SOP for Good Documentation Practices (GDP)

Standard Operating procedure to implement the good documentation practices in quality assurance, quality control, production and other departments.

1.0 OBJECTIVE

To lay down the procedure for good documentation practices.

2.0 SCOPE

This SOP shall be applicable for all quality system documents. This procedure also describes procedure for correcting errors in documents if any.

3.0 RESPONSIBILITY

All employees those who make entries in quality system documents.

5.0 PROCEDURE

5.1 All documentation entries shall be made with indelible black ink in clear and legible handwriting.

5.2 Verification of the document by QA shall be done by using indelible blue ink.

5.3 Green ink shall be used for issuance of BMR / BPR by QA.

5.4 Do not leave any column in the record/document unfilled. If any column in a recorded document is not applicable, write “N.A”. If no comments write NIL or put a dash ‘---‘.

5.5. Time should be expressed, as HH.MM i.e. 2 pm should be recorded as 14.00 hrs.

5.6 While issuing documents and in other record books the date should express as

DD-MM-YY or DD.MM.YY or DD/MM/YY.

While approving document the date should be expressed as DD-MM-YYYY or DD.MM.YYYY or DD/MM/YYYY.

5.7 If any page(s) are left blank, draw a line across the page from left top to right bottom of the page and write “CANCELLED” / “N.A.” (Not applicable) across the page and sign with the date.

5.8 If an entire page/paragraph is to be canceled from a written document, QA countersign is required.

5.9 No pencil entries are allowed.

5.10 Do not use correction fluid in any of the documents.

5.11 All personnel shall avoid errors during data entry.

5.12 In case an entry error has occurred, the same shall be corrected as described below:

5.12.1 Do not overwrite the wrong entries. Cross it out with a line permitting the reading of original entry.

5.12.2 Clearly write the correct entry near the cross out.

5.12.3 Initial / Sign and put the date, on which the correction was made. Wherever appropriate, the reasons for correction shall be recorded.

5.12.4 If the correction is made on a date after the date of original entry, it must be corrected as mentioned above and countersigned and dated by the supervisor or QA.

5.13 If an entire line/ paragraph/page to be deleted from a sequential record (e.g. log book or stock card) the following steps to be taken.

5.13.1 Cross out with a line

5.13.2 Write a comment explaining the reason for deletion near the cross out.

6.0 ABBREVIATIONS

6.1 SOP: Standard Operating Procedure

6.2 N.A.: Not Applicable

6.3 QA: Quality Assurance

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