

Standard Operating Procedure

Title: Documentation Rule for GMP Documents

Department	Quality Management	Document no	QMS-020
Prepared by:		Date:	Supersedes:
Checked by:		Date:	Date Issued:
Approved by:		Date:	Review Date:

Document Owner

Quality Assurance Manager

Affected Parties

All Sydco Colleagues

Purpose

To outline the procedure for the correct way to fill out documents which have a direct bearing on the quality of the product, as required by the Code of Good Manufacturing Practice.

Scope

All Quality documents, and recorded information relating to the batch history of products manufactured at Sydco.

It is the responsibility of all personnel who make an entry in a GMP document to follow this procedure.

Definition

SOP	Standard Operating Procedure
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Related Documents

Form-400	Employee Signature Register
QMS-015	Quality Documentation Management and Change Control
MAN-030	Production Logbook
QMS-090	Evaluation of Batch Documentation and Release for Sale
LAB-025	Laboratory Workbook

EHS Statement

There is no EHS impact.

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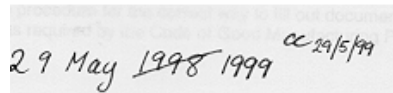
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- 5.4. The recording of information on scrap pieces of paper is not permitted. All recorded information relevant the batch history of a product must only be made on controlled documents, logbooks or workbooks.
- 5.5. Documents including Logbooks and Work Books that require data or any other information to be entered manually must be designed in a way that allows:
 - Sufficient space for the entry
 - Adequate spacing between entries, and
 - For a clear indication of what is to be entered.
- 5.6. Where any headings, items or spaces on a document cease to be used, it should be removed as soon as possible. See **SOP QMS-015**, for initiating a change to a Quality document.
- 5.7. Be consistent with date and time.
- 5.8. Be current. Never use deleted or obsolete document.


6. Corrections

- 6.1. Any corrections made to a document must be initialled or signed and dated by the person making the change. The correction must permit the reading of the original information. Only a single line through the middle of the original, incorrect entry should be made. If an entry error is made, no explanation for the correction is required. If the error was made for any other reason, a detailed reason for the error and correction must be recorded.
- 6.2. The use of correction fluid or "Liquid Paper" must not be used for correcting errors or for any other reason. The use of erasers is also prohibited.

[Example of CORRECT way to correct errors]



[Example of INCORRECT way to correct errors]



7. Summary of Changes

Version #	Revision History
QMS-020	New

End of Procedure