Table of Contents

1. Scope 2
2. Objective 2
3. Definitions 2
4. Responsibility 2
5. Procedure 3
6. Precautions 6
7. References 6
8. Appendices 6
9. Revision History 6
1. **Scope**

This Standard Operating Procedure (SOP) applies to the staff and students of the Pharmacy Department, University of Malta to provide the training requirements to be followed.

2. **Objective**

To define the training requirements to be followed by staff and students at the Pharmacy Department.

3. **Definitions**

   3.1. **Activity:** Any form of procedure that is to be carried out in the laboratory. This may include the use of laboratory equipment or taking part in a practical session.

   3.2. **High Level SOPs:** The most important SOPs present in the Quality Management System (QMS) of the laboratories. These are the Master SOP (SOP/PD/101), Good Laboratory practice SOP (SOP/PD/102), Health and Safety in the Laboratory SOP, Training SOP (SOP/PD/104) and Laboratory Logbooks SOP (SOP/PD/105).

   3.3. **Training:** The familiarisation of the user with an SOP before s/he starts to make use of a system, equipment or medical device. It is important for the user to be trained on the SOPs so as to ensure that activities are carried out correctly and safely.

4. **Responsibility**

   4.1. The designated Laboratory Officer or Laboratory Assistant is responsible for ensuring that this SOP is followed.

   4.2. The Laboratory Officer is responsible for notifying the members of the Department each time a new version of an SOP is issued.

   4.3. The demonstrator responsible for a particular session, has to ensure that undergraduate students have followed the appropriate SOPs.
5. Procedure

5.1. Ensure that members of the Department (staff and students) that are to perform an activity in one of the laboratories, are trained on the high level SOPs.

5.2. Ensure that members of the Department (staff and students) that are to make use of an equipment or medical device, are also trained on these high level SOPs.

5.3. Ensure that members of the Department (staff and students) that are to make use of an equipment or medical device, are trained on the respective equipment SOP.

5.4. Ask for assistance when information in an SOP is not understood. Always ask a designated Laboratory Officer or Assistant to clarify any difficulties.

5.5. Sign the ‘Read and Understood’ form (Appendix SOP/PD/104_02/A1) after training on the SOP has been completed.

5.6. Train yourself each time a new version of the SOP is issued.

5.7. Sign the Read and Understood form for the new version of the SOP again after training is complete.
5.8 Flow Chart

Start

Performing activity in lab trained on high level SOPs

Yes

Using an equipment/medical device trained on high level SOPs

Yes

Using an equipment/medical device trained on respective equipment/device SOP

Yes

Cannot understand information in SOP

Yes

Ask designated laboratory officer or assistant to clarify

No

Train accordingly

Training on SOP complete

Yes

Sign its 'Read and Understood' Form (Appendix 1)

No

New version of SOP

Yes

Continue to train accordingly

No
1

Train again on new version of SOP

Training on new version of SOP complete

Yes

Sign the 'Read and Understood' Form for the new version

No

Continue to train accordingly

2

End

Valid for:
2 years from approval
6. Precautions

6.1. Emphasise to members of the Department (staff and students) about the importance of training on and signing the Read and Understood forms of the high level SOPs.

6.2. Do not allow any members of the Department (staff and students) to make use of any medical device or equipment without prior training and signing of its Read and Understood Form.

6.3. Check with the Laboratory Officer to ensure that the correct version of the SOP is being followed.

7. References

Not Applicable

8. Appendices

SOP/PD/104_02/A1 – Read and Understood Form

9. Revision History

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Amendments/ Reasons for change</th>
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<tbody>
<tr>
<td>01</td>
<td>Initial Release</td>
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<tr>
<td>02</td>
<td>Activity and High Level SOPs Definitions Reference to Equipment SOPs Inclusion of flowchart</td>
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SOP/PD/104_02/A1 – Read and Understood Form

I hereby declare that I have read and understood the above mentioned SOP

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