Cell line development for Pembrolizumab Biosimilar using AcceTTTM Technology Platform

Oncosimis Biotech Private Limited

Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	Approved	Will be monitored every six months by the IBSC committee of CCMB.
EHS Team	We abide to the guidelines provided by CCMB as Oncosimis is an Incubatee in the former.	We abide to the guidelines provided by CCMB as Oncosimis is an Incubatee in the former.
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	Yes, Oncosimis shall maintaining documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	For future, we shall maintain all waste records as it was before.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	Standard Operating Procedure (SOP) for Laboratory Disinfection Purpose: This document describes the use of disinfectants for routine laboratory decontamination of surfaces and equipment. Definitions: Antiseptic – A substance that inhibits the growth and development of microorganisms without killing them. Usually applied topically to skin. Decontamination – A process that removes the	Oncosimis shall maintain all SOP and log books for use of instrument and decontaminations.

	total burden of all classes of microorganisms, usually using chemicals, heat, and/or pressure. Disinfectant – A chemical used to reduce the microbial burden on a surface or object. Does not kill spores. Disinfection – A process that reduces microbial burden on a surface or object. Inactivation – The process of rendering an organism inert by application of heat or other means. Microbicide – A chemical that kills all classes of microorganisms. Synonymous with biocide, germicide, and antimicrobial. Sterilization - A process that removes the total burden of all classes of microorganisms, usually using chemicals, heat, and/or pressure. Principle: The effectiveness of disinfectants depends upon the population of organisms present, the concentration of both organism and disinfectant, the duration of contact, and the presence of organic debris. Common laboratory disinfectants with broad antimicrobial efficacy are working solutions of 70% ethanol and 10% sodium hypochlorite (bleach). It should not be assumed that these or any other common disinfectants are effective against all laboratory	

	pathogens. Prior to selecting a disinfectant for your laboratory, it is important to check the susceptibility and the recommended contact time of the species and strain with which you are working. Risks: The potential safety risks for routine laboratory disinfection are: • Creation of infectious aerosols • Exposure to respiratory and eye irritants Proper PPE: Personal protective clothing and equipment must be worn when using disinfectants: • The PPE to be worn when working with disinfectants should be commensurate with the highest risk or hazard designation for any single biological agent or material present prior to disinfection. • Eye and respiratory protection should be used whenever the creation of aerosols is possible. Many disinfectants are respiratory, skin, and/or eye irritants and require the use of appropriate PPE. Procedure: Apply disinfectant to contaminated or potentially	

	contaminated area. If visible or gross contamination is present, apply enough disinfectant to saturate the contamination. Let stand for the indicated contact time. Wipe thoroughly and place absorbent material in the biohazardous waste box. In case of a small (less than 10L) biological spill: 1. Cover spill area with paper towels. 2. Disinfect by pouring slowly around perimeter and into the center of spill area and let sit for 20 minutes. 3. Clean by absorbing with paper towels and place in a biohazard bag. 4. Disinfect by re-spraying the spill area with disinfectant; allow to air dry All work areas and materials that come or may come into contact with biological agents should be disinfected both before and after each use. This provides protection for personnel, the community, the environment, and your experiments. This procedure should also be followed for spills involving recombinant DNA (rDNA). Non-routine Disinfection: For disinfection or	

	decontamination outside of normal operations, such as cleaning a large piece of laboratory equipment prior to disposal, contact the Biological Safety Officer for assistance. It is necessary to produce an inventory of all biological materials that are or have been stored in the piece of equipment to be decontaminated. Disinfectant(s) will be selected based upon efficacy against the biological agents that are known or suspected to have contaminated the piece of equipment. The piece of equipment should be saturated with disinfectant to the extent that it's reasonably practicable and allowed to stand the contact time. If any processing, disassembly, or other modification of the equipment is necessary in order to facilitate decontamination, the Biological Safety Officer will perform a risk assessment and make recommendations on PPE and work	

	practices	
General Safety and Storage	We abide to the guidelines and recommendations provided by CSIR-CCMB, Hyderabad as Oncosimis is an Incubatee in the former.	We abide to the guidelines and recommendations provided by CSIR-CCMB, Hyderabad as Oncosimis is an Incubatee in the former

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	minimal risk	Project implementation doesnot create adverse air pollution	Project implementation doesnot create adverse air pollution
Water Pollution and Waste water treatment	Minimal Risk	CCMB has an in-house effluent treatment plant.	Oncosimis is an Incubatee at CCMB and all/any effluents are handled by the CCMB infrastructure.
Chemical waste	Minimal Risk.	CCMB has an in-house effluent treatment plant.	Oncosimis is an Incubatee at CCMB and all/any effluents are handled by the CCMB infrastructure.
Biological Waste	Minimal Risk	CCMB has an in-house effluent treatment plant.	Oncosimis is an Incubatee at CCMB and all/any effluents are handled by the CCMB infrastructure.
Heavy metals	Minimal Risk	Project implementation doesnot create adverse Heavy metals	Project implementation doesnot create adverse Heavy metals
Radiation Waste	Minimal Risk	Project implementation doesnot create adverse Radiation Waste	Project implementation doesnot create adverse Radiation Waste
Electronic Waste	Minimal Risk	Project implementation doesnot create adverse Electronic Waste	Project implementation doesnot create adverse Electronic Waste
Hazardous and C&D Waste	Minimal Risk	Project implementation doesnot create adverse Hazardous and C&D Waste	Project implementation doesnot create adverse Hazardous and C&D Waste

Destruction/alteration of surrounding ecosystem	Minimal Risk	Project implementation doesnot create adverse Destruction/alteration of surrounding ecosystem	Project implementation doesnot create adverse Destruction/alteration of surrounding ecosystem

3. **Occupational Health and Safety** and **risk mitigation**

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Autoclave is the only heat generating aspect of this project and this equipment and process is handled by CCMB staff.therefore tere is moderate risk.	Autoclave is the only heat generating aspect of this project	this equipment and process is handled by CCMB staff.
Chemical hazards, including fire and explosions	There is minimal risk in terms of Chemical exposure, as the main consumables used are buffers and reagents, which are non-toxic and non-hazardous as they are need for biologic production.	There is minimal risk in terms of Chemical exposure, as the main consumables used are buffers and reagents, which are non-toxic and non-hazardous as they are need for biologic production.	There is minimal risk in terms of Chemical exposure, as the main consumables used are buffers and reagents, which are non-toxic and non-hazardous as they are need for biologic production.
Pathogenic and biological hazards	No pathogenic or biological hazards are used or are exposed to in the lab of Oncosimis.	No pathogenic or biological hazards are used or are exposed to in the lab of Oncosimis	No pathogenic or biological hazards are used or are exposed to in the lab of Oncosimis
Radiological hazards	Minimal Risk	Project implementation doesnot create adverse Radiological hazards	Project implementation doesnot create adverse Radiological hazards
Electronic Waste	Minimal Risk	Project implementation doesnot create adverse	Project implementation doesnot create adverse Electronic Waste

		Electronic Waste	
Hazardous and C&D Waste	Minimal Risk	Project implementation doesnot create adverse Hazardous and C&D Waste	Project implementation doesnot create adverse Hazardous and C&D Waste
Noise	Minimal Risk	Project implementation doesnot create adverse noise pollution	Project implementation doesnot create adverse noise pollution
Process safety	1. Breakage of Glassware 2. Spillage of Reagents	Any compromise to process safety can adversely affect the health of the equipment and prolong the timelines.	Oncosimis will be procuring and using the best-in-class equipment and will be training staff to mitigate the same.

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	Spilling of Biological agents, Improper packaging and sterilization	Oncosimis shall maintain all SOP and log books for use of instrument and decontaminations
Emergency preparedness and participation of local authorities and potentially affected communities	Minimal Risk	Medical and fire emergency	Oncosimis is an Incubatee at CCMB and the staff of the former is trained by the latter periodically to address all such risks,
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**.**			

Standard Operating Procedure (SOP) for Laboratory Disinfection

Purpose: This document describes the use of disinfectants for routine laboratory decontamination of surfaces and equipment.

Definitions:

Antiseptic – A substance that inhibits the growth and development of microorganisms without killing them. Usually applied topically to skin.

Decontamination – A process that removes the total burden of all classes of microorganisms, usually using chemicals, heat, and/or pressure.

Disinfectant – A chemical used to reduce the microbial burden on a surface or object. Does not kill spores.

Disinfection – A process that reduces microbial burden on a surface or object. Inactivation – The process of rendering an organism inert by application of heat or other means. Microbicide – A chemical that kills all classes of microorganisms. Synonymous with biocide, germicide, and antimicrobial.

Sterilization - A process that removes the total burden of all classes of microorganisms, usually using chemicals, heat, and/or pressure.

Principle: The effectiveness of disinfectants depends upon the population of organisms present, the concentration of both organism and disinfectant, the duration of contact, and the presence of organic debris. Common laboratory disinfectants with broad antimicrobial efficacy are working solutions of 70% ethanol and 10% sodium hypochlorite (bleach). It should not be assumed that these or any other common disinfectants are effective against all laboratory pathogens. Prior to selecting a disinfectant for your laboratory, it is important to check the susceptibility and the recommended contact time of the species and strain with which you are working.

Risks: The potential safety risks for routine laboratory disinfection are:

• Creation of infectious aerosols

• Exposure to respiratory and eye irritants

Proper PPE: Personal protective clothing and equipment must be worn when using disinfectants:

• The PPE to be worn when working with disinfectants should be commensurate with the highest risk or hazard designation for any single biological agent or material present prior

to disinfection.

• Eye and respiratory protection should be used whenever the creation of aerosols is possible. Many disinfectants are respiratory, skin, and/or eye irritants and require the use of appropriate PPE.

Procedure:

Apply disinfectant to contaminated or potentially contaminated area. If visible or gross contamination is present, apply enough disinfectant to saturate the contamination. Let stand for the indicated contact time. Wipe thoroughly and place absorbent material in the biohazardous waste box.

In case of a small (less than 10L) biological spill:

1. Cover spill area with paper towels.

2. Disinfect by pouring slowly around perimeter and into the center of spill area and let sit for 20 minutes.

3. Clean by absorbing with paper towels and place in a biohazard bag.

4. Disinfect by re-spraying the spill area with disinfectant; allow to air dry

All work areas and materials that come or may come into contact with biological agents should be disinfected both before and after each use. This provides protection for personnel, the community, the environment, and your experiments.

This procedure should also be followed for spills involving recombinant DNA (rDNA).

Non-routine Disinfection:

For disinfection or decontamination outside of normal operations, such as cleaning a large piece of laboratory equipment prior to disposal, contact the Biological Safety Officer for assistance. It is necessary to produce an inventory of all biological materials that are or have been stored in the piece of equipment to be decontaminated. Disinfectant(s) will be selected based upon efficacy against the biological agents that are known or suspected to have contaminated the piece of equipment. The piece of equipment should be saturated with disinfectant to the extent that it's reasonably practicable and allowed to stand the contact time. If any processing, disassembly, or other modification of the equipment is necessary in order to facilitate decontamination, the Biological Safety Officer will perform a risk assessment and make recommendations on PPE and work practices.

Contact person:

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Clinical Trial Risk Management Plan (if applicable)

Oncosimis is not doing any clinical trials either for the scope of this project. So, this section is not applicable.