

Standard Operating Procedure

Title: Documentation Rule for GMP Documents

Procedure

1. Purposes of GMP Documentation

There are many different reasons for the creation and maintenance of GMP documentation. GMP documents are required for one or more of the following reasons:

- Keep track of activities
- Create legal documents
- Provide a historical record
- Provide information
- Comply with regulations.

2. Nine Characteristics of Quality GMP Record

- Permanent
- Legible
- Accurate
- Prompt (Written at the time activity was done)
- Clear (so anyone can read and understand what it meant)
- Consistent
- Complete
- Direct
- Truthful

3. Signature Register (Form-400)

A register of all employee signatures and initials is kept in the Signature Register folder located at QA division.

Only the signature or initials used on the Register is permitted to be written on documents.

4. Signatures

Operators must **not** sign or initial a document unless they have been trained in the task associated with the signature and in the significance of this signature.

Your signature on a document represents that the task has been performed in accordance with the documented requirements and any deviations have been recorded.

Your signature on a documented must be entered immediately after completion of the task.

If you are signing or initialing a document on behalf of another person, the identity of this person must be entered and you must have authority to do this, (via Delegation of Authority).

5. Entry of Data and Information

- 5.1. No part of a document that requires information or data to be entered is to be left blank. If no data entry is required, then "N/A" must be written in the space provided.
- 5.2. Hand written entries must only be made with permanent Blue or Black ink (ballpoint pens). Felt or other water-based pens must not be used due to their tendency to smudge and "run". Pencil is not permitted. **Red** pen is **limited** to recording of information by the Quality Assurance Officer and only on the 'Batch Documentation Checklists'.
- 5.3. Hand written data and additional information must be clearly legible. No overwriting is permitted. Corrections to errors must only be made in the manner described in the Section "Corrections" of this SOP.