


 <b>PCDDP</b> <small>DST/MWU Preclinical Drug Development Platform</small>		<b>Standard Operating Procedure</b>	
<b>Title</b>   Entering the GLP Area			
<b>SOP no</b>	SOP_Viv_Acces 1	<b>Issue no</b>	3
<b>Issue date</b>	23-06-2014	<b>Revision date</b>	24-06-2016
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**1. COMPILATION AND AUTHORISATION**

Action	Designated Person	Signature	Date
Compiled by:	Mrs A Fick		20/06/2014
Checked by :	Mr H Buntting		20/06/2014
Authorised by:	Mr CJJ Bester		20.06.2014

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**2. DISTRIBUTION**

Department	Name	Signature	Date
PCDDP QA Manager	L Scholtz		24-06-2014
Head: Vivarium	CJJ Bester		24.06.2014

**3. DOCUMENT HISTORY**

Date	Issue no	Reason for revision
02-07-2012	1	First issue of SOP
14-02-2014	2	Addition of test principle.
23-06-2014	3	Training Removed

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**4. POLICY and OBJECTIVE**

This SOP will establish the correct procedures required to maintain hygiene and moderate sterility within the experimental rooms on entering the GLP area. When entering the GLP area it is essential to ensure that outside contaminants and pathogenic agents are not brought in with the people entering the area.

**5. SCOPE**

This SOP concerns the hygienic practices on entering the GLP area by personnel, facility users, maintenance contractors and clients.

**6. REFERENCE DOCUMENTS**

- SOP\_Per\_Train 1 – Employee Orientation and Training

**7. ABBREVIATIONS and/or DEFINITIONS**

Abbreviation	Description
GLP	Good laboratory practice
N/A	Not applicable
SOP	Standard operating procedure

**8. RESPONSIBILITIES**

This SOP must be followed by all people who have been assessed by the GLP Animal Technician or designate, as fully competent to apply the procedure below following a period of training and experience. This SOP applies mainly to staff employed and researchers using the GLP facility, however visitors, such as clients or maintenance contractors who have been given specific permission by the Animal Technician or designate to enter the GLP area must also adhere to these procedures to maintain adequate hygiene standards. Staff in the process of gaining competence, and personnel not employed by the Vivarium may undertake the procedure if supervised by a member of the GLP area who is fully competent in the procedure.

**9. TEST PRINCIPAL**

N/A

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## 10. MATERIALS and EQUIPMENT

- White laboratory coats
- Overshoes
- Caps
- Face masks
- Disposable Gloves
- Soap
- Paper towels
- Shower facility
- Bath towels

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## 11. SAFETY

N/A

## 12. PROCEDURES

- 12.1. All staff, clients and users of the Vivarium must adhere to the rules.
- 12.2. All clients, visitors and users of the Vivarium must fill in the GLP Area entering log.
- 12.3. All staff, clients and users of the Vivarium entering the GLP Vivarium must enter through the change area. White lab coats, overshoes, caps, face masks and disposable gloves are put on.
- 12.4. The entering log sheet must be filled in upon entering the GLP area. (See addendum 2)
- 12.5. Hands (ungloved) are to be washed and dried using the basin, soap dispenser and paper towels provided in the change area before entry into the GLP unit and upon exiting the unit. This limits contamination from the outside environment into the GLP unit and the accidental transference of any agents being used within the GLP unit to the outside.
- 12.6. Animal care takers must shower on arrival at the Vivarium and put on clean protective clothing before entering the GLP area. Protective clothing are provided by the Vivarium.
- 12.7. White laboratory coats will be removed for cleaning every two weeks or when overly soiled. They will be washed and dried. All lab coats used for maintenance procedures and guests are to be disposed and replaced when they have become overly soiled or

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worn- out. All overshoes are discarded into the change area waste bin as soon as holes begin to appear in them during the day.

- 12.8. Gloves can be discarded in the change room waste bin when they have been greatly soiled during procedures or when staff members have finished handling animals from one study and want to handle animals from another study.
- 12.9. Upon exiting the area, the white laboratory coats are hung on hooks mounted on the wall in the area. Masks, gloves, caps and overshoes are discarded in the waste bin.
- 12.10. All doors must be kept closed at all times.
- 12.11. Procedures performed on the animals must adhere to the protocol accepted by the Ethical Committee
- 12.12. Only rooms designated to the user may be entered. Rooms must be left clean.

### 13. ADDENDUM

- ADDENDUM 1 [SOP\_Viv\_Acces 1 ad 1 – Entering the GLP Area – Questionnaire]
- ADDENDUM 2 [SOP\_Viv\_Acces 1 ad 1] - GLP Area entering log

<b>Title</b>	Entering the GLP Area - Questionnaire		
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1. Trainees

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1.1. New staff

- New staff will undergo level 3 training (SOP\_Per\_Train 1).
- Assessment will be with the following questionnaire:

1. Why do we have to make use of personnel protective equipment (PPE) on entering the GLP Vivarium?	
2. Who are protected by PPE?	
3. What hazards do people encounter on entering the GLP area?	
4. What soap is used for washing hands?	
5. What functions does the soap have?	
6. When must a person's hands be washed?	

1.2. Facility users, clients and maintenance contractors

- Facility users clients and maintenance contractors will undergo level 3 training (SOP\_Per\_Train 1).
- Assessment will be by observation.



### SOP Addendum

Title	GLP Area entering log		
Addendum no	SOP_DOC 1 ad 2	Issue no	3
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**GO**

Date	Time in	Time out	Purpose	Name	Sign