

**STANDARD OPERATING PROCEDURE
COX001:1**

DOCUMENT:

**PREPARATION OF STANDARD OPERATING
PROCEDURES**

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**S.O.P. CODE: COX001
10/06/2005**

EFFECTIVE:

NEXT REVISION: 10/06/2010

SUPERSEDES: NIL

INTRODUCTION

Ten reasons why every compounding pharmacy needs its own Standard Operating Procedures (SOP's)

- A performance guide for replacement staff during vacation, staff turnover, or leave of absence.
- A reference document that speeds up on-the-job training.
- Less chaos and confusion when key, trained personnel abruptly leave – less reliance on corporate memory.
- Legal protection: your processes defined in detail and in print.
- Written knowledge about who does what, where, when, why, and how.
- Written accountability crucial to effective performance evaluation.
- Consistency: the same function performed correctly time after time.
- Enhanced staff participation: people support what they help create.
- Less hunting for forms, information, supplies, and responses.
- A sense of unity around a set level of expectations and procedural means; a standard of care for everybody in the practice to actively pursue.

Prepared by:

Checked by:

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PREPARATION, ISSUE AND USE OF DOCUMENTS

Documents must be carefully and logically set out to encourage correct use and be easy to check. Documents should contain all necessary, but no superfluous data. Any headings, items or spaces on a master document that cease to be used should be removed at the earliest opportunity.

Each document must indicate or include

- the company or business name;
- purpose and title;
- a document identity number which uniquely identifies the document and indicates revision, if any;
- date of authorisation;
- date of expiry or review;
- signatures of authorising persons and, where different, the signature of the person who prepared the document and;
- page numbers (or total number of pages).
- The way in which the document is to be used, and by whom, should be clearly apparent from the document itself.

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- The reason for revision should be documented. This can be addressed in the introduction section of subsequent documents.
- Issued documents should not be handwritten. Reproduced or computer-printed documents should be clear and legible; in the case of batch documents each must be initialled to indicate a verified issue.
- Any correction made to a document should be initialled or signed and dated and the correction should permit the reading of the original information. Where appropriate, the reason for the correction should be recorded on a revision document that remains as a permanent copy of the nature and reasons for such changes. The master document should be on blue A4 size paper with all copies on white paper.
- Documents bearing instructions should be written in the imperative, ie as a direct command, as numbered steps. They should be clear, precise, unambiguous and in plain English that the user can understand. Such documents should be readily available to all concerned while carrying out the instructions.
- Documents should be kept up to date. Any amendments should be formally authorised before the document is used. In the case of permanent amendments, the amended document should be replaced at the earliest opportunity by a newly prepared document and the superseded document so marked and filed.