# 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.

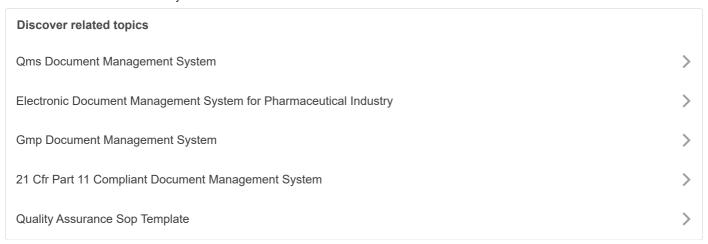
## **5.0 PROCEDURE**

- 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.

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## **6.0 ABBREVIATIONS**

6.1 SOP: Standard Operating Procedure

6.2 N.A.: Not Applicable6.3 QA: Quality Assurance

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Ankur Choudhary is India's first professional pharmaceutical blogger, author and founder of pharmaguideline.com, a widely-read pharmaceutical blog since 2008. Sign-up for the free email updates for your daily dose of pharmaceutical tips.

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