

# Standard Operating Procedure

## Title: Quality Documentation - Control, Tracking and Distribution

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- 1.3.5. TRN (Training) have an additional sign off for GMP by GMP Training Officer or QA delegate as per sign off table on the Training Report Template on **TEM-085**.
- 1.3.6. Forward the document with **Form-395** or **Form-495** to the first signatory.
- 1.3.7. On return of the signed document, update the name and date sent in the Status Box for the next signatory. Indicate the return of the signed document by ticking across the relevant name on **Form-395** or **Form-495**. These names should be ticked off in sequence.
- 1.3.8. Forward the document with **Form-395** or **Form-495** to the next person signatory.

### 1.4. Amendments to documents being circulated for Approval

If changes to the circulated document are indicated on the circulated copy, the White (Master) must be returned to DCO before the electronic copy of the document is saved into Draft folder again, and then deleted from in Circulation folder, so that the appropriate changes can be made by either the document author or the DCO.

**Note:** Changes to hard copy only documents are to be discussed with document owner and appropriate action decided.

- 1.4.1. Once the changes are made, reprint the document on White paper.
- 1.4.2. Attach the changed pages of the document behind the new printout to be circulated.
- 1.4.3. Highlight the "Repeats" header on **Form-395** or **Form-495**.
- 1.4.4. Update the Status Box in the Documentation Database with "To Be Confirmed" and the name of the first signatory and the date the document was forwarded to them.
- 1.4.5. Forward the document with **Form-395** or **Form-495** to the first signatory.
- 1.4.6. On return of the signed document, update the name and date in the Status Box with next signatory. Indicate on **Form-395** or **Form-495** the return of the signed document by ticking across the relevant name on the form, under the "Repeats" column. These names should be ticked off in sequence.
- 1.4.7. Forward the document with **Form-395** or **Form-495** to the next signatory.

### 1.5. Issuing of new documents

Once all required signatures are finalised, the Document Administrator will issue the document. See section 4 for issuing of documents.

## 2. Updating and Reviewing Existing Documents

Documents are to be reviewed after a defined period from creation or last update. See SOP **QMS-010** for different review periods for all document types. Updating of documents may occur at any time prior to required review date if necessary.

### 2.1. Reviewing / Updating Existing Documents

- 2.1.1. Each month, generate the advice of documents "Due For Review Within The Next Three Months" report in the Documentation Database and send updates to the relevant personnel. An extension of the review date may be requested. Note any extension in comments field in the Documentation Database.
  - A document may be updated prior to the review date if necessary. A request for updating of the document is sent to DCO.
  - **Note:** The appropriate person is to update / review the document. If required, check with the current version signatories for appropriateness of reviewer.
- 2.1.2. **Copy** the electronic document due to be reviewed or updated into Draft folder for editing.

**Note:** The current version of the document must remain in the 'live' folder.
- 2.1.3. Change the Status box in the Database to 'Under Review'. Type in the reviewer's name and the date the electronic copy was placed in Draft folder.
- 2.1.4. Check that the document is based on the current template for the specific document type.