state	

	Does the grantee have consent for DG > 15 KVA?	Yes		pollution control board	
	Are emissions from boilers and DG sets regularly monitored to be within the prescribed norms?				
53	Does the grantee have proper disposal process for solid and plastic waste in compliance to Solid Waste Management Rules, 2016 and Plastic Waste Management Rules, 2016?	Yes		Describe: As per guideline from SPCB	Shall be maintained as per SPCB consent
54	Is wastewater treated separately by the grantee? (Liquid waste from laboratory, chemicals, fluids, solvents, medium and cultures, coolants, etc.)	Yes		Types of wastewater: Industrial and domestic effluent Treatment of wastewater: ETP Chemical management in wastewater treatment plants: ETP	Zero liquid discharge
	Are there sludge management and cut off drains in place for wastewater?	Yes			
55	Are necessary provisions for noise cancellation in place?	Yes		Describe:	Shall be maintained as per SPCB consent
56	Are there any settlements, water bodies, cultivated land, or any other eco-sensitive areas near the grantee's premises?		No	Describe: Distance from premises:	NA
57	Are there any buffers, fire vehicle routes in the grantee's premises?	Yes			AS per IDC (industrial development corporation) rules