STANDARD OPERATING PROCEDURE

SOP Number   **_____**

SOP Title   **_____**

	NAME	TITLE	SIGNATURE	DATE
Author				
Reviewer				
Authoriser				

Effective Date:	
Review Date:	

READ BY			
NAME	**TITLE**	**SIGNATURE**	**DATE**

1.   **PURPOSE**

A brief description of the purpose of the SOP, it should describe why the SOP is required (e.g. compliance with GCP and other internal procedures and guidelines).

Any regulations or procedures referred to in "Purpose" section should be identified. The source should be given in the reference section rather than direct quotes.

2.   **INTRODUCTION**

A general introduction, with a statement of rationale.

3.   **SCOPE**

A statement that outlines the areas and context covered by the SOP.

If there are any areas in which this SOP specifically does NOT apply, these should also be mentioned.

4.   **DEFINITIONS**

When appropriate, a list of definitions should be included for terms used in the SOP. Acronyms and abbreviations should be explained at the point of use within the SOP and not listed in this section.

5.   **RESPONSIBILITIES**

A summary of the roles listed in the procedure and the responsibilities of each role holder for the procedures detailed in the SOP.

The details of the responsibilities should be a brief list of the key tasks performed. This section should not be a complete summary of the SOP.

6.   **SPECIFIC PROCEDURE**

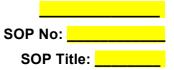This section is the main text of the SOP. It details the procedure for the task to be performed.

There should be sufficient detail, clearly expressed, to enable a trained person to perform the procedure without supervision.

There should also be sufficient detail to enable a trained person to use the document to train others to perform the task.

The use of flow diagrams may be useful, especially in complex procedures.

7.   **FORMS/TEMPLATES TO BE USED**

Where Forms/Templates are referenced in the text, the numbers and titles are listed under this section.

8. INTERNAL AND EXTERNAL REFERENCES

This section is used to list all controlled internal references (e.g. SOPs) and external references referred to within the text of the SOP only.

8.1 Internal References

Insert relevant references as required, sufficient for the user to find the source document.

8.2 External References

Insert relevant references as required, sufficient for the user to find the source document. Web references should be included were possible.

9. CHANGE HISTORY

Where the SOP is the initial version:

- SOP No: Record the SOP and version number

- Effective Date: Record effective date of the SOP or "see page 1"

- Significant Changes: State, "Initial version" or "new SOP"

- Previous SOP no.: State "NA".

Where replacing a previous SOP:

- SOP No: Record the SOP and new version number

- Effective Date: Record effective date of the SOP or "see page 1"

- Significant Changes: Record the main changes from previous SOP

- Previous SOP no.: Record SOP and previous version number

SOP no.	Effective Date	Significant Changes	Previous SOP no.