Table of Contents

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

Page

Original  
Authorised Copy  
Reading Copy

Written by:  
Reviewed by:  
Approved by:

Signature/Date:  
Signature/Date:  
Signature/Date:  

Page 1 of 23
1. **Scope**

This SOP applies to the staff and students involved in the Quality Management System (QMS) implemented for the laboratories of the Pharmacy Department, University of Malta.

2. **Objective**

To describe the procedure for developing, authorising, distributing and reviewing Standard Operating Procedures (SOPs).

3. **Definitions**

3.1. **Appendices**: All forms and sheets that are referred to in the SOP.

3.2. **Authorised Copy**: A copy of the original, marked as such, issued by the Head of Department or delegate, present at all 5 distribution points (Pharmacy Practice Resource Unit Room 131, Pharmacy Main Lab Room 134, Pharmacy Chemistry Research Lab Room 232, Research Lab at Mater Dei Hospital Room A110373 and Room 238) to aid the user to carry out an activity in the laboratory.

3.3. **Copies box**: A box situated on the front page of the SOP to indicate whether the SOP is an original, authorised or reading copy.

3.4. **Definitions**: A list of defined keywords included in the SOP and listed in alphabetical order.

3.5. **Distribution Points of Authorised Copies Form**: A form kept with the Original SOP used to document all the distribution points of the authorised copies of the SOP.

3.6. **Flow Chart**: Graphical representations of the procedure were the steps are represented by different symbols which are linked together by arrows to indicate the process flow direction.

3.7. **Header**: Consists of 6 boxes located at the top part of each page.
3.8. **Objective:** Describes the aim/s of the SOP.

3.9. **Original:** The ink-signed copy of the SOP that is kept at the Head of Department’s office.

3.10. **Precautions:** A list of safety measures to ensure that the procedure is carried out safely (when applicable).

3.11. **Procedure:** Describes the steps required to perform the activity towards which the SOP is directed.

3.12. **Quality Management System (QMS):** A system that outlines the policies and procedures necessary to define, control and improve the many processes that will ultimately lead to laboratory services of recognised value.

3.13. **Read and Understood Form:** A form issued with each new or revised authorised SOP to record the individuals who have read and understood the SOP. It is then filed with the respective original SOP.

3.14. **Reading Copy:** A copy of the SOP, marked as such, that should not be used to perform an activity but used for information purposes only.
3.15. **Reference Number**: A unique SOP identification code consisting of SOP/PD (PD stands for Pharmacy Department) followed by a 3 digit number, were the first digit indicates the level of the SOP:

SOP/PD/1XX: 1-High level SOPs  
SOP/PD/2XX: 2-Low Level SOPs for point of care testing medical devices  
SOP/PD/3XX: 3-Low Level SOPs for pharmaceutical equipment  
The last two digits are increased by increments of 1.

3.16. **References**: A list of published materials which are used to compile the SOP. The Vancouver Style referencing system is used and guidelines on this can be accessed from: www.nlm.nih.gov/bsd/uniform_requirements.html.

3.17. **Responsibility**: Identifies the personnel that are primarily responsible for developing, maintaining and following the SOP.

3.18. **Revision History**: A table to record the amendments made each time a new version of the SOP is issued.

3.19. **Scope**: Area to which the SOP applies.

3.20. **Section**: Refers to one of the nine components that are present in the table of contents which, together make up the backbone of the SOP (Scope, Objective, Definitions, Responsibility, Procedure, Precautions, References, Appendices and Revision History). A section will incorporate a heading followed by various subheadings.

3.21. **SOP Review Database**: A database to record all the revision dates carried out on each SOP.

3.22. **Standard Operating Procedure (SOP)**: A set of written instructions that document an activity.

3.23. **Table of contents**: Lists the nine sections making up the SOP according to the order to which they are listed, together with their respective page numbers.

3.24. **Template**: A form to be used as a basis for creating other documents in a standard way.
3.25. **Validity Period:** 2 years from the authorisation date.

3.26. **Version Number:** A 2 digit number separated from the reference number by an underscore sign (SOP/PD/XXX_XX). First version is denoted as ‘01’.

3.27. **Written, Reviewed, Approved Table:** A table situated on the front page of the SOP which includes the names and signatures of the author, reviewer and authoriser of the SOP together with the date of development, review and authorisation.

4. **Responsibility**

4.1. The Head of Department or delegate is responsible to ensure that the system is managed in the appropriate manner.

4.2. The Laboratory Officer must review SOPs and make sure that they are up to date.

4.3. Every member of the Department (staff and students), is responsible for following the current SOP and having read and understood the procedure beforehand.

5. **Procedure**

5.1. **SOP Development**

5.1.1. Access SOP template from the computer (SOP/PD/101_02/A1).

5.1.2. Save as ‘SOP Name-Reference Number-Version Number’ to ensure that SOP template remains intact.

5.1.3. **Margins**

5.1.3.1. Ensure top and bottom margins are set at 2.54cm and left and right margins at 3.17cm.

5.1.3.2. Ensure margins of the header from the top and the footer from the bottom are set at 1.25cm.

5.1.4. **Header**

5.1.4.1. Input SOP title in Header Box D.
5.1.4.2. Input Reference and Version Number in Header Box E.

5.1.5. Scope

5.1.5.1. Indicate the scope of the SOP.

5.1.6. Objective

5.1.6.1. Describe the objective of the SOP.

5.1.7. Definitions

5.1.7.1. Define the keywords that are mentioned in the SOP.

5.1.8. Responsibility

5.1.8.1. Assign clear responsibilities for the procedure.

5.1.9. Procedure

5.1.9.1. Describe the Procedure.

5.1.9.2. Use the ‘Flow Chart Symbols’ Table (SOP/PD/101_02/A2) to summarise the procedure into flow chart/s and include as the last section of the procedure.

5.1.10. Precautions

5.1.10.1. List the precautions (when applicable).

5.1.11. References

5.1.11.1. List the references in alphabetical order.

5.1.12. Appendices

5.1.12.1. List and include the appendices referred to in the SOP.
5.1.13. **Font**

5.1.13.1. Ensure font size is ‘Times New Roman’ size 12 Black.

5.1.13.2. Ensure bold typeface is used for the headings, numberings and table of contents.

5.1.14. **Line spacing**

5.1.14.1. Ensure single line spacing is used and that space before and after is 0 point.

5.1.14.2. Ensure a space is left between the main heading and the subheading or text.

5.1.15. **Numbering**

5.1.15.1. Ensure main heading and subheadings of each section are numbered correctly:
Main Heading (1)
First Subheading (1.1)
Subsequent Subheading (1.1.1)
Same Subheading of a Section (1.1.2)

5.1.15.2. Ensure second and subsequent sections are numbered using this stated format and always increasing the first digit by increments of 1 (example for the second section: 2, 2.1, 2.1.1 and so on).

5.1.16. **Indentation**

5.1.16.1. Ensure document indentation is correct:
Main Heading (1): From position 0 with text position at 0.63cm
First Subheading (1.1): From position 0.63cm to 1.27cm
Second Subheading (1.1.1): From position 1.27cm to 1.93cm
Third Subheading (1.1.1.1): From position 1.93cm 3.17cm.
5.1.17. Alignment

5.1.17.1. Ensure all text is justified

5.1.18. Table of contents

5.1.18.1. Input page numbers of each section accordingly.

5.1.19. Written, reviewed, approved table

5.1.19.1. Fill in ‘Written, Reviewed, Approved’ Table
5.1.19.2. Save SOP
5.1.19.3. Print SOP and this will be the Original
5.1.19.4. Ensure author, reviewer and authoriser sign the original.

5.2. SOP Authorisation and Distribution

5.2.1. A copy of the Original is made by the Head of Department to be able to issue an authorised copy.
5.2.2. File the original in the appropriate file in the Head of Department’s office (Rm233).
5.2.3. Mark authorised copies by marking the ‘Authorised Copy’ box and indicate the distribution point.
5.2.4. Document the distribution points of each authorised copy in the ‘Distribution Points of Authorised Copy’ Form (SOP/PD/101_02/A3). File form with original SOP.
5.2.5. File the authorised copies at each respective distribution point.
5.2.6. Ensure that all staff and students making use of the laboratories sign the ‘Read and Understood’ Form (SOP/PD/101_02/A4).
5.2.7. If it is required to issue a reading copy of the SOP, The Head of Department is to make a copy of the original or authorised copy.
5.2.8. Mark ‘Reading Copy’ in the copies box and destroy immediately after use.

5.3. SOP Review

5.3.1. Review every SOP at least once every 2 years. If no amendments are made, extend the validity period by a further 2 years.
5.3.2. When an SOP is to be revised:

5.3.2.1. Cancel and archive the original copy of the SOP.
5.3.2.2. Collect and destroy all the authorised copies from the distribution points and ensure that they are all accounted for.
5.3.2.3. Make the required amendments to the SOP and update table of contents and version number accordingly.
5.3.2.4. Document the amendments made in the Revision History box.
5.3.2.5. Repeat steps 5.1.19 and 5.2.
5.3.2.6. Include the review date in the ‘SOP Review Database’ (SOP/PD/101_02/A4).
5.4. Flow Charts

5.4.1. Developing, Authorising and Distributing a new SOP

```
Start

Access SOP template

Save SOP with name, reference and version number

Page margins set correctly

Yes

Margins of header footer set at 1.25cm

Yes

Input SOP title in Header Box D

Input Reference and Version Numbers Header Box D

Indicate Scope

Describe Objective

Include definitions

Assign Responsibilities

No

Set accordingly

Set accordingly
```

Page 10 of 23
Master

All text justified

Input page numbers of each section table of contents

Fill in Written, Reviewed, Approved table accordingly

Save SOP

Print SOP

Author, reviewer, authoriser signed original

Issue authorised copies

File original in appropriate Room 233

Mark authorised copies by marking ‘Authorised Copy’ box and indicate distribution point

Document distribution points of each authorised copy in the Distribution Points of Authorised Copy Form

Form signed by authoriser

Ask to sign

Yes

No

Yes

No

Yes

No
3

File form with Original

File authorised copies at each respective distribution point

Read and Understood form signed by staff and students

No

Ask to sign

Yes

Reading copy required

No

Yes

Issue a reading copy

Mark ‘Reading Copy’ in Copies box

Destroy immediately after use

End
5.4.2 Reviewing, Authorising and Distributing a Revised SOP

Start

Review SOP

No

Require revision

Yes

Extend validity period by a further 2 years

1

Cancel and archive original of previous version

Collect and destroy all authorised copies of previous version from all distribution points

Make required amendments and update table of contents and version number

Document amendments made in revision history box

Fill in Written, Reviewed, Approved table accordingly

Save SOP

Print SOP

Yes

Author, reviewer, authoriser signed original

2

No

Ask to sign
Issue authorised copies

File original in the Head of Department’s Office

Mark authorised copies by marking ‘Authorised Copy’ box and indicate distribution point

Document distribution points of each authorised copy in the Distribution Points of Authorised Copy Form

Form signed by authoriser

Yes

File authorised copies at each respective distribution point

No

Ask authoriser to sign

Yes

Read and Understood form signed by staff and students

No

Ask to sign

Yes

Include review date in the SOP Review Database (Appendix 4)

No

Yes

Reading copy required

Yes

No
3

Issue a reading copy

Mark ‘Reading Copy’ in Copies box

Destroy immediately after use

End
6. Precautions

Not Applicable

7. References


8. Appendices

SOP/PD/101_02/A1 – SOP Template

SOP/PD/101_02/A2 – Flow Chart Shapes Table

SOP/PD/101_02/A3 – Distribution Points of Authorised Copies Form

SOP/PD/101_02/A4 – SOP Review Database
9. Revision History

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<td>Change in the overall structure of the SOP</td>
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<td>Inclusion of Flow Charts and Flow Charts Shapes Table</td>
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1. Scope

[Insert Text]

2. Objective

[Insert Text]

3. Definitions

[Insert Text]

4. Responsibility

[Insert Text]

5. Procedure

[Insert Text]

6. Precautions

[Insert Text]

7. References

[Insert Text]

8. Appendices

SOP/PD/XXX_XX/AX: [Insert Text]

9. Revision History

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### Flow Chart Symbols Table*

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<thead>
<tr>
<th>Name of Symbol</th>
<th>Shape of Symbol</th>
<th>Meaning of Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terminator</td>
<td>oval</td>
<td>Oval represents the START and END of a procedure</td>
</tr>
<tr>
<td>Process</td>
<td>rectangle</td>
<td>Rectangle represents a step in a procedure</td>
</tr>
<tr>
<td>Decision</td>
<td>diamond</td>
<td>Diamond represents a decision criterion, e.g.: YES/NO</td>
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<tr>
<td>Connector</td>
<td>circle</td>
<td>Circle represents a transition to/from another page when the flow chart cannot fit in a single page or the connection is not graphically possible</td>
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<tr>
<td>Decision Arrows</td>
<td>diamond with YES and NO arrows</td>
<td>Decision arrows emerge from a diamond and lead towards 2 (or more) alternative steps</td>
</tr>
<tr>
<td>Connector Arrow</td>
<td>arrow</td>
<td>Arrow represents a connection between activities</td>
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</table>

*Adapted from EMEA Work Instructions on creating flow charts for Standard Operating Procedures and Work Instructions (see references).
**SOP/PD/101_02/A3 – Distribution Points of Authorised Copies Form**

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SOP/PD/101_02/A4 – SOP Review Database

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